

Regulatory Guide 10.8

*Instructions for Preparation of
Radioactive Materials License Application -
Medical*

Revised September 2016



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Instructions for the Preparation of Application for License - Medical

Contents of an Application

The following paragraphs explain the information requested on form RHF-1M:

- Item 1a.** Enter the name, mailing address, email address, fax and telephone number of the applicant physician or institution. It is particularly important that the mailing address be sufficiently complete so all correspondence to the licensee will reach persons actually responsible for the radiation safety program.
- Item 1b.** List the addresses and locations where radioactive material will be used or stored if other than the address stated in Item 1a. If multiple addresses are to be 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 1a; e.g., a P.O. Box may be more suitable for Item 1a in some cases, but a P.O. Box does not adequately describe the location of use. **Item 1b must be an in-state address.**
- Item 2.** Enter the name, telephone number (including area code), and email address of the individual to be contacted.
- Item 3.** Indicate whether this is an application for a new license, an amendment, or a renewal.
- Item 4.** List the names of all persons who will use, supervise, or direct the use of radioactive material. This list should include the physicians who supervise other physicians in training and/or who will direct technologists or other medical personnel in the use of radioactive material for human or nonhuman use. Non-physicians may be authorized to use radioactive material for nonhuman use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

- A. Approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radionuclide sources;
- B. Prescription of the radiopharmaceutical or source of radiation, and the amount or dose to be administered;
- C. Determination of the route of administration; and
- D. Interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

Items A-D may be delegated to physicians who are in training under the supervision* of authorized physician-users.

* Supervision means that the physician-user has adequately instructed the physician(s) in training in the specific human use and has ascertained that they are receiving training in the safe use of these materials in humans. It also means that the physician-user periodically reviews and documents the work of those supervised and assures that proper medical records are made of each use. It does not mean that the physician-user is necessarily present for each radiopharmaceutical administration.

Properly trained technicians, technologists, or other medical personnel under an authorized user's direction may be delegated the following activities:

- A. The preparation and quality control testing of radiopharmaceuticals and sources of radiation;
- B. The measurement of radiopharmaceutical doses prior to administration;
- C. The use of appropriate instrumentation for the collection of data to be used by the physician; and
- D. The administration of radiopharmaceuticals and radiation from radionuclide sources to patients, as permitted under applicable federal, state, and local laws.

Item 5. 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. If the Radiation Safety Officer is assisted by an Associate Radiation Safety Officer, consultant or part-time employee, state the ARSO's or consultant's name and describe their duties, responsibilities, and the amount of time to be devoted to the radiation safety program. **Also submit the name of the person responsible for the radiation program on a daily basis.**

Item 6a. For routine human use, the applicant may check the boxes of **WAC 246-240-151, WAC 246-240-157, WAC 246-240-201, and/or WAC 246-240-301** for which the license is requested. **WAC 246-240-151 and WAC 246-240-157** consist of the more commonly used diagnostic procedures that involve radiopharmaceuticals; **WAC 246-240-201** consists of routine therapeutic procedures that involve radiopharmaceuticals; and **WAC 246-240-251** consists of sealed sources used primarily for therapeutic procedures. **WAC 246-240-351** consists of sealed sources used in therapeutic devices such as gamma stereotactic radiosurgery, high dose rate afterloaders, and teletherapy.

Generally, for unsealed radioactive material, possession limits are not listed on the license.

For **sealed sources used for therapy** the possession limit requested for each radionuclide should be sufficient to include material held as radioactive waste and to allow for extra sources onsite when reloading is required.

Item 6b. For routine human use not listed and for nonhuman use, list each radionuclide to be used, the chemical and physical form, and the maximum quantity (in millicuries or becquerels).

List the manufacturer's name, model number, and activity (in millicuries or becquerels) for all sealed sources. Sealed sources (excluding Radium 226) used for calibration and reference standards are authorized under WAC 246-240-110 and need not be listed, except for Gd-153, which exceeds the activity limits authorized by WAC 246-240-110.

Describe the intended use for each radionuclide and form listed in Item 6b. A specific authorization must be obtained from the department to perform studies involving the use of radioactive material in animals. The information required is specified in Item 23.

If the radioactive material is for human use and has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that 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. If a study is to be conducted under a protocol approved by an FDA-approved Radioactive Drug Research Committee, submit a copy of the FDA letter granting approval; state the radionuclide, chemical form, possession limit, and use; and submit a complete copy of the protocol.

Item 7. Radiation Safety Committee. In accordance with WAC 246-240-051 an institution applying for a radioactive materials license for human use may be required to establish a radiation safety committee. This committee evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes. Membership of the committee must include at a minimum:

- A. Physicians specializing in nuclear medicine, internal medicine or radiation oncology, at least one of whom will use or directly supervise the use of radioactive material for diagnosis and/or treatment of humans;
- B. A person with special competence in radiation safety;
- C. A representative of the institution's Administration; and
- D. A representative of the nursing staff.

Submit the following information:

- A. The responsibility and duties of the committee;
- B. The meeting frequency of the committee (at least quarterly or semi-annually); and
- C. The name and specialty of each member of the committee. Members so named are allowed to delegate their attendance at the Radiation Safety Committee meetings when they are unable to personally attend.

Attachment A to the medical application contains an example of typical responsibilities and duties for a radiation safety committee. Indicate, by checking the appropriate box in Item 7, that the responsibilities, duties, and meeting frequency will be as described in Attachment A, and sign, date, and include the attachment with the application. **Attachment A (Radiation Safety Committee), the application cover page, and Attachment P (ALARA), may each be signed only by the representative of the institution's administration.**

Item 8. Radiation Safety Officer/ARSO. Include a description of the duties and responsibilities of the Radiation Safety Officer (RSO) and/or Associate Radiation Safety Officer. **Attachment B** contains typical duties for an RSO. If these duties/ responsibilities are adopted, indicate by checking the appropriate box in Item 8 of form RHF-1M and sign, date, and include Attachment B, (or submit an equivalent description). Attachment B also contains the RSO/ARSO Certification & Delegation of Authority. This must be signed by both the proposed RSO/ARSO and a representative of licensee Administration.

Item 9. Training and Experience

- A. **Authorized User(s).** If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license name and number (if issued by the Department) or a full, complete, and current copy of the license if issued by another Agreement State or the NRC.

If the physician has not been previously authorized to use the radioactive material being requested, state where they are licensed to practice medicine, and submit a complete description of their training and experience. *Remember to submit a copy of the current and valid license to practice medicine in Washington State.* Use Form RHF-2M to describe the physician's training and experience. Criteria for acceptable training and experience are contained in WAC 246-240 and/or Appendix A of these instructions.

- B. **Radiation Safety Officer.** If the RSO is not one of the physicians named in Item 4, submit a complete description of their training and experience. Form RHF-2M may be used to describe the RSO's training and experience. Where a consultant is employed to assist the RSO, the institution remains responsible for the proper performance of the radiation safety program as required by the license, and the institution's RSO will be expected to review the consultant's work and sign the required reports and records.

Item 10. Instrumentation. Instruments generally required in a typical nuclear medicine operation are:

- A. Survey instruments
- (1) A low-level survey meter, with a thin window of 1-7 mg/cm², to perform contamination surveys. This instrument will usually be calibrated for Beta efficiency; and when used for contamination surveys, will yield results in counts per minute (CPM).
 - (2) A high-level survey meter, such as an ionization-type, capable of reading up to at least 1 Roentgen per hour to measure radiation exposure rates that may exist in the vicinity of generators and therapeutic quantities of radioactive material such as ¹³¹I, Co-60, or Ir-192.
 - (3) A low-level meter calibrated for the energy of interest, to be used for low-energy therapy seed surveys where such use is requested.
- B. Dose calibrators and other instruments to assay radiopharmaceuticals and therapy sources.
- C. Instruments used for diagnostic procedures in nuclear medicine (e.g., gamma camera, PET scanner, thyroid probe, well counter, scintillation counter for in-vitro studies).
- D. Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

Attachment C to the medical application contains a form which may be used to describe the instruments. Complete this form, listing the instruments to be used. If this form is not used, attach equivalent information. Check the appropriate box in Item 10 of Form RHF-1M.

Item 11. 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 inadequate to determine the proper functioning and response of an instrument.***

Daily constancy checks and battery checks of survey instruments should be made before each use and should be supplemented at least every 12 months with a 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.* Survey instruments should also be calibrated after any repair or maintenance which may affect the calibration of the instrument.

A dose rate survey instrument may be considered properly calibrated at one point when the exposure rate measured by the instrument differs from the true exposure rate by less than 10 percent.

Instruments used to quantify results of required surveys, such as well-counters, must be calibrated at least annually with a NIST-traceable source of radioactive material of appropriate energy and activity from an authorized vendor. Constancy checks must be performed and documented daily when such instrumentation is used.

Beta efficiency calibrations are appropriate for contamination instruments and probes. 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. 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) The nuclide and either (a) activity (in millicuries or becquerels) 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 Institute of Standards and Technology (NIST).
- (3) The accuracy** of the source(s).
- (4) The step-by-step procedures, including associated radiation safety procedures, such as the dose rates in areas near the location where dose rate meter calibrations are performed for each instrument, should include a two-point calibration (at about 1/3 and 2/3 of full scale) on each scale used for radiation protection surveys.*

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify name, address, and the license number. Contact the firm or consultant that will provide the calibration to determine whether information concerning calibration services and procedures has been filed with the Department. If this information has not been filed, submit it with your application, including details of the information the outside firm will supply you about the results of the calibration.

Indicate whether the outside firm or consultant is NVLAP-certified. If not a Washington licensee, include a copy of the certification. Section 1 of Attachment D to the medical application contains an acceptable procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 11 of the application form. A sample "Certificate of Instrument Calibration" is also provided for use by a consultant in reporting calibration results. Indicate, by checking the appropriate boxes in Item 11 of Form RHF-1M if the procedures described in Attachment D will be followed; sign, date, and include Attachment D (or submit equivalent procedures).

B. Dose Calibrator. All radiopharmaceuticals must be assayed for activity to an accuracy of \pm 20 percent of the true value prior to being administered to patients. The usual method for performing assay is with a dose calibrator. Upon installation, and periodically thereafter, dose calibrators must 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.

Submit a description of your calibration procedures. These should include, as a minimum:

- (1) The manufacturer's name and model number of any sealed sources to be used;
- (2) The nuclide and activity (in millicuries or becquerels) of radioactive material in the standards;
- (3) The accuracy and traceability of the standard; and
- (4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

- (1) The instrument and operating parameters;

- (2) The assay method;
- (3) The method of calibration;
- (4) The frequency of calibration; and
- (5) The standards/source(s) 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 11 of this application. Indicate, by checking the appropriate box in Item 11 of **Form RHF-1M**, if the procedure in Attachment D for calibrating dose calibrators will be followed, (or submit equivalent procedures).

C. Instruments Used for Diagnostic Imaging Purposes. Calibration, quality control, and maintenance of instrumentation used for diagnostic procedures should be performed routinely in accordance with the manufacturer's recommendations. On the space provided in Attachment D or on a separate sheet include a description of calibration and quality control program, including tests and checks performed, the frequency with which they are performed, and records that are maintained.

* 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.

** The maximum deviation of the nominal value of the source from the true value. The manufacturer normally provides this information.

Item 12 Facilities and Equipment.* Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) at each location where radioactive material will be used or stored. Include a description of the area(s) assigned to the receipt, storage (including waste), preparation, security and measurement of radioactive material.

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

- A. Use and storage of Mo-99/Tc-99m, Ge-68/Ga-68, and/or Sr-82/Rb-82 generators;
- B. Storage of radiopharmaceuticals (refrigerated and non-refrigerated);
- C. Special shielding for high-energy nuclides, such as those used for PET procedures;
- D. 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, if generators are used, as well as other solid waste.) If this area is located outside your department, describe how the material will be secured, and designate on area diagram. Confirm that this area will be surveyed at least weekly.
- E. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block).

Identify areas adjacent to use and storage locations, and show that adequate steps have been taken to ensure radiation levels in immediate unrestricted areas do not exceed the limits specified in WAC 246-221-060 (see Example Diagram, e.g. Suite 301, next page.)

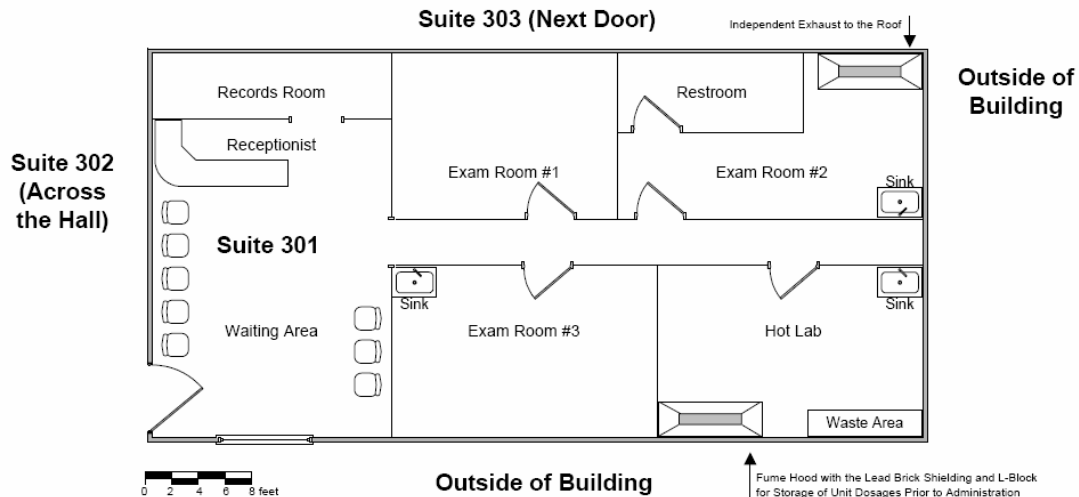
Shielding requirements for the walls, floor, and ceiling should be evaluated for each nuclear medicine room based on total workload, the energy of radiation, and the presence of patients with activity in the room. **Adequate distances must be allowed between technologists and patients containing radioactive material.**

* See also U.S. Nuclear Regulatory Commission Regulatory Guide 8.18, Revision 2, and NUREG-0267, Rev 1 for checklists of facilities, equipment, and procedures to consider in designing hospitals for medical use of radioactive material.

If gas is to be used, submit a facility diagram that specifies the location and the measured airflow rate of each air exhaust vent and each air supply vent in areas where gas 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. (See Figure N-1 of Attachment N for an example of the type of diagram to be submitted). Where only aerosol is to be used, confirm by checking the appropriate box on Attachment N that it will be administered in a properly shielded delivery system and that resultant aerosol waste will be decayed in a properly shielded enclosure for decay and disposal.

For other facilities or scenarios 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. Draw diagrams to a specified scale, or indicate dimensions, on 8.5 x 11 size paper.

EXAMPLE



- Suite 301 is on the top floor.
- Suite 301 is located at a corner of the building.
- Suite 302 is occupied by an accounting firm.
- Suite 303 is occupied by a law firm.
- Directly below Suite 301 is an insurance company.

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Provide a diagram (8.5 x 11 inches) of your facility, including shielding provisions in millimeters or inches of Lead/Pb.

Item 13. Personnel Training Program. *Radiation workers* (e.g., nuclear medicine technologists, or nurses) must receive instruction specified in WAC 246-222-030. Note that many of these items pertain to circumstances at a particular institution; therefore, it may not be assumed that this instruction has been adequately covered by prior occupational training, board certification, etc. Outline and submit the program for providing the necessary instruction.

Ancillary personnel (e.g., clerical, EKG technicians, housekeeping, dosimetrists, security etc) 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, lectures), frequency of training, duration of training, and subject matter, and how that training will be documented and maintained for inspection.

Verify that personnel will be properly instructed:

- A. Before assuming duties with, or in the vicinity of, radioactive materials;
- B. During annual refresher training; and
- C. Whenever there is a significant change in duties, regulations, or the terms or conditions of the license.

Instruction required by WAC 246-222 must include:

- A. All terms of the license pertinent to radiation safety;
- B. Areas where radioactive material is used or stored;
- C. Potential hazards associated with radioactive material;
- D. Radiological safety procedures appropriate to their respective duties;
- E. Pertinent regulations and license conditions;
- F. Obligation to report unsafe conditions to the RSO;
- G. Appropriate response to emergencies or unsafe conditions;
- H. Right to be informed of their radiation exposure and bioassay results; and
- I. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by WAC 246-222.

Attachment E provides a minimum training program. If this program is adopted, check the appropriate box in Item 13 of Form RHF-1M and complete, sign, date, and include Attachment E (or submit an equivalent training program).

Item 14. Procedures for Ordering and Receiving Radioactive Material. Describe procedures for ordering radioactive materials, for receiving materials during off-duty hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures should ensure that possession limits are not exceeded, that radioactive materials ordered for human use are adequately verified upon receipt and checked before use, that radioactive materials are secured at all times against unauthorized removal or use, and that radiation levels in unrestricted areas do not exceed the limits specified in WAC 246-221-060(1).

Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours should be issued **written instructions** for 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 spread of contamination.

Attachment F to the application contains sample procedures and instructions for ordering and receiving packages containing radioactive material. Attach a copy of your procedures or, if the procedures in Attachment F are to be followed, complete, sign, date, and include Attachment F.

Item 15. Procedures for Safely Opening Packages Containing Radioactive Materials. Although WAC 246-221-160 exempts certain packages from immediate monitoring, WAC 246-221-160(4) requires 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, and for compliance with WAC 246-221-160. 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 (a) surveying packages, (b) wearing gloves while opening packages, (c) checking packing material for contamination after opening, (d) verifying package contents, and (e) recording all survey results, both positive and negative.

Attachment G contains a description of an acceptable procedure for safely opening packages. Indicate, by checking the appropriate box in Item 15 of **Form RHF-1M** that the procedure in Attachment G will be followed, then sign, date, and include Attachment G, (or attach equivalent procedures).

Item 16. General Rules for the Safe Use of Radioactive Material. Describe the general instructions to be followed by physicians, nuclear pharmacists, medical physicists, 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 material and the laboratory equipment to be used when 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 hard beta- and/or gamma-emitting materials are handled. 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, elevators, or in corridors, as applicable.

- G. Explain requirements for storage of materials, labeling of containers, and identification of areas where radioactive materials are used. Describe the shielding used for areas where large amounts of radioactive material are stored.
- H. Specify personnel monitoring devices to be used, where to obtain them, where to store them when not in use, 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.
- J. Describe contamination control procedures, including (1) prohibitions against smoking, eating, chewing, 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 use or handle unsealed radiopharmaceuticals to monitor their hands after each procedure and at the end of the day.

For smaller programs, **Attachment H** to the sample application contains an acceptable set of laboratory rules for the safe use of radioactive material. Indicate by checking the appropriate box in Item 16 of RHF-1M. If Attachment H rules will be followed, sign, date, and include Attachment H, (or attach equivalent procedures).

Item 17. Emergency Procedures. Describe the emergency instructions to be posted in all areas where radioactive materials are used. These instructions should: (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); (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency; and (c) instruct personnel 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**. Indicate, by checking the appropriate box in Item 17 of **RHF-1M**, that you will follow the emergency procedures, sign, date, and include Attachment I, (or submit a copy of equivalent procedures). **Remember to complete required information such as names, work phone numbers and cell phone numbers of emergency contacts.**

Item 18. 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 maintenance of adequate records of surveys. *** Remember to include a diagram of the use and storage area(s) with the survey points keyed to the diagram.**

If the application is to cover multiple users and areas of use, the individual user should perform surveys of their own work areas in addition to those performed by the radiation safety staff. Acceptable procedures and frequencies for routine surveys are described in **Attachment J**. Indicate, by checking the appropriate box in Item 18 of Form RHF-1M that you will follow those survey procedures, sign, date, and include Attachment J, (or submit equivalent procedures).

* Regulatory Guide 8.23 Rev 1 "Radiation Safety Surveys at Medical Institutions" provides further information on acceptable survey procedures.

Item 19. Waste Disposal. Describe specific methods used for disposal of waste material. 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. Waste may be held for decay until radiation levels, as measured in a low background area with a low-level survey meter with all shielding removed, have reached background levels. Then, after radiation labels have been removed or obliterated and appropriate survey and background results recorded, the waste may be disposed as normal trash;
- B. Release into a sanitary sewer in conformance with WAC 246-221-190. There are no regulatory limitations for patient excreta disposed via sanitary sewer. Describe the methods for controlling the sewerage disposals of radioactive wastes in order to ensure that disposals do not exceed the limits specified in WAC 246-221-190;
- C. Release into the air in conformance with WAC 246-221-070 and WAC 246-247;
- D. Other methods specifically approved by the department in accordance with WAC 246-221-180; or
- E. Transfer to a person or firm properly licensed to receive such waste, e.g., commercial waste disposal firms (see WAC 246-221-170). Submit the name and the NRC or Agreement State license number of the commercial firm(s) selected.

The Department is encouraging licensees to reduce the volume of wastes 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 (paragraphs A and B above).

Attachment K contains a form which may be used to supply the information requested in Item 19 of the application form. Indicate, by checking the appropriate box in Item 19 of Form RHF-1M, that you will dispose of wastes as specified on the form; complete, sign, date, and include Attachment K, (or attach equivalent information).

Item 20. Therapeutic Use of Radiopharmaceuticals. Describe special precautions* for patients treated with unsealed radioactive material authorized by WAC 246-240-201, therapy for which a Written Directive is required. Although **radiopharmaceutical therapy** procedures are often performed on an outpatient basis, appropriate procedures should be established because hospitalization is still sometimes required.

- A. Describe radiation safety procedures associated with the care of therapy patients, including:
 - (1) Procedures for assigning patients to rooms. Private rooms should be designated for I-131 therapy patients or any other patients who may constitute an internal or external exposure hazard for roommates;
 - (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 (see NUREG-0267));
 - (3) Procedures for surveys of:
 - (a) Areas, equipment, and personnel involved in administration of radiopharmaceuticals;
 - (b) The patient's room on a daily basis;

- (c) Unrestricted areas (i.e., areas adjacent to the patient’s room);
 - (d) Linens and other items removed from the patient’s room; and
 - (e) The patient’s room before it is reassigned to another patient.
- (4) Records of surveys to be recorded on the patient’s chart and in radiation safety office records;
 - (5) Instructions to nursing staff (**see Attachment L**);
 - (6) Personnel monitoring procedures for medical and nursing staff;
 - (7) Procedures for disposal of wastes, including:
 - (a) Patient excreta
 - (b) Surgical dressings
 - (c) Other disposable items;
 - (8) Procedures to be followed in case of emergency surgery or death (see NRC Report Nos. 37 and 48); and
 - (9) Procedures for release of patients, including:
 - (a) Criteria for release of patients. (Reg Guide 8.39.)
 - (b) Instructions to patients and families (see NCRP Report Nos. 37 and 48, and Reg Guide 8.39).

* See Regulatory Guide 8.23 and NUREG-0267.

- 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. Guidance on situations requiring bioassay for I-131 and appropriate action levels may be found in Regulatory Guide 8.20, Rev.2, “Bioassay Program Criteria for I-125 and I-131”; and
 - (3) Surveys to limit the spread of contamination and procedures for decontamination. Surveys (e.g., measurement of I-131 in air, measurement of I-131 in the thyroid glands of laboratory personnel, contamination surveys of personnel, equipment, and facilities) should also be performed to determine compliance with WAC 246-221-040 and WAC 246-221-070.

Submit detailed responses to Items 20A and 20B. (In lieu of submitting a detailed response to Item 20a, state that you will follow the procedures in Attachment L. Complete, sign, date, and return Attachment L.)

Item 21. Therapeutic Use of Sealed Sources. Describe special procedures for patients treated with; High Dose Rate Remote Afterloader devices; stereotactic radiosurgery devices (Gamma Knives); permanent implant therapy seeds, and radioactive materials authorized in WAC 246-240-251. These procedures* 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; and (3) any calculations or measurement data used to check the adequacy of the shielding and other facility protection specifications. Radiation levels in unrestricted areas must be less than 2 millirems in any 1 hour, and less than 100 millirems in any 7 consecutive days (see WAC 246-221-060);
- B. Special precautions to be used while using or handling HDR, therapy seeds, or other sealed sources;
- C. Your method for determining the radiation doses to the extremities of personnel handling sealed sources;
- D. The equipment and shielding available for transporting sources between storage and the place of use;
- E. *Your method for maintaining source accountability at all times.* This should include a description of sign-in and sign-out procedures, periodic (at least quarterly) inventory, and the method for determining that all sources are accounted for and nonpermanent implant sources returned to storage immediately following explant and cleaning;
- F. *Surveys to be performed* during the course of treatment and at the conclusion of treatment using instruments calibrated to the approximate energy of those sources being surveyed. **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 documented source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied as well as confirming that all permanent implant sources have been accounted for; and
- G. *Special instructions for nursing personnel* who care for patients treated with sealed sources. (**Attachment M** to this guide contains a description of procedures to be followed for patients treated with sealed sources.)

Submit detailed responses to Item Nos. 21A through 21F. In response to Item 21G, indicate by checking the appropriate box in Item 21 that the procedures described in Attachment M will be followed; complete, sign, date, and include Attachment M, (or submit equivalent procedures).

Item 22. Procedures and precautions for Use of Radioactive Gases and Aerosols. The use of radioactive gases (e.g., Xe-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 department requires that each applicant make such determinations for their own unique situation and submit evidence to the department sufficient to adequately support the request.

Attachment N contains instructions for submitting an application to use Xe-133 or aerosol. The information requested in Attachment N must be submitted, if either or both are requested.

Item 23. Procedures and Precautions for Use of Radioactive Material in Animals. Describe additional procedures to be followed if radionuclides will be used in animals, including

- (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, dealing with waste; and
- (D) Procedures for ensuring that 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.
- (E) If animals are to receive therapeutic radioiodine, include complete procedures for bioassay of licensee personnel as well as pertinent air concentration calculations and, as necessary, air sampling for release to restricted and unrestricted areas.

* Guidance on facilities, equipment, and procedures is available in NUREG-0267.

Item 24. Procedures and Precautions for use of Radioactive Materials Specified in Item 6b.

Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 6b, e.g., air sampling, other special surveys, bioassay, leak testing of sealed sources, including radiation safety precautions, etc.

Bioassay may be required when individuals work with millicurie quantities of I-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassay 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 bioassay has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material.** Guidance on bioassay programs for I-125 and I-131 is provided in Regulatory Guide 8.20, Rev 2. Guidance for bioassay programs for other radionuclides is available from the Office of Radiation Protection.

Item 25. Personnel Monitoring, Bioassay and Sealed Source Leak Test Programs.

- (A) **Personnel Monitoring Devices.** Provide the name of the organization furnishing film, thermoluminescent dosimeter (TLD) or Luxel (OSD) service. Specify the frequency with which the devices are changed and evaluated, and give a description of the type; e.g., whole-body, or extremity.. Where feasible, rings should be worn on the index finger for measuring hand exposures. 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, and frequency of readings and recording exposures. Use **Attachment O** to provide personnel monitoring information.
- (B) **Bioassay Program.** If I-125 and/or I-131 is handled or processed, include bioassay program information. Regulatory Guide 8.20 Rev 2 provides criteria for the development and implementation of a bioassay program. The program as described in Regulatory Guide 8.20 Rev 2 may be used to satisfy the bioassay program requirement. If the Regulatory Guide 8.20 Rev 2 program is not compatible with your operation, submit a description of an equivalent program. **Attachment O** should be used to provide bioassay program support information. **Where iodine is received and used in capsule form only, bioassay is not required unless capsules are opened, breached, or crushed.**
- (C) **Sealed Source Leak Test Program.** Pursuant to WAC 246-221-080, each radioactive sealed source possessed under the provisions of a specific license, other than H-3, 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 six-month intervals or at time intervals specified by the license. Use Attachment O to provide sealed source leak test program information.

Item 26. 'For Private Practice Applicants Only'.

- (A) State the name and address of the hospital that has agreed to admit your patients containing radioactive material and/or where the Authorized User physician has admitting privileges.

Item 27. "ALARA" - As Low As Reasonably Achievable. WAC 246-220-007 states that "persons engaged in activities under licenses issued by The Washington State Department of Health pursuant to the Atomic Energy Act of 1954, as amended, shall, in addition to complying with the requirements set forth in Chapter 246-221 WAC, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable (ALARA). The term 'as low as reasonably 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. Applicants/licensees may adopt the model program described in **Attachment P** of the application or may develop and submit for Department review an equivalent alternate program. If the model program in Attachment P is adopted, check the appropriate box in Item 27 on Form RHF-1M. Attachment P should be completed, dated and signed by a representative of Administration, and must be attached to the request for licensing action.

Item 28. WRITTEN DIRECTIVE PLAN. Please complete and attach your facility's Written Directive Plan complete with sample Written Directive forms for each modality of use. If you administer no therapeutic radioactive material and no amounts of Iodine - 131 as Sodium Iodide greater than 30 microcuries, please so state, and check the "N/A" box. **Remember to submit a complete Written Directive Plan for unsealed therapy, teletherapy, gamma knife, HDR, and/or brachytherapy seed programs.**

Item 29. LICENSE FEE REQUIRED. Please be certain to enter the fee category code for the license. If the application is for a **new** license, remember to submit the one-time fee for new license application review and the fee for one year as listed for your fee category.

Item 30. APPLICANT CERTIFICATION. Provide the signature of an individual authorized by management to represent an applicant institution, (or the signature of an individual physician, in the case of private practice or a non-institutional clinic,) with the date of signature.

Amendments

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, provided that no such amendment is necessary if a licensee changes survey instruments or diagnostic imaging equipment as long as the replacement equipment is of equivalent or better detection capability and is accepted as an equivalent according to others in the same field),

procedures, authorized users, Radiation Safety Officer, Associate Radiation Safety Officer, or radioactive material to be used. The amendment must be approved and issued in writing by the Department **prior** to the proposed change(s).

Applications for license amendments may be filed either on an application form, in letter form or via email using a PDF with a valid electronic signature. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. 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 must be signed and dated by a representative of the licensee's administrative management (e.g., the hospital administrator, or the Radiation Safety Officer if such signing approval has been requested by the licensee and granted by the Department). An original of the application for amendment should be prepared, and submitted, as is the case for new or renewal applications.

Prepare an original and one copy of the application. Retain the copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplements to it. Mail the original only to: Washington State Department of Health, Office of Radiation Protection, Box 47827, Olympia, Washington 98504, Attention: Radioactive Materials Section.

Instructions - Appendix A Acceptable Training & Experience for Medical Use

1. General Criteria

Any human use of radioactive material (i.e., the internal or external administration of radioactive material, or the radiation therefrom, to human beings) must be carried out by, or under the supervision of, a physician. A physician means a doctor of medicine or a doctor of osteopathy licensed by the state of Washington to dispense drugs in the practice of medicine.

Chapter 246-240 WAC states that the Department will approve a license application by an institution for medical use of radioactive material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in: (a) basic radionuclide handling techniques; and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Similar criteria are established in WAC 246-240 for the approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Department has found acceptable for physicians and others involved in the use of radiopharmaceuticals or sealed sources of radioactive material.

2. Training for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radionuclide handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Department.

3. Training for:

A. *Uptake, Dilution & Excretion Studies* is specified in WAC 246-240-154.

B. *Training for Imaging & Localization Studies* is specified in WAC 246-240-163.

ALTERNATIVES: Certification by (1) the American Board of Nuclear Medicine, or (2) the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology or Nuclear Medicine (or other board-certifications noted on the U.S. NRC website as acceptable) will be accepted as evidence that a physician has adequate training and experience to use radioactive material authorized in WAC 246-240-151 & WAC 246-240-157. The NRC website can be found at: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- C. *Use of Unsealed Radioactive Material for Which a Written Directive is Required* is specified in WAC 246-240-210.**
- D. *Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries)* is specified in WAC 246-240-213.**
- E. *Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries)* is specified in WAC 246-240-216.**
- F. *Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive* is specified in WAC 246-240-219.**
- G. *Use of Manual Brachytherapy Sources* is specified in WAC 246-240-278.**

NOTE: Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology; certification as a British “Fellow of the Faculty of Radiology” (FCR) or “Fellow of the Royal College of Radiology” (FRCR); or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the information requested. Physicians certified as FCR or FRCR must also submit evidence of specialization in radiotherapy. Evidence of previous approval by the state, the NRC or another Agreement State may also be submitted in lieu of the information requested above. In this case, the applicant should specify the name and number of the state license or submit a copy of the Agreement State or the NRC license on which the applicant-physician was specifically listed as an authorized user.

- H. *Ophthalmic Use of Strontium-90* is specified in WAC 246-240-281.**
- I. *Use of Sealed Sources for Diagnosis* is specified in WAC 246-240-304**
- J. *Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units* is specified in WAC 246-240-399.**
- K. *Therapeutic Use of Unsealed Radioactive Material* is specified in WAC 246-240-460.**
- L. *Treatment of Hyperthyroidism* is specified in WAC 246-240-213.**
- M. *Treatment of Thyroid Carcinoma* is specified in WAC 246-240-216.**
- N. *Use of Brachytherapy Sources* is specified in WAC 246-240-278.**
- O. *Use of Therapeutic Medical Devices* specified in WAC 246-240-351.**
- P. *Radiation Safety Officer* is specified in WAC 246-240-069.**
- Q. *Authorized Medical Physicist* is specified in WAC 246-240-072.**
- R. *Authorized Nuclear Pharmacist* is specified in WAC 246-240-075**
- S. *Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and/or Nuclear Pharmacist* is specified in WAC 246-240-078.**