



REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.7

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY USE OF SMALL QUANTITIES OF BYPRODUCT MATERIAL

1. INTRODUCTION

This guide describes the type of information needed by the NRC staff to evaluate an application for a specific license for laboratories using millicurie quantities of byproduct material (reactor-produced radionuclides). This type of license is provided for under Title 10, Code of Federal Regulations, Part 30, "Rules of General Applicability to Licensing of Byproduct Material."

Paragraph 20.1(c) of 10 CFR Part 20, "Standards for Protection Against Radiation," states that "... persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, 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 NRC staff position on this important subject. License applicants should give consideration to the ALARA philosophy as described in Regulatory Guide 8.10, in the development of plans for work with licensed radioactive materials.

2. LICENSE FEES

An application fee is required for most types of licenses. The applicant should refer to §170.31, "Schedule of Fees for Materials Licenses," of 10 CFR Part 170 to determine the amount of fee that must accompany the application. Review of the ap-

plication will not begin until the proper fee is received by the NRC.

3. FILING AN APPLICATION

A license application for byproduct material should be submitted on Form NRC-313, "Application for Byproduct Material License" (see the appendix to this guide). All items on the application form should be completed in sufficient detail for the NRC to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form NRC-313 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 Form NRC-313) and its purpose (e.g., radiation safety instructions).

The application should be completed in triplicate. The original and one copy should be mailed to: Radioisotope Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. One copy of the application, with all attachments, should be retained by the applicant, since 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.

*Form NRC-313 was formerly designated Form AEC-313. Existing copies of Form AEC-313 may still be used.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

The guides are issued in the following ten topical divisions:

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|-----------------------------------|------------------------|
| 1. Power Reactors | 6. Products |
| 2. Research and Test Reactors | 7. Transportation |
| 3. Fuels and Materials Facilities | 8. Occupational Health |
| 4. Environmental and Siting | 9. Antitrust Review |
| 5. Materials and Plant Protection | 10. General |

Requests for single copies of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Document Control.

4. CONTENTS OF AN APPLICATION

Most items of Form NRC-313 are self-explanatory (see instructions with the form). The following comments apply to the indicated numbered items of the form.

Item 1(a). Specify the applicant corporation or other legal entity by name and address of principal office. Individuals should be designated as the applicant only if the use of the byproduct 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 code.

Item 1(b). Specify the street address of the location of use if the address differs from the one given in Item 1(a). If use is to be at more than one location, the specific address of each should be given. Describe the extent of use and the facilities and equipment at each location. A post office box address is not acceptable.

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

Item 5. Specify the name of the person who will be designated as the radiation protection officer.* This person should be responsible for implementing the radiation safety program and therefore readily available to the users in case of difficulty and should be trained and experienced in radiation protection and in the use and handling of radioactive materials.

Item 6(a) and (b). Describe the byproduct material by isotope, chemical and/or physical form, and activity, in millicuries or microcuries. A separate possession limit for each nuclide should be specified. Possession limits requested should cover the total anticipated inventory, including stored materials and waste, and should be commensurate with the applicant's needs and facilities for safe handling.

If the use of sealed or plated sources is contemplated, the isotope, manufacturer, and model number of each sealed or plated source should be specified. If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device should be specified.

Item 7. The use to be made of the radioactive materials should be clearly described. Sufficient detail should be given to allow a determination of the potential for exposure to radiation and radioactive materials of both those working with the materials and the public.

*The terms "radiation protection officer" and "radiological safety officer" are synonymous.

Items 8 and 9. A resume of the training and experience of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibilities for radiological safety should be submitted. The resume should include the type (on-the-job or formal course work), location, and duration of the training. Training should cover (1) principles and practices of radiation protection; (2) radioactivity measurements, standardization, and monitoring techniques and instruments; (3) mathematics and calculations basic to the use and measurement of radioactivity; and (4) biological effects of radiation. The description of the use of radioactive materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. 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 Commission will vary markedly with certain factors.

The use of microcurie quantities of a few non-volatile radioactive materials by a person with a minimum of training and experience under precisely specified and carefully controlled conditions subject to the surveillance of a competent and adequately trained radiation protection officer may be justified. 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 tutelage of a licensed user.

Persons using millicurie 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 under Item 8 of Form NRC-313.

The use of larger quantities of material (approaching a curie) 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 of Item 8 of Form NRC-313 but should also have extensive experience working with radioactive material and a thorough working knowledge of the equipment required to handle the material safely.

Items 10 and 11. Specify for each radiation detection instrument the manufacturer's name and model number, the number of each type of instrument available, the type of radiation detected (alpha, beta, or gamma), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness in mg/cm², and the type of use. The type of use would normally be monitoring, surveying, assaying, or measuring.

Describe the instrument calibration procedure. State the frequency, and describe the methods and procedures for the calibration of survey and 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 14), contamination samples (e.g., air samples, surface "wipe" samples), and bioassay samples (see Item 12).

An adequate calibration of survey instruments usually 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 or other frequent checks of survey instruments should be supplemented every 6 months with a two-point calibration on each scale of each instrument with the two points separated by at least 50% of the scale. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

If the applicant proposes to calibrate his survey instruments, a detailed description of planned calibration procedures should be submitted. The description of calibration procedures should include, as a minimum:

- a. The manufacturer and model number of each radiation source to be used.
- b. The nuclide and quantity of radioactive material contained in each source.
- c. The accuracy of the source(s). The traceability of the source to a primary standard should be provided.
- d. The step-by-step procedures, including associated radiation safety procedures, and
- e. The name and pertinent experience of each person who will perform the calibrations.

If the applicant intends to contract out the calibration of instruments, the name, address, and license

number of the firm should be specified together with the frequency of calibration. The applicant should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Commission. If information concerning calibration procedures has not been filed, it should be obtained and submitted.

Quantitative measuring instruments used to monitor the adequacy of containment and contamination control such as those used for measuring leak test, air, effluent, bioassay, work area, and equipment contamination samples should usually be calibrated prior to each use. The procedures and frequency for calibration of such instruments should be submitted and should include:

- a. The name of the manufacturer and model number of each of the standards to be 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, ± 5 percent of the stated value and traceable to a primary standard, such as that maintained by the National Bureau of Standards.
- 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 12. Personnel monitoring is required if a person is likely to receive in a calendar quarter 313 millirems to the body, 4.69 rems to the extremities, or 1.88 rems to the skin (lower limits apply to those under 18 years of age; see §§20.101 and 20.202 of 10 CFR Part 20). Personnel monitoring is also required if a person enters a high radiation area (greater than 100 millirems per hour). If personnel monitoring equipment will be used, the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service and the frequency for changing badges, dosimeters, etc., should be specified. If pocket chambers or pocket dosimeters will be used, the useful range of the device, in milliroentgens, the frequency of reading, and the procedures for maintaining and calibrating the devices should be specified.

If personnel monitoring will not be used, the applicant should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in the preceding paragraph.

The applicant should show that the need for bioassays has been thoroughly considered and should establish the adequacy of the proposed bioassay

program in relation to the proposed program of use of radioactive material. Bioassays are normally required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 depending on the type of work, equipment, and procedures followed. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be considered and discussed in relation to each such material, procedure, etc. Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,"* may be consulted.

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 should be specified and described in detail. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

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 13. The equipment and facilities for each site of use should be described in detail. The proposed equipment and facilities for each operation to be conducted should be adequate to protect health and minimize danger to life and property. In describing available equipment and facilities, the following types of information should be included, as appropriate:

a. Physical plant, laboratory, or working area facilities. Fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, and all processing, work, and protective clothing change areas should be described.

b. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Special provisions for shielding and containment to minimize personnel exposure should be described.

c. Storage containers and facilities. These should provide both shielding and security for materials.

d. The number, type, and length of remote handling devices.

* A copy of this guide may be obtained by a written request to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Office of Standards Development.

Item 14.

a. Survey Program. Commission regulations require that surveys be made to determine if radiation hazards exist in a facility in which radioactive materials are used or stored (see §20.201, 10 CFR Part 20). A survey should 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 material are well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement instruments to determine the nature and extent of radiation and radioactive material or, as a minimum, confirm the results of a theoretical determination.

A radiation protection program should include the following surveys for radioactive contamination and radiation:

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

(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; checking shutters and containment, etc.).

(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; etc.).

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, when the quantity of material present changes, or when changes occur in their containment systems or methods of use. Repetitive surveys may also be necessary to control the location of radioactive materials in the handling system and in the case of the use of sealed sources outside a shielded container.

For operations involving materials in gas, liquid, or finely divided forms, the survey program should be designed to monitor the adequacy of containment and control of the materials involved. The program should include air sampling, monitoring of effluents,

and surveys to evaluate contamination of personnel, facilities, and equipment.

The description of an air sampling program should include the area where samples will be taken, the frequency of sampling, and the location of the sampler with respect to workers' breathing zones. Assays performed to evaluate air samples and the methods used to relate results to actual personnel exposures should also be described.

The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid radioactive material releases. Theoretical evaluations should be supplemented by stack monitoring, water sampling, and other environmental monitoring appropriate for the planned and potential releases.

For operations involving only sealed sources, a survey program should include evaluation and/or measurement of radiation levels for storage and use configurations. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be performed following any changes in operation, shielding, or use.

The types, methods, and frequency of surveys should be specified. Guidance may be obtained from the National Council on Radiation Protection Report No. 10, "Radiological Monitoring Methods and Instruments,"* and the International Atomic Energy Agency's Technical Report Series No. 120, "Monitoring of Radioactive Contamination on Surfaces."**

b. Records Management Program. Provision for keeping and reviewing records of surveys; materials inventories; personnel exposures; receipt, use, and disposal of materials, etc., should be described. Persons responsible for keeping and reviewing records should be identified.

c. Emergency Procedures. The applicant should submit written emergency procedures for employees in case of spills, fires, release or loss of material, or accidental contamination of personnel, including decontamination procedures and the names of persons who are to be notified in an emergency.

d. Sealed-Source Leak-Test Procedures. Sealed sources containing more than 100 microcuries of a beta or gamma emitter or more than 10 microcuries of an alpha 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 kit manufacturer or distributor and the kit model designation should be given. If the applicant intends to perform his own leak tests without the use of a commercial kit, the following information should 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 15. The procedures for disposing of byproduct material waste should be described. Under NRC regulations, a licensee may dispose of waste in the following ways:

a. Transfer to a person properly licensed to receive such waste in conformance with paragraph 20.301(a) of 10 CFR Part 20. 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.

b. Release into a sanitary sewer in conformance with §20.303 of 10 CFR Part 20. Depending on water usage, releases of up to 1 curie per year are permitted.

c. Burial in soil in conformance with §20.304 of 10 CFR Part 20. Up to 12 burials per year are permissible. The allowable quantity depends upon the radionuclide.

d. Release into air or water in concentrations in conformance with §20.106 of 10 CFR Part 20. Possible exposure to persons offsite limits the amount that may be released.

e. Treatment or disposal by incineration in conformance with §20.305 of 10 CFR Part 20. This must be specifically approved by the Commission.

f. Other methods specifically approved by the Commission pursuant to §20.302 of 10 CFR Part 20.

*Copies may be obtained from NCRP Publications, P.O. Box 4867, Washington, D.C. 20008.

**Copies may be obtained from UNIPUB, Inc., P.O. Box 433, New York, N.Y. 10016.

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 byproduct material to be used.

Applications for license amendments may be filed either on the application form or in letter form. 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.

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 NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313, 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.

APPENDIX

Form AEC-313 (2-73) 10 CFR 30	UNITED STATES ATOMIC ENERGY COMMISSION APPLICATION FOR BYPRODUCT MATERIAL LICENSE	Form approved Budget Bureau No. 38-20037		
<p>INSTRUCTIONS—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Materials Branch, Directorate of Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the licensee is subject to Title 10, Code of Federal Regulations, Part 20, and the license fee provisions of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 16 and the appropriate fee enclosed. (See Note in Instruction Sheet)</p>				
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7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)				

(Continued on reverse side)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8 TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a Principles and practices of radiation protection			Yes No	Yes No
b Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
c Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d Biological effects of radiation			Yes No	Yes No

9 EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

10 RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary)					
TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mR/hr)	WINDOW THICKNESS (mg/cm ²)	USE (Monitoring, surveying, measuring)

11 METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE
12 FILM BADGES, DOSIMETERS, AND BIO ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier)

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13 FACILITIES AND EQUIPMENT Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached (Circle answer) Yes No
14 RADIATION PROTECTION PROGRAM Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.
15 WASTE DISPOSAL If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE (This item must be completed by applicant)

16 THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

License Fee Category \$ _____ Applicant named in item 1 _____

Fee Enclosed \$ _____ By: _____

Date _____ Title of certifying official _____

WARNING.—18 U. S. C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.