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Standard Review Plan
For Applications For
Licenses of Broad Scope

[Regulatory Guide 10.5, Revision 3]
[Applications for Licenses of Broad Scope]

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards

STANDARD REVIEW PLAN FOR APPLICATIONS
FOR LICENSES OF BROAD SCOPE

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STANDARD REVIEW PLAN FOR APPLICATIONS FOR BROAD SCOPE LICENSES

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. NRC regulation 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope For Byproduct Material," provides for three distinct categories of licenses for broad scope, i.e., Type A, Type B and Type C. 10 CFR 33.11 defines these types of licenses. This guide is intended to outline the information to be provided in the preparation and review of applications for Type A and B licenses, which authorize use of licensed materials in a variety of fields and occupations, e.g., manufacturing and commercial distribution of licensed materials in calibration and/or test sources, measuring devices, universities limited to academic research and development, medical institutions involved in research using human subjects, both medical and nonmedical applications, or a combination of the above areas. Broad licenses authorize possession of a wide variety of radioactive material without each radionuclide and authorization specifically listed on the license. The guidance outlined in this Regulatory Guide presents a philosophical approach which should aid in the development of a radiation safety program and the preparation of an application which is acceptable to the NRC staff. Your application for a broad license can also include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material to be possessed under the provisions of paragraph 30.32(d) of 10 CFR Part 30. However, you should submit separate applications for use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad license.

1.2 Concept and Conditions of Broad Scope Licenses

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

1. Engaged 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, normally an applicant should have had a limited specific license for at least a 5 year period.
2. A good regulatory performance record, based on NRC licensing and inspection of prior activities.
3. A radioactive materials utilization program of such scope that the organization requires 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 those organizations involved in an extensive radioactive material program where the demand is great for a 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 is required to be controlled by a radiation safety committee and qualified radiation safety officer and staff, whereas a Type B license is controlled by an individual, i.e., a radiation safety officer.

NOTE: 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 use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the radiation safety committee (Type A) or the radiation safety officer (Type B). Therefore, individuals are not specifically named on the license as users nor are the radionuclides limited to narrow, specific uses. These types of licenses are intended for licensees that 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 paragraph 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad licenses shall not:

1. conduct tracer studies in the environment involving the direct release of radioactive material (field users);
2. receive, acquire, own, possess, use, transfer, or import 3.7×10^{15} becquerel (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 Commission under 10 CFR Part 32 (manufacture or transfer of exempt and generally licensed items), 10 CFR Part 34 (radiography), or 10 CFR Part 35 (medical-human use) 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.

REVIEWERS:

The applicant should: be familiar with the NRC regulations, requirements, and procedures; have demonstrated a need for a broad scope license to avoid numerous amendments for multiple materials, uses, and users; and have

established a good performance record with the NRC both in licensing and inspection. The provision for 5 years of operation under a limited specific license is to be used as guidance, not as an absolute requirement. An exception to this suggested minimum experience of 5 years can be considered on the merits of a licensee who has a program of sufficient size, variety, and frequency of amendments that the flexibility of a broad license is genuinely needed. Early consideration (less than 5 years of operation) for a broad license may be appropriate; for example, if the radiation safety officer and some members of the proposed radiation safety committee have had appropriate experience with other broad scope licenses. On the other hand, frequent amendments that indicate a turnover of key personnel (not the additions of personnel for program growth) would raise questions of adequate continuity and organization for administration of a broad license. There must be close communication between the regions, inspection, and licensing staffs when evaluating new requests. The use of a pre-licensing visit prior to issuance of any new broad licenses should also be considered.

Medical Institution Broad Scope Licenses

Broad scope licenses which involve either medical or nonmedical research using human subjects require the establishment of specialized subcommittees and use of U.S. Food and Drug Administration (FDA)-approved committees, e.g., Radioactive Drug Research Committees (RDRC), Institutional Review Boards (IRB), when evaluating research requests. Appendix A provides a general flow diagram which may be used in determining the need for a human use subcommittee and/or one or more of the FDA (or other Federal agency) Committees to supplement your RSC and its review process.

REVIEWERS:

A broad scope medical Type A license is intended to accommodate those organizations involved in an extensive radioactive material program where the demand is great for a variety of radionuclides and uses. The RSC has the responsibility to review and approve users of byproduct material for those activities, including medical research, for which they are qualified. Therefore, individuals are not specifically named on the license as users nor

are the radionuclides limited to narrow, specific uses. These licenses are intended for licensees that cannot operate under a more limited specific license without seriously disrupting their programs. Only true "Medical Institution" broad scope licenses as described below will maintain the medical broad scope program code (2110).

This guidance pertains only to medical broad scope licenses which will maintain the medical broad scope program code because they meet the following criteria:

- a. The licensee has an active medical research program;
- b. The medical research program involves human use and may include use of radioactive drugs approved for use by the FDA or the licensee's RDRC.
- c. The licensee has and uses an Institutional Review Board (IRB) and/or other appropriate review committees to approve the research studies based on ethical considerations, scientific merit, and radiation safety;
- d. The licensee uses a broad spectrum of byproduct materials and has demonstrated a need for any byproduct material with atomic numbers between 1-83 inclusive;
- e. The licensee has sufficient staff, facilities, and resources (financial, equipment, etc.) to protect health and safety as determined by NRC staff; and
- f. The Radiation Safety Committee is composed of members who demonstrate sufficient ability by training and experience to name authorized users and approve facilities and new procedures.

Note: Policy and Guidance Directive FC 86-1, Revision 1, provides the list of approved RDRC's.

Provided that broad scope medical licensees have staff qualified in radiopharmacy/radiochemistry, dosimetry, nuclear medicine, etc., they are exempted from the provisions of sections 35.49(a), 35.100, 35.200,

35.300, 35.400, and 35.500 of 10 CFR Part 35. This allows flexibility for broad scope licensees in preparing and processing byproduct material, but does not affect the authorized uses identified on the license. However, you should 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. You 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".

The NRC has promulgated amendments to 10 CFR Part 35 "Medical Use of Byproduct Material," that require medical use licensees including broad scope 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. 10 CFR 35.32 (effective January 27, 1992) requires each applicant for a new license, as applicable, 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. Existing medical licensees should have submitted by January 27, 1992, 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.

You should submit your quality management program 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.

REVIEWERS:

Medical licenses that are currently identified with the broad medical program code but only need the broad scope license for non-medical purposes should have their license reclassified. If the license includes medical use authorization in accordance with 10 CFR 35.100, 35.200, and 35.300, but the licensee either does not participate in medical research or participates only

in Investigational New Drug (IND) studies, and does not meet the criteria listed above, the license should be reclassified as a Specific Medical Use License of Limited Scope. These licenses may include broad scope authorizations for non-medical research and development pursuant to 10 CFR 30.4. A typical license format for Medical Institution Limited with Broad Non-Human Research is provided in Attachment 1.

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. You must submit an amendment to your license 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). You should also describe the mechanisms used to record this review.

REVIEWERS:

Authorized Users

The medical broad scope licensee may only approve medical/human use authorized users who have equivalent training and experience criteria to that detailed in 10 CFR Part 35, Subpart J.

A licensee may request a license amendment to be exempted, pursuant to 10 CFR 35.19, from the requirement to Subpart J. Such exemptions would be granted (in the form of a license amendment) to make case-by-case exceptions to Subpart J, provided the following:

1. the findings required in 10 CFR 35.19 can be made;
2. the licensee requests this authority in writing;
3. exceptions are only made for unique/non-routine clinical studies which are within the physician's field of expertise;

4. *minimum training and experience criteria are developed for these exceptions and are submitted for NRC staff license review;*
5. *exceptions are not used to circumvent the Part 35, Subpart J requirements for routine studies.*

Compliance with Part 35

Medical broad scope licensees are required to comply with the prescriptive and performance criteria of 10 CFR Part 35 for all medical and human use activities but may submit separate criteria for laboratory research areas. Exemptions to Part 35 may be granted for licensee approval of authorized users; alternate suppliers of byproduct material and reagent kits to those specified in 10 CFR 35.49; and requirements for the use of non-IND/NDA radiopharmaceuticals. Standard license conditions have been developed to clarify the requirement for Part 35 compliance (ref: Conditions 19 and 20 of Attachment 1-2, "Type A Broad Scope Medical" model license). Exemptions to Part 35 are exemplified by Condition 12 of Attachment 1-2.

1.3 Applicable Regulations

In addition to 10 CFR Part 33, other regulations pertaining to this type of license are found in 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections"; 10 CFR Part 20¹, "Standards for Protection Against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 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 Materials Licenses and Other Regulatory Services,..."; and 10 CFR Part 171, "Annual Fees: Materials

¹ 10 CFR Part 20 was revised and became effective June 20, 1991 (56 FR 23391, May 21, 1991), although licensees were not required to implement the rule until January 1, 1994. The purpose of the revision was ... "to modify the NRC's radiation protection standards to reflect developments in the principles and scientific knowledge underlying radiation protection that have occurred since Part 20 was originally issued more than 30 years ago." Appendix B includes a list of regulatory guides issued by NRC to assist licensees in meeting the requirements in the revised 10 CFR Part 20.

Licenses, Including Holders of Certificates of Compliance, Holders of Sealed Source and Devices Registrations, Holders of Quality Assurance Program Approvals and Government Agencies Licensed by the NRC."

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.

1.4 As Low As Is Reasonably Achievable (ALARA) Philosophy

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 principles to achieve occupational doses and doses to the members of the public that are as low as is reasonable achievable (ALARA)." ALARA concepts and philosophy are discussed in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable."

Applicants for broad scope licenses need to address ALARA considerations in all aspects of the applicant's programs, e.g., monitoring and controlling external and internal personnel exposure, monitoring and controlling air and liquid effluent. ALARA considerations including establishment of administrative action levels and monitoring programs need to be documented in your application.

Medical institutions applying for a license must incorporate ALARA provisions into their program. 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 acceptable to the NRC staff.

1.5 Radiological Emergency Plans

10 CFR 30.32(i)(1) requires applicants that request possession of radioactive materials in both unsealed or certain sealed forms in excess

of specifically listed quantities, to address the need for an Emergency Plan.

Should your assessment support the need for an emergency plan, the plan must be submitted with your application pursuant to 10 CFR 30.32(i). The NRC has published Regulatory Guide DG-3005, "Standard Format and Content for Emergency Plan for Fuels Cycle and Materials Facilities" to assist applicants in the preparation of emergency plans.

REVIEWERS:

Most byproduct material licensees, except those who need multi-curie amounts of iodine-131, iodine-125, or certain other nuclides in unsealed forms, can maintain their possession limits below those requiring an emergency plan as specified in 10 CFR 30.32(i)(1). If the sum of the nuclide ratios exceeds the threshold for emergency planning and it appears that the quantities could be reduced below the threshold, it is suggested that the reviewer contact the applicant (this may be done by phone) to discuss the requirements for emergency planning and options to reduce the requested possession limits below the threshold. If the applicant agrees, the necessary reduction of certain possession limits or the omission of certain nuclides may be done by the reviewer in issuing the license instead of requiring the applicant to file an amended application. If the applicant does not choose to reduce the possession limit below the threshold, the applicant must either submit an evaluation which demonstrates that an emergency plan is unnecessary, in accordance with 10 CFR 30.32(i)(1)(i), or submit an emergency plan as delineated in 10 CFR 30.32(i)(1)(ii).

1.6 Financial Assurance and Recordkeeping Requirements

The NRC has established technical and financial regulations for decommissioning of licensed facilities (53 FR 24018, June 27, 1988). The regulations address the decommissioning planning needs, timing, funding methods, and environmental review requirements for 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 of the rule 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 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.

REVIEWERS:

NMSS Policy and Guidance Directive FC 90-2, "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements for Source, Byproduct, and Special Nuclear Material License Applications", should be used when reviewing license applications for compliance with decommissioning requirements. Licensees are expected to follow the guidance outlined in Regulatory Guide 3.66 if financial assurance is necessary. Any problem encountered which cannot be resolved through the use of current guides and the P & G Directive should be coordinated through NMSS or the OGC lawyer assigned to review financial plans. It is important to assure that the license tracking system (LTS) is updated whenever financial assurance is accepted.

1.7 Decommissioning Plan Requirements

10 CFR 30.36, "Expiration and termination of licenses," requires that licensees submit, on or before the expiration date, a completed NRC Form 314 when they decide to terminate their license (a copy of Form 314 is provided in Appendix C). 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 a licensee to submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously 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 you are required to provide financial certification pursuant to 10 CFR 30.35, 40.36, or 70.25, then the submission of a decommissioning plan should be part of your application.

NRC Regulatory Guide 3.65, "Standard Format and Content of Decommissioning Plans For Licensees Under 10 CFR 30, 40, and 70", provides guidance 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 the complete decommissioning of the facility.

REVIEWERS:

Most applications for routine R&D activities, i.e., μ Ci-mCi quantities per use, contain procedures for cleanup activities related to routine processing and handling of spills. The licensee is required, pursuant to 10 CFR 30.35(g), to keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. Applicants utilizing large quantities and/or high radiotoxicity nuclides (e.g., >3.7 GBq (100 mCi) per use or alpha emitters [Cf-252, Po-210, etc.]) should be queried regarding decommissioning/release criteria, and the necessity for a decommissioning plan pursuant to 10 CFR 30.36(c)(2)(i).

License transmittal letters should clearly state that release of facilities/addresses listed on the license for unrestricted use is not permitted without prior NRC approval. However, release criteria should be submitted in an application and, when deemed adequate, tied into the license granting authorization to the licensee for release of individual laboratories/equipment. This process reduces the number of individual amendments dealing with routine release of use areas. To utilize this provision, license applications must incorporate information regarding close-out survey release criteria to be followed and records to be retained regarding released areas.

Acceptable release criteria are similar to the decontamination limits specified in Regulatory Guides 8.21, 8.23, and 10.8 and include the following:

- 1. description of the survey record to be retained;*
- 2. person performing the survey;*
- 3. instrumentation used;*
- 4. release criteria, and*
- 5. commitment to maintain the records relevant to decommissioning (10 CFR 30.35(g)).*

1.8 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 and this regulatory guide, a prelicensing visit will be scheduled by the NRC at your facility. For renewal of broad scope licenses, a prerenewal visit or conference may be scheduled.

A prelicensing visit provides the NRC staff an opportunity to better evaluate your 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 license and to discuss and agree on additional information and commitments that may be needed. If a broad license is not warranted, continuation of your program with an appropriate specific license can be discussed.

REVIEWERS:

Policy and Guidance Directive FC 84-9, Revision 1, "Licensing Visits for Byproduct Material Licensees," outlines current NMSS expectations regarding license site visits. Experience has shown licensing site visits to be extremely valuable in resolving and clarifying licensing deficiency questions.

Also, visits have identified a number of licenses of broad scope which were not warranted and subsequently downgraded. It is recommended when scheduling a site visit that a tentative agenda be agreed to. Agendas typically include: facility tours; meetings with RSO, RSC, and management staffs; discussions with radiation safety support staff; and review of facilities and equipment. A written summary report should be prepared documenting the site visit and incorporated into the license file. For renewal of broad scope licenses, a conference could be held with the licensee if a visit is not feasible.

2. FILING AN APPLICATION

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

You should complete all items in the application in enough detail for the NRC to determine that your proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory criteria 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, do not submit proprietary information unless absolutely necessary. If submittal of such information is necessary, follow the procedure 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 your application. Do not submit personal information about your individual employees 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.

You should file your application in duplicate. Retain one copy for yourself. If you are located in an Agreement State, you should file an application with the NRC only if you wish to possess and use licensed material in States subject to NRC jurisdiction. All other applicants and all federal agencies should file applications with the Nuclear Regulatory Commission 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 subject to its jurisdiction.

3. CONTENTS OF AN APPLICATION

The following comments apply to the indicated items of NRC Form 313 (Appendix D):

REVIEWERS:

Check whether the application has been signed by the certifying official (Item 13). If not, make a copy of the unsigned application form and return the original with a deficiency letter. Keep the copy until the original is signed and returned. Due to timeliness goal constraints, you may proceed with the review of an unsigned application.

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.

REVIEWERS:

This item is for information only. No review is necessary.

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, it is not appropriate for a private individual to apply for a broad license.

REVIEWERS:

The applicant must be an entity such as a corporation, college, university, medical institution, or research institution. An individual, division, or department within an entity should not be a licensee.

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

REVIEWERS:

The applicant's mailing address typically requires no action. However, NMSS Policy and Directive Guidance 84-2 addresses the issue of Return Mail and actions to be taken should mail be returned. Each region and reviewer should be particularly sensitive to changes in addresses or loss of contact with licensees, since the potential for the loss or abandonment of licensed materials exists.

Item 3: Location 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, you must give the specific address of each location. In addition, identify facilities designed or established for special uses, e.g., panoramic dry/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 you plan to use radioactive material in portable gauging devices at temporary job sites, so indicate, and describe your procedures for transportation, storage, and access controls. Acceptable radiation safety program commitments and use procedures for portable gauging

devices used at temporary jobs sites are contained in NRC Regulatory Guide FC 407-4, "Guide for the Preparation of Applications for Licenses for the Use of Sealed Sources in Portable Gauging Devices".

If you plan to use radioactive material in field studies, these activities must be specifically identified and authorized on your license. Appendix C contains information required for field use of licensed material.

REVIEWERS:

Each location of use should be clearly identified. A street address or designation of a particular building on a college or campus is adequate identification. A Post Office Box or similar designation is not acceptable. In addition, as indicated above, the license must identify high level/risk uses and specialized facilities to enable NRC staff to individually evaluate these facilities. The lack of clear and specific information regarding specialized facilities and locations of use is a deficiency; request clarification from the applicant. If the applicant plans to use radioactive material at temporary job sites, carefully review the procedures for transportation, use, temporary storage of radioactive material, security, and radiological control. If the uses are routine gauging and radiography, information equivalent to that which is obtained for specific licensees should be incorporated into the license.

If the applicant requests use of radioactive material for field studies, the guidance provided in Appendix C and P&GD 84-20 outline actions to be taken by license reviewers when evaluating such requests.

Item 4: Person To Be Contacted About Application

You should specify the individual that is cognizant of your proposed radioactive materials program and can answer questions about the application. Provide his or her telephone number. This individual, usually the Radiation Safety Officer or a principal user of radioactive materials, will serve as the point of contact during the review of the

application and during the period of the license. If this individual is not your full-time paid employee, specify his or her position and relationship to you. Notify the NRC if the person assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment unless this contact person is the RSO. An individual is not generally considered a "certifying official" unless so designated, i.e., amendments and renewals signed by this individual would not be accepted. Please refer to Item 13, "Certification".

REVIEWERS:

This item is for information only. No review is necessary. For legal purposes, should you review a document signed by someone other than the original signatory of the application or a management representative, request documentation from the applicant/licensee that this individual is authorized to make legally binding commitments on the part of the licensee; otherwise, it will be necessary to have another individual who is so authorized to sign the document.

Item 5: Material To Be Possessed

Describe the byproduct material you wish to possess by isotope, chemical or physical form, and quantity in curie, millicurie, etc. You should state the maximum quantity of each radioactive material you wish to possess at any one time and the total cumulative quantity for all materials. Your 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 Appendix D. The maximum quantity for each individual nuclide and total cumulative possession should be commensurate with your 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. A separate listing is also required in Items 5a, 5b, and 5c for sealed sources needed in quantities larger than requested (e.g., bone mineral analyzers, 35,400 sealed sources, brachytherapy after-loaders, portable and non-portable gauging devices). Large activity sealed sources used in devices (e.g. self-contained irradiators, panoramic irradiators, instrument calibrators) should be described by manufacturer and model number under Item 5b.

If you desire to use an irradiator under a broad license, you should follow the guidance contained in NRC Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the use of Self-Contained Dry Source-Storage Gamma Irradiators" and draft NRC Regulatory Guide Task FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators". However, 10 CFR 35.17 prohibits use of 100,000 curies or more of byproduct material in sealed sources for irradiation of material under a broad 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 possessed under your license should be included, i.e., materials received awaiting use, materials in use/process, and that categorized as waste awaiting disposal.

REVIEWERS:

The atomic number 83 is designated an upper limit because specialized facilities, instrumentation, and containment for transuranics (alpha and neutron emitters) must be considered. Radionuclides above 83 may be included in a broad license, but are usually listed separately in the application and license. Exceptions may be considered on their merits. For example, it may be appropriate to consider a separate listing of atomic number 84 and up (as appropriate) with a different possession limit than for atomic numbers 1 to 83. The reviewer can also exercise judgement and discretion in shortening

lists of individual nuclides for the basic 1 to 83 or 3 to 83 group. Review of past inspection reports have proven to be a valuable resource in dealing with licensees, when it's believed that the requested possession limits may be unwarranted. Attachment 1 contains typical license formats for: (1) Type A Broadscope R&D License; (2) Broadscope Medical License; and (3) Medical Institution Limited with Broad R&D. If an irradiator is listed on the license, the reviewer should assign a secondary program code, as appropriate.

Item 6: Purpose of Use of Licensed Material

Describe in general terms the purposes for which you will use licensed material and explain why you need a broad license rather than amendments to an existing specific license. The uses should be consistent with your prior licensed activities. Although the NRC staff only needs a general description of your activities, you should provide sufficient information to enable them to have a clear understanding of each use. The information provided regarding "Purpose of Use" is understood by the NRC staff as a self-imposed limitation contained within your application. If a broad scope licensee desires to initiate an intended use other than that described in its application and tied down in its license, it would be necessary to submit an amendment to your license to modify/expand the "purpose of use". In addition, if the newly added purpose of use includes a relatively unique or specialized activity (e.g. sealed source fabrication), you may be required to submit the criteria used by the RSC in evaluating in-house requests for such use. Regulatory Guide 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 of sealed sources and devices with the NRC.

Applicants requesting 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.

REVIEWERS:

If the applicant's program under present and previous licenses listed under Item 10.1 of the application does not show a need for the flexibility of a broad license, it may be desirable to suggest that a continuation of conventional specific licensing would be more appropriate. Alternatively, request the applicant to provide information regarding expansion plans that would subsequently warrant a broad license. Since this is a discretionary matter, the reviewers should discuss it with their supervisors on a case-by-case basis before contacting the licensee with this suggestion. Review of past inspection reports and discussions with inspectors familiar with the program have proven to be a valuable resource in assessing need.

Note that 10 CFR 33.17 lists a number of activities that broad licensees may not do unless specifically authorized pursuant to other parts of the regulations. Section 161h of the Atomic Energy Act and paragraphs 30.32(d), 40.31(d), and 70.21(b) of the regulations permit a single application to be considered for any activity for which licenses are required by the Act, provided the application specifies the activities requested and complies with NRC regulations. Such other activities may be authorized in a broad license by appropriate conditions subject to policy determinations by licensing management.

If you desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, then the information outlined in Appendix E must be included with your application and such field studies specifically authorized in your license. 10 CFR 51.22(c)(14)(v) identifies as a "categorical exclusion" (from the requirement to prepare an environmental assessment or impact statement) the use of radioactive material for research and development and for educational purposes. However, this "categorical exclusion" does not encompass, among other things, performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study, (e.g. tagging of animals or insects which remain in the wild). These type of requests may require an environmental report filed by the applicant 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: Management Control and Responsibilities

7.1 Senior Management

A broad scope license is issued by the NRC to accommodate those institutions involved in an extensive radioactive materials program where the demand is great for a variety of radionuclides and uses. Therefore, the NRC grants significant latitude to licensee management to develop and implement an appropriate radiation safety program. Consequently, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. 10 CFR 33.13 and 33.14 require that Type A and Type B broad scope applicants, respectively, establish administrative controls and provisions relating to organization and management, including management review, necessary to assure safe operations.

Management responsibility 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 a radiation safety committee 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 your personnel regarding NRC regulations and/or license provisions. The licensee retains the ultimate responsibility, nevertheless, for the conduct of licensed activities. It is also essential that the institution devote sufficient financial resources (i.e., equipment, personnel, materials) as necessary to support the radiation protection program.

Your application should discuss senior management oversight and mechanisms used by management to ensure adequate control over licensed broad scope activities. The NRC expects senior management oversight to include regular meetings with the Radiation Safety Committee, Radiation

Safety Officer and support staff, and annual audits of the program to assure safe operations and compliance with regulatory requirements. The audit program should include mechanisms to correct and resolve identified problems in an expeditious manner (program audits are discussed in Item 10.4).

Your application should include an organizational chart depicting your management structure, reporting paths and flow of authority, including your statement empowering the Radiation Safety Committee, outlining its authority to oversee the licensed program and responsibility for control and direction of the radiation safety program and the Radiation Safety Officer.

The operational oversight for a Type B broad scope program is specified, in part, in 10 CFR 33.14(b)(1) which states in part "... appointment of a radiological safety officer who is qualified by training and experience..." If you are applying for a Type B license, as indicated above for the Type A license and RSC, your application 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.

REVIEWERS:

The applicant should include with the license application, a signed certification of the RSO's responsibilities and authority such as provided in Appendix F.

7.2 Radiation Safety Committee

For Type A and medical broad scope programs, you are required to establish a Radiation Safety Committee (RSC) pursuant to 10 CFR 33.13(c)(1). The RSC should be responsible for establishment of appropriate policies and procedures to assure control of procurement and use of byproduct material, completion of safety evaluations of proposed uses and users, and overall development and implementation of the radiation safety program.

The RSC should consist of such persons as the Radiation Safety Officer, at least one representative of management, and at least one technical person, 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 license. For medical broad scope programs, the RSC also should include a representative of the nursing service, and the technical person refers to an authorized user of each type of use permitted by the license. The RSC Chairman should be named on the license application. A license amendment is required if there is a change in the Chairman. The other members need only be listed by title and qualifications, not by name.

If fewer members than compose the full committee are authorized to act for the committee, the number of members constituting a quorum, as well as their names or fields of expertise, should be specified. The minimum members considered acceptable for a quorum by NRC staff would be: Chairperson, RSO, management representative, committee member(s) representing the department/area from whom the radioactive material request originated and any other committee member whose field of expertise is necessary to assure all safety aspects have been addressed. For medical broad scope programs, to establish a quorum and conduct business, 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 be able to realistically manage the scope of the program and other assigned duties or responsibilities if the RSO is the Chairperson.

Your application should describe RSC meeting frequency and criteria for selecting RSC members, and include a specific and detailed description of the control functions of the committee and the administrative procedures by which these functions are carried out. 10 CFR Part 35 requires that the RSC at a medical institution meet at least quarterly. Appendix G

provides a general outline of duties and responsibilities, representative of those considered acceptable to the NRC staff.

REVIEWERS:

The radiation safety manual developed by the RSC should not be included as part of a tie-down condition. This will allow changes to be made without resubmission as a license amendment. However, any radiation protection procedures that may impact health and safety may require NRC review before changes are made and should be submitted separately from the radiation safety manual.

7.3 Radiation Safety Officer

Broad scope licensees are required to appoint a Radiation Safety Officer (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; communicate with senior management and the RSC regarding program implementation and compliance status; and be available to provide advice and assistance 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.

List and describe the training and experience of the RSO in radiation protection and with radiation and radioactive materials. If he or she is not a full-time paid employee of your organization, please provide the individual's affiliation with your institution and state how many hours per week the individual will be available to oversee your NRC-licensed program. Also specify provisions for contacting this individual during

emergencies, off-hour contact and a general description of his or her other obligations. Generally, the NRC staff does not consider the use of consultants or part-time employees acceptable as RSOs for broad scope programs and, in most cases, would consider it 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 delineating RSO duties, responsibilities, and authority for carrying out the radiation safety program. List the responsibilities and duties of the RSO in your application. The extent of these responsibilities and duties will depend on the scope of the proposed broad scope license. Appendix H provides a general outline of duties and responsibilities, representative of those considered acceptable to the NRC staff.

REVIEWERS:

The RSO's responsibilities and duties listed in Appendix H should be commensurate with the scope of the licensee's program. The duties listed are those that are usually performed by the RSO and his or her staff and that constitute good practice for conducting a program in compliance with the specific regulatory requirements of 10 CFR Parts 19 and 20, and license conditions. Since the duties of the RSO for a non-medical program are not specified in the regulations, it is not necessary that the RSO's duties and procedures correspond to each item on the list of suggested duties. However, since the RSO is a key person in the licensed organization to ensure compliance with the requirements of the regulations and license conditions, the statement of duties along with training and experience, past performance, and the prelicensing conference should provide assurance that the licensee understands and is competent to manage the program under a broad scope license. A complete description of the RSO's qualifications and duties is an important part of such assurances. Less than 5 years of experience and prior performance may be acceptable if the applicant's qualifications (as described in the application and supplemented by a review of his or her past performance under other NRC licenses and by the prelicensing conference) appear adequate

for the scope of the proposed broad license. An RSO should have an essentially full-time commitment to radiation safety and other related duties. A consultant RSO is generally not considered acceptable for broad scope programs and should be reviewed carefully on a case-by-case basis. A key in the review is prior experience in the oversight of a materials program, i.e., either as a RSO or under the direct supervision of a RSO.

7.4 Radiation Safety Office Staff (RSOS)

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 professionals will vary with the scope of the broad scope program. Your application should include a description of the duties and responsibilities of the RSOS and an assessment regarding 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 your proposed radiation protection program. If you consider current staffing to be minimally acceptable, a projected timetable when full staffing may be achieved 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. Examples of employees who will need training are authorized 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 each training program will vary from licensee to licensee. The detail and content will be dependent upon the scope of the program (i.e., Type A, Type B or medical broad scope), possession limits, type of isotopes used, size of program in terms of number of laboratories and users, laboratory classification scheme, types of studies being performed, etc.

Broad scope licensees need to develop a system for retraining authorized users, laboratory supervisors and technicians that is performance-based (i.e., "hands-on"), as well as classroom training on changing requirements. Your application should describe the program in place for training your staff. Appendix I provides an example of a broad scope training program which is acceptable to 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, you should have already described your facilities and equipment in previous license correspondence. However, these descriptions should be resubmitted as part of your license application. Also, describe any new or altered facilities and equipment that are essential to the license being sought. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally, should be specifically described. These would include, for example, room irradiators, specialized iodination/tritiation facilities, alpha laboratories, large scale waste processing and storage facilities (including decay-in-storage locations, incinerators, compactors, liquid reclamation processors, etc.), individual laboratories processing 100 millicuries (3.7 GBq) or more of radioactive materials per experiment or process, nuclear pharmacies, and specifically designed therapy rooms and/or storage areas (radiopharmaceuticals and/or sealed sources).

Your administrative procedures for internal control of users under the broad license (discussed in Item 10) should include provisions for determination that your facilities and equipment are adequate for all proposed uses. Your application should include a laboratory or facility classification scheme which relates toxicity and quantity of radioactive material to minimum facility and equipment requirements. The International Atomic Energy Agency (IAEA) as well as other health physics and industrial hygiene professional organizations have developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, surveys) versus the

hazard and quantity of byproduct materials to be used². NRC staff recommends that applicants consider the development of such a classification scheme, since all aspects of the radiation safety program can be correlated to it. The use of the IAEA document is not meant to be an endorsement, but simply a reference. Each applicant's scheme should be based upon the types and quantities which 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 provides radionuclide toxicity and laboratory classification information excerpted from the IAEA Standard. Your application should describe the minimum facilities and equipment required for each laboratory classification.

Describe the radiation detection and monitoring equipment available to both the radiation safety office and authorized users. List the type and number of instruments available (e.g., ion-chambers, G-Ms, air samplers, liquid scintillation counters). In addition, describe your instrument calibration program including calibration procedures and frequency. If a 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.

REVIEWERS:

It is not necessary to make a detailed review of the facilities and equipment that will be used under the broad license, unless it is a special purpose as indicated above. Rather, it is sufficient for the reviewer to determine, through the prelicensing conference and reference to past licenses, inspection reports and the applicant's description of intended uses and proposed criteria described in Item 10, that the applicant has established an adequate mechanism to evaluate facility and equipment needs. The reviewer should resolve with the applicant any question or indications of inadequate facilities that arise in the course of reviewing its application and its past licenses or in the prelicensing conference.

² IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition."

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. This regulation requires applicants to have engaged in a reasonable number of activities involving the use of byproduct material and to have established administrative controls and provisions related to organization and management, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations under the license. Your radiation safety program description should be in narrative form and include the elements identified below. The requirement to develop, document, and implement a radiation protection program commensurate with the scope of the license request is contained in 10 CFR 20.1101 with recordkeeping requirements related to the program being contained 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

10 CFR 33.13 and 33.14 require the establishment of appropriate administrative procedures to assure: (1) control of procurement and use of byproduct material; (2) completion of safety evaluations of proposed uses/users of byproduct material which 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 recommends development of radiation safety manuals or other formal documents for informing your staff of safety criteria and good health physics practices, NRC regulations and license commitments. Submit either a complete description of these administrative procedures or copies of formal documents you have issued (or will issue) to your staff.

10.2.1 Control of Procurement and Use

Your application should describe the administrative procedures you have established to ensure that all procurement, use, and users of radioactive material are properly authorized by the license and approved by the RSC. The NRC 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 you do not use such centralized procedures, describe how your procedure prevents unauthorized procurement and use.

10.2.2 Safety Evaluations of Proposed Uses/Users

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

10.2.3 Emergency Procedures

Your application should describe the program in place for handling spills, fires, releases or loss of material, and accidental contaminations of personnel. You should discuss provisions of immediate response and handling of such incidents including off-hours notification of your staff, State and local authorities, and the NRC, when applicable. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, it should be clearly understood by your staff who 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 address, at a minimum, the following:

- a. Initial response actions and responsibilities, including immediate safety precautions for people and property.
- b. Area and facility access control and security.
- c. Internal and external notification mechanisms and responsibilities.
- d. Provisions for medical and offsite agency assistance.

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

Consider the establishment of an Emergency Response Team comprised 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

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

10.2.5 Other Procedures

Your application should include other administrative procedures as deemed necessary to guide, control and

ensure consistency in the implementation of the radiation protection program. You should consider, for example, standard operating procedures (SOPs) for routine health physics activities, including those conducted by the RSOS (e.g., radiation and contamination survey methods, smear analysis, source leak testing, air sampling, bioassays, etc.). Your application should contain a commitment that certain changes to the radiation safety program described in Appendix F 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 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 assure that licensed possession limits are not exceeded and that material is accountable throughout the institution at any given time. Sufficient staff and equipment should be devoted to the inventory and accountability control program.

Your application must include a description of your inventory, control and accountability program for licensed material.

10.4 Audits and Appraisals

10 CFR 33.13 and 33.14 require applicants to establish administrative controls and provisions relating to management review necessary to assure safe operations. 10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation

program content and implementation. The radiation safety program review and/or 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. 10 CFR 20.2102 requires licensees 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

You should discuss senior management oversight and mechanisms used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and compliance status of the institution's licensed program. This 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. You should also consider establishment of RSC subcommittees to evaluate and audit those areas of the program within their area of expertise.

10.4.2 Radiation Safety Officer and Staff Audits

You should describe the audit mechanism implemented by the RSO and his/her staff to determine user compliance with the terms and conditions of the NRC license, RSC approved permits and for adherence to good health physics practices. Your audit program should include routine unannounced inspections of each authorized user's laboratory and practices to supplement and audit the routine monitoring performed by authorized users. We recommend that the laboratory inspections include the following:

- a. Review of user inventory and survey records.
- b. Evaluation of user and technician training through discussion and observation of work practices.
- c. Performance of independent surveys of user work areas.
- d. Evaluation of compliance with RSC permit and safety manual requirements.
- e. Provision for performance-based instruction to users and technical level staff.

You should indicate the types and frequencies of monitoring performed by the RSO. The intervals of surveys and audits should be frequent enough to assure 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 proposed based upon activity and use (e.g., high level laboratories, Type A (weekly), intermediate laboratories,

Type B (monthly), and low-level laboratories, Type C (quarterly)).

10.5 Safety Evaluations of Proposed Uses/Users

10 CFR 33.13 and 33.14 require that Type A and Type B broad scope applicants, respectively, establish procedures to assure completion of safety evaluations of proposed uses of byproduct material which 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.

Your application should contain the criteria (NRC staff recommends that criteria for committee members be maintained in manual form) to be used by each committee member when evaluating qualifications of users, facility and equipment adequacy and determining personnel monitoring and survey requirements. Appendix K provides guidelines for evaluation of applications for use of byproduct material.

Since your RSC will assume the responsibility for the review of users and uses of radioactive materials, your 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 proposed user request and RSC approval forms or permits should be submitted for review with your application.

Broad licenses involving a wide range of uses should consider the development of a classification scheme of 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 your classification scheme should be based upon the types and uses anticipated at your 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., 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 which will be applied when approving uses. It is understood that certain permits issued by the RSC may deviate from the classification scheme due to unusual circumstances; however, it is expected that broad licensees will adhere to the classification scheme closely and when deviations occur, that justification and documentation of the deviation will be maintained for review by NRC inspection staff. Your safety evaluation procedures and criteria should include and describe how your RSC will evaluate and apply requirements for the following:

- a. The proposed use of material considering the quantity and form requested, potential radiological hazards associated with such use and mechanisms for external and internal exposure control, contamination controls and waste disposal.
- b. Training and experience for authorized users and individuals working under the supervision of an authorized user (e.g., technicians). Specialized training for certain users should also be included, (e.g., incinerator operators, waste compaction personnel, and animal handlers).
- c. Facilities and equipment for each specific use.
- d. Material handling and operating procedures including provisions for requiring users to conduct surveys to confirm that radiation levels and/or contamination levels are within specific guidelines. The type and frequency of surveys must take into consideration the amount and types of radioactive material used or being stored.

REVIEWERS:

The licensee should be allowed flexibility in its procedures for conducting and approving such evaluations; however, its procedures and criteria should be adequate to determine that individual users are qualified to use materials safely and that the facilities are appropriate and adequate. Broad licensees are expected to provide detailed review criteria which they will use to evaluate "in-house" requests. Since these type licensees have assumed, in part, the role and responsibility of the NRC licensing staff, it is essential that we have assurances that the criteria is at least equivalent in scope and philosophy to that of the NRC. In addition, it is believed that by obtaining a better understanding of the applicant's review processes, the numerous conflicts encountered during inspection and subsequent enforcement proceedings will be reduced. Experience has shown that pre-licensing site visits are essential in explaining the NRC position on this important matter.

10.6 Exposure Control and Monitoring

You should describe the procedures and mechanisms established to control and monitor both internal and external radiation exposure. The procedures should include general criteria for all intended radionuclides of use 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 which are accessible to personnel. Surveys should be conducted by the authorized user and supplemented by radiation safety office surveys. Surveys conducted by authorized users 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 laboratories (Type A), daily; intermediate laboratories (Type B), weekly; and low-level laboratories (Type C), 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 also include external radiation and contamination action or trigger levels for both restricted and unrestricted areas.

Explain which surveys are the responsibility of the authorized user and those which will be performed as part of your 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 tests (e.g., DOP, charcoal absorption efficiency) and the frequency of tests to be performed on ventilation and filtration systems. This discussion should be separated by system, i.e., hood, glove boxes, filter systems (e.g., HEPA, charcoal), etc. If you use a recognized standard, indicate the reference or provide a copy.

Specify the criteria used to assign personnel monitoring devices, i.e., film/TLD whole body and extremity badges, direct reading dosimeters, and the frequency of device processing for the various laboratory types. Indicate the supplier (required to be NVLAP approved pursuant to 10 CFR 20.1501(c)) of your 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", NUREG-0938, "Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure," and Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

Describe the criteria used to set the type and 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 your laboratory classification scheme and 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 the aforementioned Regulatory Guide 8.23.

Item 11: Waste Management

You should describe your methods for disposal of radioactive waste. Your application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (radioactive from nonradioactive, short from long half-life, liquid from solid waste). The following items should be considered and addressed in your application:

- a. Transfers to a recipient (usually a waste disposal service company or the original supplier) properly licensed to receive such waste in accordance with 10 CFR 20.2001(a). State the name and license number of the receiving company.

- b. Storage of radioactive materials with half-lives greater than 65 days should be characterized regarding volume and anticipated time in residence at your 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 For Fuel Cycle and Material Licensees", outlines the provisions and requirements for interim storage. If you find that the interim storage provision applies to your program, it will be necessary to address in your application the information outlined in the above Information Notice.
- c. Release into air and water pursuant to 10 CFR 20.1302 and 20.2003, respectively. You should discuss the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements.
- d. Treatment or disposal by incineration in conformance with 10 CFR 20.2004. If you propose to treat or dispose of licensed material by incineration, you must address the items listed in Appendix L, "Incineration Guidelines for Material Licensees," and receive 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 as radioactive waste, transferred to a specific licensee, or contains non-detectable radioactivity.
- e. Waste volume reduction operations which could create a radiological hazard to your employees or the general public must be described in detail in your application. For example, if you plan to use compactors to reduce volume, include the following:

- (1) 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 your operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.)
 - (2) The type, quantities, and concentrations of waste to be compacted.
 - (3) An analysis of the potential for airborne release of radioactive material during compaction activities.
 - (4) The location of the compactor(s) within your waste processing area(s) as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of your procedures for monitoring filter blockage and exchange.
 - (5) Methods used to monitor worker breathing zones and/or exhaust systems.
 - (6) The types and frequencies of surveys that will be performed for contamination control in the compactor area.
 - (7) The instruction provided to compactor operators including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste and examining containers for defects.
- f. Disposals without regard to the radioactivity of hydrogen-3 and carbon-14 contained in scintillation counting media and in animal tissue in concentrations of 0.05 microcuries or less per gram, subject to certain restrictions stated in 10 CFR 20.2005 need not be described in the application.

- g. Licensees who were previously authorized to bury radioactive materials pursuant to 10 CFR 20.304 prior to January 28, 1981, should describe the locations, condition and current status of these former sites, i.e., controlled or uncontrolled, active monitoring of the site, and current condition of burial site.
- h. Other methods specifically approved by the NRC pursuant to 10 CFR 20.2002.

Your 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, i.e., 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 10-20%) of the limits specified in Appendix B, Table II, 10 CFR Part 20.

Furthermore, due to 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 exceed the specified ALARA action point.

Item 12: License Fees

10 CFR 170.12(a) requires that an application fee be paid in full for most types of licenses, including applications for license amendments and renewals. You should refer to 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspection, and import and export licenses," of 10 CFR Part 170 to determine the amount of the fee that must accompany your application. An application received without a fee or with an inadequate fee will be returned to you. All application fees may be charged irrespective of the NRC's disposition of the application or your withdrawal of the application. In addition, applicants should be aware that continuance of license authorization is contingent upon satisfactory payment of annual and NRC inspection fees. You should 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 which 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 application, 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, D.C. 20555 or (301) 492-7225.

Item 13: Certification

Applications for new, or renewal or amendment of, 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. Furthermore, to prevent undue delay, each request for an amendment and/or a renewal signed by an individual not clearly recognized as a "Certifying Official", should be accompanied by a statement from management indicating the individual's authority to sign official documents related to licensing.

4. AMENDMENTS TO A LICENSE

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

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If licensed activities change or require modification such that information provided in your application does not represent your operations, or intended uses or individual maximum uses/applications of licensed material require change, you must file an amendment application prior to

initiating any such changes. Until approval of the amendment, you must comply with the terms and conditions of your current license.

An application for a license amendment may be prepared either on the application form (NRC Form 313) or in letter form and should be submitted in duplicate to the address specified in Section 2 of this guide. Your application should identify your license by number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and identify the pertinent information by date, page, and paragraph.

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

5. RENEWAL OF A LICENSE

Licenses are generally issued for a period of up to 5 years. NRC staff believe, due to the scope and complexity regarding the use of byproduct materials, that a broad licensee 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 to the address specified in Section 2 of this guide. This application should be an entirely new application for renewal, i.e., as if it were an application for a new license without referring to previously submitted information.

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

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 Appendix B, Table II, 10 CFR Part 20, when averaged over a twenty-four hour period, and (2) be a fraction (approximately 10 percent) of the limits specified for air in Appendix B, Table II, 10 CFR Part 20, when averaged over one year. Describe how your proposed activities will meet these criteria or describe why they are not reasonably achievable.
7. Describe the method of measurement or estimation of the concentration of radioactive material appearing in ash residue. Include the minimum detectable activity (MDA) which can be measured. Unless you present scientific evidence to the contrary, you must use the most conservative assumption.
8. Describe the procedures for handling, storing, and disposing of ash from the incinerator. If you wish 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: Your 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/or radioactive material during all phases of the operation, including instruction given to personnel handling the combustibles and the ash.
11. Obtain other federal, state and local incineration permits, as applicable. Compliance with NRC regulations does not relieve the licensee from other Federal, State, and local regulations concerning incineration of radioactive material, operation of the incinerator, or the 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 are in the process of being met.

ATTACHMENT 1

Examples of "Type A" Broadscope License Formats

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Type A Broad Scope License	In accordance with application dated August 30, 1990	
2.	3. License number 34-99999-01 is amended in its entirety to read as follows:	
	4. Expiration date January 31, 1996	
	5. Docket or Reference No 030-00099	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Numbers between 1-83, inclusive except as specified below	A. Any	A. 200 millicuries of each radionuclide with a total possession limit of 16 curies
B. Any byproduct material with Atomic Numbers between 84-103, inclusive except as specified below	B. Any	B. 1 millicurie of each radionuclide with a total possession limit of 5 millicuries
C. Hydrogen-3	C. Any	C. 10 curies
D. Carbon-14	D. Any	D. 1 curie
E. Phosphorus-32	E. Any	E. 1 curie
F. Sulfur-35	F. Any	F. 1 curie
G. Cesium-137	G. Sealed Source (Nuclear Chicago Qualicon 5174)	G. 1 source not to exceed 500 millicuries
H. Plutonium-239	H. Encapsulated as Pu-Be neutron sources (Monsanto Research Model XR34)	H. 4 sources not to exceed 80 grams each and 1 source not to exceed 8.2 grams

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License number

34-99999-01

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6. Byproduct, source,
and/or special nuclear
material

7. Chemical and/or
physical form

8. Maximum amount that
licensee may possess
at any one time
under this license

I. Cesium-137

I. Sealed sources (3M
Company Models 4P6E,
4F6H, 4D6L, and 4F6S;
or U.S. Nuclear Model
375)

I. 1 source not to
exceed 3.5 curies

J. Americium-241

J. Sealed sources
(registered pursuant
to Section 32.210 of
10 CFR Part 32 or an
Agreement State)

J. No single source
to exceed 50
millicuries with a
total possession
limit of 1 curie

K. Cesium-137

K. Sealed sources
(registered pursuant
to Section 32.210 of
10 CFR Part 32 or an
State)

K. No single source
to exceed 10
millicuries with a
total possession
limit of 150
millicuries

9. Authorized Use:

A. through G. Research and development as defined in Section 30.4 of
10 CFR Part 30 (excluding animal studies*), and student
instruction. Instrument calibration.

H. To be used in a Monsanto Model XYZ neutron howitzer for laboratory
experiments and student instruction.

I. To be used for the licensee's instrument calibration only.

J. and K. To be used in moisture/density gauges registered with the NRC
pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement
State, for the measurement of moisture/density content of
materials.

[*Reviewer's Note: Delete "excluding animal studies" if appropriate information
regarding use of animals is provided by licensee.]

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number:

34-99999-01

Docket or Reference number:

030-00099

Amendment No. 01

CONDITIONS

- 10.(1) Licensed material shall be used only at the licensee's facilities located at University facilities bounded by Presidential Drive and East Street.

[Reviewer's Note: Detailed information on location(s) of use should be provided in the licensee's backup information.]

- 11.(34) The Radiation Safety Officer for this license is Kevin G. Null.
- 12.(22) Licensed material in Subitems 6.A. through 6.K. shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- 13.(162) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
- 14.(36) A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen 3; or
 - (ii) they contain only radioactive gases; or
 - (iii) the half-life of the isotope is 30 days or less; or

**MATERIALS LICENSE
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- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting materials; or
- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

15.(155) The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

16.(44A) A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer and approved by NRC.

(44B) B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

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- 17.(42) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.
- [Reviewers Note: New Part 20, 20.1901(b) obviates need for this condition.]
- 18.(154) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
- 19.(129) The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 20.(156) Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
- 21.(149) This license does not authorize commercial distribution of licensed material.
- 22.(152) The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
- 23.(153) The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

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Amendment No. 01

24.(136) The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

25.(165) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of unsealed licensed material or readily dispersible source material to quantities less than 105 times the applicable limits in Appendix C of 10 CFR Part 20, as specified in 10 CFR 30.35.

[Reviewer's Note: This is a general possession limit for intermediate level decommissioning financial assurance. This or other similar conditions should be used based on decommissioning financial assurance guidance.]

26.(38) Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 1, 1978
- B. Letter dated January 17, 1982
- C. Letter dated July 31, 1989.

For the U.S. Nuclear Regulatory Commission

Date: _____

By

Materials Licensing Section, Region III
799 Roosevelt Road
Glen Ellyn, Illinois

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Broad Medical-University (Type A) Medical Center</p> <p>2. 301 Presidential Drive Cleveland, OH 60698</p>	<p>In accordance with application dated January 1, 1990</p> <p>3. License number 99-99999-16 is amended in its entirety to read as follows:</p> <p>4. Expiration date January 31, 1997</p> <p>5. Docket or Reference No 030-99916</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with Atomic Numbers between 1-83, inclusive except as specified below</p> <p>B. Hydrogen-3</p> <p>C. Carbon-14</p> <p>D. Molybdenum-99</p> <p>E. Technetium-99m</p> <p>F. Iodine-125</p> <p>G. Iodine-131</p> <p>H. Any byproduct material with Atomic Numbers between 3-83, inclusive except as specified below</p> <p>I. Cesium-137</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an State)</p> <p>I. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 100 millicuries of each radionuclide with a total possession limit of 2 curies</p> <p>B. 500 millicuries</p> <p>C. 500 millicuries</p> <p>D. 200 curies</p> <p>E. 200 curies</p> <p>F. 5 curies</p> <p>G. 5 curies</p> <p>H. No single source to exceed 1.5 curies. Total possession not to exceed 10 curies</p> <p>I. 3.5 curies</p>

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6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

J. Cesium-137

J. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State)

J. 2 sources not to exceed 720 curies each

K. Iridium-192

K. Sealed sources (BYK Mallinckrodt, Model C1-LBV)

K. 2 sources not to exceed 10 curies each

9. Authorized Use:

A. through G. Medical diagnosis, therapy, and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30, (excluding animal studies*) and student instruction. Instrument calibration.

H. Medical therapy and research in humans and animal studies.

I. To be used in J. L. Shepherd Model 28-6B calibrator of the licensee's instrument calibration only.

J. To be used in AECL Gammacell 1000 Model B irradiator for irradiation of medical specimens and research materials, excluding explosive and/or flammable materials.

K. One source to be used in Nucletron Microselectron-HDR for interstitial, intracavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

[*Reviewer's Note: Delete "excluding animal studies" if appropriate information regarding use of animals is provided by licensee.]

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License number
99-99999-16

Docket or Reference number
030-99916

Amendment No. 01

CONDITIONS

- 10.(1) Licensed material shall be used only at the licensee's facilities located at University facilities bounded by Presidential Drive and East Street.

[Reviewer's Note: Detailed information on location(s) of use should be provided in the licensee's backup information.]

- 11.(34) The Radiation Safety Officer for this license is Mary Blackwell, Ph.D.

- 12.(15) A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.

- (16) B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR Part 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee. [Exceptions may be made on a case-by-case basis in accordance with the procedures described in letter(s) dated _____.]

[Reviewer's Note: Exceptions should be made as outlined in the Guidance for Licensing Medical Facilities with Broad Scope Programs.]

- (17) C. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

- 13.(162) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

- 14.(36) A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210.

- B. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

- C. In the absence of a certificate from a transferor indicating that a test has been made, a sealed source or detector cell received from another person shall not be put into use until tested.

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- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen 3; or
 - (ii) they contain only radioactive gases; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting materials; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken.
- G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
- 15.(81) Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.

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Docket or Reference number:

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16.(111) The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400, and 10 CFR 35.500 and every six months for all other sources and/or devices.

17.(44A) A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer and approved by NRC.

(44B) B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

18.(42) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

[Reviewer's Note: New Part 20, 20.1901(b) obviates need for this condition]

19.(112) Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400 and 10 CFR 35.500 the licensee may use for any medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable Food and Drug Administration (FDA) and other Federal and State requirements.

20.(113) The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except sections 35.49(a) and (b), 35.100, 35.200, and 35.300.

21.(154) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

22.(129) The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

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- B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
- D. A record of each disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

23.(156) Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

24.(136) The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Reviewers's Note: Use (118)(119)(120)(121) and (125) for remote high dose rate afterloaders.

25.(118) In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

26.(119) In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each MicroSelectron-HDR remote afterloading brachytherapy procedure.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

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- C. Make a record of the survey including the survey instrument use, dose rate expressed in mrem/hr (μ Sieverts/hr), time, date and name of the individual making the survey.
- D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

27.(120) Prior to initiation of a treatment program, and subsequent to each source exchange, using the MicroSelectron-HDR afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:

A radiation survey shall be made of:

- A. The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.
- B. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:
 - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101 (10 CFR 20.1201).
 - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

28.(121) The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

- A. Installation and replacement of sources contained in the MicroSelectron-HDR afterloading brachytherapy unit.
- B. Any maintenance or repair operations on the MicroSelectron afterloading brachytherapy unit listed in Item 9. Subitem L. involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

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- 29.(125) A. Access to the room housing the MicroSelectron-HDR afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.
- D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
- 30.(165) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of unsealed licensed material or readily dispersible source material to quantities less than 105 times the applicable limits in Appendix C of 10 CFR Part 20, as specified in 10 CFR 30.35.

[Reviewer's Note: This is a general possession limit for intermediate level decommissioning financial assurance. This or other similar conditions should be used based on decommissioning financial assurance guidance.]

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31.(39) Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 1, 1978
- B. Letter dated January 17, 1982
- C. Letter dated July 31, 1989.

For the U.S. Nuclear Regulatory Commission

Date: _____

By

Materials Licensing Section, Region III
799 Roosevelt Road
Glen Ellyn, Illinois

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with application dated January 1, 1990	
1. Medical Institution Limited With Broad Non-Human Research		3. License number 99-99999-01 is amended in its entirety to read as follows:	
2. 405 Rosewood Boulevard Cleveland, OH 60698		4. Expiration date	January 31, 1997
		5. Docket or Reference No	030-99901
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed	
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed	
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 3 curies	
E. Any byproduct material identified in 10 CFR 35.500	E. Any diagnostic source identified in 10 CFR 35.500	E. 5 curies	
F. Any byproduct material with Atomic Numbers between 1 through 83, except as specified below	F. Any	F. 100 millicuries of each radio- nuclide with total possession limit of 2 curies	
G. Hydrogen-3	G. Any	G. 500 millicuries	
H. Carbon-14	H. Any	H. 500 millicuries	

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- | | | |
|---|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| I. Iodine-131 | I. Any | I. 5 curies |
| J. Iodine-125 | J. Any | J. 5 curies |
| K. Cesium-137 | K. Sealed source | K. One source not to exceed 380 curies |
| L. Iridium-192 | L. Sealed source (BYK Mallinckrodt Model C1 LBV) | L. 2 sources not to exceed 10 curies each |

9. Authorized Use:

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
- B. Any imaging and localization procedure approved in 10 CFR 35.200.
- C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
- D. Any brachytherapy procedure approved in 10 CFR 35.400.
- E. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g)
- F. through J. Research and development as defined in Section 30.4 of 10 CFR Part 30, (excluding animal studies*). Instrument calibration.
- K. To be used in Nordion Gamma cell 1000 Elite Irradiator for blood and blood products.
- L. One source to be used in Nucletron Microselectron-HDR for interstitial, intracavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

[*Reviewer's Note: Delete "excluding animal studies" if appropriate information regarding use of animals is provided by licensee.]

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Docket or Reference number
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CONDITIONS

- 10.(1) Licensed material shall be used only at the licensee's facilities located at 405 Rosewood Blvd., Cleveland, Ohio.
- 11.(34) The Radiation Safety Officer for this license is Mary O'Neal, Ph.D.
- 12.(14) A. Licensed material listed in Subitems 6A. through E. above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- | <u>Authorized User</u> | <u>Materials and Use</u> |
|-------------------------|---|
| Nancy W. Smith, M.D. | 35.100; 35.200; 35.300; -
in vitro studies |
| Thomas J. Winston, M.D. | 35.400; 35.500 -
in vitro studies |
| Mary J. Adams, M.D. | 35.100 -
in vitro studies |
- (17) B. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
- 13.(162) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
- 14.(36) A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration, referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a test has been made, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

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E. Sealed sources need not be leak tested if:

- (i) they contain only hydrogen 3; or
- (ii) they contain only a radioactive gas; or
- (iii) the half-life of the isotope is 30 days or less; or
- (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting materials; or
- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

15.(81) Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.

16.(111) The licensee shall conduct a physical inventory every three months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59, 10 CFR 35.400, and 10 CFR 35.500 and every six months for all other sources and/or devices.

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- 17.(44A) A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer and approved by NRC.
- (44B) B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
- 18.(42) In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.
- [Reviewer's Note: New Part 20, 20.1901(b) obviates need for this condition.]
- 19.(154) Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
- 20.(129) The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 21.(152) The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
- 22.(156) Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

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23.(158) The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

24.(136) The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Reviewer's Note: Use (118)(119)(120)(121) and (125) for remote high dose rate afterloaders.

25.(118) In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

26.(119) In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each MicroSelectron-HDR remote afterloading brachytherapy procedure.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey including the survey instrument use, dose rate expressed in mrem/hr (μ Sieverts/hr), time, date and name of the individual making the survey.
- D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

27.(120) Prior to initiation of a treatment program, and subsequent to each source exchange, using the MicroSelectron-HDR afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:

A radiation survey shall be made of:

- A. The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.

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Docket or Reference number

030-92901

Amendment No. 01

- B. All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:
- (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101 (10 CFR 20.1201).
 - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).
- 28.(121) The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:
- A. Installation and replacement of sources contained in the MicroSelectron-HDR afterloading brachytherapy unit.
 - B. Any maintenance or repair operations on the MicroSelectron afterloading brachytherapy unit listed in Item 9. Subitem L. involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
- 29.(125) A. Access to the room housing the MicroSelectron-HDR afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
 - C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Commission.
 - D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

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- 30.(165) In addition to the possession limits in Item 8, the licensee shall further restrict the possession of unsealed licensed material or readily dispersible source material to quantities less than 105 times the applicable limits in Appendix C of 10 CFR Part 20, as specified in 10 CFR 30.35.

[Reviewer's Note: This is a general possession limit for intermediate level decommissioning financial assurance. This or other similar conditions should be used based on decommissioning financial assurance guidance.

- 30.(39) Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 1, 1978
- B. Letter dated January 17, 1982
- C. Letter dated July 31, 1989.

For the U.S. Nuclear Regulatory Commission

Date: _____

By

Materials Licensing Section, Region III
799 Roosevelt Road
Glen Ellyn, Illinois

ATTACHMENT 2

CHECKLIST FOR REVIEW OF APPLICATIONS
FOR BROADSCOPE LICENSES

Applicant: _____
Date of Application: _____
Control Number: _____
Docket Number: _____
License Number: _____

License Type (A) _____, (B) _____, (Broadscope Medical) _____

_____ Application Signed
_____ Fee

Reviewer Signature _____
Management or Senior Reviewer Signature _____

Do not proceed with the technical review of an application until it is signed (a signed transmittal letter is acceptable) and the fee is satisfactory. Other obvious omissions may be noted and communicated to the applicant at the same time as a request for signature or fee. Place completed checklist in docket file with license application.

Item 2. Name and Address of Applicant

_____ Applicant is an entity

Item 3. Address and Locations of Use

_____ 1. Multiple locations of use

* Specific address provided for each location

_____ 2. Special Use Facilities Identified

* Iodination Facilities >10mCi (370 MBq)

* Alpha Labs

* Individual Labs using >100mCi (3.7 GBq)

* Others, e.g., incinerator, compactors, irradiators, animal facilities

_____ 3. Temporary job sites

* Storage and access controls adequate

_____ 4. Description of proposed activities at each place of use

Item 4. Name and Telephone number of person to be contacted

_____ Certifying official satisfies NRC criteria

Item 5. Material requested (nuclide, form, quantity)

_____ 1. Emergency Plan/Contingency Plan

_____ Not necessary, 30.32(i)(1) and 30.72, Schedule C or

_____ Reviewed and approved in accordance with DG-3005

_____ 2. Financial Assurance

_____ Not necessary, (NMSS P&G Directive FC 90-2, worksheet completed and filed in backup) or

_____ Financial Assurance Submittal reviewed and in accordance with R.G. 3.66, and

_____ Financial Acceptance Letter on File

_____ 3. Decommissioning Plan Requirements (30.36)

_____ Adequately addressed in application, if applicable

* Format and content in accordance with R.G. 3.65

_____ 4. Proposed radionuclides and sources specified in sufficient detail

_____ Large activity sealed sources specifically listed

_____ Sources in devices described by manufacturer and model number

_____ Irradiator use requested

_____ Sealed Source and Device Registry checked, or determined not necessary in accordance with P&GD 2-05 (FC 84-22)

_____ 10 CFR 33.17 prohibitions satisfied

Item 6. Purpose of Use

_____ 1. Is general description for types and forms of uses provided?

_____ 2. Is a possession limit per radionuclide and cumulative total indicated?

* Possession limits reasonable based upon applicant's prior experience

- _____ 3. Are uses other than routine research requested (e.g., special uses such as gauges, irradiators, fabrication of sources, tritium targets, static eliminators, animal nuclear medicine studies)? If so, is the applicant's criteria for evaluating internal requests for such uses adequate?

* For fabrication of sources/devices, refer to R.G.s 10.10, 10.11, and P&G Directive 84-5

- _____ 4. Field studies involving release of radioactivity to the environment? If so, environmental assessment conducted as required. (Refer to P&G Directive FC 84-20)

Item 7. Management Control and Responsibilities

7.1. Senior Management

- _____ 1. Organization chart provided

* RSC and RSO have direct reporting path to senior management

* Management statement providing RSC sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and/or license provisions

- _____ 2. Commitment for periodic oversight or audit of program including interaction with RSC/RSO

7.2 Radiation Safety Committee (RSC)

- _____ 1. Duties and responsibilities of committee adequately defined

- _____ 2. Titles and Qualifications of members provided; name, title and qualifications of RSC chairman provided.

* Representation for all proposed activities of use including adequate management representation

- _____ 3. Quorum requirement and voting membership specified

- _____ 4. Control functions and administrative procedures described (refer to checklist Item 10 for details)

- _____ 5. Routine meeting frequencies specified

- _____ 6. Record of meetings maintained

7.3 Radiation Safety Officer (RSO)

- _____ 1. Qualifications of RSO adequate

- _____ 2. Duties and responsibilities of RSO, including program management experience
- _____ 3. Adequate authority documentation provided with application
- _____ 4. Full time RSO devoted to program; if not, has license provided sufficient information to demonstrate its ability to implement daily program?

7.4. Radiation Safety Officer Staff (RSOS)

- _____ 1. Staffing description provided and adequate, i.e., number and qualification sufficient to support requested users and uses
- _____ 2. Duties and responsibilities of radiation safety staff adequately defined

Item 8. Training of Individuals Working in or Frequenting Restricted Areas

- _____ 1. Commitment for training and retraining, including provisions for performance-based training
- _____ 2. Comprehensive program tailored to various types of radiation workers
 - * RSOS
 - * Incinerator Operators
 - * AUs and Lab Workers
 - * Ancillary Staff
 - * Animal Caretakers
- _____ 3. Training program includes review of emergency procedures and response criteria
- _____ 4. Commitment for trainee testing and training record retention

Item 9. Facilities and Equipment

- _____ 1. Adequate reference to prior applications, if applicable, i.e., non-broadscope specific licensee requesting broad authorization
- _____ 2. Licensee has provided adequate description of facilities and equipment for those special uses proposed under Item 6 above
 - * Gamma Irradiators
 - * Animal Facilities
 - * Sub-critical Assemblies
 - * Waste Storage and Processing Facilities
 - * Iodination Facilities
 - * Nuclear Pharmacy

- _____ 3. Criteria provided correlating equipment and facilities to a scheme involving radiotoxicity and use
- _____ 4. Description of types and numbers of survey and monitoring instruments available in both RSOS and authorized users
- _____ 5. Calibration of survey and monitoring instruments adequate and equivalent to NRC guidance

Item 10. Radiation Protection Program

10.1 Administrative Procedures

- _____ 1. Adequate control and procurement procedures
 - * Package procurement, receipt and opening procedures
 - * On and offsite transfer procedures
- _____ 2. Safety Evaluations of Proposed Users and Uses
 - * RSC guidelines/procedures established for conducting safety evaluations
 - * Example of AU application and approval forms used by the RSC and RSO, submitted to NRC
 - * Laboratory facilities and equipment included in safety evaluations
 - * Criteria addressed for evaluating and approving qualifications of authorized users (e.g., 33.15(b) minimum). Training and qualifications concepts correlated to a laboratory use and classification scheme
 - * Laboratory survey and handling procedures included in safety evaluations
 - * Personnel monitoring procedures included in safety evaluations
 - * Waste handling and disposal procedures included in safety evaluations
 - * Inventory and accountability mechanisms and record requirements included in safety evaluations
 - * Lab classification scheme submitted based upon radiotoxicity and activity

_____ 3. Evaluation for human research

- * Existence of RDRC and IRB recognized by FDA, as required
- * Policies developed for informed consent and to avoid ethical conflict-of-interest

_____ 4. Emergency procedures provided and provisions for periodic exercises discussed. Mechanism for contacting staff during off hours, e.g., RSO, users and/or a response team. Spill kits strategically located

_____ 5. Laboratory operating and handling procedures adequate

- * Special handling provisions for high activity and toxicity materials
- * Prohibitions against specific unsafe practices
- * Radiation Safety Manual(s) developed and submitted to NRC for information

_____ 6. Quality Management Program submitted and satisfies 10 CFR 35.32 requirements

- * Format and content consistent with R.G. 8.33

10.2 Material Inventory and Accountability

_____ Procedures for maintaining inventory and control of materials adequate (continuous, running inventory provisions may be necessary)

10.3 Audit and Appraisal Program

_____ 1. Senior management and/or RSC audits

- * Audit of overall program
- * Audit of RSO/RSOS performance

_____ 2. RSO and RSOS program audits

- * AU laboratory audits and surveys
- * Audits of nuclear medicine, oncology and quality management program, as applicable

10.4 Exposure Controls and Monitoring

It is important that the appropriate fee accompany your 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.

REVIEWERS:

Check the licensing and inspection history of the licensee to determine whether additional information on a particular aspect of the program is needed. A pre-renewal visit may be appropriate prior to the review of the application to ascertain if the requested scope of use described in the licensee's application is based upon a real need.

If you do not wish to renew your license, you must dispose of all licensed radioactive material in a manner authorized by 10 CFR Part 20. Complete NRC Form 314, "Certificate of Disposition of Materials," (Appendix B) and send it to the NRC before the expiration date of your license with a request that your 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 you cannot dispose of all the licensed radioactive material in your possession before the expiration date of your license, you must request a license renewal for storage only. The renewal is necessary to avoid violating NRC's regulations that do not authorize possession of licensable material without a valid license.

DEFINITIONS AND ACRONYMS

As used in this Standard Review Plan:

1. Authorized User: An individual specifically named and authorized by the radiation safety committee to use licensed material, or for medical use, a physician, dentist, or podiatrist who is authorized for the medical use of byproduct material.
2. Certifying Official: An individual authorized by an institution's management to sign official license documents and correspondence.
3. Institutional Review Board (IRB): A U.S. Food and Drug Administration (FDA) approved committee responsible for evaluating risk and benefit of human use medical research proposals (ref: 20 CFR Parts 51 and 56).
4. 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.
5. Laboratory Technician: An individual whose normal duties involve laboratory research-related work with radioactive materials under the supervision of an authorized user.
6. Radiation Worker: Any individual whose duties require work with radioactive material.
7. Radioactive Drug Research Committee (RDRC): A U.S. Food and Drug Administration (FDA) approved committee responsible for evaluating and approving proposals for radioactive drug research in human subjects (ref: 21 CFR Part 361).
8. Radiation Safety Committee (RSC): A committee responsible for development and administration of an institution's broad scope radioactive material program including responsibility for approval of all proposals for radionuclide use and users.

9. Radiation Safety Officer (RSO): An individual, to be identified on the license, responsible for day-to-day operation of a radiation protection program within an institution.
10. Radiation Safety Office Staff (RSOS): A technical support staff responsible for day-to-day operation of a radiation protection program within an institution, as directed by an RSO.

APPENDIX A

FLOW DIAGRAM TO AID IN DETERMINING LICENSEE'S COMMITTEE NEED RELATING TO 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 APPROVED BY FDA?

---- (YES) ----

LICENSEE MAY BE AUTHORIZED FOR
HUMAN RESEARCH IF LICENSEE HAS
PROCEDURES TO REQUIRE INTENDED
STUDY BE REVIEWED BY APPROPRIATE
COMMITTEE³

(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
NDA⁴

(NO)

COORDINATE REVIEW WITH NMSS

³ 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 nonradiolabeled form of drug

⁴ For example: Phase II/Phase III Clinical Trials

APPENDIX B

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

1. Regulatory Guide 8.7, Revision 1, "Instructions for Recording and Reporting Occupational Exposure Data"
2. Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"
3. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace"
4. Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"
5. Regulatory Guide 8.35, "Planned Special Exposures"
6. Regulatory Guide 8.36, "Radiation Dose to the Embryo/Fetus"
7. Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities"

APPENDIX C

NRC FORM 314

Certificate of Disposition of Materials

CERTIFICATE OF DISPOSITION OF MATERIALS

(All items **MUST** be completed, please print)

LICENSEE NAME AND ADDRESS	LICENSE NUMBER
	LICENSE EXPIRATION DATE

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

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

☐ 1. NO MATERIALS HAVE EVER BEEN POSSESSED OR PROCURED 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 TRANSFERRED ON

DATE	TO	WHICH HAS NRC LICENSE NUMBER
------	----	------------------------------

OR

☐ 3. ALL MATERIALS PROCURED AND/OR POSSESSED BY THE LICENSEE UNDER THE LICENSE NUMBER CITED ABOVE HAVE BEEN TRANSFERRED ON

DATE	TO	WHICH HAS LICENSE NUMBER	ISSUED BY THE STATE OF
------	----	--------------------------	------------------------

OR

☐ 4. MATERIALS HAVE BEEN DISPOSED OF IN THE FOLLOWING MANNER. (Describe specific disposal procedures—if additional space is needed, use the reverse of this form, or provide attachments)

AN AGREEMENT STATE PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED, AND THE ENERGY REORGANIZATION ACT OF 1974.

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

☐ 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
------	------------------

4. MAIL ALL FUTURE CORRESPONDENCE REGARDING THIS LICENSE TO

RETURN TO:

DIRECTOR, DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

CERTIFYING OFFICIAL

SIGNATURE

DATE

PRINTED NAME AND TITLE

APPENDIX D

NRC FORM 313

Application for Material License

NRC FORM 313
(3-82)
10 CFR 30.32, 33,
34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB NO. 3150-0120
EXPIRES 5-30-83

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 3.25 HOURS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNH88 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20546, AND TO THE PAPERWORK REDUCTION PROJECT (N150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

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 MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20546

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 SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2800
ATLANTA, GA 30323

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
788 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

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

MATERIAL RADIATION PROTECTION SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8054

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

NUCLEAR MATERIALS SAFETY SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1460 MARIA LANE
WALNUT CREEK, CA 94596-5388

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 (includes 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 AND 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 170.37):

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, 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.

SIGNATURE - CERTIFYING OFFICER:

TYPED/PRINTED NAME:

TITLE:

DATE:

FOR NRC USE ONLY

TYPE OF FEE: FEE LOG: FEE CATEGORY: COMMENTS:

AMOUNT RECEIVED:

CHECK NUMBER:

APPROVED BY:

DATE:

APPENDIX E

INFORMATION REQUIRED FOR FIELD USE OF BYPRODUCT MATERIAL

1. A complete 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 from 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 (RSOS), to reviewing records, reports from the RSO, results of NRC inspections and written safety procedures, and observing audits performed by the RSO and RSOS to ensure the adequacy of the institution's management control systems. These reviews may be conducted by an independent auditor, however, this does not relieve the RSC of the responsibility to ensure that the reviews are conducted in accordance with regulations. Examples of program review include, but are not limited to, the following:
 - a. Periodic review of protocol/user permits issued by the RSC (e.g., review of each permit at 1-2 year intervals).
 - b. Review of letters of agreement with offsite emergency response agencies.
 - c. 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/licensees.
 - d. Review of audit findings (of RSC approved users and facilities) by the RSOS.
3. Conduct 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.

4. Develop procedures and criteria for training and testing each category of worker. (Refer to Appendix I).
5. Establish methods for maintaining records of the committee's proceedings and safety evaluations of proposed users and uses of radioactive materials. Submission of these documents would be useful in understanding your program⁵.
6. Develop 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 list of current committee members and their appropriate training and experience.

NOTE: If this request is for a medical broad scope license, the requirements of 10 CFR 35.22 should be included in the description of the RSC duties and responsibilities.

⁵ 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 new contractor is NVLAP approved); or references to particular pieces of equipment, etc. 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. 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. Proper delivery, receipt, and conduct of radiation surveys of all shipments of radioactive material arriving at or leaving from the institution and packaging and labelling all radioactive material leaving the institution.
6. Distribute and process personnel monitoring equipment, determine the need for and evaluation of bioassays, monitor personnel exposure and bioassay records for trends and high exposures, and notify individuals and their supervisors of 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 and regulations, etc.

8. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and maintenance of 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, e.g., receipt, transfer, and survey records as required by 10 CFR 30.51, "Records," and 10 CFR Part 20, Subpart L, "Records."⁶
15. Periodic meetings with and reports to licensee management and Radiation Safety Committee.

NOTE: If this request is for a medical broad scope license, the requirements of 10 CFR 35.21 should be included in the description of RSO duties and responsibilities.

⁶ NUREG-1460, "Guide to Reporting and Recordkeeping Requirements" provides information on compliance with the requirements specified in Title 10 of the Code of Federal Regulations.

APPENDIX I

CONCEPT AND ELEMENTS OF A BROAD SCOPE TRAINING PROGRAM

1. Concept

The Radiation Safety Committee (in consultation with the Radiation Safety Officer (RSO)) is responsible for developing and instituting your radiation protection program. Your program for training should provide a commitment to initial training, retraining, or continuing education. The type and amount of instruction may be structured based on past training and experience, and commensurate with potential radiological health protection problems in the area(s) the employee is (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/her direction. This orientation includes the following subjects:

- a. Applicable regulations and license conditions;
- b. Areas where radioactive material is used and stored;
- c. Potential hazards associated with radioactive material;
- d. Appropriate radiation safety procedures;
- e. Special in-house rules;
- f. Individual's obligation to report unsafe conditions to the RSO and/or applicable authorities;

- g. Appropriate response to emergencies or unsafe conditions;
- h. Worker's right to be informed of occupational radiation exposure and bioassay results; and
- i. Locations of pertinent regulations, licenses, and other material required by regulations.

3. Authorized Users

In addition to the above, the training and experience of authorized users should be at least equivalent to that specified in 10 CFR 33.15(b)(1)(2):

- a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and
- b. 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 description is for users authorized under a Type C license, which generally involve use of radioactive material in microcurie to low millicurie quantities. Therefore, your program of instruction should be correlated to your laboratory classification scheme. Additional training would be required for the Type A and B laboratories. Training to achieve the requirements of item b may be provided by the RSO or his/her qualified staff. Such training should be documented. Alternatively, training specified in item b may have been obtained at a different institution; however, its scope and adequacy should be documented and approved by the Radiation Safety Committee.

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

4. Radiation Workers (Working Under the Supervision of an Authorized User)

In addition to 10 CFR 19.12 instruction, each radiation worker supervised by an authorized user must receive specific documented instruction from the authorized user and the radiation safety office staff. The authorized user works directly with new staff until the authorized user is confident in the worker's abilities and understanding of NRC regulations, license provisions and "in-house" safety instructions. The authorized user is responsible for documenting the staff member's completion of his/her instruction and certification of the worker's use of materials with limited supervision, i.e., not under the authorized user's physical presence.

5. Performance Based Training

In addition to basic didactic 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 transmit specific instructions, at least annually, regarding the authorized user's responsibilities for providing training to the staff. An assessment of the comprehension and abilities of staff through random interviews with the authorized users and/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, nursing, 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 regarding both the radiological aspects of their duties as well as 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 authorized 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 required to be shared with the radiation workers and filed by the authorized user or supervisor along with the material authorizing the use of licensed material. Thus, it is the responsibility of the authorized user to provide evidence of the worker having received this and other pertinent information. It should be the responsibility of the Radiation Safety Office to audit this program.

8. Emergency Procedures and Specialized Training

You should provide emergency procedures and specialized training and retraining to all applicable workers. All individuals who work with radioactive materials and 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 assure appropriate, timely and adequate response to accident situations. Emergency procedure instruction is considered an excellent performance-based training opportunity which could be incorporated into a retraining program.

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

Training records should include:

- a. List of topics;
- b. Approximate time spent on each topic;
- c. Name(s) of instructor(s) and student(s);
- d. Dates of training;
- e. Written assessment or test for each student, documenting satisfactory completion of the training; and
- f. Location and materials involved in the training provided.

You should provide details of your in-house training program(s). Include in your description the following information:

- a. The name(s), training and experience of the individual(s) providing formal training; and
- b. An outline of your 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 frequency and 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

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

Group 4: low toxicity

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

TABLE II: LIMITATIONS ON ACTIVITIES IN VARIOUS TYPES OF WORKING PLACE OR LABORATORY¹

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

¹Laboratory 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 non-porous work surfaces, it may be possible to increase the upper limits of activity for Type C laboratories towards the limits for Type B for toxicity groups 3 and 4.

APPENDIX K

RADIATION SAFETY COMMITTEE CRITERIA FOR APPROVING RESEARCH AUTHORIZATIONS

Establish criteria used by the RSC/RSO when evaluating requests for research authorizations for new facilities and new uses. Each member should have detailed guidance to assess training and experience, and facilities and equipment needs for each research request to include, but not be limited to:

Authorized Users:

- | | |
|--------------------|--|
| Human research - | Meet training and experience requirements in 10 CFR Part 35, Subpart J. |
| Non-human research | Training and experience commensurate with proposed use - see Appendix I. |

Authorized 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. Human Research
 - Radioactive Drug Research Committee or Institutional Review Board

APPENDIX L

INCINERATION GUIDELINES FOR MATERIAL LICENSEES

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

You do not need specific NRC approval in order 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 you have reviewed your program and confirmed that you have waste which requires specific NRC approval for incineration, please provide all of the information specified below:

1. State specifically the isotopes and the maximum activity of each isotope that you wish to incinerate 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 your procedures for assuring that these frequencies and activities will not be exceeded.
3. Describe the characteristics of the incinerator and site, including: (a) height of stack, (b) rated air flow (cubic feet per hour, or similar units), (c) proximity of the stack or other discharge to occupied areas, (e.g., residences, school, or hospital) (d) distance to the nearest air intake ducts of adjacent building(s). Describe any scrubbers, filters, or air cleaning equipment which is present.
4. State how you will determine the concentration of radionuclides released, both as airborne effluent, and as any liquid effluent from scrubbers, condensers, or associated systems. Describe any stack monitoring which is planned.