



U.S. NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REGULATORY RESEARCH

DRAFT REGULATORY GUIDE AND VALUE/IMPACT STATEMENT

10-95-163

February 1985  
Division 10  
Task FC 408-4

PROPOSED REVISION 2 TO REGULATORY GUIDE 10.5

GUIDE FOR THE PREPARATION OF APPLICATIONS  
FOR TYPE A LICENSES OF BROAD SCOPE

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This regulatory guide and the associated value/impact statement are being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the value/impact statement. Comments on the value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by May 15, 1985.

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

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## 1. INTRODUCTION

### 1.1 PURPOSE OF GUIDE

This guide describes the information you need to provide when applying for a Type A license of broad scope (hereinafter termed a broad license) for byproduct material. The NRC regulation 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," provides for such a license. Section 33.11 of 10 CFR Part 33 defines a Type A license. Such licenses authorize possession of a wide variety of radioactive material without having each radionuclide and authorization listed on the license. Your application for a broad license can also include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material applied for under the provisions of paragraph 30.32(d) of 10 CFR Part 30. However, you should submit separate applications for uses of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad license.

### 1.2 CONCEPT AND CONDITIONS OF BROAD LICENSES

Broad licenses differ from all other types of materials licenses in that they are primarily based on the administrative procedures and organizational qualifications of the licensee to operate safely under the license rather than on a detailed review by the NRC of the qualifications, equipment, and procedures for each use and user. The applicant, through its radiation safety officer and radiation safety committee and based on past experience and performance under specific licenses, performs these detailed reviews in lieu of such reviews by the NRC.

Except for activities specifically excluded from broad licenses by paragraph 33.17(a) of 10 CFR Part 33, a broad license can cover any licensed material the applicant needs and for which it qualifies. The exclusions stated in paragraph 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad licenses may not

(1) conduct tracer studies in the environment involving direct release of radioactive material (field uses), (2) use 100,000 curies or more of byproduct material for irradiation of materials, (3) conduct activities licensed under 10 CFR Part 32 (manufacture or transfer of exempt and generally licensed items), 10 CFR Part 34 (radiography), or 10 CFR Part 35 (medical-human use), or (4) add or cause the addition of byproduct material to any food or other product designed for ingestion or inhalation by or application to a human being. Separate license applications should be submitted for these activities.

Broad licenses will be issued only to organizations that have:

1. Considerable prior experience in the use of radioactive materials under specific licenses of limited scope. Although not specified in the regulations, it is recommended that an applicant have had a limited specific license for at least a 5-year period.

2. A good performance record, including satisfactory understanding of and compliance with regulatory requirements and license conditions, based on NRC licensing and inspection of prior activities.

3. A radioactive materials utilization program of such scope that the organization needs a variety of radionuclides and the operational flexibility to cover numerous uses and users.

4. An administrative organization and procedures appropriate and adequate to ensure safe operations and to review and approve proposed uses, users, facilities, and procedures under the license.

### 1.3 APPLICABLE REGULATIONS

In addition to 10 CFR Part 33, other regulations pertaining to this type of license are found in 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 40, "Domestic Licensing of Source Material"; 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; and 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

This regulatory guide identifies the information needed to complete NRC Form 313 when applying for a Type A license of broad scope for byproduct material. The information collection requirements in NRC Form 313 have been cleared under OMB Clearance No. 3150-0120.

#### 1.4 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 20.1(c) of 10 CFR Part 20 states "...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. As an applicant, you should consider the ALARA philosophy as described in Regulatory Guide 8.10 in the development of plans for work with licensed radioactive materials.

#### 1.5 RADIOLOGICAL CONTINGENCY PLANNING

The Nuclear Regulatory Commission has an extensive program to reevaluate and upgrade the requirements for emergency preparedness of its major material licensees. In advance of comprehensive rulemaking, the NRC has required radiological contingency planning by certain licensees whose licensed activities exceed the criteria published in NUREG-0767, "Criteria for Selection of Fuel Cycle and Major Materials Licenses Needing Radiological Contingency Plans"\* (July 1981). These criteria include a schedule of possession limits above which contingency planning is required. A number of transuranic radionuclides have limits of less than 1 curie. The most restrictive limits for atomic numbers 1 to 83 are:

\*Copies may be obtained from the NRC/GPO Sales Program, U.S. Nuclear Regulatory Commission, Washington, DC 20555.



<u>Radionuclide</u>	<u>Curies</u>
I-129	1.0
I-131	3.3
I-125	8.0
P-32	15.0
Sr-90	25.0

You should submit a radiological contingency plan if (1) you request possession of radionuclides in forms other than as sealed sources and (2) the sum of the quotients of the requested quantities for individual radionuclides divided by the quantities of those radionuclides specified in the schedule of possession limits is greater than one.

You should consult NUREG-0767 for detailed calculations, but as an approximation, if the sum of the quotients for the above-listed nuclides with atomic numbers 1-83 is less than 0.9 and if no transuranic materials are required, a radiological contingency plan will probably not be required. If a contingency plan is required, review NUREG-0762, "Standard Format and Content for Radiological Contingency Plans for Fuel Cycle and Materials Facilities,"\* for further information.

## 1.6 PRELICENSING CONFERENCE

After an application has been reviewed by the NRC and found to be complete and responsive to NRC Form 313 and this regulatory guide, a prelicensing conference may be scheduled by the NRC at your facility. The NRC licensing staff and perhaps a member of the inspection staff would participate in this visit. You should be represented by your radiation safety officer (RSO), the chairman and preferably other members of your radiation safety committee (RSC), and one or more representatives of institutional management. The management representatives may or may not be members of the RSC and may be present for the entire conference or only for the summary, as is frequently the case during licensee inspections.

\*Copies may be obtained from the NRC/GPO Sales Program, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Discussions during the conference provide the NRC staff with a better understanding of your program and qualifications than can be obtained from the review of the written application. The conference includes observation and discussion of your facilities and equipment as they exist and as they will be provided for new or expanded uses.

A prelicensing conference provides the NRC staff with an opportunity to evaluate whether your program needs a broad license. It also provides the NRC staff an opportunity to impress on your management, RSO, and RSC the importance of their responsibilities under a broad license and to discuss and agree on additional information or commitments that may be needed. If a broad license is not warranted, the NRC staff may suggest and agree on continuation of your program with an appropriate specific license.

## 2. FILING AN APPLICATION

You should apply for a license by completing NRC Form 313 (see Appendix A). You should complete Items 1 through 4, 12, and 13 on the form itself. For Items 5 through 11, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number on the application to which it refers. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

You should complete all items in the application in enough detail for the NRC to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

Please note that license applications are available for review by the general public in the NRC Public Document Rooms. Do not submit proprietary information unless absolutely necessary. If submittal of such information is necessary, follow the procedure in § 2.790 of 10 CFR Part 2. Failure to follow this procedure may result in disclosure of the proprietary information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs

or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

You should file your application in duplicate. Retain one copy for yourself, because the license will require that you possess and use licensed material in accordance with the statements and representations in your application and any supplements to it.

Federal agencies should file applications with the U.S. Nuclear Regulatory Commission Regional Office as stated below.

If you are located in an Agreement State, you should file an application with the NRC only if you wish to possess and use licensed material in States subject to NRC jurisdiction. All other persons should file applications with the Nuclear Regulatory Commission Regional Office for the State in which they are located.

If you are located in Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, or Vermont, send your applications to the U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 475 Allendale Road, King of Prussia, PA 19406.

If you are located in Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, or West Virginia, send your applications to the U.S. Nuclear Regulatory Commission, Region II, Material Radiation Protection Section, 101 Marietta Street, Suite 2900, Atlanta, GA 30323.

If you are located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, send your applications to the U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, IL 60137.

If you are located in Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, or Wyoming, send your applications to the U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011.



If you are located in Alaska, Arizona, California, Hawaii, Nevada, Oregon, Washington, or U.S. territories and possessions in the Pacific, send your applications to the U.S. Nuclear Regulatory Commission, Region V, Material Radiation Protection Section, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

### 3. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of NRC Form 313.

#### Item 1 - LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check subitem C.

#### Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

Applicants should be corporations or other institutional entities. Because a broad licensee must have a radiation safety committee, it is not appropriate for a private individual to apply for a broad license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used, as specified in Item 3.

#### Item 3 - LOCATIONS OF USE

You should specify each location of use by the street address, city, and State or other descriptive address (such as 5 miles east on Highway 10, Anytown, State) to allow us to easily locate your facilities. A Post Office Box address is not acceptable. If byproduct material is to be used at more than one location, you must give the specific address of each location. In Items 5 through 11 of the application, describe the intended use and the facilities and equipment at each location.

If you plan to use radioactive material at temporary job sites, specify so and describe your procedures, including your procedures for transportation, storage, control of material against access by unauthorized users, and control of contamination.

#### Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

You should name the individual who knows your proposed radioactive materials program and can answer questions about the application. Provide his or her telephone number. This individual, usually the radiation safety officer or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify his or her position and relationship to you. Notify the NRC if the person assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

#### Item 5 - MATERIAL TO BE POSSESSED

Describe the byproduct material you wish to possess by isotope, chemical or physical form, and quantity in millicuries or microcuries. You should state the maximum quantity of each radioactive material you wish to possess at any one time. The usual entry is "\_\_\_\_ millicuries of each byproduct material with atomic numbers 1-83; total possession limit \_\_\_\_ millicuries or curies." The maximum quantities for individual nuclides and total possession should be commensurate with your needs, facilities, procedures, and personnel and should be consistent with your prior licensed activities. If a few nuclides will be needed in much larger quantities than others, they should be listed separately in Items 5a, 5b, and 5c, rather than increasing the quantity of all nuclides to include these larger quantities. If certain nuclides in the form of sealed sources will be needed in quantities larger than requested in Items 5a, 5b, and 5c in any form, these should be listed separately. Larger sealed sources should also be described by manufacturer and model number under Item 5b. Similarly, if certain relatively more hazardous nuclides (e.g., strontium-90) are not needed or are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 should be stated separately. Stored wastes should be included in establishing both individual nuclide and total maximum quantities. A typical entry for Items 5a, 5b, and 5c would be:

5a(1) Any byproduct material with atomic numbers 3-83 except as specified below.

5b(1) Any

5c(1) 50 millicuries of each radionuclide with atomic numbers 3 to 83, with a total possession limit of 2 curies except as specifically listed below.

- (2) Hydrogen-3
- (3) Carbon-14
- (4) Iodine-125
- (5) Strontium-90
- (6) Cesium-137

- (2) Any
- (3) Any
- (4) Any
- (5) Any
- (6) Sealed Source  
XYZ Co.  
Model 123

- (2) 1 curie
- (3) 500 millicuries
- (4) 300 millicuries
- (5) 1 millicurie
- (6) 5 curies

#### Item 6 - PURPOSE FOR USE OF LICENSED MATERIAL

Describe in general terms the purposes for which you will use licensed material and explain why you need a broad license rather than amendments to a specific license. The uses should be consistent with your prior licensed activities. Examples of appropriate uses are "research and development as defined in paragraph 30.4(q) of 10 CFR Part 30" and "processing or manufacture for distribution to authorized recipients." (Authorized recipients are persons who hold a specific license or a general license from the NRC or an Agreement State to receive such material or who are exempt from licensing requirements for the receipt of such material.)

"Processing or manufacture for distribution to authorized recipients" authorizes the in-house possession and use of radioactive material associated with such distribution, but it does not authorize the manufacture or transfer of any of the items or products for which separate specific licenses are required by 10 CFR Part 32. You must submit a separate application and license fee for the activities licensed pursuant to Part 32.

A broad license may include sealed sources for uses related to the basic purpose of the broad license (e.g., research and development or calibration of instruments). If you desire to use an irradiator under a broad license, you should follow the guidance in separate regulatory guides that cover licenses

for large sealed sources contained in irradiators.\* However, according to § 33.17 of 10 CFR Part 33, you may not use 100,000 curies or more of byproduct material in sealed sources for irradiation of material under a broad license.

A broad license does not authorize industrial radiography or human use of byproduct material unless these activities are specifically authorized pursuant to Part 34 or Part 35, respectively.

A broad license does not authorize the use of radionuclides in field studies that involve release of radioactive materials to the environment unless such studies are specifically authorized by a condition of the license. You should discuss proposals for such field uses with NRC licensing personnel before you submit an application for a license or license amendment.

## Item 7 - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY--THEIR TRAINING AND EXPERIENCE

### 7.1 Radiation Safety Officer

You are required to appoint a radiation safety officer (RSO) by paragraph 33.13(c)(2) of 10 CFR Part 33. The RSO should have an academic degree in physical or biological science or engineering and specific training in radiation health sciences and should have considerable professional experience (generally about 5 years) with radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. List and describe the training and experience of the RSO. If he or she is not a full-time paid employee of your organization, please provide his or her affiliation and state how many hours per week he or she will be available for RSO duties.

\*This guidance is contained in Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators." However, the NRC recently revised this guidance and issued two draft regulatory guides for public comment: Second Proposed Revision 1 to Regulatory Guide 10.9 (Task FC 402-4), "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Irradiators," and Task FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators."



## 7.2 Radiation Safety Committee

You are required to establish a Radiation Safety Committee (RSC) by paragraph 33.13(c)(1) of 10 CFR Part 33. The RSC should consist of such persons as the radiation safety officer, at least one representative of management, and technical persons representing the departments, groups, or activities that will use radioactive materials under the broad license. Each technical member of the RSC should have training and experience in the use of radioactive materials and radiation safety, but this background need not be as extensive as that of the RSO. The administrative member or members of the RSC should ensure management support of the radioactive materials program and due consideration of the financial, legal, and business interests of the organization. Administrative members of the RSC need not have a background in radiation safety.

You should identify the chairman and members of the RSC and their positions in your organization. Describe each member's formal training and work experience with radioactive materials and radiation safety. Either a resumé for each individual or a generic description of the minimum requirements for these positions may serve to describe training and experience.

## Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

You need not complete this item in an application for a broad license. Training for individuals working in or frequenting restricted areas will be included in Item 10.

## Item 9 - FACILITIES AND EQUIPMENT

Since broad licenses will be issued only to applicants who have had prior experience in the use of radioactive materials under other licenses, you will already have described your facilities and equipment. If these prior descriptions are still current, so indicate in Item 9 by stating: "See the application for license number \_\_\_\_." If not current, describe any new or altered facilities and equipment that are essential to the license being applied for. Your administrative procedures for internal control of uses under the broad license (discussed in Item 10) should include provisions for determination that your facilities and equipment are adequate for all uses to be conducted under the broad license.



## Item 10 - RADIATION SAFETY PROGRAM

The formal requirements for a radiation safety program under a broad license are contained in § 33.13 of 10 CFR Part 33. This regulation requires the applicant to have engaged in a reasonable number of activities involving the use of byproduct material and to have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. You should describe these organizational matters and internal procedures of your proposed program. Your description should be in narrative form and should include the elements identified below.

### 10.1 Previous Licenses

List the present and previous radioactive materials licenses for which this application requests a continuation or expansion of activities.

### 10.2 Radiation Safety Committee

Your RSC should establish policies and overall guidance for your radioactive materials program and should review, approve, and record safety evaluations of proposed uses of radioactive material before such use. The RSC should conduct a periodic audit of the safety program and review the activities of the RSO and the records that must be maintained to ensure compliance with conditions of the license and applicable parts of NRC's regulations. The RSC should meet as often as necessary to conduct its business (but not less than quarterly) and should keep minutes of committee meetings and activities.

You should describe the responsibilities and duties assigned to the RSC, the authority delegated to the RSC, and the frequency and quorum required for RSC meetings.

### 10.3 Radiation Safety Officer

The RSO should be responsible for the day-to-day coordination and management of the radiation safety program within your organization and should ensure compliance with the conditions of your license and the parts of the NRC's

regulations applicable to radiation safety. The RSO should report to top management in a staff capacity, should have ready access to all levels of the organization, and should have authority to immediately terminate a project that is found to be a threat to health, safety, or property. The RSO position for a broad-license program is usually a full-time assignment and is sometimes supported by a staff. You should indicate whether the RSO position is a full-time assignment and should state the size of the staff.

You should list the responsibilities and duties of the RSO in your application. The extent of these responsibilities and duties will depend on the scope of the proposed broad license; however, the following should be considered and included, if applicable:

1. Coordinating the RSC's review of safety evaluations of all proposed uses of radioactive material.
2. Generally overseeing all activities involving radioactive material, including conducting routine monitoring and special surveys of all areas in which radioactive material is used. The RSO generally conducts periodic surveys of work areas to supplement and audit routine monitoring by authorized users. You should indicate the types and frequencies of monitoring and surveys to be performed by the RSO.
3. Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the RSC.
4. Receiving, opening, and delivering all shipments of radioactive material arriving at the institution and receiving, packaging, and shipping all radioactive material leaving the institution.
5. Maintaining an inventory of all radionuclides at the institution and limiting the quantities of radionuclides to the amounts authorized by the license. The inventory record should include the name of the person responsible for each quantity of radionuclide, where it will be used or stored, and the date the quantity was delivered to that person. When items are removed from the inventory, it should show how and when the radionuclide was disposed of.
6. Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records and monitoring effluents.
7. Storing all radioactive materials not in current use, including wastes.
8. Distributing personnel monitoring devices and arranging for their processing, determining the need for and evaluating bioassays, keeping records

of personnel exposures and bioassays, notifying individuals and their supervisors of exposures that are approaching maximum permissible amounts, and recommending and supervising appropriate remedial action.

9. Performing or arranging for calibration of instruments.

10. Performing leak tests on sealed sources.

11. Conducting training programs and otherwise instructing personnel in the proper procedures before they are allowed to use radioactive material and as required by changes in procedures, equipment, regulations, etc. All individuals working in or frequenting a restricted area must receive certain instructions according to § 19.12 of 10 CFR Part 19. These individuals include not only radiation workers but also others such as clerical, custodial, and maintenance personnel.

12. Furnishing consulting services on all aspects of radiation safety to personnel at all levels of responsibility.

13. Monitoring and maintaining special filter systems associated with the use, storage, or disposal of radioactive material.

14. Supervising decontamination in case of contaminating accidents.

15. Maintaining other records not specifically designated above, e.g., records of surveys, radiation monitoring, and disposal as required by § 20.401 of 10 CFR Part 20, and records of receipts, transfers, and surveys as required by § 30.51 of 10 CFR Part 30.

#### 10.4 Administrative Procedures

You should establish administrative procedures to ensure control of procurement and the use of byproduct material and to ensure completion of safety evaluations of proposed uses of radioactive material under paragraph 33.13(c)(3) of 10 CFR Part 33. The safety evaluations should include a determination of the adequacy of facilities and equipment, training and experience of the users, and operating or handling procedures.

##### 10.4.1 Control of Procurement and Use

Your application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. Licensees usually have a procedure that centralizes all purchases or other

procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If you do not use such a centralized procedure, describe how your procedure prevents unauthorized procurement and use.

#### 10.4.2 Safety Evaluations of Proposed Uses

Your application should describe in detail the procedures and criteria for conducting the safety evaluations for approving uses and users. Some licensees with broad licenses use application forms and guidance adapted from NRC forms and regulatory guides to do the equivalent of a licensing review of each proposed use. A copy of your request and approval forms, if available, would be helpful to the NRC in its review of your application. Your procedures and criteria should include the evaluation and approval of:

1. Training and experience requirements for project supervisors and individual users who will use material without direct supervision.
2. Facilities and equipment for each specific use. The following should be considered:
  - a. Shielding,
  - b. Containment (hoods, filters, gloveboxes),
  - c. Restricted area controls and posting,
  - d. Remote handling equipment, and
  - e. Survey and monitoring instruments.

You should also include a commitment to keep, for the duration of your license, records of proposed uses approved by the RSC.

#### 10.5 Bioassays

Bioassays are appropriate when individuals work with iodine-131, iodine-125, or hydrogen-3 in quantities, chemical and physical forms, and activities that make it likely that radionuclides will be ingested, inhaled, or absorbed. Guidance on bioassay programs for iodine-131 and iodine-125, including the levels and types of handling for which bioassays are indicated, is provided in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131." Similar guidance

for bioassay programs for hydrogen-3 is available from the licensing office of the NRC with which your application will be filed.

Your application for a broad license should include a discussion of your proposed use of bioassays, including the types and quantities of isotopes and the types and frequency of manipulations for which bioassays will be performed. If you propose to use bioassays less conservatively than is recommended in the guidance discussed above, you should state your rationale.

#### 10.6 Emergency Procedures

Your application should include a copy of your emergency procedures for spills, fires, release or loss of material, and accidental contamination of personnel. These procedures should be posted in all restricted areas and should include instructions for:

1. Initial response to provide immediate safety precautions for people and property,
2. Securing the area,
3. Notifications, and
4. Requesting assistance.

Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, only properly qualified people should conduct decontamination and recovery operations. After the area is secure, the clean-up and recovery operations should be planned by the RSO or other qualified individuals on a case-by-case basis.

#### Item 11 - WASTE MANAGEMENT

You should describe your methods for disposal of radioactive waste. Your application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from nonradioactive, short half-life from long half-life, and liquid from solid waste). Under NRC regulations, you may dispose of waste in the following ways:



1. Transfer to a recipient (usually a waste disposal service company or the original supplier) properly licensed to receive such waste in accordance with paragraph 20.301(a) of 10 CFR Part 20. State the name and license number of the receiving company (which should be contacted in advance to determine any limitations that may apply to its acceptance of waste).
2. Release into a sanitary sewer in conformance with § 20.303 of 10 CFR Part 20.
3. Release into air or water in concentrations allowed by § 20.106 of 10 CFR Part 20.
4. Treatment or disposal by incineration in conformance with § 20.305 of 10 CFR Part 20. This method must be specifically approved by the NRC.
5. Disposal without regard to the radioactivity of hydrogen-3 and carbon-14 contained in scintillation-counting media and in animal tissue in concentrations of 0.05 microcurie or less per gram, subject to certain restrictions stated in § 20.306 of 10 CFR Part 20. This method of disposal need not be described in the application.
6. Other methods specifically approved by the NRC pursuant to § 20.302 of 10 CFR Part 20.

#### Item 12 - LICENSE FEES

An application fee paid in full is required by paragraph 170.12(a) of 10 CFR Part 170 for most types of licenses, including applications for license amendments and renewals. You should refer to § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of the fee that must accompany your application. An application received without a fee or with an inadequate fee may be returned to you. All application fees may be charged irrespective of the NRC's disposition of the application or your withdrawal of the application.

#### Item 13 - CERTIFICATION

The application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of the applicant's knowledge and belief. Unsigned applications will be returned for proper signature.

#### 4. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the Nuclear Regulatory Commission's regulations.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; NRC regulations do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form (NRC Form 313) or in letter form and should be submitted in duplicate to the address specified in Section 2 of this guide. Your application should identify your 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.

You must send the appropriate fee for a license amendment with your application. The NRC will not accept an application for filing or processing before the proper fee is paid in accordance with § 170.12 of 10 CFR Part 170.

#### 5. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. You must send an application for renewal to the address specified in Section 2 of this guide. You may submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information. As an alternative, you may:

1. Review your current license to determine whether the information accurately represents your current and anticipated program. Identify any additions, deletions, or other changes and then prepare information appropriate for the required additions or changes.

2. Review the documents you have submitted in the past to determine whether the information in them is up to date and accurately represents your management control program, facilities, equipment, personnel, radiation safety procedures, locations of use, and any other information pertinent to your program. Identify by date the documents that are representative of your current program. Since your current license includes documents submitted in the past, any out-of-date or superseded documents should be identified and changes should be made in these documents as necessary to reflect your current program.

3. Review the NRC regulations to ensure that any changes in the regulations are appropriately covered in your program description.

4. After you have completed your review, submit two copies of a letter, with the proper fee, requesting renewal of your license and providing the information specified in items 1, 2, and 3, as necessary. If your current license and supporting documents accurately reflect your current program, state that operations will continue in accordance with these documents and applicable NRC regulations and license conditions.

5. Include the name and telephone number of the person to be contacted about your renewal application, and include your current mailing address if it is not on your license.

If you file your application for license renewal at least 30 days before the expiration date of your license and include the appropriate fee for license renewal, your present license will automatically remain in effect until the NRC takes final action on your application for renewal. However, if you file an application less than 30 days before the expiration date and the NRC cannot process it before that date, you would be without a valid license when your license expires.

It is important that the appropriate fee accompany your application for license renewal. In accordance with § 170.12 of 10 CFR Part 170, the NRC will not accept an application for filing or processing before the proper fee is paid.

If you do not wish to renew your license, you must dispose of all licensed radioactive material in a manner authorized by 10 CFR Part 20. Complete NRC Form 314, "Certificate of Disposition of Materials," and send it to the NRC before the expiration date of your license with a request that your license be terminated.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating NRC's regulations that do not allow you to possess licensable material without a valid license.

NRC FORM 313 (9-81) 10 CFR 30.32, 33, 34, 35 and 40	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB NO. 3150-0120 EXPIRES 6-30-93 ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 125 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFOR- MATION AND RECORDS MANAGEMENT BRANCH (MRSB 7114) U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555 AND TO THE PAPERWORK REDUCTION PROJECT (3150- 0120) OFFICE OF MANAGEMENT AND BUDGET WASHINGTON DC 20503		
<h2 style="margin: 0;">APPLICATION FOR MATERIAL LICENSE</h2>				
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.				
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p><b>APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</b></p> <p>U.S. NUCLEAR REGULATORY COMMISSION            DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS            WASHINGTON, DC 20555</p> <p><b>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:</b></p> <p>CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,            MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,            RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION I            NUCLEAR MATERIALS SAFETY SECTION B            475 ALLENDALE ROAD            KING OF PRUSSIA, PA 19406</p> <p>ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA,            PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR            WEST VIRGINIA, SEND APPLICATIONS TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION II            NUCLEAR MATERIALS SAFETY SECTION            101 MARIETTA STREET, SUITE 2800            ATLANTA, GA 30322</p> </div> <div style="width: 48%;"> <p><b>IF YOU ARE LOCATED IN:</b></p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR            WISCONSIN, SEND APPLICATIONS TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION III            MATERIALS LICENSING SECTION            799 ROOSEVELT ROAD            GLEN ELLYN, IL 60137</p> <p>ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA,            NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH,            OR WYOMING, SEND APPLICATIONS TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION IV            MATERIAL RADIATION PROTECTION SECTION            611 RYAN PLAZA DRIVE, SUITE 1000            ARLINGTON, TX 76011</p> <p>ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON            AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS            TO:</p> <p>U.S. NUCLEAR REGULATORY COMMISSION, REGION V            NUCLEAR MATERIALS SAFETY SECTION            1460 MARIA LANE, SUITE 210            WALNUT CREEK, CA 94698</p> </div> </div>				
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.				
<div style="display: flex;"> <div style="width: 50%; border-right: 1px solid black; padding-right: 5px;"> <p>1. THIS IS AN APPLICATION FOR (Check appropriate item):</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p> </div> <div style="width: 50%; padding-left: 5px;"> <p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)</p> </div> </div>				
<p>3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p>				
<div style="display: flex; justify-content: space-between;"> <p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>TELEPHONE NUMBER</p> </div>				
<p>SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.</p>				
<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number, b. chemical and/or physical form, and c. maximum amount          which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED</p>			
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR          TRAINING AND EXPERIENCE</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p>			
<p>9. FACILITIES AND EQUIPMENT</p>	<p>10. RADIATION SAFETY PROGRAM</p>			
<p>11. WASTE MANAGEMENT</p>	<p>12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">FEE CATEGORY</td> <td style="width: 30%;">AMOUNT ENCLOSED \$</td> </tr> </table>		FEE CATEGORY	AMOUNT ENCLOSED \$
FEE CATEGORY	AMOUNT ENCLOSED \$			
<p>13. CERTIFICATION (Must be completed by applicant): THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE          BINDING UPON THE APPLICANT.</p> <p>THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS          PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN          IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</p> <p>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.</p>				
<p>SIGNATURE—CERTIFYING OFFICER</p>	<p>TYPED/PRINTED NAME</p>	<p>TITLE</p>		
<p>DATE</p>				
<b>FOR NRC USE ONLY</b>				
<p>TYPE OF FEE</p>	<p>FEE LOG</p>	<p>FEE CATEGORY</p>		
<p>COMMENTS</p>				
<p>AMOUNT RECEIVED</p>	<p>CHECK NUMBER</p>			
<p>APPROVED BY</p>				
<p>DATE</p>				



## DRAFT VALUE/IMPACT STATEMENT

### 1. BACKGROUND

Among the licenses issued by the NRC are those of broad scope for byproduct material. In December 1980, the NRC issued Revision 1 of Regulatory Guide 10.5 to provide guidance for preparing applications for these licenses. The guide was prepared for use with application Form NRC-313I, which was superseded in July 1984 by a new application form, NRC Form 313. This proposed revision of Regulatory Guide 10.5 is to provide up-to-date guidance in a format compatible with the new NRC Form 313.

### 2. PROPOSED ACTION

#### 2.1 Description

An applicant for a license of broad scope is required to have a program that complies with NRC regulations and to describe this program in the license application. The proposed action is to issue Revision 2 of Regulatory Guide 10.5 to conform to the new NRC Form 313 and to state guidance in a more straightforward manner. There have been no changes in guidance with regard to health and safety requirements.

#### 2.2 Need

Revision 2 of Regulatory Guide 10.5 is needed to provide up-to-date guidance that conforms to the new NRC Form 313.

#### 2.3 Value/Impact

##### 2.3.1 NRC

The review and approval of applications for the use of byproduct material would be facilitated by the instructions and guidance to be provided in the proposed regulatory guide. The proposed action would clearly detail the

regulations to be followed and the information required for licensing and implementing an acceptable program. Staff review time would be shortened because less correspondence would be needed to compensate for the lack of sufficient detail in license applications.

#### 2.3.2 Other Government Agencies

Other government agencies would not be affected unless they are applicants.

#### 2.3.3 Industry

The proposed action would contribute to a reduction in the time required for preparing a license application. An applicant would spend less time trying to interpret NRC regulations and requirements for information. More importantly, the proposed action would provide information for the design and implementation of a more effective radiation safety program, thereby minimizing the exposure of workers to radiation.

#### 2.3.4 Public

No impact on the public is foreseen.

#### 2.3.5 Workers

Workers may benefit from the guide through potentially reduced exposure to radiation as discussed in Item 2.3.3.

### 2.4 Decision on Proposed Action

Revision 2 to Regulatory Guide 10.5 should be prepared because of the benefits previously discussed.

## 3. TECHNICAL APPROACH

Not applicable.

#### 4. PROCEDURAL APPROACH

##### 4.1 Alternatives

Regulatory Guide 10.5 presently exists. Revision 2 of the guide is necessary because of a change in the application form. The only alternative is to discontinue use of the guide altogether and write individual letters to applicants.

##### 4.2 Discussion

A regulatory guide is the most effective way to transmit information about regulations and licensing requirements. A regulatory guide ensures uniform transmission of information to applicants. Individual letters would be inefficient and, depending on the reviewing official, may not uniformly convey the same information to each applicant. Revision of the guide is the most effective alternative.

#### 5. STATUTORY CONSIDERATIONS

##### 5.1 NRC Authority

Authority for the proposed action is derived from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, and implemented through the Commission's regulations.

##### 5.2 Need for NEPA Assessment

Issuance or amendment of guides for the implementation of regulations in Title 10, Chapter I, of the Code of Federal Regulations is a categorical exclusion under paragraph 51.22(c)(16) of 10 CFR Part 51. Thus, an environmental impact statement or assessment is not required for this action.

6. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps appear to exist.

7. SUMMARY AND CONCLUSIONS

The guide, when disseminated, will assist the NRC and the industry in reviewing and preparing applications that conform to the new NRC Form 313 for the use of byproduct material. The regulatory guide should be revised.