U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
December 1976

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.2

GUIDANCE TO ACADEMIC INSTITUTIONS APPLYING FOR SPECIFIC BYPRODUCT MATERIAL LICENSES OF LIMITED SCOPE

1. INTRODUCTION

This guide describes the type of information that should be submitted in applications for specific licenses of limited scope for the possession and use by academic institutions of byproduct material (reactor-produced radionuclides). It does not apply to applications for specific licenses of broad scope, licenses for source or special nuclear materials, or licenses for kilocurie irradiation sources. It includes the general principles that will be considered in evaluating an applicant's proposed radiation safety measures. 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" (10 CFR Part 30). Other regulations pertaining to this type of license are found in 10 CFR Part 19, "Notice, Instructions, and Reports to Workers; Inspections," and 10 CFR Part 20, "Standards for Protection Against Radiation." The applicant should carefully study the regulations and this guide and submit all information requested.

The Nuclear Regulatory Commission (NRC) will normally issue a single license to cover the academic institution's entire radioisotope program. Separate licenses are not normally issued to different departments of an academic institution, nor are they issued to individuals associated with the institution.

If the institution has an extensive radioisotope program with a need for a great variety of radionuclides for many uses, it may wish to apply for a specific license of broad scope. This type of license is described in 10 CFR Part 33, "Specific Licenses of Broad Scope for Byproduct Material." Information on the preparation of applications for specific licenses of broad scope or other types of licenses not covered by this guide may be obtained from: Radioisotopes 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.

Separate license applications should be submitted for special nuclear material (see 10 CFR Part 70), source material (see 10 CFR Part 40), or kilocurie sources used in gamma irradiation facilities. Information on the preparation of license applications for special nuclear material and for gamma irradiators may also be obtained from the NRC Radioisotopes Licensing Branch.

Before proceeding further, an applicant should determine if the institution's needs are in excess of the quantities specified in § 30.71, Schedule B, 10 CFR Part 30. It is not necessary to submit an application to the NRC for quantities of byproduct material that may be obtained pursuant to the exemption in § 30.18.

Three general principles that will be considered in evaluating proposed radiation safety measures are recognition by the institution of:

1. The management's* responsibility for the safety of employees and the public;

2. Its responsibility for maintaining offsite releases as low as is reasonably achievable (ALARA) and avoiding significant increases in environmental radioactivity; and

3. Its responsibility for minimizing exposures to employees, students, and visitors.

*Lines indicate substantive changes from previous issue.

* *Management* is defined as those persons authorized by the charter of the academic institution to make its policies and direct its activities.

This guide is intended only for general guidance in preparation of the license application and should not be considered a substitute for the applicant's careful safety evaluation of the proposed use of byproduct material. The applicant must ensure that the application correctly and adequately describes the radiation safety measures and procedures to be followed in order to provide adequate protection and satisfy the three general principles listed above.

Paragraph 20.1(c) of 10 CFR Part 20 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." 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 application will not begin until the proper fee is received by the NRC or an exemption is granted pursuant to § 170.11(4) of 10 CFR Part 170.

3. FILING AN APPLICATION

A license application for byproduct material should be submitted on Form NRC-313,* "Application for Byproduct Material License." 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.

The application should be completed in triplicate. The original and one copy should be mailed to: Radioisotopes 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.

4. INFORMATION TO BE SUBMITTED

Since the space on the Form NRC-313 is usually not sufficient to contain all the required information, additional sheets should be appended. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number (Form NRC-313) and its purpose, e.g., radiation safety instructions, survey procedures, or instructions for opening packages.

Item 1(a) Enter the name and corporate address of the academic institution.

Item 1(b) List all addresses and locations where byproduct material will be used or stored if other than that in Item 1(a), e.g., university-owned farm, second campus, research station. A post office box number should not be stated as the address for a place of use. These addresses and locations will become part of the license conditions, if the license application is approved, and the addresses or locations at which radioactive materials or radioactive wastes are located or stored may not be changed without obtaining a license amendment.

Item 2 List all departments or similar subdivisions of the institution where byproduct material will be used, e.g., biology, physics, chemistry, department of research.

Item 3 State previous byproduct license number if this is an application for renewal or amendment (see Sections 5 and 6 of this guide).

Item 4 List all individuals who will use or directly supervise the use of byproduct material. Give the title or position and describe the training and experience of each individual as outlined in Items 8 and 9.

Item 5 State name(s) and title(s) of person(s) designated by, and responsible to, the institution's management for the coordination of the institution's radiation protection program (sometimes designated the "Radiation Safety Officer").

Item 6(a) List each radionuclide to be used and specify the particular nuclides to be licensed for use by each individual named in Item 4.

Item 6(b) List the chemical and physical form and maximum quantity (in millicuries) of each radionuclide to be possessed at any one time. State separate possession limits for each chemical and physical form requested, e.g., iodine-131 as iodide and as labeled proteins. List the manufacturer, model number, and quantity for all sealed sources. The possession limit for each radionuclide should include material held as radioactive wastes.

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

Item 7 Describe the intended use for each radionuclide and form listed in Items 6(a) and 6(b). Any use of radioactive material in animals should be indicated. (Human use applications should be filed separately.)

Note: For Items 8 through 15, the applicant will find it necessary to append additional sheets to provide complete information.

Items 8-9 Items 8 and 9 should be completed for each individual named in Items 4 and 5 of the application form. Use separate appended sheets for each individual. Describe the training and experience of the radiation protection officer listed in Item 5, including his experience in using radiation and radioactive materials and his training in radiation protection. The radiation protection officer should be responsible to management for the overall radiation program within the institution. A statement describing this individual's responsibilities and authority for carrying out the radiation safety program should be provided.

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 $mg \cdot cm^{-2}$, 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 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 the source(s) to be used,

b. The nuclide and quantity of radioactive material contained in the source,

c. The accuracy of the source(s) and the traceability of the source to a primary standard,

d. The step-by-step procedures including associated radiation safety procedures, and

e. The name(s) and pertinent experience of person(s) 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 this information concerning calibration procedures has not been filed, it should be obtained and submitted.

Instruments that will be used for quantitative measurements to determine compliance with Commission regulations (e.g., leak test measurements, effluent monitoring) should be calibrated at 6-month intervals. A description of the procedure for calibration of such instruments should be submitted and should include:

a. The manufacturer and model number of the source(s),

b. The nuclide and quantity of radioactive material in the source(s),

c. The accuracy of the source(s) and the traceability of the source to a primary standard,

d. The step-by-step procedures for calibration, including associated radiation procedures, and

e. The name(s) and pertinent experience of person(s) who will perform the calibrations.

Item 12 State the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service and specify the frequency with which the badges are changed and evaluated. If pocket chambers or pocket dosimeters are used, state the useful range, frequency of reading, and the procedures for maintaining and calibrating the devices.

Describe the criteria, procedures, and equipment used for performing bioassays. If a commercial bioassay service is to be used, provide the name and address of the firm. Bioassays may be required when individuals work with millicurie quantities of hydrogen-3 in organic compounds, iodine-125, or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that radioactive material will be ingested, inhaled, or absorbed into the body. The institution should show in its application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the institution's intended use of radioactive material.

Item 13 Describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials. A diagram should be submitted showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should also include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Diagrams should be drawn to a specified scale, or dimensions should be indicated. The locations of the facilities and equipment should be specified with respect to the addresses and locations given in Item 1(b).

Item 14 Written radiation safety procedures to be followed by users should be provided as part of the application and should include the following items:

a. Procedures for ordering radioactive materials, for receipt of materials during off-duty hours, and for notification of responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured against unauthorized removal at all times, and that radiation levels in unrestricted areas do not exceed the limits specified in § 20.105 of 10 CFR Part 20. It is preferable that all radioactive materials be received in one location so that they may be reliably accounted for and surveyed expeditiously.

b. Procedures for examining incoming packages for leakage, contamination, or damage and for safely opening packages in accordance with § 20.205 of 10 CFR Part 20. The monitoring should be performed as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending upon the quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination. Even though § 20.205 exempts certain packages from *immediate* monitoring, all packages should be monitored before they are opened.

c. A description of training required for laboratory personnel or students who are involved in or associated with the use of radioactive materials. The description should include the form of training (e.g., formal course work, lectures), the duration of training, the subject matter included, and the means of determining the proficiency of each person handling radioactive materials. The training program should be of sufficient scope to ensure that all personnel using radioactive materials receive proper instruction in accordance with § 19.12 of 10 CFR Part 19 and are knowledgeable in radiation safety procedures and techniques pertinent to their respective duties.

d. A copy of general instructions to be followed by laboratory personnel or students while working with radioactive materials. These instructions should:

(1) Outline control procedures for obtaining permission to use radioactive materials at the institution; give limitations on quantity to be handled per student or allowed per experiment.

(2) Explain what laboratory apparel to wear and what safety equipment to use (e.g., use of laboratory coats, gloves, and remote pipetting devices).

(3) Prescribe limitations and conditions on handling liquid or loose (unencapsulated or dispersible) radioactive materials and what laboratory equipment to use in working with them. For example, explain when materials and operations should be confined to radiochemical fume hoods or gloveboxes and explain what shielding or remote handling equipment is to be used when hard beta- or gamma-emitting materials are handled.

(4) Instruct the user about routine survey and monitoring procedures for each contamination control zone.

(5) Instruct the user about movement of materials between rooms, halls, or in corridors, if applicable.

(6) Explain requirements for storage of materials and labeling of containers and how areas will be identified where radioactive materials are used. Explain where and how contaminated articles and glassware are to be handled and stored.

(7) Specify personnel monitoring devices to be used, where to obtain them, and instructions given on

recording exposure results or properly turning in personnel monitoring devices for processing at appropriate intervals.

(8) Instruct the user in waste disposal procedures to follow in the laboratory, including limitations for disposal of liquid or solid wastes by the user and procedures to use for waste storage within each laboratory.

(9) Explain what records are to be kept for the use and disposal of materials.

(10) Describe sealed-source leak-test procedures.

(11) Describe contamination control procedures, including restrictions against smoking and consumption of food and beverages.

e. A copy of emergency instructions to be posted in all laboratory areas where radioactive materials are used. These instructions should (1) 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 areas, containment of the spill, (2) state the telephone numbers of the responsible persons to be notified in case of an emergency, and (3) instruct personnel on appropriate methods for reentering, decontaminating, and recovering facilities that may have been accidentally contaminated.

f. Procedures to be followed if radioisotopes will be used in animals, including (1) a description of the animal housing facilities, (2) a copy of instructions provided to animal caretakers for handling animals, animal wastes, and carcasses, (3) instructions for cleaning and decontaminating animal cages, and (4) procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

g. A description of the routine survey program, including the areas to be surveyed, the types and levels of radiation and contamination considered to be acceptable, and provisions for maintaining records of surveys. The individual user should supplement the surveys performed by the radiation safety staff. Regularly used laboratories should be surveyed for contamination at the end of each workday (except when quantities less than those in Appendix C to 10 CFR Part 20 are handled by an employee at any one time), and the user should maintain records of such surveys in units required by 10 CFR Part 20, even if only a single measurement is necessary.

Item 15 Provide a complete description of specific methods used by the licensee for waste disposal of byproduct material. A licensee may dispose of waste by:

a. Transfer to a person properly licensed to receive such waste, e.g., commercial waste disposal firm (see Section 20.301 of 10 CFR Part 20).

b. Release into a sanitary sewer in conformance with Section 20.303 of 10 CFR Part 20.

c. Burial in soil in conformance with Section 20.304 of 10 CFR Part 20.

d. Release into the air in conformance with Section 20.106 of 10 CFR Part 20.

e. Other methods specifically approved by the NRC pursuant to Section 20.302 of 10 CFR Part 20.

Note: No licensee may dispose of byproduct material waste by incineration unless specifically authorized by the NRC (see Section 20.305 of 10 CFR Part 20).

Item 16 The application must be signed by a person authorized to sign on behalf of the academic institution. This will usually be an executive officer of the institution, the dean of the particular school, the business manager, or some other designated official.

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.

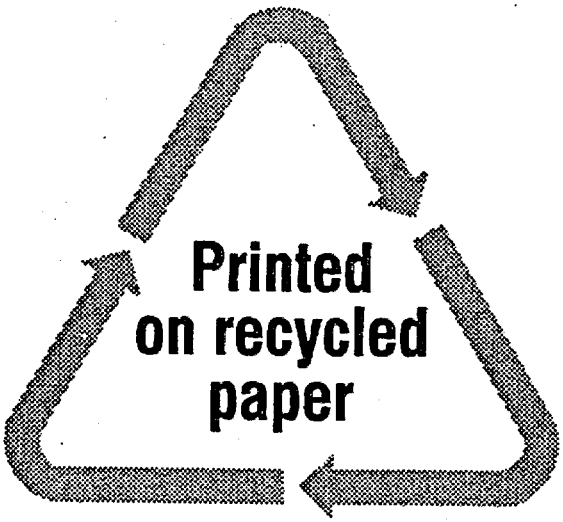
Applications for license amendments may be filed either on the application form or in letter form. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should 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 pertinent information by date, page, and paragraph.



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