U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
April 1977

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.3

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR SPECIAL NUCLEAR MATERIAL LICENSES OF LESS THAN CRITICAL MASS QUANTITIES

1. INTRODUCTION

1.1 Purpose of Guide

This guide describes the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of special nuclear material. It is intended for applicants requesting authorization to possess and use up to 2,000 grams of plutonium, total, in the form of sealed plutonium-beryllium neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass. The latter quantities are considered to be 350 grams of contained uranium-235, 200 grams of uranium-233, 200 grams of plutonium (in any form other than plutonium-beryllium neutron sources), or any combination of them in accordance with the following formula:

$$\frac{\text{grams U-235}}{350} + \frac{\text{grams U-233}}{200} + \frac{\text{grams Pu}}{200} = 1$$

For each kind of special nuclear material, the applicant should determine the ratio between the requested quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination should not exceed unity if this guide is applicable. For example, the following in combination would not exceed the limitation of the formula:

$$\frac{175\ (\text{grams contained U-235})}{350} + \frac{50\ (\text{grams U-233})}{200} + \frac{50\ (\text{grams Pu})}{200} = 1$$

1.2 Applicable Regulations

Special nuclear material licenses are issued pursuant to Part 70, "Special Nuclear Material," of Title 10, Code of Federal Regulations. Special nuclear material, by definition in 10 CFR Part 70, means plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission determines to be special nuclear material or any material artificially enriched by any of the foregoing. In addition to 10 CFR Part 70, the regulations pertaining to special nuclear material licenses 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 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions;" and 10 CFR Part 170, "Fees for Facilities and Materials Licenses Under the Atomic Energy Act of 1954, as Amended." The applicant should study carefully the regulations and this guide and should submit all information requested.

1.3 Items Requiring Separate Applications

Activities that involve the receipt, possession, use, and transfer of special nuclear material in quantities and forms sufficient to form a critical mass are not within the scope of this guide.

1.4 As Low As Is Reasonably Achievable (ALARA)

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 Exposure 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 the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC.

3. FILING AN APPLICATION

A license application for special nuclear material should be filed in letter form and should provide the information specified in §70.22, "Contents of Applications," of 10 CFR Part 70. All items 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.

Each separate sheet or document submitted with the application should be identified as to its purpose, e.g., response to an item of the regulation, radiation safety instructions, etc. Seven copies of the application should be completed. The original and five copies 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 licensee follow the statements and representations set forth in the application and any supplement to it.

3.1 Proprietary Information

The information required in applications usually can be presented without the use of proprietary data. When its use cannot be avoided, the proprietary information should be separated from the rest of the application, and an application for withholding from public inspection should be made in accordance with the requirements of §2.790 of 10 CFR Part 2, "Rules of Practice."

3.2 Safeguards and Criticality

For licenses included in the scope of this guide, no safeguard information is required in an initial application. The Commission uses an electronic data processing procedure to record the location, by licensee, of special nuclear material. This system uses a three-letter Reporting Identification Symbol (RIS) to identify licensees who must submit material transfer reports and periodic material status reports in accordance with §§70.53, "Material Status Reports," and 70.54, "Nuclear Material Transfer Reports," of 10 CFR Part 70. Applicants will be assigned an RIS and will be informed how it is to be used following issuance of the license. Requirements for reports will be forwarded under separate cover following the issuance of either a license or an amendment authorizing greater than 1 gram of special nuclear material.

No information concerning criticality provisions is required if no more than 450 grams of plutonium as plutonium-beryllium neutron sources are requested. For quantities greater than 450 grams as neutron sources, no criticality information is required provided adequate procedures to ensure that no more than 450 grams will be used or stored at any single site are submitted.

4. CONTENTS OF AN APPLICATION

4.1 Specification of Applicant

The applicant corporation, institution, government agency, or other legal entity should be specified by name, street address of principal office, and the state where incorporated. Any control or ownership exercised over the applicant by any alien, foreign corporation, or foreign government should be indicated. The principal officials of the applicant corporation should be indicated by name, title, address, and citizenship. Individuals should be designated as the applicant only if the use of the special nuclear material is not connected with employment with a corporation or other entity. If the applicant is an individual, the individual should be specified by full name, age, citizenship, and street address, including state and zip code. The individual applicant should also indicate three personal references identified by name, address, and citizenship.

4.2 Specification of Activities To Be Performed

The operations for which the special nuclear material will be used and a general plan for carrying out the activity should be described. This information should be specified for each location where the special nuclear material will be used. Each individual operation should be described. The purpose of this descriptive information is to enable the Commission to determine that the special nuclear material will be used for activities permitted under the Commission's regulations and the Atomic Energy Act of 1954, as amended.

4.3 Specification of Special Nuclear Material

The special nuclear material requested should be identified by isotope; chemical or physical form; activity in curies, millicuries, or microcuries; and mass in grams. Specification of isotope should include principal isotope and significant contaminants. Major dose-contributing contaminants present or expected to build up are of particular interest. For example, the quantity of plutonium-236 present in plutonium-238 should be specified.

Possession limits requested should cover the total anticipated inventory, including stored materials and waste.

If the application is for a sealed source or plated source, the special nuclear material content and manufacturer's name and model number of each sealed or plated source should be specified. If a sealed source will be used in a device (holder, gage, analyzer, etc.), the manufacturer's name and model number of the device should be identified. Each source should be keyed to the specific devices used with it.

4.4 Technical Qualifications of Personnel

A resume of the training and experience of each person who will directly supervise the use of material or will have radiological safety responsibilities should be submitted. The resume should include the type of training (e.g., on-the-job or formal course work), the location where the training was received, and the duration of the training. Training should include subjects such as (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 actual use of radioactive materials or equivalent experience 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 should be commensurate with the proposed use of the material requested in the application.

4.5 Description of Equipment, Facilities, and Instrumentation

The equipment, facilities, and radiation detection instrumentation for each site of use should be described in detail. The proposed equipment and facilities for each activity must 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:

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

2. Storage containers and facilities. Consideration of both shielding and security of materials should be indicated.

3. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc., actually employed in the daily use of material. Shielding and containment provision for loose materials designed to minimize personnel exposure should be described.

4. Physical plant, laboratory, or working area facilities. A description of all fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, including the design specifications and capabilities of these systems, should be included. All processing, work, and change areas should be described. Applications for chemical or physical processing operations should include a description of the controls for fire prevention and the firefighting equipment available. Sketches showing laboratory or plant arrangements and the nature and use of areas adjacent to areas in which special nuclear materials will be processed should be submitted.

5. Radiation detection instruments to be used. The manufacturer's name and model numbers, the number of each type available, the type of radiation detected (alpha, beta, gamma, or neutron), the sensitivity range (milliroentgens per hour, neutrons per second, or counts per minute), the window thickness in mg/cm^2, and the type of use for each instrument should be specified. The type of use would normally be monitoring, surveying, assaying, or measuring.

Instrument calibration provisions should be described. State the frequency, and describe the methods and procedures for 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, contamination samples (e.g., air samples, surface smear-test samples), and bioassay samples (see Item 4.6.3.3).

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

* Lines indicate substantive changes from previous issue.

be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% 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 each source. 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 survey instruments, the name, address, and license number of the calibration 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% 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.

4.6 Proposed Procedures To Protect Health and Minimize Danger

Procedures should be established to ensure compliance with provisions of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections," and 10 CFR Part 20, "Standards for Protection Against Radiation." The procedures should be specific for the activities for which a license is sought. Depending on the types and quantities of materials and the scope of use, the following information should be submitted:

4.6.1 Specification of Radiation Safety Responsibilities and Duties

The responsibilities and duties of management, any radiation safety committees, radiation safety officers, and users should be clearly established. Individuals having radiation safety responsibilities should be identified by name, and pertinent training and experience should be described (see Section 4.4). Assignment of duties should cover all aspects of the radiation safety program.

4.6.2 Personnel Monitoring

1. Personnel monitoring equipment (film badge, TLD, dosimeters) should be specified, including the type of radiation monitored (beta, gamma, or neutron), the frequency of evaluation, and the type of services to be obtained from a commercial supplier. This specification should include whether the monitoring is to evaluate whole body or extremity exposure. If dosimeters are to be used, the type, range, frequency of reading, and maintenance and calibration provisions should be specified.

2. If no personnel monitoring is specified, the applicant should submit an evaluation of expected exposures from the proposed use. This evaluation should demonstrate that no individual is likely to receive a dose in any calendar quarter in excess of 0.31 rems to the whole body, blood-forming organs, lens of the eye, or gonads; 4.69 rems to extremities (hands, forearms, feet, or ankles); or 1.88 rems to the skin of the whole body from all sources and types of occupational exposures.

3. For processing operations where a potential for internal deposition of radioactive material exists, a bioassay program may be required. Regulatory Guide 8.11, "Applications of Bioassay for Uranium," deals with depleted, natural, and enriched

uranium, but the general requirements and methods are applicable for a special nuclear material bioassay program.

4.6.3 Radiation Survey Program

1. A survey is defined as an evaluation of the radiation hazards incident to production, use, release, disposal, or presence of radioactive materials. When appropriate, such evaluation includes a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present in air, water, or other materials and on surfaces. The types, methods, and frequency of surveys should be specified according to the nature and complexity of the special nuclear material program.

2. For operations involving only sealed sources, a survey program should include evaluation and/or measurement of gamma and neutron 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, use, or location of the device.

3. For operations involving materials in forms other than as sealed sources, the survey program should also be designed to monitor the adequacy of containment and contamination control. The program should include air sampling, bioassays, monitoring effluent releases, and surveys to evaluate alpha contamination of personnel, work areas, and equipment.

a. The specification of an air sampling program should include the areas where samples will be taken, the frequency of sampling, the relationship to the processing or maintenance phase, and orientation of sampler with respect to workers' breathing zones. The type of assays that will be performed to evaluate air samples and the methods used to relate results to actual personnel exposures should be described.

b. The effluent monitoring program for releases to unrestricted areas should encompass all airborne and liquid releases. Calculational evaluations should be supplemented by stack monitoring appropriate for the planned and potential releases.

c. The survey program for evaluating alpha contamination of personnel and plant surfaces should include provisions for monitoring protective clothing, hands, and feet of workers leaving restricted areas before breaks and at the end of shifts. Evaluation (alpha and/or gamma levels) of gloves or other protective clothing, equipment, or tools required during processing should be described. Surface contamination evaluation should include unrestricted areas such as lunch rooms, offices, etc. The survey program to monitor cleanup efforts for work areas where dust or loose materials are produced or spread should be described. Reasonable efforts should be made to remove all residual contamination. Acceptable limits of fixed and removable contamination for facilities in restricted areas should be set.

4. Acceptable limits of fixed and removable contamination for facilities and equipment in unrestricted areas and for release for unrestricted use should be set. For example, after reasonable effort to remove all residual contamination, if maximum alpha levels are 300 dpm*/100 cm^2 or less and the average is 100 dpm/100 cm^2 or less, unrestricted use is permissible, provided that removable alpha contamination does not exceed 20 dpm/100 cm^2. These guidelines apply to all special nuclear material except mixtures of the naturally occurring isotopes of uranium (U-234, U-235, U-238) for which the levels may be a factor of 5 higher.

5. A survey program for pilot studies and initial phases of a full-scale production operation needed for evaluating and verifying actual hazards may be more extensive than the survey program that may be appropriate for the day-to-day program. Provisions for the evaluation of all changes in operation should be made.

4.6.4 Waste Disposal

1. Wastes generated as a result of operations involving special nuclear material need to be disposed of in a safe manner. Such wastes may include items such as contaminated tools, gloves, clothing, absorbent materials, filters, resin columns, decontamination solutions, or process wastes (see §§20.301-20.305, which deal with waste disposal, of 10 CFR Part 20).

2. Wastes that are soluble or readily dispersible in water may be disposed of via the sanitary sewer system subject to the concentration and daily, monthly, and annual limits specified in §20.303 of 10 CFR Part 20. For example, up to 0.1 microcurie of uranium-233 may be disposed of daily, provided the concentration in sewage released does not exceed 9×10^{-4} microcurie/milliliter when diluted by the average daily quantity of sewage. Releases to sewage of all radioactive materials by a licensee are limited to one curie/year and average monthly concentrations not exceeding restricted area water concentrations.

* Alpha disintegrations per minute, not counts per minute.

3. Burial in soil is another method of waste disposal.* Such burials are subject to the 4-foot depth, 6-foot separation, and 12/year limitations of §20.304 of 10 CFR Part 20. The quantity per burial is limited to 10 microcuries for special nuclear material.

4. The most commonly used method of disposal is transfer to a commercial firm licensed to accept such wastes. Lists of such firms are available from the Commission upon request. In dealing with such firms, prior contact is recommended to determine specific services provided.

5. Other methods of disposal may be considered and justified on a case-by-case basis. The information specified in §20.302 of 10 CFR Part 20 should be submitted to support a request for any alternative methods of disposal. This information should include the quantities and kinds of materials, the levels of radioactivity, a description of the manner and conditions of disposal, an evaluation of environmental considerations, and the control procedures.

6. The applicant should specifically indicate how wastes will be disposed of.

4.6.5 Record Management

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

4.6.6 Material Control Provisions

Procedures for ordering materials, receiving materials, notifying responsible persons upon receipt, and opening packages should be indicated. Section 20.205 of 10 CFR Part 20 requires monitoring of certain packages upon receipt, depending on the quantity of radioactive material contained and its form. Packages containing less than 10 microcuries of plutonium, 100 microcuries of uranium-233, or 1 millicurie of uranium-235 are exempt from monitoring. Monitoring of external surfaces is required if these quantities are exceeded. If removable contamination in excess of 0.01 microcurie/100 cm^2 is found on the external surface of the outer container, notification of the shipper and the Commission is required. Packages containing sealed sources are exempt from surface monitoring requirements as "special form." Monitoring of external radiation levels is also required for certain quantities.

*The Commission is considering amendments to 10 CFR Part 20 that would prohibit the disposal of transuranium elements by burial in soil pursuant to §20.304. If adopted, the amendments would require that such waste be transferred to the Commission for storage as soon as practicable but within 5 years after its generation.

4.6.7 Sealed-Source Leak-Testing Provisions

1. Plutonium-beryllium sealed neutron sources and certain plutonium gamma sources are required by license condition to be tested for leakage and contamination at intervals not to exceed 6 months. Sealed sources designed as alpha sources and other plutonium sources must be tested at intervals not to exceed 3 months. When the supplier does not certify that such tests have been performed within the appropriate interval, the sources are not to be used until leak tested. The test should be capable of detecting the presence of 0.005 microcurie of alpha contamination on the test sample. The test sample should be taken from the source or from appropriate accessible surfaces of the device in which the sealed source is permanently mounted or stored where contamination could appear if the source were defective. Records of leak-test results are required by license condition to be maintained for inspection by the Commission. Any leaking sources must be withdrawn from use. Provision for decontamination, repair, or disposal should be made.

2. If the applicant desires to perform his own leak tests, the following information should be submitted:

a. Qualifications of personnel who will perform the leak test,

b. Safety procedures to be followed during the test,

c. Test procedures and materials or commercial kit to be used, and

d. Type, manufacturer's name, and model number of the instrument to be used for assay of test samples.

4.6.8 General Safety Instructions

A copy of the general radiation safety instructions to be followed by laboratory or field personnel while working with radioactive material should be submitted.

4.6.9 Emergency and Decontamination Procedures

A copy of emergency procedures to be posted in all laboratory or work areas where radioactive materials are used should be submitted. These instructions should describe immediate action to be taken in case of an emergency in order to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures are turning off the ventilation systems, evacuation of the area, reentry, procedures for containment of spills, etc. The instructions should specifically state the names and telephone numbers of responsible persons to be notified.

4.6.10 Procedures for Training Personnel

A description of the training program for all personnel who are involved in or associated with the use of material should be submitted. The description should include the form of training (e.g., formal course work, lectures, on-the-job instructions, and written instructions or manuals), the duration of training, retraining provisions, and the subject matter to be included.

5. AMENDMENTS TO A LICENSE

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 special nuclear material to be used.

Applications for license amendments may be filed 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 70.33(b) of 10 CFR Part 70.

Renewal applications should be filed in the same manner as the original application, 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.