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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0005

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APPLICATIONS FOR LICENSES OF BROAD SCOPE

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by **January 25, 1995.**

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1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This guide outlines the type and extent of information needed by the NRC staff to evaluate applications for a specific license of broad scope for byproduct material. The NRC regulation 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," provides for three distinct categories of licenses of broad scope, i.e., Type A, Type B, and Type C, which are defined in 10 CFR 33.11. This guide outlines the information to be provided in the preparation of applications for Type A and B licenses that authorize the use of licensed materials in a variety of fields and occupations, e.g., manufacturing and commercial distribution of licensed materials in calibration and test sources and measuring devices, universities limited to academic research and development, and medical institutions involved in research using human subjects. Broad scope licenses authorize possession of a wide variety of radioactive material without having each radionuclide and authorization specifically listed on the license.

An application for a broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material to be possessed under the provisions of 10 CFR 30.32(d). However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license. The guidance in this regulatory guide represents a philosophical approach that should aid in the development of a radiation safety program as well as the preparation of an application that is acceptable to the NRC staff.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are

issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

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

1.2 CONCEPT AND CONDITIONS OF BROAD SCOPE LICENSES

Broad scope licenses will be issued only to organizations that have:

1. Experience in a reasonable number of activities involving the use of byproduct materials under specific licenses of limited scope. Although the degree of experience is not specified in the regulations, an applicant usually has had a limited specific license for at least 5 years.

2. A good regulatory performance record, based on NRC licensing and inspection of prior activities.

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

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

A broad scope license is intended to accommodate organizations involved in an extensive radioactive materials program with a great variety of radionuclides and uses. Type A and B licenses are 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). The use of byproduct materials authorized by a Type A license must be controlled by a Radiation

Safety Committee (RSC) and a qualified Radiation Safety Officer (RSO) and staff, whereas a Type B license is controlled by an individual, i.e., a Radiation Safety Officer. Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the Radiation Safety Officer and the range of intended uses. Type B licenses are not as diverse as Type A licenses.

Broad scope licenses may authorize the use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the RSC (Type A license) or the RSO (Type B license). Therefore, individuals are not specifically named on the license as users nor are the radionuclides limited to narrow, specific uses. Broad scope licenses are for licensees who cannot operate under a more limited specific license without seriously disrupting their programs.

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

1. Conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users);

2. Receive, acquire, own, possess, use, transfer, or import devices containing 3.7×10^{15} becquerels (Bq) (100,000 curies (Ci)) or more of byproduct material in sealed sources for irradiation of materials;

3. Conduct activities for which a specific license issued by the NRC under 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"; or 10 CFR Part 35, "Medical Use of Byproduct Material," is required; or

4. Add or cause the addition of byproduct material to any food or other product designated for ingestion or inhalation by, or application to, a human being.

1.3 MEDICAL INSTITUTION BROAD SCOPE LICENSES

Broad scope licenses that involve medical or nonmedical research using human subjects require establishing specialized subcommittees and using committees established in accordance with criteria promulgated by the U.S. Food and Drug Administration (FDA), e.g., Radioactive Drug Research Committees (RDRCs) or Institutional Review Boards (IRBs), when evaluating research requests. Appendix A to this guide provides a flow diagram that may be used in determining the need for a human use subcommittee or one or more of the FDA (or other Federal agency) committees to supplement the RSC and its review process.

Provided that broad scope medical licensees have staff qualified in radiopharmacy, radiochemistry, dosimetry, nuclear medicine, etc., they are exempted from the provisions of 10 CFR 35.49(a), 35.100, 35.200, 35.300, 35.400, and 35.500. This exemption allows flexibility for broad scope licensees in preparing and processing byproduct material, but it does not affect the authorized uses identified on the license. Applicants must, of course, commit to possessing and using byproduct material for medical use in accordance with the prescriptive and performance criteria in other sections of 10 CFR Part 35. Applicants should commit to instituting procedures at least equivalent to those described in NRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."

Amendments to 10 CFR Part 35, "Medical Use of Byproduct Material," require medical use licensees, including broad scope Type A medical licensees, to establish and implement a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. According to 10 CFR 35.32, which became effective January 27, 1992, each applicant for a new license, as applicable, is required to submit a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC. Medical licensees should have submitted written

certification that the quality management program has been implemented along with a copy of the program. The written quality management program is in addition to a written radiation protection program required by 10 CFR 20.1101.

The quality management program should be submitted pursuant to 10 CFR 35.32. The NRC has developed Regulatory Guide 8.33, "Quality Management Program," to assist applicants in the preparation of an acceptable program.

Broad scope medical licensees who want to approve physicians, dentists, or podiatrists to use byproduct material for medical purposes must commit to evaluating individuals using the criteria detailed in "Subpart J - Training and Experience Requirements" of 10 CFR Part 35. Licensees must submit amendments to their licenses requesting NRC review of physicians who do not meet the specific training and experience criteria. Generally, these requests will be forwarded to the NRC Advisory Committee on Medical Use of Isotopes (ACMUI). The mechanisms used to record the review of any individual's training and experience should be described.

1.4 APPLICABLE REGULATIONS

In addition to 10 CFR Part 33, other regulations pertaining to broad scope licenses are found in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation";[1] 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 35, "Medical Use of Byproduct Material"; 10 CFR Part 40, "Domestic Licensing of Source Material"; 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"; 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"; and 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC."

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[1]Appendix B is a list of regulatory guides issued by NRC to assist licensees in meeting the requirements in the revised 10 CFR Part 20.

1.5 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Regarding ALARA, 10 CFR 20.1101(b) states that "The licensee shall (emphasis added) use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." ALARA concepts and philosophy are discussed in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

Applicants for broad scope licenses must address ALARA considerations in all aspects of their programs, e.g., monitoring and controlling external and internal personnel exposure, monitoring and controlling air and liquid effluents. ALARA considerations, including establishing administrative action levels and monitoring programs, need to be documented in the application.

Medical institutions applying for a license must incorporate ALARA provisions into their program. In Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix G, "Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA," outlines criteria that are acceptable to the NRC staff.

1.6 RADIOLOGICAL EMERGENCY PLANS

Applicants who request possession of radioactive materials in both unsealed and certain sealed forms in excess of specifically listed quantities must address the need for an Emergency Plan, according to 10 CFR 30.32(i)(1). Should this assessment support the need for an emergency plan, the plan must be submitted with your application pursuant to 10 CFR 30.32(i). Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," provides guidance to applicants on the preparation of emergency plans.

1.7 FINANCIAL ASSURANCE AND RECORDKEEPING REQUIREMENTS

The NRC has established technical and financial regulations for decommissioning of licensed facilities (see 53 FR 24018, June 27, 1988). The regula-

tions address the planning needs, timing, funding methods, and environmental review requirements for decommissioning public and private facilities holding licenses under 10 CFR Parts 30, 40, 50, 70, and 72, with the exception of uranium mills. The intent of the regulations is to ensure that the decommissioning of all licensed facilities will be accomplished in a safe and timely manner and that licensees will provide adequate funds to cover all costs associated with decommissioning. The financial assurance requirements are addressed in 10 CFR 30.35(c), 40.36(c), and 70.25(c).

NRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," provides guidance acceptable to the NRC staff on the information to be provided for establishing financial assurance for decommissioning and a standard format for presenting the information.

1.8 DECOMMISSIONING PLAN REQUIREMENTS

When a licensee decides to terminate its license, 10 CFR 30.36, "Expiration and Termination of Licenses," requires that the licensee submit, on or before the expiration date, a completed NRC Form 314 (a copy of Form 314 is provided in Appendix C to this guide). In addition, 10 CFR 30.36, 40.42, and 70.38 require certain licensees to submit, on or before the license expiration date, a plan for completion of decommissioning when the licensee decides to terminate the license. In particular, those sections require the licensee to submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been approved by the NRC and could increase potential health and safety impacts to workers or to the public. The specific criteria for submission of a plan for completion of decommissioning are delineated in 10 CFR 30.36(c)(2). If a licensee is required to provide financial certification pursuant to 10 CFR 30.35, 40.36, or 70.25, a decommissioning plan should be submitted as part of the application.

NRC Regulatory Guide 3.65, "Standard Format and Content of Decommissioning Plans for Licensees Under 10 CFR Parts 30, 40, and 70," provides guidance on decommissioning plans acceptable to the NRC staff and establishes a standard format for presenting the information. This guidance is also applicable to requests for license amendments to decontaminate portions of a nuclear

facility and release those portions for unrestricted use at a time other than when the facility is completely decommissioned.

1.9 PRELICENSING CONFERENCE

After an application for broad scope authority has been reviewed by the NRC staff and found to be generally complete and responsive to NRC Form 313 (see Appendix D) and this regulatory guide, a prelicensing visit will be scheduled by the NRC at the facility. For renewal of broad scope licenses, a visit or conference may also be scheduled.

A prelicensing visit provides the NRC staff an opportunity to better evaluate the proposed program and the necessity for a broad license. It also provides the NRC staff an opportunity to meet with licensee management and others responsible for the radiation protection program and stress the importance of their responsibilities under a broad scope license and to discuss and agree on additional information and commitments that may be needed. If a broad license is not warranted, continuation of the program with an appropriate specific license can be discussed.

2. FILING AN APPLICATION

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

All items in the application should be completed in enough detail for the NRC to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect health and minimize danger to life and property. Please note that license applications are available for review by the general public in the NRC Public Document Rooms; therefore, proprietary information

should not be submitted unless absolutely necessary. If submittal of such information is necessary, the procedure to be followed is in 10 CFR 2.790. Failure to follow this procedure may result in disclosure of proprietary information to the public or substantial delays in processing the application. Personal information about individual employees should not be submitted unless necessary. Home addresses and telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by the NRC.

The application should be filed in duplicate, with one copy retained by the applicant. Applicants located in Agreement States should file an application with the NRC only if they wish to possess and use licensed material in States subject to NRC jurisdiction. All other applicants and all Federal agencies should file applications with the NRC Regional Office for the State in which they are located. Appendix D of 10 CFR Part 20 lists the NRC Regional offices and the States within their jurisdiction.

3. CONTENTS OF AN APPLICATION

The following guidance applies to the indicated items of NRC Form 313 (see Appendix D).

ITEM 1: LICENSE INFORMATION

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

ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Applicants should be corporations or institutional entities. Because a broad scope licensee must have a Radiation Safety Committee (or RSO for Type B licensees), it is not appropriate for a private individual to apply for a broad scope license.

The address specified here should be the mailing address for correspondence, which may be the same as the address at which the material will be used, as specified in Item 3.

ITEM 3: LOCATIONS OF USE

Specify each proposed location of use by the street address, city, and State or other descriptive address (e.g., 5 miles east on Highway 10, Anytown, State). A Post Office Box address is not acceptable. If byproduct material is to be used at more than one location, give the specific address of each location. In addition, identify facilities designed or established for special uses, e.g., panoramic dry or wet irradiators, waste storage facilities used for long-term storage, high-level laboratories (i.e., iodination labs processing quantities greater than 370 MBq (10 mCi), alpha labs or individual labs processing licensed material in quantities greater than 3.7 GBq (100 mCi) per single use), incinerators, waste compactors, and animal facilities.

If radioactive material in portable gauging devices will be used at temporary job sites, so indicate, and describe the procedures for transportation, storage, and access controls. Guidance on acceptable radiation safety program commitments and use procedures for portable gauging devices used at temporary jobs sites is being developed and has been proposed in Draft Regulatory Guide FC 407-4, "Guide for the Preparation of Applications for Licenses for the Use of Sealed Sources in Portable Gauging Devices."

If radioactive material is to be used in field studies, the activities must be specifically identified and authorized on the license. Appendix E contains information required for field use of licensed material.

ITEM 4: PERSON TO BE CONTACTED ABOUT APPLICATION

The individual who is cognizant of the proposed radioactive materials program and can answer questions about the application should be specified, along with his or her telephone number. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not a full-time employee, his or her position and relation-

ship should be specified. The NRC should be notified if the person assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment unless this contact person is the RSO. An individual is not generally considered a "certifying official" unless so designated, and amendments and renewals not signed by a designated certifying official, would not be accepted. Please refer to Item 13, "Certification," of this regulatory guide.

ITEM 5: MATERIAL TO BE POSSESSED

Describe the byproduct material that is proposed for possession by isotope, chemical or physical form, and quantity (e.g., by curie, millicurie). State the maximum quantity of each radioactive material to be possessed at any one time and the total cumulative quantity for all materials. The possession request should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-contained irradiators, instrument calibrators, and medical applications, both routine and non-routine. An acceptable format for identifying the type, form, and quantity of radioactive material requested for a "Type A" broadscope program is provided in Item 5 of Form 313 (see Appendix D). The maximum quantity for each individual nuclide and the total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and personnel. If certain nuclides will be needed in much larger quantities than others, they should be listed separately in Items 5a, 5b, and 5c, rather than increasing the quantity of all nuclides to include these larger quantities. Sealed sources needed in quantities larger than requested (e.g., bone mineral analyzers, sealed sources under 10 CFR 35.400, brachytherapy after-loaders, portable and nonportable gauging devices) should also be listed separately in Items 5a, 5b, and 5c. High-activity sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, and instrument calibrators) should be described by manufacturer and model number under Item 5b.

For guidance on the use of an irradiator under a broad scope license, see NRC Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators." Additional guidance is proposed in Draft Regulatory Guide FC 403-4, "Guide for

the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators." However, 10 CFR 33.17 prohibits the use of 100,000 curies or more of byproduct material in sealed sources for irradiation of material under a broad scope license. Similarly, if certain relatively more hazardous nuclides (e.g., strontium-90, americium-241) are needed only in smaller quantities, they should be listed separately. The maximum quantities of nuclides with atomic numbers above 83 also should be stated separately. When establishing both individual nuclide and total maximum quantities, all materials to be possessed under the license should be included, i.e., materials received awaiting use, materials in use or process, and those categorized as waste awaiting disposal.

ITEM 6: PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Describe in general terms the purposes for which the licensed material will be used and explain why a broad scope license is need rather than amendments to an existing specific license. The uses should be consistent with prior licensed activities. Although the NRC staff only needs a general description of activities, sufficient information should be provided to enable the staff to have a clear understanding of each use. The information provided regarding "purpose for which licensed material will be used" is understood by the NRC staff to be a self-imposed limitation contained within the application. If a broad scope licensee desires to initiate a use other than those described in its application and committed to in its license, it would be necessary to submit an amendment to the license to modify or expand the "purpose." In addition, if the newly added purpose includes a unique or specialized activity (e.g., sealed source fabrication), the licensee may have to submit the criteria used by the RSC in evaluating in-house requests for such use. Regulatory Guides 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," and 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," provide guidance for the evaluation and registration with the NRC of sealed sources and devices.

Applicants who request authorization to distribute material possessed pursuant to 10 CFR Part 30 must request and obtain approval for such activities, and when applicable, request and obtain a separate license pursuant to 10 CFR Part 32.

Applicants who desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of those studies must include the information outlined in Appendix E of this guide with their application and list other field studies specifically authorized in their license. A "categorical exclusion" (from the requirement to prepare an environmental assessment or impact statement) is granted by 10 CFR 51.22(c)(14)(v) for the use of radioactive material for research and development and for educational purposes. However, this "categorical exclusion" does not encompass, among other things, the performance of field studies in which licensed material is deliberately released directly into the environment for purposes of a study (e.g., tagging of animals or insects that remain in the wild). These types of requests may necessitate an applicant filing an environmental report and an environmental assessment by NRC pursuant to 10 CFR Part 51. Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape, may be eligible for a "categorical exclusion" pursuant to 10 CFR 51.22(c)(14)(xvi).

ITEM 7: INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7.1 Senior Management

A broad scope license is issued by the NRC to accommodate institutions involved in an extensive radioactive materials program with a variety of radionuclides and uses. The NRC grants significant latitude to licensee management to develop, implement, and maintain an appropriate radiation safety program. Consequently, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Applicants for Type A and Type B broad scope licenses are required by 10 CFR 33.13 and 33.14, respectively, to establish sufficient administrative controls

and provisions relating to organization and management, including management review, as necessary to ensure safe operations.

Management responsibility and liability is often underemphasized in applications and often poorly understood by licensee employees and managers. Type A and medical broad scope licensees are required to establish an RSC that represents management when reviewing and approving safety evaluations. Therefore, senior management should delegate to the RSC and RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions. The licensee retains the ultimate responsibility for the conduct of licensed activities. It is also essential that the institution devote sufficient resources (i.e., equipment, personnel, and materials) to support the radiation protection program.

A license application should discuss senior management oversight and the mechanisms to be used by management to ensure adequate control over licensed broad scope activities. The NRC expects senior management oversight to include regular meetings with the RSC, RSO, and support staff, along with annual audits of the program to assure safe operations and compliance with regulatory requirements. The audit program should include mechanisms to correct and resolve problems in an expeditious manner. (Program audits are discussed in Item 10.4.)

The application for a Type A license should include an organizational chart depicting the management structure, reporting paths, and flow of authority, including the statement empowering the RSC, outlining its authority to oversee the licensed program and responsibility for control and direction of the radiation safety program and the RSO.

The operational oversight for a Type B broad scope program is specified, in part, in 10 CFR 33.14(b)(1), which states, "The appointment of a radiological safety officer who is qualified by training and experience. . . ." An application for a Type B license, as indicated above for the Type A license and RSC, should include an organizational chart and management statement describing the RSO's authority. Appendix F provides a sample certification that the RSO understands and accepts the responsibilities of the position.

7.2 Radiation Safety Committee

For Type A and medical broad scope programs, the licensee is required to establish an RSC pursuant to 10 CFR 33.13(c)(1). The RSC should be responsible for establishing appropriate policies and procedures to ensure control of the procurement and use of byproduct material, completion of safety evaluations of proposed uses and users, and the overall development and implementation of the radiation safety program.

The RSC should consist of the RSO; at least one representative of management; and at least one user authorized by the RSC, trained and experienced in the safe use of radioactive materials, from each of the departments, groups, or activities that will use radioactive materials under the broad scope license. For medical broad scope programs, the RSC should also include a representative of the nursing service and a physician authorized user for each type of medical use permitted by the license, as well as users authorized by the RSC for nonmedical use. The RSC chairperson should be named on the license application. A license amendment is required if the RSC chairperson changes. The other members need only be listed by title and qualifications, not by name.

The number of members constituting a quorum, as well as their names or fields of expertise, should be specified when a quorum of the RSC is empowered to act for the committee. The NRC staff considers the minimum acceptable quorum would be the chairperson, RSO, management representative, committee member or members representing the department or area from which the radioactive material request originated, and any other committee member whose field of expertise is necessary to ensure all safety aspects have been addressed. To have a quorum and conduct business for medical broad scope programs, at least one-half of the Committee's membership representing medical use activities must be present, including the RSO and the management representative.

The RSO's role, as a member of the RSC, should be to provide technical expertise to the RSC. The NRC does not recommend that the RSO and the RSC chairperson be the same individual. The RSO is responsible for the day-to-day operations of the radiation safety program and may not realistically be able to manage the whole program and other assigned duties or responsibilities if he or she is also the chairperson.

An application should describe the frequency of RSC meetings and the criteria for selecting RSC members; it should include a specific and detailed description of the control functions of the RSC and the administrative procedures by which these functions are carried out. The RSC at a medical institution is required by 10 CFR Part 35 to meet at least quarterly. Appendix G of this guide provides an outline of the duties and responsibilities of the RSC that are acceptable to the NRC staff.

7.3 Radiation Safety Officer

Broad scope licensees are required to appoint an RSO pursuant to 10 CFR 33.13(c) and 33.14(b). The RSO should be responsible for oversight of the day-to-day radiation protection program established by the RSC, should communicate with senior management and the RSC regarding program implementation, compliance status, and should be available to provide advice and guidance on radiological safety matters.

The RSO should have an academic degree in physical or biological science or engineering, specific training in radiation health sciences, and considerable professional experience (generally about 5 years) with a broad spectrum of radioactive materials. The RSO's professional experience should include the application of this training to the management and administration of a radiation safety program related to the types, quantities, and uses of the radioactive material to be used under this license. A previous background in program and staff management is also desirable.

The training and experience of the RSO in radiation protection and with radiation and radioactive materials should be listed and described. If he or she is not a full-time employee of the organization, describe the individual's affiliation with the institution and state how many hours per week the individual will be available to oversee the NRC-licensed program. Also specify provisions for contacting this individual during emergencies and off-hours and provide a general description of his or her other obligations. Generally, the NRC staff does not consider the use of consultants or part-time RSOs acceptable for broad scope programs; in most cases, the position of RSO is a full-time commitment. The RSO should report directly to senior management, have ready access to all levels of the organization, and have the authority to

immediately terminate any activities that are found to be a threat to public health, safety, or property.

A statement should be included in the application delineating the RSO's duties, responsibilities, and authority for carrying out the radiation safety program. The extent of these responsibilities and duties will depend on the proposed broad scope license. Appendix H to this guide provides an outline of duties and responsibilities of the RSO under a broad scope license, representative of those considered acceptable to the NRC staff.

7.4 Radiation Safety Office Staff

The RSO is supported by a staff of health physics professionals who assist in the maintenance and control of the licensed program. The number and qualifications of these professionals will vary with the scope of the program. The application should include a description of the duties and responsibilities of the radiation safety office staff and an assessment of the staffing levels and qualifications of this support staff. The assessment should be sufficient to demonstrate that the technical staff are adequate to implement, support, and oversee the proposed radiation protection program. If the current staffing is considered minimally acceptable, a projected timetable for achieving full staffing should be included. A projection of future needs would also be useful.

ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

A broad scope licensee must provide initial and refresher training to all individuals who will use, or may come in contact with, radioactive material. Employees who will need training include all users; laboratory supervisors and technicians; radioactive material incinerator and waste compactor operators; housekeeping, nursing, and security personnel; and radiation safety office staff. It is understood that training programs will vary from licensee to licensee. The detail and content will depend on the scope of the program (i.e., Type A, Type B, or medical broad scope), possession limits, type of isotopes used, size of the program in terms of the number of laboratories and

users, laboratory classification scheme, types of studies being performed, etc.

Broad scope licensees need to develop a system for retraining all users, laboratory supervisors, and technicians that is performance-based (i.e., "hands-on"), as well as classroom training on changing requirements. The application should describe the existing program for training the staff. Appendix I to this guide is an example of a broad scope training program that is acceptable to the NRC staff.

ITEM 9: FACILITIES AND EQUIPMENT

Since broad scope licenses will be issued only to applicants who have had prior experience in the use of radioactive materials under other licenses, each applicant's facilities and equipment have already been described in previous license correspondence. However, these descriptions should be resubmitted as part of the license application. Any new or altered facilities and equipment that are essential to the license being sought should also be described. Facilities and equipment used for special applications should be specifically described if they might have a significant impact on workers or the public if radioactive material were accidentally released. These would include, for example, room irradiators, specialized iodination or tritiation facilities, alpha laboratories, large-scale waste processing and storage facilities (including decay-in-storage locations, incinerators, compactors, and liquid reclamation processors), individual laboratories processing 3.7GBq (100 millicuries) or more of radioactive materials per experiment or process, nuclear pharmacies, and specifically designed therapy rooms or storage areas for radiopharmaceuticals or sealed sources.

Administrative procedures for internal control of users under the broad license (discussed in Item 10) should include provisions for determining that facilities and equipment are adequate for all proposed uses. The application should include a laboratory or facility classification scheme that relates the toxicity and quantity of radioactive materials to minimum facility and equipment requirements. The International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (for example,

for equipment and facilities, user training, personnel monitoring, or surveys) in relation to the hazard and quantity of byproduct materials to be used.[2] The NRC staff recommends that applicants consider developing such a classification scheme, since all aspects of the radiation safety program can be correlated to it. The IAEA document is not meant to be a model, but simply a reference. Each applicant's scheme should be based upon the types and quantities of byproduct materials that are anticipated to be needed. The criteria used to develop the classification scheme should be made into a manual and provided to each RSC member for use when evaluating requests to use licensed materials. Appendix J to this guide has been excerpted from the IAEA Standard and it provides information on radionuclide toxicity and laboratory classification. A license application should describe the minimum facilities and equipment required for each laboratory classification.

The radiation detection and monitoring equipment available to both the radiation safety office and all users should be described, and the type and number of instruments available (e.g., ion-chambers, G-Ms, air samplers, liquid scintillation counters) should be listed. In addition, the instrument calibration program, including calibration procedures and frequency, should be described. If a contractor or vendor will calibrate instruments, confirm that such calibrations will be done by persons specifically authorized by the NRC or an Agreement State to perform such services.

ITEM 10: RADIATION SAFETY PROGRAM

The formal requirements for a radiation safety program under a broad license are contained in 10 CFR 33.13 and 33.14. Applicants for a Type A license must have engaged in a reasonable number of activities involving the use of byproduct material. Applicants for both Types A and B licenses must have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. The radiation safety program description should be in narrative form and

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[2]IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides," International Atomic Energy Agency, Vienna, Austria, 1973 Edition.

include the elements identified below. The requirement to develop, document, and implement a radiation protectio ogram commensurate with the scope of the license request is contained in 10 CFR 20.1101; recordkeeping requirements related to the program are in 10 CFR 20.2102.

10.1 Previous Licenses

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

10.2 Administrative Procedures

NRC regulations at 10 CFR 33.13 and 33.14 require the establishment of appropriate administrative procedures to ensure (1) control of the procurement and use of byproduct material and (2) the completion of safety evaluations of proposed uses and users of byproduct material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and operating or handling procedures. The NRC staff recommends the development of radiation safety manuals or other formal documents for informing the licensee staff of safety criteria, good health physics practices, NRC regulations, and license commitments. The application should include either a complete description of these administrative procedures or copies of the formal documents that have been issued (or will be issued) to the staff.

10.2.1 Procedures for Control of Procurement and Use

An application should describe the administrative procedures established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. The NRC staff recommends a procedure that centralizes all purchases or other procurement through an authorized purchasing agent in order to verify that the procurement and use are authorized under the license. If such centralized procedures are not used, describe the procedures that are used to prevent unauthorized procurement and use.

10.2.2 Safety Evaluations of Proposed Uses and Users

Item 10.5 below describes the requirements for this important aspect of a broad scope program.

10.2.3 Emergency Procedures

An application should describe the programs in place for handling spills, fires, release or loss of material, and accidental contaminations of personnel. Discuss provisions for immediate response and handling of such incidents, including off-hours notification of appropriate staff, State and local authorities, and, when applicable, the NRC. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should understand whom they should contact and that only qualified and experienced individuals should conduct decontamination and recovery operations.

A copy of the emergency procedures should be posted in all restricted areas and should address, at a minimum:

1. Initial response actions and responsibilities, including immediate safety precautions for people and property.

2. Area and facility access control and security.

3. Mechanisms and responsibilities for notifying internal staff and external authorities.

4. Provisions for medical and offsite agency assistance.

Consider the strategic placement of emergency spill kits at specified locations throughout the institution for use by all users and the radiation safety staff. These kits should be inspected periodically and replenished as necessary.

Consider establishing an Emergency Response Team composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

10.2.4 Operating and Handling Procedures

An application should include laboratory operating and handling procedures that describe radiation safety instructions to ensure adequate external and internal exposure controls, including contamination controls, waste disposal practices, criteria for personnel and area monitoring, the use of protective clothing and equipment, and prohibitions of specific unsafe practices.

10.2.5 Other Procedures

An application should include other administrative procedures as deemed necessary to guide, control, and ensure consistency in the implementation of the radiation protection program. An applicant should consider, for example, standard operating procedures (SOPs) for routine health physics activities, including those conducted by the radiation safety office staff (e.g., radiation and contamination survey methods, smear analysis, source leak testing, air sampling, bioassays). The application should contain a commitment that certain changes to the radiation safety program described in Appendix F to this guide must be approved by the RSC.

10.3 Licensed Material Inventory and Accountability

A broad scope license authorizes possession and use of a vast array of radionuclides in relatively liberal quantities, typically for medical use, research, and research and development. These liberal possession limits, combined with a large number of individual users and locations of use, can create material inventory and accountability problems if they are not properly managed. Consequently, applicants should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to ensure that licensed possession limits are not exceeded and that material is accounted for throughout the institution at any given time. Sufficient staff and equipment should be devoted to the inventory and accountability control program.

An application must include a description of the inventory control and accountability program for licensed material.

10.4 Audits and Appraisals

Applicants are required by 10 CFR 33.13 and 33.14 to establish administrative controls and provisions relating to management review necessary to ensure safe operations. The regulations in 10 CFR 20.1101(c) require the licensee to periodically (at least annually) review the radiation program content and implementation. The radiation safety program review and audits are the responsibility of management. Management may fulfill this responsibility either by having this audit conducted by the RSC or by contracting with an independent auditor to review the program. This auditor should be accompanied by management, the RSO, and available representatives of the RSC. The auditor's results of the program review should be submitted to the RSC for formal documented committee review and action. Licensees are required by 10 CFR 20.2102 to maintain records of the radiation protection program, including (1) the provisions of the program and (2) audits and other reviews of the program contents and implementation.

10.4.1 Management and Radiation Safety Committee Audits

An application should discuss senior management oversight and the mechanisms used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program. This oversight may include independent audits of the program, frequent meetings with the RSC, and periodic tours of selected facility areas.

The RSC should be fully aware of the operations and activities of the Radiation Safety Office through frequent and routine meetings. The RSC should conduct periodic interactive management audits and evaluations of the Radiation Safety Office's performance, including the RSO's. Results of the RSC's audit and program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions. An institution should also

consider establishing RSC subcommittees to evaluate and audit those areas of the program within their area of expertise.

10.4.2 RSO and Staff Audits

An application should describe the audit mechanism implemented by the RSO and his or her staff to determine user compliance with the terms and conditions of the NRC license, RSC-approved permits, and good health physics practices. The audit program should include routine unannounced inspections of each user's laboratory and practices to supplement and audit the routine monitoring. The laboratory inspections should include:

1. Review of user inventory and survey records.

2. Evaluation of user and technician training through discussion and observation of work practices.

3. Performance of independent surveys of user work areas.

4. Evaluation of compliance with RSC permit and safety manual requirements.

5. Provision for performance-based instruction to users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Type A broad scope licensees typically perform these surveys and audits at least quarterly. However, schedules of surveys and audits may be based on activity and use (e.g., high-level Type A laboratories could be weekly, intermediate Type B laboratories could be monthly, and low-level Type C laboratories could be quarterly).

10.5 Safety Evaluations of Proposed Uses and Users

NRC regulations at 10 CFR 33.13 and 33.14 require that applicants for Type A and Type B broad scope licenses, respectively, establish procedures to ensure completion of safety evaluations of proposed uses of byproduct material that take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. The review and approval must be documented by the RSC prior to use of the byproduct material.

The application should contain the criteria to be used by each committee member when evaluating the qualifications of users, the adequacy of facilities and equipment, and the personnel monitoring and survey requirements. The NRC staff recommends that criteria for committee members be maintained in manual form. Appendix K provides guidelines for granting research authorizations for the use of byproduct material.

Since the RSC will assume the responsibility for the review of users and uses of radioactive materials, the application must provide enough detail to assure the NRC staff that the RSC evaluations are sufficient in scope and depth to satisfy 10 CFR 33.13(c)(3) and 33.14(b)(2). A copy of the forms or permits for proposed user requests and RSC approvals should be submitted for review with the application.

Licensees with broad licenses involving a wide range of uses should consider developing a classification scheme for radionuclides according to relative toxicity per unit activity as discussed previously under Item 9. This classification scheme can be used to correlate standards of design for laboratories based upon toxicity and levels of activity used. The development of the classification scheme should be based on the radionuclide types and uses anticipated at the specific institution. Once a classification scheme has been developed, other required safety functions can be developed and incorporated into the criteria used by the individual committee members when reviewing applications, e.g., for bioassays and frequencies, direct and removable contamination surveys, air sampling provisions, personnel monitoring. The submission of a classification scheme and criteria is intended to demonstrate to the NRC staff the minimum standards that will be applied when approving uses. It is understood that certain permits issued by the RSC may

deviate from the classification scheme because of unusual circumstances; however, it is expected that licensees will adhere to the classification scheme closely, and when deviations occur it is expected that justification and documentation of the deviation will be maintained for review by the NRC inspection staff. Safety evaluation procedures and criteria should include a description of how the RSC will evaluate and apply requirements for:

1. The proposed use of material, considering the quantity and form requested, the potential radiological hazards associated with such use, and the mechanisms for external and internal exposure control, contamination controls, and waste disposal.

2. Training and experience for users to be authorized by the RSC and individuals working under the supervision of those users (e.g., technicians). Specialized training for certain users should also be included (e.g., for incinerator operators, waste compaction personnel, and animal handlers).

3. Facilities and equipment for each specific use.

4. Material handling and operating procedures, including provisions for requiring users to conduct surveys to confirm that radiation levels and contamination levels are within specific guidelines. The type and frequency of surveys should be determined by the amount and types of radioactive material used or being stored.

10.6 Exposure Control and Monitoring

The procedures and mechanisms established to control and monitor both internal and external radiation exposure should be described. The procedures should include general criteria for all radionuclides that may be used and specialized criteria to address control and monitoring when higher levels of radionuclide activity or toxicity are used.

10.6.1 External

Describe the type and frequency of radiation surveys that will be conducted in areas where radioactive materials are used or stored and in adjacent unrestricted areas that are accessible to personnel. Surveys should be conducted by the user and supplemented by Radiation Safety Office surveys. Surveys conducted by supervising users authorized by the RSC should consist of both external radiation and contamination smear surveys in various laboratory use and storage areas, at frequencies commensurate with the quantity and form of radioactive material in use or storage (e.g., high-level or Type A laboratories could be daily, intermediate or Type B laboratories could be weekly; and low-level or Type C laboratories could be monthly or quarterly). In addition, surveys of work areas should be performed throughout the day when radioactive materials are actively in use. The survey program should cover external radiation and provide action or trigger levels for contamination in both restricted and unrestricted areas.

Explain which surveys are the responsibility of the user and which will be performed as part of the radiation safety audit program. Characterize laboratories and facilities according to the radiological hazard and indicate the types and frequencies of monitoring and surveys performed by designated staff. NRC Regulatory Guides 8.21, "Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants"; 8.23, "Radiation Safety Surveys at Medical Institutions"; and 10.8, "Guide for the Preparation of Applications for Medical Use Programs," contain information and criteria for establishing monitoring programs.

Provide information regarding the type of tests (e.g., DOP, charcoal absorption efficiency) and the frequency of tests to be performed on ventilation and filtration systems. This discussion should be presented by system, for instance, hood, glove boxes, filter systems (e.g., HEPA, charcoal). If a recognized national standard is used, specify the reference or provide a copy.

Specify the criteria used to assign personnel monitoring devices such as film and TLD whole body and extremity badges and direct reading dosimeters, and specify the frequency for processing the devices for the various laboratory types. Indicate the supplier (required to be NVLAP-approved pursuant to 10 CFR 20.1501(c)) of the dosimetry system.

10.6.2 Internal

Describe the criteria used to determine the type and frequency of bioassay (both in vivo and in vitro) that will be performed to evaluate intakes. Guidance on bioassay programs is provided in NUREG/CR-4884, "Interpretation of Bioassay Measurements";[3] NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure" (1983),[3] and Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."[3]

Describe the criteria used to set the type of survey and the frequency at which routine surveys for airborne radioactive materials are performed, e.g., air sampling of breathing zones and general work areas, hood and room ventilation air flow rate measurement, and stack effluent sampling. The air sampling criteria should be incorporated into the laboratory classification scheme and should provide enough detail that the NRC staff is assured that appropriate steps will be taken to manage and monitor such exposures. Guidance on an acceptable air sampling program is contained in Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions."[3]

ITEM 11: WASTE MANAGEMENT

Describe the methods used for disposal of radioactive waste. The application should include, as appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from nonradioactive, short from long half-life, liquid from solid waste). The following items should be considered and addressed in the application:

11.1 Transfers to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in

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[3]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328 (telephone (202)512-2249 or (202)512-2409); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

accordance with 10 CFR 20.2001(a). State the name and license number of the receiving company.

11.2 Storage of radioactive materials with half-lives greater than 65 days should be characterized as to volume and anticipated time in residence at the facility prior to disposal. The NRC does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, low-level radioactive waste (LLW) should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,"[4] outlines the provisions and requirements for interim storage. If the interim storage provision applies to a program, the application should address the topics outlined in Information Notice 90-09.

11.3 Radioactive materials released into air and water in conformance with 10 CFR 20.1302 and 20.2003, respectively. Discuss the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements.

11.4 Treatment or disposal by incineration in conformance with 10 CFR 20.2004. If licensed material will be treated or disposed of by incineration, address the items listed in Appendix L, "Incineration Guidelines for Material Licensees," to this guide and obtain specific approval from the NRC. Applicants proposing incineration should be aware that a notice in the Federal Register may be required before disposal of ash as ordinary waste can be approved. However, approval of incineration pursuant to 10 CFR 20.2004 does not require notice in the Federal Register if the ash is disposed of as radioactive waste, transferred to a specific licensee, or contains nondetectable radioactivity.

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[4]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

11.5 Waste volume reduction operations that could create a radiological hazard to employees or the general public must be described in detail in the application. For example, if compactors will be used to reduce volume, include:

- A description of the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated in the expected operations. The description might include manufacturer's specifications, annotated sketches, or photographs.

- The type, quantities, and concentrations of waste to be compacted.

- An analysis of the potential for airborne release of radioactive material during compaction activities.

- The location of the compactors within the waste processing areas, as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange.

- Methods used to monitor worker breathing zones, exhaust systems, or both.

- The types and frequencies of surveys that will be performed for contamination control in the compactor area.

- The instructions provided to compactor operators, including instructions on protective clothing, checks for proper functioning of equipment, methods of handling uncompacted waste, and examining containers for defects.

11.6 Disposals that contain radioactivity from hydrogen-3 and carbon-14 in scintillation counting media and in animal tissue in concentrations of 0.05

microcurie or less per gram, subject to certain restrictions stated in 10 CFR 20.2005, need not be described in the application.

11.7 Licensees who were authorized prior to January 28, 1981, to bury radioactive materials pursuant to 10 CFR 20.304 should describe the locations, conditions, and current status of these former sites, i.e., controlled or uncontrolled, any active monitoring of the site, and the current condition of the burial site.

11.8 Other methods of disposal specifically approved by the NRC pursuant to 10 CFR 20.2002.

An application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points, e.g., hoods and incinerator stacks. To be in compliance with the ALARA philosophy stated in 10 CFR 20.1101, radioactive material waste stream concentrations should be a fraction (generally 10 to 20%) of the limits specified in Table II of Appendix B to 10 CFR Part 20. Furthermore, because of the variability of inventory control programs for monitoring disposal and releases of byproduct material in use, a program for physically measuring releases should be in place whenever releases may exceed the specified ALARA action point.

ITEM 12: LICENSE FEES

According to 10 CFR 170.12(a), an application fee must be paid in full for most types of licenses, including applications for license amendments and renewals. Refer to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses," to determine the amount of the fee that must accompany the application. An application received without a fee or with an inadequate fee may be returned. All application fees may be charged irrespective of the NRC's disposition of the application or the licensee's withdrawal of the application. In addition, applicants should be aware that continuance of

license authorization is contingent upon satisfactory payment of the annual and NRC inspection fees. Refer to 10 CFR 171.16, "Annual Fees: Material Licensees, Holders of Certificates of Compliance, Holders of Sealed Source and Device Registrations, Holders of Quality Assurance Program Approvals and Government Agencies Licensed by the NRC," and the aforementioned 10 CFR 170.31 for the appropriate fee. The NRC has approximately 38 fee categories that cover various uses of licensed materials.

Applicants should be aware that they may be responsible for fees in each category applicable to their application or license. Questions pertaining to NRC license applications or to annual and inspection fees should be referred to the U.S. Nuclear Regulatory Commission, License Fee and Debt Collection Branch, Division of Accounting and Finance, Office of the Controller, Washington, DC 20555, telephone (301)415-7544.

ITEM 13: CERTIFICATION

Applications for new, renewed, or amended licenses must be signed and dated by a representative of the corporation or entity who is authorized to sign official documents and to certify that the application contains information that is true and correct to the best of the applicant's knowledge and belief. Unsigned applications will be returned for proper signature. To prevent undue delay, each request for an amendment or a renewal signed by an individual not clearly recognized as a "Certifying Official" should be accompanied by a statement from the licensee's management indicating the individual's authority to sign official documents related to licensing.

4. AMENDMENTS TO A LICENSE

After a license has been issued, licensees must conduct their programs in accordance with (1) the statements, representations, and procedures contained in the application, (2) the terms and conditions of the license, and (3) the NRC's regulations.

It is the obligation of the licensee to keep the license current and to anticipate the need for a license amendment insofar as possible. If licensed activities change or require modification such that information provided in

the application does not represent current operations, intended uses, or individual maximum uses, the license must be amended. An application for an amendment must be filed before initiating any such changes. Until approval of the amendment, the licensee must comply with the terms and conditions of the current license.

An application for a license amendment may be prepared either on the application form (NRC Form 313, see Appendix D) or in letter form and should be submitted in duplicate to the address specified in Section 2 of this guide. The application should identify the existing license by number and 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.

The appropriate fee for a license amendment must accompany the application. The NRC will not accept an application for filing or processing before the proper fee is paid in accordance with 10 CFR 170.12.

5. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. The NRC staff believe, because of the scope and complexity of the use of byproduct materials, that a licensee with a broad scope license should review the program in its entirety prior to the end of each license authorization period. Once this review has been completed, the licensee must complete an application for renewal and send it to the address specified in Section 2 of this guide. This application for renewal should be submitted as an entirely new application, i.e., as if it were an application for a new license without referring to previously submitted information.

If an application for license renewal is filed at least 30 days before the expiration date of the license and includes the appropriate fee for license renewal, the current license will automatically remain in effect until the NRC takes final action on the application for renewal. However, if an application is filed less than 30 days before the expiration date and the NRC cannot process it before that date, the current license would not be valid after the expiration date.

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

If a licensee does not wish to renew a license, all licensed radioactive material must be disposed of in a manner authorized by 10 CFR Part 20. NRC Form 314, "Certificate of Disposition of Materials" (see Appendix C), should be completed and sent to the NRC before the expiration date of the license with a request that the license be terminated. Licensees applying for termination of their licenses must be aware of the NRC requirements contained in 10 CFR 30.36, "Expiration and Termination of Licenses."

If a licensee cannot dispose of all the licensed radioactive material in its possession before the expiration date of the license, it must request a license renewal for storage only. The renewal is necessary to avoid violating NRC's regulations that prohibit possession of licensable material without a valid license.

DEFINITIONS AND ACRONYMS

Authorized User: A physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

Authorized User for Nonmedical Use: An individual specifically named and authorized by the Radiation Safety Committee to use licensed material.

Certifying Official: An individual authorized by an institution's management to sign official license documents and correspondence.

Institutional Review Board (IRB): A committee, established in accordance with criteria promulgated by the U.S. Food and Drug Administration (FDA), responsible for evaluating risk and benefits of human use medical research proposals (see 21 CFR Parts 51 and 56).

Laboratory Classification Scheme: A system of evaluating and assigning a ranking to a laboratory or facility, based on its suitability as a radioactive material use area.

Laboratory Technician: An individual whose normal duties involve laboratory research-related work with radioactive materials under the supervision of an approved or authorized user.

Radiation Safety Committee (RSC): A committee responsible for development and administration of a broad scope institution's radiation safety program, including responsibility for approval of all proposals for radionuclide use and users.

Radiation Safety Office Staff: A technical support staff responsible for the day-to-day operation of a radiation safety program within an institution, as directed by an RSO.

Radiation Safety Officer (RSO): An individual, identified on the license, responsible for the day-to-day operation of a radiation safety program within an institution.

Radiation Worker: Any individual whose duties require work with radioactive material.

Radioactive Drug Research Committee (RDRC): A committee, established in accordance with criteria promulgated by the U.S. Food and Drug Administration, and whose members are approved by the FDA, responsible for evaluating and approving proposals for radioactive drug research involving human subjects (see 21 CFR Part 361).

APPENDIX A

FLOW DIAGRAM TO AID IN DETERMINING THE NEED FOR COMMITTEES FOR HUMAN RESEARCH

IS LICENSEE DOING HUMAN RESEARCH? ---- (NO) ---- INSTITUTIONAL REVIEW BOARD (IRB) OR RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC) NOT REQUIRED. ONLY NEED RADIATION SAFETY COMMITTEE (RSC) PER 10 CFR PART 33.

(YES)

IS LICENSEE A MEDICAL INSTITUTION? ---- (NO) ----COORDINATE REVIEW WITH NMSS

(YES)

DOES LICENSEE HAVE OR HAVE ACCESS TO IRB AND RDRC? ---- (YES) ---- LICENSEE MAY BE AUTHORIZED FOR HUMAN RESEARCH IF LICENSEE HAS PROCEDURES TO REQUIRE INTENDED STUDY BE REVIEWED BY APPROPRIATE COMMITTEE[1]

(NO)

IS THE RESEARCH LIMITED TO THE PROVISIONS OF AN FDA IND OR NDA? ---- (YES) ---- RESEARCH CAN BE CONDUCTED UNDER THE PROVISIONS OF SUBPARTS D - I, PART 35 AND PROVISIONS OF IND OR NDA[2]

(NO)

COORDINATE REVIEW WITH NMSS

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[1] For example: IRB required for such studies as development of emerging medical technologies, physiological studies using radioactive tracers, IND studies, RDRC-approved studies. RDRC required for such studies as biodistribution studies, radioactive drug studies when IND is for nonradiolabelled form of drug.

[2] For example: Phase II/Phase III Clinical Trials.

APPENDIX B

REGULATORY GUIDES TO ASSIST LICENSEES WITH THE IMPLEMENTATION OF THE REVISED PART 20

Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Radiation Exposure Data"

Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Binassay Program"

Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace"

Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses"

Regulatory Guide 8.35, "Planned Special Exposures"

Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus"

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"

NRC FORM 314 U.S. NUCLEAR REGULATORY COMMISSION
(5-92)
10 CFR 30.36(e)(1)(iv)
10 CFR 40.42(e)(1)(iv)
10 CFR 70.38(e)(1)(iv)

APPROVED BY OMB: NO. 3150-0028
EXPIRES: 05/31/95

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 30 MINUTES. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0028), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

CERTIFICATE OF DISPOSITION OF MATERIALS

INSTRUCTIONS: ALL ITEMS MUST BE COMPLETED -- PRINT OR TYPE
SEND THE COMPLETED CERTIFICATE TO THE NRC OFFICE SPECIFIED ON THE REVERSE

LICENSEE NAME AND ADDRESS	LICENSEE NUMBER
	LICENSE EXPIRATION DATE

A. MATERIALS DATA *(Check one and complete as necessary)*

THE LICENSEE OR ANY INDIVIDUAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE LICENSEE CERTIFIES THAT:
(Check and/or complete the appropriate item(s) below.)

☐ 1. NO MATERIALS HAVE EVER BEEN PROCURED OR POSSESSED BY THE LICENSEE UNDER THIS LICENSE.

OR

☐ 2. ALL MATERIALS PROCURED AND/OR POSSESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. *(If additional space is needed, use the reverse side or provide attachments.)*

Describe specific material transfer actions and, if there were radioactive wastes generated in terminating this license, the disposal actions including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

For transfers, specify the date of the transfer, the name of the licensed recipient, and the recipient's NRC licensee number or Agreement State name and license number.

If materials were disposed of directly by the licensee rather than transferred to another licensee, licensed disposal site or waste contractor, describe the specific disposal procedures *(e.g., decay in storage)*.

B. OTHER DATA

☐ 1. OUR LICENSE HAS NOT YET EXPIRED; PLEASE TERMINATE IT.

2. WAS A RADIATION SURVEY CONDUCTED TO CONFIRM THE ABSENCE OF LICENSED RADIOACTIVE MATERIALS AND TO DETERMINE WHETHER ANY CONTAMINATION REMAINS ON THE PREMISES COVERED BY THE LICENSE? *(Check one)*

☐ NO *(Attach explanation)*
☐ YES, THE RESULTS *(Check one)*
☐ ARE ATTACHED, or
☐ WERE FORWARDED TO NRC ON *(Date)*

3. THE PERSON TO BE CONTACTED REGARDING THE INFORMATION PROVIDED ON THIS FORM	NAME	TELEPHONE NUMBER *(Include Area Code)*

4. MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO

CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. SECTION 1001 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.

APPENDIX D

NRC FORM 313 (6-93)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - ☐ A. NEW LICENSE
   - ☐ B. AMENDMENT TO LICENSE NUMBER _____
   - ☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9.	FACILITIES AND EQUIPMENT	10.	RADIATION SAFETY PROGRAM
11.	WASTE MANAGEMENT	12.	LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY / AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR 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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

NRC FORM 313 (6-93)

PRINTED ON RECYCLED PAPER

APPENDIX E

INFORMATION REQUIRED FOR FIELD USE OF BYPRODUCT MATERIAL

1. A complete license application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.

2. A complete experimental protocol.

3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases.

4. A description of the expected radiation dose to humans.

5. The written permission of the property owner to use radioactive materials at the proposed site.

6. A letter from the appropriate State health authorities indicating that they have reviewed your application and concur with your request.

APPENDIX F

RADIATION SAFETY OFFICER CERTIFICATION

We certify that the individual to be named on this license to perform the function of Radiation Safety Officer:

1. Has read and understands the NRC regulations applicable to this license and the specific conditions in the license,
2. Has sufficient technical knowledge to perform the duties of a Radiation Safety Officer,
3. Has and will continue to have sufficient time to perform the duties of the Radiation Safety Officer,
4. Has and will continue to get sufficient resources to accomplish the tasks of the Radiation Safety Officer,
5. Is completely willing to perform the functions of the Radiation Safety Officer, and
6. Has and will continue to receive the support of the management of this licensee in ensuring that all licensed activities will be conducted in accordance with NRC regulations and the specific terms of the license.

Radiation Safety Officer Applicant _____

Date _____

Corporate Officer/Certifying Official _____

Date _____

APPENDIX G

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY COMMITTEE (RSC)

1. Meet as often as necessary to conduct business but not less than quarterly.

2. Conduct periodic reviews and audits of the Radiation Safety Program and devote sufficient time, along with the Radiation Safety Officer (RSO) and the Radiation Safety Office staff, to reviewing records, reports from the RSO, results of NRC inspections, and written safety procedures, along with observing audits performed by the RSO and the Radiation Safety Office staff to ensure the adequacy of the institution's management control systems. These reviews may be conducted by an independent auditor, but this does not relieve the RSC of the responsibility to ensure that the reviews are conducted in accordance with regulations. Examples of program reviews include, but are not limited to, the following:

   - Periodic review of protocol or user permits issued by the RSC (e.g., review of each permit at 1- to 2-year intervals).

   - Review of letters of agreement with offsite emergency response agencies.

   - Review of procedures for controlling and maintaining inventories, procurement of radioactive material, individual user and institutional cumulative possession limits, transfer of radioactive materials within the institution, and transfer of radioactive material to other persons or licensees.

   - Review of audit findings (of RSC-approved users and facilities) by the Radiation Safety Office staff.

3. Conduct radiation safety evaluations of proposed users and uses. Procedures and criteria established for making safety evaluations of proposed uses of radioactive material are described in Item 10 of the guide.

4. Develop procedures and criteria for training and testing each category of worker. (Refer to Appendix I to this guide.)

5. Establish methods for maintaining records of the committee's proceedings and radiation safety evaluations of proposed users and uses of radioactive materials. (These documents would be useful in understanding an applicant's program if they were submitted with the application.)[1]

6. Develop radiation safety manuals as necessary to ensure proper program implementation and good health physics practices. There should be an ongoing review of the existing safety manual for adequacy and completeness. The specific manuals should not be submitted as part of the license application to allow flexibility for changes.

7. Maintain a list of current committee members and their appropriate training and experience.

NOTE: If this request is for a medical broad scope license, the description of the RSC's duties and responsibilities must include the requirements of 10 CFR 35.22.

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[1] Although specific criteria and procedures are 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 or for servicing and calibrating personnel dosimeters (providing the new contractor is NVLAP approved), or references to particular pieces of equipment. By careful use of this technique, the applicant can avoid the necessity for frequent license amendments.

APPENDIX H

DUTIES AND RESPONSIBILITIES OF A BROAD SCOPE RADIATION SAFETY OFFICER

1. Maintain surveillance of overall activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.

2. Determine compliance with rules and regulations, license conditions, and the conditions of project approvals authorized by the Radiation Safety Committee.

3. Monitor and maintain absolute and other special filter systems associated with the use, storage, or disposal of radioactive material.

4. Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR 19.12, 10 CFR Part 20, and 10 CFR Part 35 (if applicable).

5. Oversee proper delivery, receipt, and conduct of radiation surveys of all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.

6. Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching maximum permissible amounts, and recommend appropriate remedial action.

7. Conduct training programs and otherwise instruct 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. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records.

9. Store radioactive materials not in current use, including wastes.

10. Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.

11. Maintain an inventory of all radioisotopes at the institution and limit the quantity of radionuclides at the institution to the amounts authorized by the license.

12. Immediately terminate any activity that is found to be a threat to public health and safety or property.

13. Supervise decontamination and recovery operations.

14. Maintain other records not specifically designated above, for example, records on receipts, transfers, and surveys as required by 10 CFR 30.51, "Records," and Subpart L, "Records," of 10 CFR Part 20.[1]

15. Hold periodic meetings with and provide reports to licensee management and the Radiation Safety Committee.

NOTE: If this request is for a medical broad scope license, the description of the RSO's duties and responsibilities must include the requirements of 10 CFR 35.22.

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[1]See NUREG-1460, "Guide to NRC Reporting and Recordkeeping Requirements" (USNRC, November 1992), which provides information on compliance with the requirements specified in Title 10 of the Code of Federal Regulations. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC: the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328 (telephone (202)512-2249 or (202)512-2409); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

APPENDIX I

CONCEPT AND ELEMENTS OF A BROAD SCOPE TRAINING PROGRAM

1. CONCEPT

The Radiation Safety Committee (RSC) (in consultation with the Radiation Safety Officer (RSO)) is responsible for developing and instituting the radiation safety program. The program for training should provide a commitment to initial training, retraining, and continuing education. The type and amount of instruction may be based on past training and experience, and it should be commensurate with potential radiological health protection problems in the areas in which the employees are expected to work. Performance-based training and continuing education, based on site-specific (laboratory classification) criteria, are considered important aspects of the training program.

2. ELEMENTS

All radiation workers must receive instruction in accordance with 10 CFR 19.12 prior to beginning work with licensed materials. This instruction may be in the form of an orientation session led by the RSO or a qualified staff member under his or her direction. This orientation is to include the following subjects:

- Applicable regulations and license conditions,
- Areas where radioactive material is used and stored,
- Potential hazards associated with radioactive material,
- Appropriate radiation safety procedures,
- Special in-house rules,
- Individual's obligation to report unsafe conditions to the RSO or applicable authorities,
- Appropriate response to emergencies or unsafe conditions,
- Worker's right to be informed of occupational radiation exposure and bioassay results, and

- Locations of pertinent regulations, licenses, and other material required by regulations.

3. NONMEDICAL USERS AUTHORIZED BY RSC

In addition to the training detailed above, the training and experience of users authorized by the RSC to independently use or supervise the use of byproduct material should be at least equivalent to that specified in 10 CFR 33.15(b)(1) and (2):

(1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(2) At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used.

The above citation is for users authorized under a Type C license, which generally involves the use of radioactive material in microcurie to low-millicurie quantities. Any program of instruction should be correlated to the licensee's specific laboratory classification scheme. Additional training would be required for the Type A and B laboratories. Training to meet the requirements of 10 CFR 33.15(2) may be provided by the RSO or the RSO's qualified staff. Such training should be documented. Training specified in 10 CFR 33.15(2) may have been obtained at a different institution; its scope and adequacy should be documented and approved by the RSC.

Training and experience for physician authorized users must meet the criteria outlined in Subpart J of 10 CFR Part 35.

4. RADIATION WORKERS (UNDER THE SUPERVISION OF A USER APPROVED BY THE RSC)

In addition to the 10 CFR 19.12 instruction, each radiation worker supervised by a user must receive specific written instruction from the user and

the Radiation Safety Office staff. The user is to work directly with new staff members until the user is confident in the worker's abilities and understanding of NRC regulations, license provisions, and "in-house" safety instructions. The user is responsible for documenting the staff member's completion of his or her instruction and certification of the worker's use of radioactive materials with limited supervision, i.e., not in the presence of the user.

5. PERFORMANCE-BASED TRAINING

In addition to basic classroom and laboratory instruction, it is recommended that there be an emphasis on performance-based (on-the-job) training, i.e., "hands-on" training specific to the individual's duties, to ensure safe handling of radioactive materials in accordance with the ALARA philosophy. The Radiation Safety Office should instruct the users, at least annually, regarding the authorized users' specific responsibilities for providing training to the staff. An assessment of the comprehension and abilities of the staff through random interviews with the users or the radiation workers should be included in the Radiation Safety Audit program.

6. OTHER RADIATION WORKERS AND ANCILLARY STAFF

The RSO is responsible for developing a comprehensive radiation training program such that all other users, e.g., technical radiation safety staff, nurses, waste handlers, animal caretakers, and ancillary staff (janitorial, housekeeping, security, etc.) understand the radiation hazards associated with their work and are able to take appropriate actions to prevent unnecessary exposure. Special programs must be developed to instruct each different group with appropriate information in accordance with 10 CFR Part 19. This information may be conveniently incorporated into an institution's general safety orientation training program. For example, waste handlers need to be trained in the radiological aspects of their duties as well as the chemical and biological considerations.

7. SUPPLEMENTARY CONTINUING EDUCATION

To supplement education and to update training, the NRC staff strongly recommends that the Radiation Safety Office issue a regular (at least quarterly) radiation safety newsletter or memo to users and supervisors. The newsletter or memo should contain information important to the operation of the Radiation Safety Program and the safe handling of radioactive materials. This information should be shared with the radiation workers and filed by the user or supervisor along with the material authorizing the use of licensed material. Thus, it is the responsibility of the user to provide evidence that each worker has received this and other pertinent information. The Radiation Safety Office should be responsible for auditing this program.

8. EMERGENCY PROCEDURES AND SPECIALIZED TRAINING

Emergency procedures, specialized training, and retraining should be provided to all applicable workers. All individuals who work with radioactive materials and who frequent radioactive use and storage areas should understand emergency procedures applicable to their duties. Reliance on introductory orientation and review of tapes pertaining to accidents involving radioactive materials is normally not sufficient to ensure appropriate, timely and adequate response to accident situations. Instruction in emergency procedures is considered an excellent performance-based training opportunity that could be incorporated into a retraining program.

Specialized, duty-specific training should be provided to individuals involved in such activities as radioactive waste handling and processing, incinerator operations, animal research, and those attending to patients who contain radioactive material.

9. RECORDS OF TRAINING

Training records should include:

- A list of topics,
- The approximate time spent on each topic,

- The names of instructors and students,

- The dates of the training,

- A written assessment or test for each student that documents satisfactory completion of the training,

- The location of the training and the materials involved in the training.

Details of in-house training programs should be provided, including the following information:

- The names, training, and experience of the individuals providing the formal training and

- An outline of the program for providing the necessary instruction. Confirm that, in addition to providing relevant instruction before assuming duties, appropriate training will be provided whenever there is a significant change in duties, instructions, procedures, or regulations, and confirm that continuing, site-specific training will be provided (state the frequency and the methods to be used).

APPENDIX J

TABLE 1: RADIONUCLIDES CLASSIFIED ACCORDING TO RELATIVE RADIOTOXICITY
(Excerpted from IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition")

Group 1: Very High Radiotoxicity

^{210}Pb ^{226}Ra ^{227}Th ^{231}Pa ^{233}U ^{238}Pu ^{243}Am ^{244}Cm ^{249}Cf
^{210}Po ^{228}Ra ....

Group 2: High Toxicity

^{22}Na ^{56}Co ^{95}Zr ^{125}Sb ^{131}I ^{144}Ce ^{181}Hf ^{207}Bi ^{228}Ac
^{36}Cl ^{60}Co ^{125}I ^{192}Ir ....

Group 3: Moderate Toxicity

^{7}Be ^{48}Sc ^{65}Zn ^{91}Sr ^{103}Ru ^{125m}Te ^{140}La ^{153}Gd ^{187}W ^{198}Au
^{14}C ^{48}V ^{69m}Zn ^{90}Y ^{32}P ^{35}S ^{51}Cr ^{24}Na ....

Group 4: Low Toxicity

^{3}H ^{58m}Co ^{71}Ge ^{87}Rb ^{97}Nb ^{103m}Rh ^{131m}Xe ^{125}Cs ^{191m}Os ^{232}Th
^{15}O ^{85}Kr ^{99m}Tc

TABLE II: LIMITATIONS ON ACTIVITIES IN VARIOUS TYPES OF WORKING PLACES OR LABORATORIES

Radiotoxicity of radionuclides	Minimum quantity	Type of working place or laboratory required		
	μCi	Type C	Type B	Type A
1. very high	0.1	<10 μCi	10 μCi-10 mCi	10 mCi or more
2. high	1.0	<100 μCi	100 μCi-100 mCi	100 mCi or more
3. Moderate	10	<1 mCi	1 mCi-1 Ci	1 Ci or more
4. low	100	<10 mCi	10 mCi-10 Ci	10 Ci or more

NOTE: Laboratory types correspond to the laboratory classification criteria of IAEA Safety Standard, Safety Series No. 1. Type C is a good-quality chemical laboratory. Type B is a specially designed radioisotope laboratory. Type A is a specially designed laboratory for handling large activities of highly radioactive materials. In the case of a conventional modern chemical laboratory with adequate ventilation and nonporous work surfaces, it may be possible to increase the upper limits of activity for Type C laboratories toward the limits for Type B for toxicity groups 3 and 4.

APPENDIX K

RADIATION SAFETY COMMITTEE
CRITERIA FOR APPROVING RESEARCH AUTHORIZATIONS

The Radiation Safety Committee (RSC) is to establish criteria to be used by the RSC or RSO when evaluating requests for authorizations for research for new facilities and new uses. Each RSC member should have detailed guidance to assess the training and experience, as well as the facilities and equipment needs for each research request, to include but not be limited to:

Research Involving Human Subjects	Meet training and experience requirements in Subpart J of 10 CFR Part 35.
Research Not Involving Human Subjects	Training and experience commensurate with proposed use -- see Appendix I to this guide.

Approved Uses:

1. Facilities and Equipment
   - lab layout
   - space limitations
   - storage of radioactive material
   - location and type of equipment

2. Operating and Handling Procedures
   - training of supervised individuals
   - ordering and receipt of radioactive material
   - monitoring of radioactivity
   - procedures for handling radioactive spills
   - waste disposal
   - storage of radioactive material

3. Research Involving Human Subjects
   - Radioactive Drug Research Committee
   - Institutional Review Board
   - Informed consent of the human subject

APPENDIX L

INCINERATION GUIDELINES FOR MATERIAL LICENSEES

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. The NRC may request additional information regarding proposed commercial incinerators as appropriate to adequately assess the potential impact on the public health and safety and the environment.

Specific NRC approval is not needed to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon-14 in low concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After review of the program and confirmation of waste that requires specific NRC approval for incineration, a licensee should provide all the information specified here.

1. State the specific isotopes and the maximum activity of each isotope that is to be incinerated per burn. Indicate the form of the waste (e.g., paper, bedding, animal carcasses).

2. State the maximum number of burns to be performed in any one week and the maximum number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

3. Describe the characteristics of the incinerator and site, including: (1) height of the stack, (2) rated air flow (cubic feet per hour or similar units), (3) proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital), and (4) distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters, or air cleaning equipment that is present.

4. State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers, or associated systems, will be measured or otherwise determined. Describe any stack monitoring that is planned.

5. Submit calculations demonstrating that concentrations of radioactive material in the effluent air at the stack or unrestricted area will be in accordance with the requirements of 10 CFR 20.1301 and 20.1302.

6. In order to be in compliance with the as low as reasonably achievable (ALARA) requirement stated in 10 CFR 20.1101(b), the gaseous effluent from the incinerator stack should (1) not exceed the limits specified for air in Table II of Appendix B to 10 CFR Part 20 when averaged over a 24-hour period and (2) be a fraction (approximately 10%) of the limits specified for air in Table II of Appendix B to 10 CFR Part 20, when averaged over 1 year. Describe how proposed activities will meet these criteria or describe why they are not reasonably achievable.

7. Describe the method of measuring or estimating the concentration of radioactive material appearing in ash residue. Include the minimum detectable activity (MDA) that can be measured. Unless scientific evidence to the contrary is presented, the most conservative assumption must be used.

8. Describe the procedures for handling, storing, and disposing of ash from the incinerator. To dispose of the ash as normal waste, except for ash containing only radioactive material with a physical half-life of less than 65 days, include the information specified in 10 CFR 20.2002. (NOTE that a request to dispose of ash as ordinary waste in accordance with 10 CFR 20.2002 may be published by the NRC in the Federal Register for public comment.)

9. For radioactive materials with a physical half-life of less than 65 days, describe the procedures for monitoring the ash to determine that the radioactivity in the ash cannot be distinguished from background. Describe the type of radiation detection instrumentation, instrument sensitivity, and sampling and surveying techniques that will be used to determine that the radioactivity in the ash cannot be distinguished from background.

10. Describe procedures to prevent or limit exposure of personnel to radiation and radioactive material during all phases of the operation,

including the instruction given to personnel handling the combustibles and ash.

11. Obtain other Federal, State, and local incineration permits, as applicable. Compliance with NRC regulations does not relieve the licensee from the need to comply with other Federal, State, and local regulations concerning incineration of radioactive material, operation of the incinerator, or disposal of the ash. Submit evidence that all regulations concerning incineration of radioactive material, operation of the incinerator, or disposal of the ash have been met or will be met.

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the previous draft of this guide when it was published for public comment (Task FC 408-4, February 1985). No changes were necessary, so a separate value/impact statement for this draft guide has not been prepared. A copy of the draft value/impact statement is available for inspection or copying for a fee in the NRC Public Document Room at 2120 L Street NW, Washington, DC, under Task FC 408-4. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

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