



U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 10.5

APPLICATIONS FOR TYPE A LICENSES OF BROAD SCOPE

1. INTRODUCTION

1.1 Purpose of Guide

This guide describes the type and extent of information needed by the NRC staff to evaluate an application for a Type A specific license of broad scope for byproduct material (reactor-produced radionuclides). This type of license is provided for under Title 10, Code of Federal Regulations, Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material."

The Type A specific license of broad scope will be issued only to those institutions that (1) have had previous experience operating under a specific institutional license and (2) have an established comprehensive radiation management program. The Type A license is intended to accommodate those institutions involved in an extensive radioactive material program where the demand is great for a variety of radionuclides for many uses. This type of license is the most comprehensive issued and may be written to cover a wide range of radionuclides (e.g., all radionuclides with atomic numbers 1 through 83) for use under the control of a radiation safety committee. The license may authorize any use of byproduct radioactive material by anyone in accordance with review and approval procedures established by the radiation safety committee. Therefore, individuals are not named on the license as users of radioactive material nor are radionuclides limited to narrow, specific uses. This type of license is intended for use by licensees that cannot operate under a more limited specific license without seriously inconveniencing their programs.

1.2 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"

*The substantial number of changes in this revision has made it impractical to indicate the changes with lines in the margin.

USNRC REGULATORY GUIDES

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

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

to Domestic Licensing of Byproduct Material"; 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 and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

1.3 Items Requiring Separate Applications

1.3.1 Gamma Irradiation Facilities

A separate application should be submitted for sealed sources of quantities greater than 100 curies for gamma irradiation facilities. Applicants for licenses to operate an irradiator facility should refer to Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators."

1.3.2 Source and Special Nuclear Materials

Separate applications should be submitted for these materials in accordance with Part 40, "Domestic Licensing of Source Material," and Part 70, "Domestic Licensing of Special Nuclear Material," of 10 CFR. Source material is defined in paragraph 40.4(h) of 10 CFR Part 40 as (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores that contain by weight 1/20 of one percent (0.05%) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material.

Special nuclear material is defined in paragraph 70.4(m) of 10 CFR Part 70 as (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material but does not include source material or (2) any material artificially enriched by any one of the foregoing but does not include source material. Applicants for licenses to possess and use special nuclear material should refer to Regulatory Guide 10.3, "Guide for the Preparation of Applications for Special Nuclear Material Licenses of Less than Critical Mass Quantities."

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

The guides are issued in the following ten broad divisions:

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

Copies of issued guides may be purchased at the current Government Printing Office price. A subscription service for future guides in specific divisions is available through the Government Printing Office. Information on the subscription service and current GPO prices may be obtained by writing the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Publications Sales Manager.

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After reviewing the provisions of the separate source or special nuclear material applications, the NRC may deem it appropriate to list small quantities of these materials on a Type A license, thereby issuing one license rather than two separate licenses.

1.3.3 Products Distributed to the Public

A broad specific license does not authorize the distribution to the public of products containing radionuclides. Upon request, the Material Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, will outline the type of information that the applicant should submit in support of such an application.

1.4 As Low As Is Reasonably Achievable (ALARA)

Paragraph 20.1(c) of 10 CFR 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, and the ALARA concept should be incorporated into the radiation protection program.

Medical institutions applying for a license should also give consideration to Regulatory Guide 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," and the associated report, NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable."

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 and Other Regulatory Services," 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 Type A licenses of broad scope should be submitted on Form NRC-313(I),¹ "Application for

¹ Medical institutions filing for a Type A license of broad scope may alternatively apply on Form NRC-313(M).

Byproduct Material License-Industrial" (see the appendix to this guide). All items on the application form should be completed in sufficient detail for the NRC staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property, so as to provide a basis for the NRC staff to make the findings under §33.13 of 10 CFR Part 33.

Since the space provided on Form NRC-313(I) is limited, the applicant should append, as needed, additional sheets to provide complete information. Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate item number (Form NRC-313(I)) and its purpose, e.g., "Item 13, Facilities and Equipment."

The application should be completed in triplicate. The original and one copy should be mailed to the Material 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.

4. CONTENTS OF AN APPLICATION

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

Item 5. Street Address

Only the main address for buildings in close proximity need be specified, such as for separate laboratory buildings on a single campus. However, if byproduct materials will be used in widely separated locations operating under one license, an address should be given for each location.

Item 6. Individual Who Will Supervise Use

For this item the applicant should write: "Radioactive materials are to be used by or under the direct supervision of individuals designated by the radiation safety committee." The applicant should also state the name of the chairman of the committee.

Item 8A. Element and Mass Number

The usual entry is, "Any byproduct material with atomic numbers 1 through 83." If alpha-particle emitters are to be excluded, it should be so stated. If radionuclides with atomic numbers above 83 are included, they should be specifically identified.

Item 8B. Chemical and/or Physical Form

For chemical and physical forms, the applicant should write the word "Any."

Item 8C. Name of Manufacturer (Sealed Sources)

Write "Not applicable." These sources need not be listed for a Type A license.

Item 8D. Maximum Activity [to be] Possessed

Possession limits should be stated. A possession limit is that quantity of radioactive material that a licensee may have in his possession at any one time. For example the applicant might write, "A total of 5 curies with a limit of 100 millicuries for each radionuclide between atomic numbers 3 and 83 inclusive and, in addition, up to 500 millicuries of tritium." If the applicant requires higher possession limits for certain radionuclides, such needs should be clearly stated. It may also be necessary to limit the quantity of more hazardous radionuclides such as strontium-90. The possession limits for radionuclides with atomic numbers above 83 should be stated separately from those requested for atomic numbers 1 through 83. The total possession limit (i.e., the total quantity of all radionuclides that the applicant desires to possess at any one time) should include those radionuclides with atomic numbers above 83. The requested possession limit should be commensurate with the applicant's needs and facilities for safe handling. Stored wastes should be included in establishing both individual and total possession limits.

Item 8E. Use of Licensed Material

Describe in general terms the purposes for use of licensed material. An example of an acceptable description for some applicants might be, "Research and development, as defined in paragraph 30.4(q) of 10 CFR Part 30." In addition, use involving the following must be specified: research, diagnosis, or therapy for human use or for animal use.

A Type A broad license does not authorize the use of radionuclides in the field where release of radioactive material to the environment is involved. Approval of requests for such uses is dependent upon supporting information specific to such uses. Upon request, the Material Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, will describe the type of information necessary for an applicant proposing such uses.

Item 9. Storage of Sealed Sources

Write "Not applicable." It is not necessary to complete this item for a Type A license.

Item 10. Radiation Detection Instruments

Do not complete Item 10 as shown in Form NRC-313(1). Instead, on a separate sheet referencing Item 10, list the radiation instruments that the applicant will have available by type and minimum number, e.g., "Radiation survey instruments—6." The list should include instrumentation such as that used for air monitoring and sampling. The applicant should specify the type of instruments that will be made available to individual users.

Item 11. Calibration of Instruments

Describe the instrument calibration procedure. 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. Other instruments and systems may include measuring instruments used to assay sealed-source leak-test samples, 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 that are to be used for quantitative measurements 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 after 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. However, readings within ± 20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

If contractors are to calibrate the instruments for the applicant, the names, addresses, and license numbers of the calibrating firms should be given along with the frequency of calibration for each type of instrument.

Item 12. Personnel Monitoring Devices

Personnel monitoring is required to ensure compliance with §§ 20.101, "Radiation Dose Standards for Individuals in Restricted Areas," and 20.202, "Personnel Monitoring," of 10 CFR Part 20. Personnel monitoring is always required if a person enters a high radiation area (greater than 100 millirems per hour). If personnel monitoring equipment is to be used, the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service and the frequency for changing badges, dosimeters, etc., should be specified. If pocket chambers or pocket dosimeters are to be used, the useful range of the device, in milliroentgens, the frequency of reading the devices, and the procedures for maintaining and calibrating the devices should be specified.

If personnel monitoring is not to be used, the applicant should submit calculations or documentation from radiation surveys demonstrating that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 10 CFR Part 20.

The applicant should show that the need for bioassays has been considered and should establish the adequacy of the proposed bioassay program in relation to the proposed program of use of radioactive material. Bioassays are normally required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131, depending on the

type of work, equipment, and procedures followed. Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," and a document entitled "Guidelines for Bioassay Requirements for Tritium"² may be consulted. Other materials may also be used in physical or chemical forms and under conditions that present an opportunity for uptake by the body through ingestion, inhalation, or absorption. A bioassay program to determine and control the uptake of radioactive material should be considered and discussed in relation to each such material, procedure, etc. Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," may be consulted.

The criteria to be used in determining the need for bioassays, the type and frequency of bioassays that will be performed, and the bioassay procedures should be specified and described in detail. If a commercial bioassay service is to be used, the name and address of the firm should be provided.

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

Item 13. Facilities and Equipment

A general description should be provided of facilities and equipment (e.g., buildings, hood ventilation and filtering systems, general air and stack monitoring systems, remote handling equipment) and access control methods used in association with the handling and storage of byproduct material.

The applicant should state the basic criteria established by the radiation safety committee for each category of use. For example, for facility requirements, the applicant should state requirements for (1) low-level tracer laboratories, (2) facilities for use of alpha-emitters, (3) high-level (100 mCi or more) beta-gamma laboratories, and (4) radioiodine use.

Indicate for each category of use the minimum physical plant requirements, such as fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, and effluent filter systems. Include an explanatory sketch of each area (i.e., site, building, laboratory room) where hazardous materials are used and stored or where hazardous operations are performed (e.g., a centralized radioisotope laboratory used for iodinations or bulk waste storage).

Item 14. Waste Disposal

The procedures for disposing of byproduct material waste should be described.

Under NRC regulations, a licensee may dispose of waste in the following ways:

² A copy may be obtained by a written request to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Fuel Cycle and Material Safety, Washington, D.C. 20555, Attention: Director, Office of Nuclear Material Safety and Safeguards.

a. Transfer to a person properly licensed to receive such waste in conformance with paragraph 20.301(a) of 10 CFR Part 20. The name of the firm (which should be contacted in advance to determine any limitations that the firm may have on acceptance of waste) should be given.

b. Release into a sanitary sewer in conformance with § 20.303 of 10 CFR Part 20. Depending on water usage, releases of up to 1 curie per year are permitted.³

c. Release into air or water in concentrations in conformance with § 20.106 of 10 CFR Part 20. The amount of waste that may be released is limited because of possible exposure to persons offsite.

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

e. Other methods specifically approved by the Commission pursuant to § 20.302 of 10 CFR Part 20.⁴

In writing the procedures for disposing of byproduct material waste, the applicant should consider that the NRC expects each licensee to do the following:⁵

1. Maintain a current set of DOT and NRC regulations concerning the transfer, packaging, and transport of low-level radioactive waste material.

2. Maintain a current set of requirements (license) placed on the waste burial firm by the Agreement State of Nevada, South Carolina, or Washington before packaging low-level radioactive waste material for transfer and shipment to the Agreement State licensee. If a waste collection contractor is used, obtain the appropriate requirements from the contractor.

3. Designate, in writing, people in your organization who are responsible for the safe transfer, packaging, and transport of low-level radioactive material.

4. Provide management-approved, detailed operating procedures to all personnel involved in the transfer, packaging, and transport of low-level radioactive material. Attention should be given to controls on the chemical and physical form of the low-level radioactive material and on the containment integrity of the packaging.

5. Provide initial training and periodic retraining in the DOT and NRC regulatory requirements, the waste-burial license requirements, and in your operating procedures for

³ A proposed rule to increase the amount of tritium and carbon-14 that may be released into sanitary sewers and to allow unrestricted disposal of scintillation liquids and animal tissue containing very low concentrations of tritium and carbon-14 was published for public comment on October 8, 1980 (45 FR 67018).

⁴ Effective January 28, 1981, radioactive waste may no longer be buried in soil without specific NRC approval (45 FR 71761).

⁵ This list is taken from Inspection and Enforcement Bulletin No. 79-20, "Packaging, Transport, and Burial of Low-Level Radioactive Waste," August 10, 1979.

all personnel involved in the transfer, packaging, and transport of radioactive material. Maintain a record of training dates, attendees, and subject material for future inspections by NRC personnel.

6. Provide initial training and periodic retraining to those employees who operate the processes that generate waste to ensure that the volume of low-level radioactive waste is minimized and that such waste is processed into acceptable chemical and physical form for transfer and shipment to a low-level radioactive waste burial facility.

7. Establish and implement a management-controlled audit of all transfer, packaging, and transport activities to provide assurance that personnel, procedures, and process and transport equipment are functioning properly.

8. Perform semiannually a management-controlled audit of your activities associated with the transfer, packaging, and transport of low-level radioactive waste. Maintain a record of all audits for future inspections by NRC or DOT inspectors.

Additional up-to-date guidance on waste disposal may be obtained by writing or telephoning the Material Licensing Branch.

Items 15, 16, and 17. "Radiation Protection Program," "Formal Training in Radiation Safety," and "Experience"

For Items 15, 16, and 17, supply the following information as a single narrative.

a. Radiation Safety Committee

Paragraph 33.13(c)(1) of 10 CFR Part 33 requires that a radiation safety committee be established. This committee should be composed of such persons as a radiation safety officer, a representative of management, other persons trained and experienced in the safe use of radioactive materials, and others whose fields of expertise complement the functions of the committee. One of the main functions of the radiation safety committee is to administer the institution's radioactive material program. The committee should have the authority and responsibility for approval and disapproval of all proposals for radionuclide use prior to purchase of the materials.

The following information concerning the committee should be submitted:

(1) A list of members of the committee. The committee members who have an essential radiation safety function, such as the chairman and the radiation safety officer, should be listed by name. Members with a less important safety function, e.g., student representative, nursing representative, administration representative, etc., may be listed by title and minimum qualifications.

(2) A description of each member's training and experience with radiation and radioactive material.

(3) A specific and detailed description of the control functions of the committee and the administrative procedures by which these functions are carried out, including the following:

(a) Responsibilities, duties, and authority of the committee.

(b) Frequency at which the full committee (or quorum) meets to discuss and act on proposals for the use of radionuclides. Committee meetings should be held at least quarterly. If fewer members than compose the full committee are empowered to act for the committee, the number of members constituting a quorum, as well as their names or fields of expertise, should be specified.

(c) Procedures and criteria established for making safety evaluations of proposed uses of radioactive material. The procedures and criteria should include consideration of the adequacy of facilities and equipment; operating, handling, and emergency procedures; and the experience and training of the proposed users of greater than exempt quantities of the material.

(d) Criteria established by the committee on who will receive training and how much training by category of worker (e.g., users of greater than exempt quantities of radionuclides, technicians, health and safety personnel, janitorial workers, etc.). Procedures for providing the training to each category of worker (refer to §19.12 of 10 CFR Part 19). Criteria and procedures for determining an acceptable level of knowledge. Identification of which records of training, testing, and competency determination are to be maintained.

(e) Procedures used for controlling and maintaining inventories, procurement of radioactive material, individual possession limits, total possession limit, transfer of radioactive material within the institution, and transfer of radioactive material to persons outside the institution.

(f) Methods employed for maintaining records of the committee's proceedings and safety evaluations of proposed uses of radioactive material.

(g) Periodic review of the safety program, including review of records required to be maintained.

b. Radiation Safety Officer⁶

Paragraph 33.13(c)(2) of 10 CFR Part 33 requires that a radiation safety officer (RSO) be appointed. The RSO should be responsible for the day-to-day operation of the radiation protection program within the institution. A description of his training and experience in radiation protection and with radiation and radioactive material should be provided.

⁶The title "radiation safety officer" is used synonymously with "radiation protection manager" by many licensees; other titles are equally acceptable.

The RSO should have specific formal training in radiological health (i.e., college level or its equivalent) and should have specific experience in radiation protection with the types, quantities, and use of the radioactive material to be used under the license. A statement should be included delineating RSO duties, responsibilities, and authority for carrying out the radiation safety program. Radiation protection should be the primary responsibility of the RSO. The extent of the RSO's responsibility and authority will depend on the scope of the proposed program; however, the following should be considered:

(1) General surveillance over all activities involving radioactive material, including routine monitoring and special surveys of all areas in which radioactive material is used.

(2) Determining compliance with rules and regulations, license conditions, and the conditions of project approval specified by the radiation safety committee.

(3) Monitoring and maintaining absolute and other special filter systems associated with the use, storage, or disposal of radioactive material.

(4) Furnishing consulting services on all aspects of radiation protection to personnel at all levels of responsibility.

(5) Receiving, delivering, and opening all shipments of radioactive material arriving at the institution and receiving, packaging, and shipping all radioactive material leaving the institution.

(6) Distributing and processing personnel monitoring equipment, determining the need for and evaluation of bioassays, keeping personnel exposure and bioassay records, and notifying individuals and their supervisors of exposures approaching maximum permissible amounts and recommending appropriate remedial action.

(7) Conducting training programs and otherwise instructing personnel in the proper procedures for the use of radioactive material prior to use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.

(8) Supervising and coordinating the radioactive waste disposal program, including keeping waste storage and disposal records and monitoring effluents.

(9) Storing all radioactive materials not in current use, including wastes.

(10) Performing leak tests on all sealed sources.

(11) Maintaining an inventory of all radioisotopes at the institution and limiting the quantity of radionuclides at the institution to the amounts authorized by the license. The inventory should include the name of the person responsible for each quantity of radioisotopes, where it will be used or stored, and the date the quantity was delivered

to that person. Items are removed from the inventory by showing how and when the radioisotope was disposed of.

(12) The authority to terminate immediately a project that is found to be a threat to health or property.

(13) Maintaining other records not specifically designated above, e.g., receipt, transfer, and survey records as required by §30.51, "Records," of 10 CFR Part 30.

c. Radiation Protection Procedures

A formal set of rules, instructions, and procedures for procurement, disposal, and safe handling of radionuclides within the institution should be established by the radiation safety committee. A copy of these rules and procedures in the form in which they will be given to all personnel under the jurisdiction of the committee should be submitted.⁷ Where instructions are given with respect to an action necessary for compliance with NRC regulations (e.g., waste disposal), such instructions should be specific and not consist of a simple reference to the regulations.

The written radiation protection procedures should be clear and concise and should cover the following:

(1) Process for obtaining permission to use radioactive materials at the institution.

(2) Care, selection, and use of protective apparel and other equipment and facilities.⁸

(3) Limitations and conditions (special equipment, facilities, and procedures) relative to handling liquid, gaseous, finely divided, or uncontained radioactive materials⁹ and the equipment to use in working with them. For example, the types of materials and operations that should be confined to ventilated equipment with filtered exhaust systems (radiochemical fume hoods or glove boxes) and the types and amounts of shielding and remote handling equipment to be used with hard beta- or gamma-emitting materials should be defined.

(4) Special equipment, procedures, and precautions to be used in working with neutron and alpha-particle emitters and radionuclides that decay by spontaneous fission.

⁷ Although a specific set of rules and procedures is required as a basis for evaluating the license application, the applicant may specify that certain portions of the documents may be revised without prior notification of the NRC staff. For example, the applicant may specify in the application that the institution will make the following changes without notifying the NRC: Changes dictated by NRC rule changes, changes in internal management forms or specific dates, changes in contractors for bioassay or waste disposal services or for servicing and calibrating personnel dosimeters, or references to particular pieces of equipment, etc. By careful use of this technique, the applicant can avoid the necessity for frequent license amendments.

⁸ A complete description of respiratory protection devices and procedures for fitting, sanitizing, and repairing them should be included. Credit for respiratory protection cannot be taken unless a respiratory protection program is established pursuant to §20.103 of 10 CFR Part 20.

⁹ Those applications or operations that present unusual hazards because of the nature of the material, the quantity involved, and the type of operation and that may require specialized facilities should be covered in separate instructions rather than incorporating these instructions in the main body of the radiation protection procedures.

(5) Surveying and monitoring procedures to be followed during day-to-day operations. Minimum number of operable instruments to be available for various categories of operations to proceed.

(6) Emergency procedures and instructions concerning spills, fires, release or loss of material, and accidental contamination of personnel, including decontamination procedures and those persons to be notified in an emergency.

(7) Posting and control of access to restricted areas, radiation areas, high radiation areas, etc. (see § 20.203 of 10 CFR Part 20).

(8) Requirements for material storage and safeguarding; labeling containers; processing and storing contaminated articles, including glassware; and identifying areas where radioactive material is used and stored (see § 20.203 of 10 CFR Part 20).

(9) Care and use of personnel monitoring devices, where to obtain them, and where and when to record exposure results.

(10) Requirements for bioassays, if any, and the procedures for providing bioassay samples.

(11) Transporting radioactive material between buildings and rooms.

(12) Acceptable and unacceptable levels of contamination (fixed and removable) for equipment, facilities, clothing, skin, etc., in both restricted and unrestricted areas and protective action (i.e., decontamination, disposal, etc.) to be taken with respect to unacceptable levels.

(13) Requirements and procedures for leak-testing sealed sources.

(14) Requirements and procedures for waste disposal, including limitations on disposal of liquid, gaseous, and solid wastes. If radionuclides will be administered to animals, instructions for cleaning animal quarters and handling animal excreta and carcasses should be included.

(15) Requirements and procedures for the development and maintenance of records with respect to the receipt, use, and disposal of radioactive material.

(16) Requirements and procedures for picking up, receiving, and opening packages (see § 20.205 of 10 CFR Part 20).

Item 18. Certificate

The person certifying the application must be legally authorized to make formal commitments on behalf of the applicant.

5. AMENDMENTS TO A LICENSE

Licenses 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 changes in the commitments made in the license application (e.g., RSO or members of the radiation safety committee personnel changes, procedures for which an exception was not specified in the original application, etc.).

Applications for license amendments may be filed either on the application form or in letter form. The application or letter 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 staff as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313(1), 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.

U.S. NUCLEAR REGULATORY COMMISSION

INSTRUCTIONS FOR PREPARATION OF
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

FORM NRC-313 (I)

GENERAL INFORMATION

An applicant for a "Byproduct Material (Radioisotopes) License," should complete Form NRC-313 (I) in detail and submit in duplicate to the U.S. Nuclear Regulatory Commission. The applicant should endeavor to cover his entire radioisotope program with one application, if possible. However, separate applications should be submitted for gamma irradiators. Applications for medical uses should be submitted on Form NRC-313 (M) and applications for use of sealed sources in radiography should be submitted on Form NRC-313R. Supplemental sheets may be appended when necessary to provide complete information. *Item 18 must be completed on all applications. Submission of an incomplete application will often result in a delay in issuance of the license because of the correspondence necessary to obtain information requested on the application.*

NOTE. -When the application includes one of the special uses listed below, the applicant should request the appropriate pamphlet which provides additional instructions:

1. Industrial Radiography—"Licensing Requirements for Industrial Radiography" (use application Form NRC-313R for Radiography);
2. Laboratory and Industrial Uses of Small Quantities—"Guide for Preparation of Applications for Laboratory and Industrial Uses of Small Quantities of Byproduct Material."

3. Broad License (research and development)—"Licensing Guide for Type-A Licenses of Broad Scope for Research and Development;"

4. Licensing Guides for the performance of well logging operations.
5. Licensing guide for the use of sealed sources in portable and semi-portable gauging devices.

The Commission charges fees for filing of applications for licenses as specified in Section 170.12, Title 10, Code of Federal Regulations, Part 170. The applicant should refer to Section 170.31, *Schedule of fees for materials licenses*, to determine what fee should accompany the application. No action can be taken on applications until fees are paid. Checks or money orders should be made payable to the U.S. Nuclear Regulatory Commission.

Two copies of the completed Form NRC-313 (I) and two copies of each attachment thereto, should be sent to the 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 should be retained for the applicant's file. Applications may also be filed in person at the Commission's office at 1717 H Street, N.W., Washington, D.C. or at 7915 Eastern Avenue, Silver Spring, Maryland.

EXPLANATION OF FORM NRC-313 (I)

Form NRC-313 (I) is designed for use in supplying information on programs of varying complexity. The applicant should provide complete information on his proposed program for the possession and use of licensed material. For those items that do not apply, indicate as N.A. (not applicable).

Item No.

1. Self-explanatory
2. The "applicant" is the organization or persons legally responsible for possession and use of the licensed materials specified in the application.
3. Self-explanatory
4. Self-explanatory

5. The actual sites of use should be listed as indicated. Permanent facilities such as field offices for portable gauges or devices should be identified in Item 5 by Street, Address, City and State. Temporary field locations of use should be specified as "temporary job sites of the applicant" and list the States throughout which the temporary job sites will be located. Attach additional properly keyed sheet if more space is needed.

6. Self-explanatory

7. The "Radiation Protection Officer" is the named individual who is expected to coordinate the safe use of the licensed material specified in the application and who will ensure compliance with the applicable parts of Title 10, Code of Federal Regulations.

APPENDIX (continued)

- 8 List by name each radioisotope to be possessed and used under the license. Example:

A	B
(1) Iodine-131	(1) Iodide
(2) Iodine-131	(2) Iodinated Human Serum Albumin
(3) Krypton-85	(3) Gas
(4) Cesium-137	(4) Sealed Source
C	D
(1) Not Applicable	(1) 10 millicuries
(2) N. A.	(2) 1 millicurie
(3) N. A.	(3) 1 millicurie
(4) Iso Corp Model Z-78	(4) 2 source of 150 millicuries each

Attach additional properly keyed sheets if more space is needed.

- 8 E State the use of each licensed material listed in 8 A, B, and D.

- 9 Description of containers and/or devices in which sealed sources listed in Item 8 will be stored or used. Example:

A	B
(1) #4 - Source housing	Iso. Corp
Model Z-278	

- 10-18 Self-explanatory. (For those items that do not apply, indicate as N.A. (not applicable).)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Forms NRC-313M, NRC-313a, NRC-313I, or NRC-313R. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

- AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
- PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a byproduct material license or amendment thereof.
- ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident of exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N. W., Washington, D.C.
- WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the request information is not furnished, however, the application for byproduct material license, or amendment thereof, will not be processed.
- SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

APPENDIX (continued)

FORM NRC-313 I (1-79) 10 CFR 30		U.S. NUCLEAR REGULATORY COMMISSION		1. APPLICATION FOR: <i>(Check and/or complete as appropriate)</i>	
APPLICATION FOR BYPRODUCT MATERIAL LICENSE INDUSTRIAL				a. NEW LICENSE	
<i>See attached instructions for details.</i> <i>Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.</i>				b. AMENDMENT TO LICENSE NUMBER	
				c. RENEWAL OF: LICENSE NUMBER	
2. APPLICANT'S NAME <i>(Institution, firm, person, etc.)</i> _____ TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION			3. NAME OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION _____ TELEPHONE NUMBER: AREA CODE - NUMBER EXTENSION		
4. APPLICANT'S MAILING ADDRESS <i>(Include Zip Code)</i> _____			5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED <i>(Include Zip Code)</i> _____		
(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)					
6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL <i>(See Items 16 and 17 for required training and experience of each individual named below)</i>					
FULL NAME			TITLE		
a.					
b.					
c.					
7. RADIATION PROTECTION OFFICER			<i>Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.</i>		
8. LICENSED MATERIAL					
L I N E NO.	ELEMENT AND MASS NUMBER A	CHEMICAL AND/OR PHYSICAL FORM B	NAME OF MANUFACTURER AND MODEL NUMBER <i>(If Sealed Source)</i> C	MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTI- VITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME D	
(1)					
(2)					
(3)					
(4)					
DESCRIBE USE OF LICENSED MATERIAL E					
(1)					
(2)					
(3)					
(4)					

APPENDIX (continued)

9. STORAGE OF SEALED SOURCES			
LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)			
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS						
LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)						
(2)						
(3)						
(4)						

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10	
<input type="checkbox"/> a. CALIBRATED BY SERVICE COMPANY NAME, ADDRESS, AND FREQUENCY	<input type="checkbox"/> b. CALIBRATED BY APPLICANT <i>Attach a separate sheet describing method, frequency and standards used for calibrating instruments.</i>

12. PERSONNEL MONITORING DEVICES		
TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
<input type="checkbox"/> (1) FILM BADGE <input type="checkbox"/> (2) THERMOLUMINESCENCE DOSIMETER (TLD) <input type="checkbox"/> (3) OTHER (Specify): _____ _____ _____		<input type="checkbox"/> MONTHLY <input type="checkbox"/> QUARTERLY <input type="checkbox"/> OTHER (Specify): _____ _____ _____

13. FACILITIES AND EQUIPMENT (Check where appropriate and attach annotated sketch(es) and description(s).)
<input type="checkbox"/> a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC. <input type="checkbox"/> b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC. <input type="checkbox"/> c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC. <input type="checkbox"/> d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL
a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED
b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. **RADIATION PROTECTION PROGRAM.** Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures (*if needed*), day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.
16. **FORMAL TRAINING IN RADIATION SAFETY.** Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.
 - a. Principles and practices of radiation protection.
 - b. Radioactivity measurement standardization and monitoring techniques and instruments.
 - c. Mathematics and calculations basic to the use and measurement of radioactivity.
 - d. Biological effects of radiation.
17. **EXPERIENCE.** Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

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.

a. LICENSE FEE REQUIRED (See Section 170.31, 10 CFR 170)	b. CERTIFYING OFFICIAL (Signature)
	c. NAME (Type or print)
(1) LICENSE FEE CATEGORY:	d. TITLE
(2) LICENSE FEE ENCLOSED: \$	e. DATE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN: 3150-

Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations pertaining to the notification of incidents involving the loss of control of radioactive material by a licensee. The proposed rule would add a definition of intentional misuse of licensed material and would require that a licensee notify the NRC within 24 hours of such an incident involving the potential loss of control of radioactive material that could lead to an unnecessary exposure of workers or the public.

DATES: Submit comments by (30 days after publication). Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Service Branch. Hand

deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

Documents related to this rulemaking may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Many of these documents may also be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this rulemaking.

Single copies of the proposed rule, 10 CFR Part 20, Reporting Requirements may be obtained by written request or telefax (301-504-2260) from: Distribution Services, Printing and Mail Services Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The NRC requests public comment on the proposed rule, 10 CFR Part 20 Reporting Requirements. Comments may be submitted to: Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publication Services, Mail Stop T-6D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11555 Rockville Pike, Maryland between 7:45 a.m. and 4:15 p.m. on Federal workdays. Comments on the proposed rule, 10 CFR Part 20 Reporting Requirements may be submitted electronically as indicated below.

Comments may be submitted electronically, in either ASCII text or Wordperfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the rulemaking are also available for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC subsystem on FedWorld can be accessed directly by dialing the toll free number: 1-800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Use ANSI or VT-100 terminal emulation. The NRC rulemaking subsystems can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." For further information about options available for NRC at FedWorld consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial phone number for the main FedWorld BBS: 703-321-3339; Telnet via Internet: fedworld.gov (192.239.92.3); File Transfer Protocol (FTP) via Internet: ftp.fedworld.gov (192.239.92.205); and World Wide Web using the "Home Page": www.fedworld.gov (this is the Uniform Resource Locator (URL)).

If using a method other than the NRC's toll free number to contact FedWorld, then the NRC subsystem will be accessed from the main FedWorld menu by selecting "F - Regulatory, Government Administration and State Systems" or by entering the command "/go nrc" at a FedWorld command line. At the next menu select "A - Regulatory Information Mall," and then select "A - U.S. Nuclear Regulatory Commission" at the next menu. If you access NRC from FedWorld's "Regulatory, Government Administration" menu, then you may return to FedWorld by selecting the "Return to FedWorld" option from the "NRC Main Menu." However, if you access NRC at FedWorld by using NRC's toll-free number, then you will have full access to all NRC systems, but you will not have access to the main FedWorld system. For more information on NRC bulletin

boards call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone (301) 415-6230, e-mail MLT1@NRC.GOV.

SUPPLEMENTARY INFORMATION:

I. Background

Recently, the NRC became aware of events involving the misuse of radioactive material. Although these events involved the internal exposure of workers and members of the public at levels below the dose limits specified in 10 CFR Part 20, the potential for other situations where workers or the public could be exposed to harmful levels of radiation is of concern to the Commission. These events indicate a loss of control of licensed radioactive material by the licensee as a result of intentional misuse and are significantly different in nature from those currently required to be reported to the NRC under 10 CFR Part 20. Current reporting requirements are included in §§ 20.2201, 20.2202, 20.2203, 20.2204, and 20.2206. None of these reporting requirements clearly require the licensees to submit reports to the NRC of intentional misuses of radioactive material resulting in loss of control of that material or the potential for workers or members of the public to be exposed to harmful levels of radiation. Given that situation, the Commission is concerned licensees will not report this type of event promptly.

The Commission needs to know about intentional misuses of radioactive material because such events indicate that the licensee may have lost control of the radioactive material with the result that workers and members of the public could be needlessly exposed.

II. Discussion of Proposed Rule Changes

The intent of the proposed rule is to provide the NRC with an early warning of a licensee's potential loss of control of radioactive material as a result of intentional misuse and to provide notice to the NRC that someone at a licensee's facility may be misusing radioactive material. The rationale is that although such misuse may not in the first instance result in harm to workers or the public that harm could occur if timely corrective action is not taken.

A definition of intentional misuse of licensed material would be added to define intentional misuse as intentional use of licensed material in a manner that is different from the purpose for which the license was granted and would not include accidental misuse. In addition, a new paragraph would be added to § 20.2202(b) to require a 24-hour report when such circumstances are encountered. No new requirements are being proposed regarding inadvertent misuse, e.g., accidents.

The 24-hour reporting requirement is proposed because the NRC needs prompt assurance that a licensee is taking the appropriate actions to bring the situation under control. These actions could consist of securing the affected area and accounting for all material, surveying the area and the personnel that worked in that area, and preventing the workers from receiving

further exposure to radioactive material. No exposure threshold is included in the reporting requirement because even quite small exposures could be an indication of breakdown in controls with the possibility that larger exposures could result in the future unless corrective action is taken. It is recognized that as licensees analyze unplanned exposures it may not be immediately obvious whether a particular exposure was the result of intentional misuse or an accident. In general, a report would be required for any misuse that had the potential for radiological exposure whenever the licensee cannot classify the exposure to be the result of either an allowed licensed operation or an accident and independently of whether the exposure might be above or below regulatory limits. Overexposures would continue to be reported under § 20.2203 if due to licensed operations or under § 20.2202 if due to an accident. In this regard, the NRC is considering inadvertent misuse to be classified as an accident.

Examples of events that would be covered by this requirement include the intentional administration of non-prescribed dosages to a nuclear medicine technician so that another nuclear medicine technician can test his/her imaging skills or increasing dosages to a patient to decrease imaging time, as well as intentional acts intended to harm or threaten/intimidate another worker or a member of the public.

The Commission has considered the impact on licensees from these new requirements and has weighed them against the benefits. In those instances where exposures of individuals cannot be categorized as the result of licensed operations or accidents the licensee will have to prepare and submit a report. Such events are expected to be rare. However the report will allow the NRC to react quickly to assure that the licensee takes timely and effective

corrective action to prevent further exposures and possible harm to workers or members of the public. The Commission believes that this benefit justifies the resources needed to prepare and submit reports.

However, the Commission also believes that it is essential to assure that any misuse involving intentional loss of control of licensed material is corrected on a timely basis. The Commission therefore, considers this new requirement to be necessary for assuring adequate protection of the public health and safety.

In summary, the Commission believes that these new regulatory requirements can be justified either on the basis of cost-benefit considerations or as provisions necessary for providing an adequate level of protection of the public health and safety. The Commission is proposing this new requirement as a matter of adequate protection. Therefore, for licensees for which § 50.109, "Backfitting" is applicable, this regulation is proposed under § 50.109(a)(4)(iii).

III. Agreement State Compatibility

This rulemaking will be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency of State with Federal safety requirements. The NRC has determined that a Division 1 level of compatibility should be assigned because the report required by this rulemaking are important to assure protection of public health and safety. Under this level of compatibility the Agreement States would be expected to adopt the reporting requirements essentially verbatim.

IV. Environmental Impact: Categorical Exclusion

The NRC has determined that this revised regulation is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(3)(ii), recordkeeping requirements. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this revised regulation.

V. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average XX hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202 (3150-0014), Office of Management and Budget, Washington, DC 20503.

VI. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-6230; email: MLT1@NRC.GOV

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

VII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The rulemaking imposes reporting requirements on licensees to report potential losses of control of radioactive material and that someone at a licensee's facility is misusing radioactive material that could lead to an unnecessary exposure of workers or the public.

VIII. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule and, therefore, that a backfit analysis is not required for this rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(4)(ii).

List of Subjects in Part 20

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendment to 10 CFR Part 20.

PART 20--STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

AUTHORITY: Secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 953, 955, as amended, (U.S.C. 2073, 2093, 2095, 2111,

2133, 2134, 2201, 2232, 2236), secs. 201, as amended 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

2. In § 20.1003, a definition has been added to read as follows:

§ 20.1003 Definitions.

* * * * *

Intentional misuse of licensed material means the intentional use of licensed material in a manner that is different from the purpose for which the license was granted.

* * * * *

3. In § 20.2202, paragraph (b)(3) has been added to read as follows:

§ 20.2202 Notification of incidents.

* * * * *

(b) * * *

(3) Intentional misuse of licensed material that causes or had the potential to cause exposure to workers or the public or falsification of records or logs pertaining to such a misuse.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____ 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.