WASHINGTON STATE DEPARTMENT OF HEALTH
DIVISION OF RADIATION PROTECTION

REGULATORY GUIDE 10.7

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES OF RADIOACTIVE MATERIAL

1. INTRODUCTION

This guide describes the type of information required by the department to evaluate an application for a specific license for laboratories and industries using less than ten (37) gigabecquerels (1.0 curie) of radioactive material. This type of license is provided for under Chapter 246-232 WAC, "Radioactive Material - Licensing Applicability."

WAC 246-220-007, "Statement of Philosophy," states that "...persons engaged in activities under license 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). Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the department position on this important subject. License applicants should give consideration to the ALARA philosophy, as described in U.S. Nuclear Regulatory Commission, Regulatory Guide 8.10, in the development of plans for work with licensed radioactive materials.

2. LICENSE FEES

An application fee is required for radioactive materials licenses. Refer to WAC 246-254, "License Fees for Radioactive Materials," to determine the amount of fee that must accompany the application. Review of the application will not begin until the proper fee is received by Washington State Department of Health, Revenue Accounting, Post Office Box 1099, Olympia, Washington 98507-1099.

3. FILING AN APPLICATION

Complete Form RHF-1LI, "Application for Radioactive Material License--Laboratory-Industrial." All items on the application form should be completed in sufficient detail for the department to determine that the applicant's equipment, facilities, and radiation protection program area adequate to protect health and minimize danger to life and property.

Since the space provided on Form RHF-1LI is limited, the applicant should append additional sheets to provide complete information. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number on (on Form RHF-1LI) and its purpose (e.g., radiation safety instructions.)

The application should be completed in duplicate. The original should be mailed to Washington State Department of Health, Division of Radiation Protection, 7171 Cleanwater Lane, Bldg. 5, Post Office Box 47827, Olympia, Washington 98504-7827. One copy of the application, with all attachments should be retained by the applicant since the license will require, as a condition, that the licensee follow the statements and representations set forth in the application and any supplement to it.

4. CONTENTS OF AN APPLICATION

Most items on Form RHF-1LI are self-explanatory. The following comments apply to the indicated numbered items of the form.

Item 1. Name, Mailing Address, and Street Address (if different): Specify the applicant corporation or other legal entity by name and mailing address of principal offices. Individuals should be designated as the applicant only if the use of the radioactive material is not connected with the individual's employment with a

corporation or other entity. If the applicant is an individual, the individual should be specified by full name and address, including state and zip codes.

Item 4. Individual Users: Specify the names of persons who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 4.A. Training and Experience: Complete Appendix A for the Radiation Safety Officer and each authorized user, unless this information has been previously submitted as a part of a license application. Designate which license the information was filed under.

The qualifications, training, and experience of each person should be commensurate with the material and its use as proposed in the application. The amount and type of training and experience with radiation and radioactive materials required to support a determination of adequacy by the department will vary markedly with certain factors.

In general, authorized users should have a minimum of 1 year training and experience working with the isotopes and activities requested. In addition, the RSO should have at least 1 year experience performing the RSO duties, either as an RSO or an Assistant RSO.

If other persons such as technical assistants and laboratory workers will use radioactive materials in the absence of persons specified above, the specification of the training of such personnel should include (a) instruction in radiation safety including topics covered and by whom taught, (b) on-the-job training in use of radioactive materials, and (c) determination of competency to work with the presence of supervisory personnel.

The use of becquerel (microcurie) quantities of nonvolatile radioactive materials by a person with a minimum of training and experience under controlled conditions may be justified provided it is done under the surveillance of a radiation protection officer. Such minimum training and experience may consist of a few hours of training and experience in the use of one or more radioactive materials similar to the use proposed in the application under the supervision and tutorship of a licensed user.

Persons using megabecquerels (microcurie) quantities of a number of radionuclides for general laboratory tracer work under unspecified conditions should have more extensive training and experience and, depending on the exact nature of the proposed program of use of radionuclides, may need to have completed formal course work at the college or university level covering the areas listed in Appendix A.

The use of larger quantities of material, in the gigabecquerel (millicurie) range under conditions where a potential exists for significant loss and ingestion, inhalation, or absorption of the radioactive material by those working with the material is normally done under carefully controlled conditions using specialized equipment. A person who is to use radioactive materials independently under these conditions should not only have a background of formal training in all areas described in Appendix A but should also have extensive experience working with radioactive material and a thorough working knowledge of the equipment required to handle the material safely.

Item 5 and 5.A. Radiation Safety Officer/Duties: Specify the name of the person who will be designated as the radiation safety officer or radiation protection officer (see Appendix B). This person will be responsible for implementing the radiation safety program and must therefore be readily available to the users in case of difficulty. He/she must be trained and experienced in radiation protection and in the use and handling of radioactive materials. In a small program not requiring a fulltime radiation safety officer, the duties of the

radiation safety officer may be assigned to one of the persons named under Item 4 of Form RHF-1LI. Note, however, that it must be established that the person acting as radiation safety officer will have the opportunity to devote sufficient time to the radiation safety aspects of the program for the use of radioactive materials.

Items 6, 7, and 8. Radioactive Material Description: Describe the radioactive material by isotope, chemical and/or physical form and activity. A separate possession limit for each nuclide must be specified. Possession limits requested must cover the total anticipated inventory, including stored material and waste, and should be commensurate with the applicant's needs and facilities for safety handling.

If the use of sealed or plated sources is contemplated, the isotope, manufacturer, and model number of each sealed source or plated source must be specified.

Item 8.A. Maximum Yearly Throughput: If you are applying for a new license you will have to guestimate, as accurate as possible, your yearly throughput. If this is a renewal applicant use your receipt records to indicate yearly throughput. This information is used to complete Attachment L.

Item 9. Device and Use Description: If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device must be specified. In any case, the use to be

made of the radioactive materials must be clearly described. Sufficient detail must be given to allow a determination of the potential for exposure to radiation and radioactive materials, both of those working with the materials and of the public.

Item 10. Handling Procedures: Describe how you will handle radioactive material including safety procedures in place during use, while in storage, disposal practices and security measures. Radioactive materials must be secured from unauthorized use and/or possession. This includes persons both inside and outside of your organization.

Item 11. Radiation Detection Instruments: Specify for each radiation detection instrument used in the radiation safety program the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detection (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness in mg/cm, and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring. Some programs are so small that survey instruments are not required. This is particularly true where only low energy beta isotopes are used. If the application does not need and does not plan to procure a radiation survey instrument, mark "No survey instruments possessed."

Item 12. Calibration of Detection Instruments: All radiation detection instruments possessed must be calibrated. Designate the frequency of calibration, or whether applicant will contract with approved service agency for instrument calibration. Appendix C is provided for the convenience of the applicant as acceptable procedures for calibrating dose rate instruments. The applicant may sign and submit Appendix C or equivalent procedures for the calibration of dose rate instruments.

Other instruments system requiring calibration. Meet the following criteria:

1. Describe the instrument calibration methods and procedures for the calibration of contamination monitoring instruments, as well as any other instruments and systems used in the radiation protection program, such as measuring instruments used to assay sealed-source leak-test samples (see Item 17) contamination samples (e.g., air samples, surface "wipe" samples,) and bioassay samples. A determination should be made annually and after each repair to verify that the minimum sensitivity of the instrument is appropriate for energies of the radionuclides of concern. This determination should be made using sources which are traceable to NBS.
2. An adequate calibration of instruments usually cannot be performed with response check sources. Such check sources are, however, ideal for instrument standardization. Electronic calibrations that do not involve a source of radiation are generally not adequate to determine the proper functioning and response of all components of an instrument.
3. Daily or other frequent response checks (standardization) of contamination monitoring instruments be performed.
4. Description of calibration procedures must include, as a minimum:
    a. The name of the manufacturer and model number of each of the standards used.
    b. The nuclide and quantity of radioactive material contained in each of the standard sources,
    c. A statement of the accuracy of each of the standard sources. The source accuracy should be, as a minimum, $\pm$5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Institute of Technology Standards (NIST).

d. Step-by-step calibration procedures, and if appropriate, associated radiation safety procedures, and

e. The name and pertinent experience of each person who will perform the instrument calibrations.

Item 13. Personnel Monitoring: Chapter 246-221-090 WAC specifies when personnel monitoring is required. If film badge, optical sensitive luminescence (OSL), or thermoluminescent (TLD) dosimeters will be used, specify the name of the organizational furnishing the dosimetry service and the frequency for changing badges, dosimeters, etc. Dosimeter suppliers are required to belong to the National Voluntary Laboratory Accreditation Program or NVLAP. Make sure your dosimeter supplier is a member of NVLAP. If pocket chambers or pocket dosimeters will be used, specify the useful range of the device, in milliroentgens, the frequency of reading, and the procedures for maintaining and calibrating devices.

If personnel monitoring will not be used, submit calculations or documentation's from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in WAC 246-221-090(1)(a).

Item 14. Bioassay Program: Show that the need for bioassays has been thoroughly considered and establish the adequacy of the proposed bioassay program in relation to the proposed program of use of radioactive material. Consult Washington State Department of Health, Division of Radiation Protection, Regulatory Guide Regulatory Guide 8.20 "Bioassay Program Criteria for I-125 and I-131." For further guidance in establishing a bioassay Program consult U.S. Nuclear Regulatory Guide 8.9 "Acceptable Models, Equations, and Assumptions for Bioassay Program and WAC 246-221-100."

Specify and describe in detail the criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures. Provide the name and address of the service agency if a commercial bioassay services is to be used.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well-thought-out and well-executed handling procedures.

Item 15. Facilities: Attach to the application a diagram and description of the facilities, storage areas, and equipment. If there is more than one location of use, describe in detail the facilities and equipment for each site. The proposed facilities and equipment for each operation to be conducted should be adequate to protect health and minimize danger to life and property. In describing available facilities and equipment, include the following as appropriate:

1. Physical plant, laboratory, or working area facilities. Describe fume hoods, glove boxes, waste receptacles, special sinks, ventilation and contamination systems, effluent filter systems, and all processing, work, and protective clothing change areas.

   Submit a drawing showing the location of all such equipment and the relationship of areas where radioactive materials will not be handled. In those programs where radioactive material may become airborne or may be included in airborne effluents, include a schematic description of the ventilation system in the drawing or sketch annotated to show airflow rates, differential pressures, filtration and other effluent treatment equipment and air effluent monitoring instruments. Make the drawings or sketches to scale and include the dimensions of each drawing or sketch. Label each drawing or sketch to specify the location of the facilities and equipment depicted with respect to the address(es) given in Item 1A of Form RHF-1LI.

2. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Describe special provisions for shielding and containment to minimize personnel exposure. Storage containers and facilities should provide both shielding and security for materials.
3. The number, type, and length of remote handling devices.
4. Follow the provisions of Chapter 246-221-040 WAC and Chapter 246-221-117 WAC and submit appropriate information if respiratory protective equipment will be used to limit the inhalation of airborne radioactive materials.

Item 16. Survey Program: Department regulations require that surveys be made to determine if radiation hazards exist in a facility in which radioactive materials are used or stored (Chapter 246-221-110 WAC). Surveys include the evaluation of external exposure to personnel, concentrations of airborne radioactive material in the facility, and radioactive effluents from the facility. Although a theoretical calculation is often used to demonstrate compliance with regulations regarding airborne or external radiation, it cannot always be used in lieu of a physical survey.

Except for those cases where sources of radiation and radioactive materials are well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement material or, as a minimum, confirm the results of a theoretical determination.

Attachment D is included as a convenience to the applicant in establishing an acceptable survey program. If the applicant does not wish to utilize the Attachment D standard survey program, the applicant must submit a survey program including the following surveys:

1. In laboratory or plant areas (e.g., checking for contamination on bench tops, handling and storage equipment, clothing, hands).

2. While work is being done with radiation or radioactive materials (e.g., breathing zone air surveys; general air surveys; personnel exposure measurements, including eyes and extremities).
3. In areas associated with disposal or release of radioactive materials (e.g., checking disposal containers and disposal sites; liquid, gas, and solid effluents, filters and filter-duct systems).

The frequency of surveys will depend on the nature of the radioactive materials and their use. However, surveys should be performed prior to the use of radioactive materials in order to establish a baseline. The surveys should be repeated when radioactive materials are present and changes in the use, location, or control of radioactive materials occur.

For operations involving radioactive materials in gas, liquid, or finely divided forms, the survey program must be designed to monitor the adequacy of containment and control of the materials involved. The program must include air sampling, monitoring of effluents, and surveys to evaluate contamination of personnel, facilities, and equipment. Physical effluent measurements are essential to determine compliance with Chapter 246-21-290 WAC.

Item 17. Leak Test Program: Sealed sources containing more than 100 microcuries of a beta or gamma emitter must be leak tested at 6-month intervals. Leak testing of alpha-particle-emitting sources containing more than 10 microcuries of an alpha emitter is required at 3-month intervals. If a commercial firm is to perform the leak tests, the name, address, and license number of the firm should be submitted. If the tests are to be performed using a commercial "kit", the name of the manufacturer or distributor and processor of the kit should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information must be submitted:

1. Qualifications of personnel who will perform the leak test,
2. Procedures and materials to be used in taking test samples,
3. The type, manufacturer's name, model number, and radiation detection and measurement characteristics of the instrument to be used for assay of test samples.
4. Instrument calibration procedures, including calibration source characteristics, make, and model number, and
5. The method, including a sample calculation, to be used to convert instrument readings to units of activity, e.g., microcuries.

Item 18. Records Management Program: Complete and attach Appendix E (which defines required records for laboratory and industrial use of small quantities of radioactive material). Attach to application a sample of each record form used in the radiation safety program.

Item 19. Instructions of Personnel: Appendices F and G are provided as a convenience to the applicant in establishing an acceptable training program for radiological and non-radiological workers. If the applicant does to wish to utilize these standard appendices, an equivalent description of the personnel training program must be submitted with the application as an attachment. The instructions must include, but not necessarily be limited to:

1. The availability, selection, and use of laboratory apparel and safety-related equipment and devices (e.g., laboratory coats, gloves, and remote pipetting devices).

2. Limitations and conditions required for handling liquid or uncontained (unencapsulated, dispersible, or violate) radioactive materials and special laboratory equipment required for working with these types of materials. For example, the instructions must explain when operations with materials must be confined to a radiochemical fume hood or glove box and must specify the use of appropriate shielding and remote handling equipment when energetic beta-or gamma-emitting materials are to be used.
3. The performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.
4. Safety precautions required for the movement of radioactive materials between buildings, rooms and areas within rooms.
5. Safety requirements for storage of radioactive materials, including labeling of containers of radioactive materials and posting and securing areas where radioactive materials are to be stored. This should include the storage of contaminated laboratory equipment such as glassware.
6. Requirements for posting of areas in which radioactive materials are used.
7. The availability and use of personnel monitoring devices, including the recording of radiation exposures and the procedures required for the processing of personnel monitoring devices such as thermoluminescent dosimeters and film badges in order to obtain personnel monitoring results.
8. Waste disposal procedures required, including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage, and disposal of other wastes.
9. The maintenance of appropriate records as required by Chapter 246-221 WAC and Chapter 246-232 WAC.
10. The requirements for and the method of performing or having appropriate sealed-source leak tests performed.

11. Good radiation safety practices, including the control of contamination, specification and acceptable removable and fixed contamination levels for both restricted and unrestricted areas, prohibition of smoking and the consumption of food or beverages in areas where radioactive materials my be used, and prohibition of the frequent transfer of potentially contaminated equipment between potentially contaminated areas and unrestricted areas.

12. The use of radioactive material in animals. If radioactive materials will be used in animals, instructions concerning such use should be prepared and submitted with the license application. Such instructions should include (a) specification of the facilities to be used to house the animals, (b) instructions to be provided to animal caretakers for handling animals, animal wastes, and carcasses, (c) instructions to appropriate personnel for cleaning and decontaminating animal cages, and (d) methods to be used to ensure that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive materials. A description of animal handling and housing facilities should be included under Item 24 of Form RHF-1L1.

13. Emergency procedures. These instructions must be addressed to all personnel in all laboratory and facility areas where radioactive materials will be used and must cover actions to be taken in case of accidents involving radioactive materials such as spills, fires, release or loss of material, or accidental contamination of personnel. Specifically, these instructions must (1) specify immediate actions to be taken I order to prevent or limit the contamination of personnel and areas, e.g., the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas, containment of any spills of radioactive material, (b) give the telephone numbers of individuals to be notified in case of emergency, and (c) instruct personnel in proper entry, decontamination, and recovery operations for contaminated facilities. (Note: Only properly trained individuals should attempt decontamination and recovery operations).

14. Requirements and procedures for receiving and opening packages (see Chapter 246-221-160 WAC and Chapter 246-221-180 WAC).

Item 20. Waste Disposal: Appendix H is included for the convenience of the license applicant in establishing an adequate radioactive waste disposal program. If the applicant does not wish to utilize Appendix H, the applicant's procedures for disposing of radioactive waste must be described in an attachment to the application. Under department regulations, a licensee may dispose of waste in the following ways:

1. Transfer to a person properly licensed to receive such waste in conformance with Chapter 246-221-170 WAC. The name of the firm (which should be contacted in advance to determine any limitations that the firm may have on acceptance of waste) should be given.
2. Release into a sanitary sewer in conformance with Chapter 246-221-190. Depending on waster usage, releases of up to 1 curie per year are permitted.
3. Release into air or water in concentrations in conformance with Chapter 246-221 WAC and Chapter 246-247 WAC. Possible exposure to persons offsite limits the amount that may be released.
4. Other methods specifically approved by the department pursuant to Chapter 246-221-180 WAC.

Item 21. Emergency Procedures: Appendix I is included as a guide to the applicant in establishing acceptable emergency procedures. If the applicant does not wish to utilize Appendix I, then detailed emergency procedures equivalent to Appendix I must be submitted as an attachment to the license application. For guidance in composing acceptable emergency procedures, see Appendix I and also Item 19, Paragraph (13) of this Regulatory Guide.

Item 22. Ordering and Receiving Packages: Appendix J is an example of acceptable procedures for ordering and receiving packages. If the applicant does not wish to utilize Appendix J, the applicant must submit equivalent ordering and receiving procedures as an attachment to the license application. For guidance in composing such procedures, consult Appendix J and Chapter 246-221-160 WAC.

Item 23. Opening Packages: Appendix K is included for the convenience of the applicant in establishing acceptable procedures for opening packages. If the applicant does not wish to utilize Appendix K, the applicant must submit equivalent opening procedures as an attachment to the license application. For guidance in composing such procedures, consult Appendix K and Chapter 246-221-160 WAC.

Item 24. Animal Use: If no animal use is planned, check "Not Applicable" under Item 23 in Form RHF-1LI. If animal use is anticipated or planned, submit detailed radiation safety procedures (including waste disposal) as an attachment to the license application. For guidance in composing such procedures, consult Item 19, paragraph 12.

Item 26. Air Emissions Questionnaire: Please refer to Item 8A for yearly throughput. All radioactive Material License Holders are subject to Chapter 246-247 WAC, Air Emissions. However, most licensees will be exempted because their yearly throughput will not be large enough to activate the provisions of WAC 246-247. As accurately as possible, complete Attachment L and submit with the application.

Item 27. Surety and Decommissioning: Refer to Chapter 246-235-075. Read through this section and make a determination if your facility will require a decommissioning plan and a funding plan. If your facility does qualify for a decommissioning/funding plan contact the department for further guidance.

Item 28. License Fee Required: Consult Chapter 246-254-070 WAC for determination of required license fee. List fee category in Subitem 28.A. Enter license fee in Subitem 28.B. All new applications require one time fee of $150.00. Review of license application cannot commence until license fee has been received by Department of Health, Revenue Accounting, Post Office Box 1099, Olympia, Washington 98507-1099.

Item 29. Certificate: Item 20 must be completed on all applications. The form must be dated and signed by the corporate management (not the Radiation Safety Officer unless the management has filed with the department a statement authorizing the RSO to sign all applications).

5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supportive documents. The license must therefore be amended if the licensee plans to make any changes in facilities, equipment (including monitoring and survey instruments), procedures, personnel, or radioactive material to be used.

Applications for license amendments may be filed either on the application form or in letterform, and must be signed by an appropriate corporate official. The applications should identify the license number and should clearly describe the exact nature of the changes, additions, or deletions. Reference to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph.

6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the license does not expire until final action on the application has been taken by the department as provided for in Chapter 246-235-050 WAC.

Renewal application should be filed on Form RHF-1LI, appropriately supplemented, and should contain complete and up-to-date information about the applicant's current program.

In order to facilitate the review process, the application for renewal should be submitted without reference to previously submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page, and paragraph.