NUREG-1556
Vol. 11

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Licenses of Broad Scope

Final Report

Manuscript Completed: April 1999
Date Published: April 1999

Prepared by
James P. Dwyer, Orysia Masnyk Baily,
James R. Mullauer, Torre M. Taylor

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol. 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses of Broad Scope," dated April 1999, is the eleventh program-specific guidance document developed for the new process and is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States. This document combines, updates and supersedes the guidance for applicants and licensees previously found in Draft Regulatory Guide DG-0005 dated October 1994. Included in this guidance document is a new option for Type A licensees of broad scope to have increased flexibility to make changes in some program areas and revise some procedures previously approved by the NRC without amendment of the license. This option is discussed in detail in Chapter 1 of this document.

NUREG-1556, Volume 11, is not intended to be used alone. Because broad scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution, etc.), this document frequently refers the user to other more program-specific guidance documents in the NUREG-1556 series. A single document containing all of the guidance that might be required by a broad scope licensee or an applicant for a broad scope license would be unwieldy and would quickly become obsolete as guidance in the individual program areas is revised.

This document takes a more risk-informed, performance-based approach to the information needed to support an application for a license of broad scope. This final report should be used in preparing broad scope license applications. NRC staff will use this final report in reviewing these applications.

CONTENTS

APPENDICES

FIGURES

TABLES

FOREWORD

The NRC is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG series of reports. Below is a list of volumes currently included in the NUREG-1556 series. Additional volumes are planned.

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance About Self-Shielded Irradiators Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiators Licenses	Final Report
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	Draft for Comment
8	Program-Specific Guidance About Licenses for Exempt Distribution	Final Report
9	Program-Specific Guidance About Medical Use Licenses	Draft for Comment
10	Program-Specific Guidance About Master Material Licenses	Draft for Comment
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses	Draft for Comment

The current document, NUREG-1556, Vol. 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," dated April 1999, is the eleventh program-specific guidance developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines, updates and supersedes the guidance for applicants and licensees previously found in Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope," dated October 1994. In addition, this document also contains pertinent information found in Regulatory Guides, Technical Assistance Requests, Information Notices, Policy and Guidance Directives, and Standard Review Plans, as listed in Appendix A.

This report takes a risk-informed, performance-based approach to licensing. It identifies the information needed from an applicant seeking to use sealed and unsealed byproduct material under a broad scope license. NRC's considerable experience with materials licensees indicates that radiation exposures to workers are generally low if the workers follow basic safety procedures.

A team composed of NRC staff from Headquarters and Regional offices drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to users of byproduct material under a broad scope license. A representative of NRC's Office of the General Counsel provided a legal perspective.

NUREG-1556, Vol. 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," dated April 1999, represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following uniform resource locator (URL) <http://www.nrc.gov/NRC/NUREGS/SR1556/V11/index.html>.

This document, dated April 1999, is not a substitute for NRC regulations, and compliance with this guidance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

Donald A. Cool, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

ACKNOWLEDGMENTS

The writing team thanks the individuals listed below for assisting in the development and review of the report. All participants provided valuable insights, observations, and recommendations.

The Participants

Camper, Larry W.
Combs, Frederick C.
Cool, Donald A.
Hart, Timothy
Holahan, Patricia
Hosey, Charles M.
Jones, Cynthia G.
Madera, John
Merchant, Sally L.
Pangburn, George C.
Paperiello, Carl J.
Piccone, Josephine
Roe, Mary Louise
Schwartz, Maria E.
Shanbaky, Mohamed M.
Treby, Stuart A.
Vacca, Patricia C.

The team especially wants to thank the authors of Volumes 1 through 10 of NUREG-1556, who developed much of the guidance incorporated or referenced in this document.

The team also thanks Kay Avery, D. W. Benedict Llewellyn, Steven W. Schawaroch, Gina G. Thompson, and Nora Younger of Computer Sciences Corporation.

ABBREVIATIONS

ALI	annual limit on intake
ALARA	as low as is reasonably achievable
ANSI	American National Standards Institute
BPR	Business Process Redesign
Bq	becquerel
CD-ROM	compact disk-read only memory
CFR	Code of Federal Regulations
cpm	counts per minute
Ci	curie
DFP	Decommissioning Funding Plan
dpm	disintegrations per minute
DIS	decay-in-storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
EPA	United States Environmental Protection Agency
GBq	gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
IAEA	International Atomic Energy Agency
IN	Information Notice
kBq	kilobecquerel
LLW	Low Level Radioactive Waste
MBq	megabequerel
μCi	microcurie
mCi	millicuries
mR	milliroentgen
mrem	millirem
mSv	millisievert
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
R	Roentgen
RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	Sealed Source and Device
Sv	sievert
TEDE	Total Effective Dose Equivalent

URL Uniform Resource Locator

1 PURPOSE OF REPORT

This document provides guidance to an applicant in preparing a broad scope license application and describes the criteria used by NRC staff when evaluating the application. Whereas the applicant for a limited scope license generally must submit to the NRC, for review and approval, the specific training and experience of each proposed user and the facilities and equipment available to support each proposed use, the applicant for a broad scope license normally must submit to the NRC, for review and approval, a description of the internal review process and criteria that will be used to approve users and uses. As opposed to limited scope licenses, which typically identify specific isotopes that may be possessed, the broad scope license generally authorizes the possession and use of a wide range of byproduct radioactive materials.

Because NRC grants significant decision making authority to broad scope licensees through the license, a broad scope license is not normally issued to a new licensee. An applicant for a broad scope license typically has several years of experience operating under a limited scope license and a good regulatory performance history. This document is intended to provide the additional guidance required by the experienced limited scope licensee to prepare an application for a broad scope license. Guidance related to specific program areas, which may not apply to all broad scope licensees, is not included in this document but can be found in other volumes of NUREG-1556, often referred to in this document as "the base NUREGs" or "the base documents," or in guidance documents that have not yet undergone the consolidation process.

Applicants are expected to have first established limited scope licensed programs in accordance with the guidance described in the appropriate base NUREG(s) and then use this document to complete the application for broad scope license. For example, applicants for a broad scope license who use byproduct material for research and development should review NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," for guidance. Similarly, applicants for broad scope license who use byproduct material for medical purposes should review NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses." A list of the currently available base NUREGs is included in the "Forward" to this document.

10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," provides for three distinct categories of broad scope license, i.e., Type A, Type B, and Type C, which are defined in 10 CFR 33.11.

Type A licenses of broad scope are typically the largest licensed programs and encompass a broad range of uses. Type A broad scope licensees use a Radiation Safety Committee (RSC), Radiation Safety Officer (RSO), and criteria developed and submitted by the licensee and approved by NRC during the licensing process, to review and approve all uses and users under the license. The requirements for issuance of a Type A broad scope license are described in 10 CFR 33.13. An applicant for a Type A broad scope license must establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Establishment of a RSC
- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
  - control of procurement and use of byproduct material;
  - completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
  - review, approval, and recording by the RSC of safety evaluations of proposed uses.

Type B broad scope licensed programs are normally smaller and less diverse than Type A broad scope programs. Type B broad scope licensees use an RSO and criteria developed and submitted by the licensee and approved by NRC during the licensing process, to review and approve all uses and users under the license. Because the RSO reviews and approves all uses and users under the license, and not a full RSC as established for Type A broad scope programs, the types and quantities of byproduct material authorized by the Type B broad scope license are limited to those described in 10 CFR 33.11(b) and Section 33.100, Schedule A, Column I. While the quantities of individual radionuclides described in Section 33.100, Schedule A, Column I may be large, total license possession limits are further restricted by the Unity Rule (see Section 8.5.1 for additional information on license possession limits and the Unity Rule). Generally, the scope of authorization for Type B licenses is limited to the experience and knowledge of the RSO. The requirements for issuance of a Type B broad scope license are described in 10 CFR 33.14.

An applicant for a Type B broad scope license must also establish administrative controls and provisions relating to organization and management, procedures, recordkeeping, material control, and accounting and management review that are necessary to assure safe operations, including:

- Appointment of a qualified RSO
- Establishment of appropriate administrative procedures to assure:
  - control of procurement and use of byproduct material;
  - completion of safety evaluations of proposed uses that take into consideration adequacy of facilities and equipment, training and experience of the user, and operating and handling procedures; and
  - review, approval, and recording by the RSO of safety evaluations of proposed uses.

Type C broad scope licensed programs are typically issued to institutions that do not require significant quantities of radioactive material but need the flexibility to possess a variety of different radioactive materials. Users of licensed material under these programs are approved by the licensee based on training and experience criteria described in 10 CFR 33.15(b). The types and quantities of byproduct material authorized by the Type C broad scope license are limited to

those described in 10 CFR 33.11(c) and Section 33.100, Schedule A, Column II, again, considering the Unity Rule. The requirements for issuance of a Type C broad scope license are described in 10 CFR 33.15. While 10 CFR 33.15 does not require Type C broad scope licensees to appoint an RSO, the licensee must establish administrative controls and provisions relating to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. This should include the appointment of someone responsible for the day-to-day operation of the Radiation Safety Program, such as an RSO.

Except for activities specifically excluded from broad scope licenses by 10 CFR 33.17(a), a Type A broad scope license can include any licensed material the applicant needs and for which it qualifies. An application for a Type A broad scope license can include uses of source material and special nuclear material under the same program (e.g., laboratory-scale research and development or the use of uranium as shielding) as the byproduct material to be possessed under the provisions of 10 CFR 30.32(d). However, applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the Type A broad scope license (e.g., use of source material in subcritical assemblies and special nuclear material in cardiac pacemakers).

Types B and C broad scope licenses are restricted in their possession of byproduct material by 10 CFR 33.11(b), 33.11(c), and 33.100 Schedule A. Type B and Type C licensees who require materials not specified in Schedule A will need to: (1) develop Type A broad scope programs, which would require a license amendment; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the base NUREG related to the specific use of this material and submit the information required by the license reviewer as described in that document. For example, applicants who require materials not specified in Schedule A for purposes of research and development should review NUREG-1556, Volume 7, “Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope” and submit the information described therein. Licensees are reminded that changes to the specific license of limited scope require amendment of the license.

Type B licensees who require quantities of material specified in Schedule A, but in excess of that prescribed by 10 CFR 33.11(b), will need to: (1) develop a Type A broad scope program; or (2) carry these additional materials under a separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material specified in Schedule A, but in excess of that prescribed by 10 CFR 33.11(c), will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a specific license of limited scope. Once again, changes to the specific license of limited scope require amendment of the license.

In practice, Part 33 reduces the administrative burden for both licensees and the Commission without reducing the safety standards or lessening the licensing requirements for training, experience, facilities, and equipment. Both the NRC and the licensee benefit from the reduction

in license amendments that might otherwise be needed to change authorized radionuclides, quantities, or names of individuals who may use, or supervise the use of, byproduct material.

Part 33 does not specifically permit a broad scope licensee to make other types of changes to the radiation program as described in the application, such as changing the dosimetry provider, without amendment of the license. However, NRC has permitted broad scope licensees, on a case by case basis, to build in limited program flexibility during the licensing process. For example, rather than requiring that the applicant identify the company that would provide personnel dosimetry, the broad scope licensee could specify that dosimetry would be provided by an organization holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. NRC will continue to allow licensees to build in this type of program flexibility.

Through license condition, NRC will provide even greater flexibility to Type A broad scope licensees who have developed an adequate radiation safety program oversight structure. Type A broad scope licensees and applicants for Type A broad scope license who specify the duties and responsibilities of management, the RSC, and the RSO, including: (1) review and approval of program and procedural changes by the RSC; (2) implementation of program and procedural changes; (3) audit of licensed operations to determine compliance; and (4) taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence, will be authorized, through use of the license condition listed below, to make some program changes and to revise some procedures previously approved by NRC without amendment of the license as long as the program change or revised procedure:

- Is reviewed and approved by the RSC prior to implementation;
- Satisfies regulatory requirements;
- Does not change existing license conditions; and
- Does not decrease the effectiveness of the Radiation Safety Program.

For Type A broad scope applicants or licensees requesting this additional flexibility, a clear description of the process for procedure and program review and approval must be provided. Applicants must describe how specific changes will be documented. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to the approval of each change.

Type A Broad Scope License Condition Used to Grant Additional Flexibility:

- **Notwithstanding the requirements of License Condition Number (insert number of license condition that incorporates the licensee's application and letters into the document), the licensee is authorized to make program changes and changes to procedures specifically identified in the (application dated or letter dated), which were**

previously approved by the Commission and incorporated into the license, without prior Commission approval, as long as:

- **— The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;**
- **— The revised program is in accordance with regulatory requirements, will not change license conditions, and will not decrease the effectiveness of the Radiation Safety Program;**
- **— The licensee's staff is trained in the revised procedures prior to implementation; and**
- **— The licensee's audit program evaluates the effectiveness of the change and its implementation.**

The guidance that follows in this Volume specifies that Type A broad scope licensees who have developed an adequate radiation safety program oversight structure may be granted the flexibility to make program changes and revise procedures in the areas of:

- Training for Individuals Working in or Frequenting Restricted Areas (Section 8.8)
- Audit Program (Section 8.10.1)
- Radiation Monitoring Instruments (Section 8.10.2)
- Material Receipt and Accountability (Section 8.10.3)
- Occupational Dose (Section 8.10.4)
- Safe Use of Radionuclides and Emergency Procedures (Section 8.10.6)
- Surveys (Section 8.10.7)

This report identifies the information needed to complete NRC Form 313 (Appendix B), "Application for Material License," for the use of byproduct material for licenses of broad scope. The information collection requirements in 10 CFR Part 30 and NRC Form 313 have been approved under the Office of Management and Budget (OMB) Clearance Nos. 3150-0017, and 3150-0120, respectively.

The format within this document for each item of technical information is as follows:

- Regulations — references the regulations applicable to the item
- Criteria — outlines the criteria used to judge the adequacy of the applicant's response
- Discussion — provides additional information on the topic sufficient to meet the needs of most readers
- Response from Applicant — provides suggested response(s), offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and References are self-explanatory and may not be found for each item on NRC Form 313.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as indicated on the form, the answers to those items are to be provided on separate sheets of paper and submitted with the completed NRC Form 313. For the convenience of applicants and for streamlined handling of applications in the new materials licensing process, use Appendix C to provide supporting information, attach it to NRC Form 313, and submit them to NRC. Appendix C may also be used by applicants to check applications for completeness.

Appendices D, E, F and G are sample broad scope licenses for licensees involved in research and development. Appendix D is a Type A license of broad scope, Appendix E is a Type A license of broad scope that contains the license condition authorizing additional program flexibility, and Appendix F and G are Type B and Type C licenses of broad scope, respectively. These sample licenses contain the conditions most often found on these licenses, although not all licenses will have all conditions. Applicants are encouraged to review sample licenses published in the base NUREG (i.e., that volume of NUREG-1556) that most closely applies to their type of program. Appendices H through V contain additional information on various radiation safety topics.

Within this document, the phrases or terms, "byproduct material," "licensed material," and "radioactive material," are used interchangeably.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant, other than a Federal Agency, who wishes to possess or use byproduct, source, or special nuclear material in one of these Agreement States needs to contact the responsible officials in that State for guidance on preparing an application. Applications should be filed with State officials, not with NRC. A current list of Agreement States, including the names, addresses, and telephone numbers of responsible officials, may be obtained upon request from NRC's Regional Offices. This information can also be found on the NRC Office of State Programs' web site at <http://www.hsrd.ornl.gov/nrc/asframe.htm>.

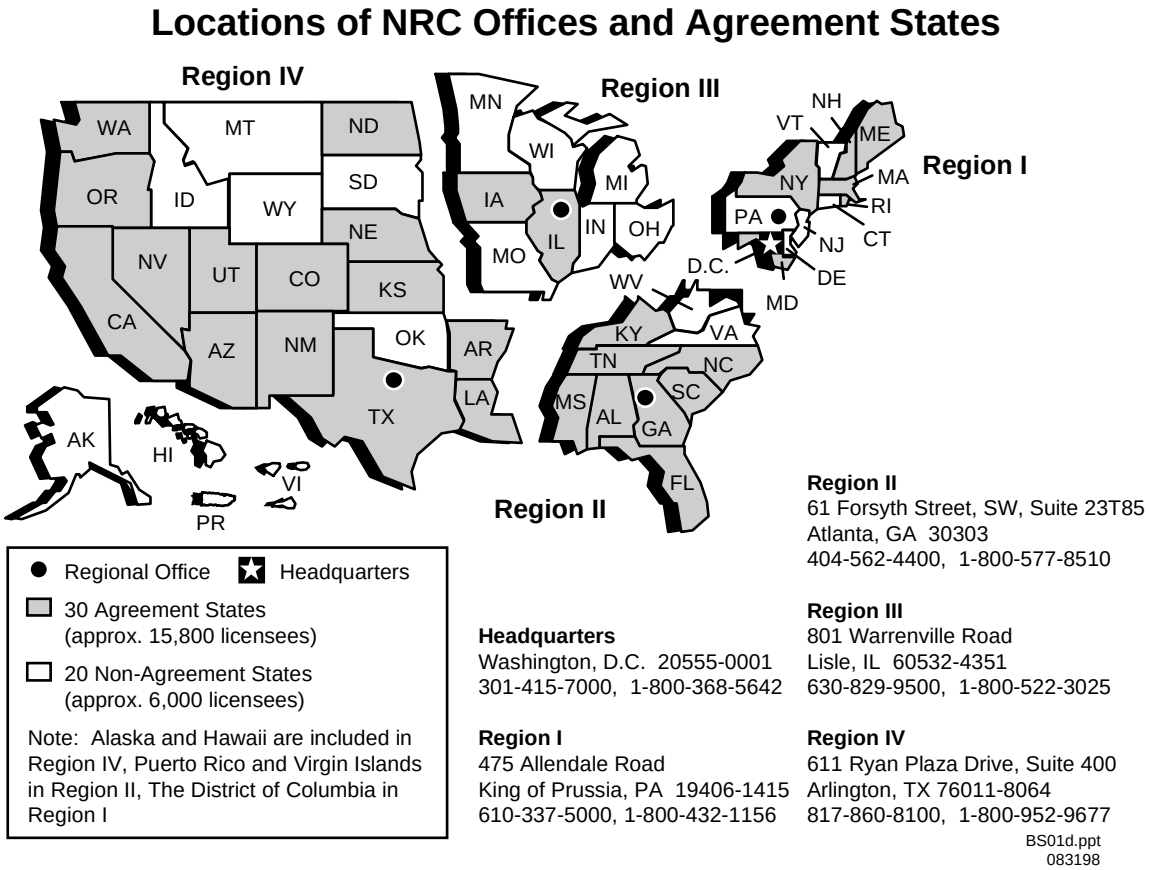


Figure 2.1 U.S Map. *Location of NRC Offices.*

NRC's materials licensees who wish to conduct operations at temporary jobsites in an Agreement State, and who are specifically authorized on the license to conduct such activities, should contact that State's radiation control program office for information about State regulations and questions of jurisdiction on Federal lands or facilities within that Agreement State's boundaries. To ensure compliance with Agreement State reciprocity requirements, licensees should request authorization well in advance of scheduled use.

In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that licensees ask their local contact for the Federal Agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in the All Agreement States Letter, SP-96-022, dated February 16, 1996. A copy of SP-96-022 can be obtained by calling NRC toll free at (800) 368-5642 and asking for the Office of State Programs (extension 415-3340). This letter can also be found on the Office of State Programs' web site at <http://www.hsrd.ornl.gov/nrc/agstates/other/sp96022.pdf>.

Table 2.1 provides a quick way to determine which agency has regulatory authority over the possession and use of byproduct, source, or special nuclear material.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal Agency, regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, US territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site not subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

3 MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. NRC believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely. NRC also believes that effective management will result in increased safety and compliance.

"Management" refers to the processes for conducting and controlling the radiation safety program and to the individuals who are responsible for those processes and have authority to provide necessary resources to ensure safety and to achieve regulatory compliance.

To ensure adequate management involvement, a duly authorized management representative *must* sign the submitted application acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of radiation safety records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license and application;
- Compliance with current NRC and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;
- Selection and assignment of qualified individuals to serve on the Radiation Safety Committee, if required, and to serve as Radiation Safety Officer for their licensed activities;
- Prohibition against discrimination of employees engaged in protected activities (10 CFR 30.7);
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10, respectively;
- Obtaining NRC's prior written consent before transferring control of the license; and
- Notifying the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

For further discussion of management responsibilities, see Section 8.7.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see NRC Inspection Manual, Inspection Procedure 87100 “Licensed Materials Programs,” and the current version of “General Statement of Policy and Procedures for NRC Enforcement Actions,” NUREG-1600. These documents are available electronically at <http://www.nrc.gov>. For hard copies of the Inspection Procedures and NUREG 1600, see Notice of Availability on the inside front cover of this report.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to the use of licensed material by broad scope licensees:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20, "Standards for Protection Against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Part 71 requires that licensees who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable requirements of the United States Department of Transportation (DOT) that are found in 49 CFR Parts 170 through 189. Copies of DOT regulations can be ordered from the Government Printing Office (GPO), whose address and telephone number are listed below.

- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC"

The following Parts of 10 CFR Chapter I contain regulations which, depending on the type or types of activities authorized by the license, may be applicable to the use of licensed material by broad scope licensees:

- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 34, "Licenses for Radiography and Radiation Safety for Radiographic Operations"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging"
- 10 CFR Part 40, "Domestic Licensing of Source Material"
- 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274"

To obtain copies of the above documents, contact the GPO on their website at <www.gpo.gov> or call GPO's Order Desk in Washington, DC at (202) 512-1800. Applicants should contact the GPO's Customer Service Desk at (202) 512-1803 for inquiries about the costs of these documents and methods of payment. Single copies of the above documents may also be obtained from the NRC's Regional Offices (See Figure 2.1 for addresses and telephone numbers). To obtain the two-volume bound version of Title 10, Code of Federal Regulations (10 CFR), Parts 0-50 and 51-199, contact the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. Note that amendments to NRC regulations are published frequently in the Federal Register. 10 CFR Parts 0-50 and 51-199 can also be found on the NRC's website at <www.nrc.gov/NRC/CFR/index/html>.

5 HOW TO FILE

5.1 PAPER APPLICATION

Applicants for a materials license should do the following:

- Be sure to use the most recent information concerning your program in preparing an application.
- Complete NRC Form 313 (Appendix B) Items 1 through 4, 12, and 13 on the form itself.
- Complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C.
- For each separate sheet, other than Appendix C, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers.
- Submit all documents on 8-1/2 x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

As required by 10 CFR 30.32(c), applications shall be signed by a duly authorized management representative; see section on "Certification."

Using the suggested wording of responses and committing to using the model procedures in this volume and other appropriate volumes of NUREG-1556 will expedite NRC's review.

All license applications will be available for review by the general public in NRC's Public Document Rooms. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information, should not be submitted unless specifically requested by NRC.

As explained in the "Foreword," NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. NRC will continue to accept paper applications. However, these will be scanned and put through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Universe.

- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM (compact disc-read only memory), and through the Internet. Additional filing instructions will be provided as these new mechanisms become available.

6 WHERE TO FILE

Applicants wishing to possess or use licensed material in any State or U. S. territory or possession subject to NRC jurisdiction must file an application with the NRC Regional Office for the locale in which the material will be possessed and/or used. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes and identifies Agreement States.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State, not NRC. However, if work will be conducted at Federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. See the section on "Agreement States" for additional information.

7 LICENSE FEES

Each application for which a fee is specified, including applications for new licenses and license amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. NRC will not issue the new or amended license prior to fee receipt. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities."

Direct all questions about NRC's fees or completion of Item 12 of NRC Form 313 (Appendix B) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. You may also call NRC's toll-free number, (800) 368-5642 and then ask for extension 415-7554.

8 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on NRC Form 313 (Appendix B).

All items in the application should be completed in enough detail for the NRC to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect health and minimize danger to life and property. Consideration shall be given, when developing your application, to the concepts of ALARA and the minimization of contamination.

Regarding ALARA, 10 CFR 20.1101(b) states that "The licensee *shall* use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." ALARA concepts and philosophy are discussed in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable." Applications for broad scope licenses must address ALARA considerations in all aspects of their programs (e.g., monitoring and controlling external and internal personnel exposure, monitoring and controlling air and liquid effluents). ALARA considerations, including establishing administrative action levels and monitoring programs, need to be documented in the application.

10 CFR 20.1406 requires that license applicants describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Like ALARA, the applicant must address these concerns in all aspects of their programs.

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 (Appendix B) and this guidance, a prelicensing visit may be scheduled by NRC at the licensee's facility. A visit or conference may also be scheduled as part of the license renewal process. A prelicensing visit provides the NRC staff with an opportunity to better evaluate the proposed program and the necessity for a broad scope 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 the program with an appropriate specific license can be discussed.

All information submitted to NRC during the licensing process will be incorporated as part of the license and will be subject to review during inspection.

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
[ ] A. New License	Not Applicable
[ ] B. Amendment to License No.	XX-XXXXX-XX
[ ] C. Renewal of License No.	XX-XXXXX-XX

Check box A if the application is for a new broad scope license. As stated in the chapter entitled "Purpose of this Report," NRC will not normally issue a broad scope license to a new licensee.

Check box B if the application is for an amendment[1] to an existing broad scope license or if the application is to upgrade a limited scope license into a broad scope license. Provide the license number.

Check box C if the application is for the renewal[1] of an existing broad scope license and provide the license number.

8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. Because of the significant authority given a broad scope licensee to oversee licensed activities, it is not appropriate for an individual to apply for a broad scope license. No individual other than the duly authorized applicant may, for any licensing matter, act on behalf of the applicant or provide information without written authorization of the applicant.

Provide the mailing address where correspondence should be sent. A Post Office box number is an acceptable mailing address. NRC should be notified of changes in mailing address so that the license can be amended. These license amendments do not require a fee.

[1] See "Amendments and Renewals to a License" later in this document. Licensees are required to request and obtain an amendment to the license before making changes in their radiation safety program. Examples of changes that require amendment are change of Radiation Safety Officer (RSO) and increases in the license possession limit.

Note: The NRC must be notified before control of the license is changed, and the licensee must receive written consent from the NRC prior to the change. The NRC must also be notified when bankruptcy proceedings have been initiated. NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses; Guidance About Changes of Control and Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," provides additional information about NRC requirements related to changes of control and bankruptcy considerations. NRC Information Notice (IN) 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability. See below for more information.

Timely Notification of Change of Control

Regulations: 10 CFR 30.34(b); 10 CFR 40.46; and 10 CFR 70.36.

Criteria: The regulations require that "No license issued or granted pursuant to the regulations, nor any right under a license, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing." Therefore, control of licenses cannot be transferred without the prior written consent of the Commission.

Discussion: Change of control may be the result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain NRC's written consent before the transaction is finalized. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses
- Materials are properly handled and secured
- Persons using these materials are competent and committed to implementing appropriate radiological controls
- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material
- The transferee has the financial resources to decommission the license, if necessary
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: None from an applicant for a new license; Appendix H, excerpted from IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed

Activities," dated December 7, 1994, identifies the information to be provided about transferring control.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain copies of IN 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities," dated December 7, 1994, and IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997. Information Notices are available on NRC's website at <www.nrc.gov/NRC/reference.html>

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. NRC needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). NRC shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant: None at time of application for a new license. Licensees must immediately (within 24 hours) notify NRC following the filing of a voluntary or involuntary petition for bankruptcy for or against the licensee.

Reference: See the Notice of Availability (on the inside front cover of this report) to obtain copies of Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996, and NRC Inspection Manual, Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing.

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Specify each proposed location of use by the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State). The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A Post Office box address is not acceptable. If byproduct material is to

be used at more than one location, give the specific address of each location. Applicants for a broad scope license need not identify each facility at a particular address where byproduct material will be used. For example, applicants can specify that byproduct material will be used on the Main Campus of ABC University located in Anytown, State.

Applicants should identify the location of all facilities designed or established for special uses, e.g., panoramic irradiators, interim or long-term waste storage facilities, high activity laboratories, iodination facilities, alpha laboratories, incinerators, and animal facilities.

If byproduct material (e.g., portable gauging devices) will be used at temporary job sites, so indicate, and describe the scope of these activities.

If byproduct material is to be used in field studies, the activities must be specifically identified and authorized on the license. Appendix I contains information required of applicants prior to granting authorization for field use of licensed material.

An NRC-approved license amendment identifying a new location of use, which is not encompassed by a location described on the existing license, is required before receiving, using and storing licensed material at that location.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of radioactive material).

Note: As discussed later under "Financial Assurance and Recordkeeping for Decommissioning," licensees must maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). Acceptable records are sketches, written descriptions of the specific locations, or room numbers where licensed material is used or stored and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Identify the individual who can answer questions about the application and include his or her telephone number. This individual, usually the Radiation Safety Officer, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not a full-time employee of the licensed entity, his or her position and relationship should be specified. No individual other than the duly authorized applicant may, for any licensing matter, act on behalf of the applicant or provide information without the applicant's written authorization. The NRC should be notified if the person assigned to this function

changes or if their telephone number changes. Notification of a contact change is for information only and would not be considered an application for license amendment (or require a fee), unless the notification involves a change in the contact person who is also the Radiation Safety Officer.

As indicated on NRC Form 313 (Appendix B), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C for this purpose and should note that using the suggested wording of responses and committing to using the model procedures in this report and others will expedite NRC's review.

8.5 ITEM 5: RADIOACTIVE MATERIAL

8.5.1 UNSEALED AND/OR SEALED BYPRODUCT MATERIAL

Regulation: 10 CFR 30.18; 10 CFR 30.32(d); 10 CFR 30.32(g); 10 CFR 30.32(i); 10 CFR 30.33(a)(2); 10 CFR 32.210; 10 CFR 33.11; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15; and 10 CFR 33.17.

Criteria: An application for a license will be approved if the requirements of 10 CFR 30.32; 10 CFR 30.33; 10 CFR 33.11; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15; and 10 CFR 33.17 are met.

Discussion: Applicants for a Type A broad scope license typically request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. When establishing individual radionuclide and total cumulative quantities, all materials possessed under the license should be included (i.e., materials received awaiting use, materials in use/process, and those categorized as waste awaiting disposal). The maximum quantity for each individual radionuclide and total cumulative possession should be commensurate with the applicant's needs, facilities, procedures, and demonstrated experience/capability. If certain individual radionuclides will be needed in much larger quantities than described in the atomic number 1-83 request, they should be listed separately rather than increasing the possession limit for all radionuclides. Similarly, if it is known that certain relatively more hazardous radionuclides (e.g., strontium-90) are needed only in smaller quantities, they should be listed separately.

If needed, an applicant for a Type A broad scope license may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 to 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. Note that authorization to possess byproduct materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium because, even though these elements

have atomic numbers within the range of 84 through 96, these materials are either source material or special nuclear material and not byproduct material.

Licensees may request source material and special nuclear material when use of these materials is directly related to the use of byproduct material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license (e.g., sub-critical assemblies and nuclear pacemakers).

A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.). Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. Before the formalization of the SSD registration process, some older sources or devices may have been specifically approved on a license. Licensees can continue to use those sources and devices specifically listed on their licenses. Sealed sources or devices containing sealed sources that are intended for use solely under broad scope licenses and are not transferred to another licensee need not be evaluated by the NRC prior to use if: (1) the licensee is authorized to possess the requested quantity of radioactive material in unsealed form; and (2) the licensee performs its own safety evaluation in accordance with the administrative procedures required by 10 CFR 33.13(c)(3)(ii), 33.14(b)(2)(ii) or 33.15(c), as appropriate. For example, a broad scope licensee who is authorized to possess and use any form of iridium-192 or cobalt-60 in the fabrication of sources and devices for industrial radiography may use the fabricated sources and devices to conduct its own licensed activities without first submitting the sources and devices to NRC (or the Agreement State) for evaluation and registration.

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SSD Registration Certificate. Information on SSD registration certificates is available on the NRC's web site at <http://www.hsrd.ornl.gov/nrc/SSDR/SSDRINDX.HTM> and may also be obtained by contacting the Registration Assistant by calling NRC's toll free number, (800) 368-5642, Extension 415-8140. For additional guidance relating to sealed sources and devices, see also NUREG-1556, Vol. 3., "Applications for Sealed Source and Device Evaluation and Registration."

Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications.

Applicants for Type A broad scope license should review the requirements for financial assurance and decommissioning before specifying possession limits for radioisotopes with a half life greater than 120 days. These requirements are discussed in Section 8.5.2 of this document.

Licensees who possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 must provide with the application either of the following:

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).

If you are required to establish an emergency plan, guidance is provided in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," dated January 1992, and Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses." NUREG 1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," dated January 1988, also contains valuable information.[2]

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows. For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity. The possession limit for a Type C broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the sum of the ratios, determined in the same manner as discussed above, for all radionuclides possessed under the license shall not exceed unity.

Type B and Type C broad scope licensees who require materials not specified in Schedule A will need to: (1) develop Type A broad scope programs; or (2) carry these additional materials under a separate specific license of limited scope. The latter option would require that the licensee review the base NUREG related to the specific use of this material and submit the information

[2] NUREG-0767, "Criteria for Selection of Fuel Cycle and Major Materials Licenses Needing Radiological Contingency Plans," dated July 1981, was superseded by 10 CFR 30.32(i) and 30.72; NUREG-0762, "Standard Format and Content for Radiological Contingency Plans for Fuel Cycle and Materials Facilities," dated November 1987, was superseded by Regulatory Guide 3.67; and NUREG-0810, "Standard Review Plan for the Review of Radiological Contingency Plans for Fuel Cycle and Materials Facilities," dated April 1987, was superseded by Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licensees."

required by the license reviewer as described in that document. For example, applicants who require materials not specified in Schedule A for purposes of research and development should review NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," and submit the information described therein.

Type B licensees who require quantities of material in excess of that permitted by 10 CFR 33.11(b), will need to: (1) develop a Type A broad scope program; or (2) carry these additional quantities under a separate specific license of limited scope, as described in the previous paragraph. Type C licensees who require quantities of material in excess of that permitted by 10 CFR 33.11(c), will need to: (1) develop, as appropriate, a Type A or Type B broad scope program; or (2) carry these additional materials under a separate specific license of limited scope.

Applicants for Type B or Type C broad scope license may consider limiting their possession of isotopes described in Schedule A with half lives greater than 120 days below that amount permitted by 10 CFR 33.11(b) or 33.11(c) respectively, to avoid being required to submit certification of financial assurance or a decommissioning funding plan. See Section 8.5.2 of this document for a discussion of Financial Assurance and Recordkeeping for Decommissioning.

Response from Applicant: Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1-83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately. A separate listing should also be submitted for sealed sources needed in larger quantities than that described in the atomic number 1-83 request. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in a Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. This information need not be submitted if the licensee is authorized to possess the requested quantity of radioactive material in unsealed form and the licensee performs the required safety evaluation of the source and device.

Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications.

Licensees who possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 must provide with the application either of the following:

- An evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or
- An emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3).

Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. Type B licensees should request the quantity of material specified in 10 CFR 33.11(b). Type C licensees should request the quantity of material specified in 10 CFR 33.11(c).

8.5.2 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

Regulations: 10 CFR 30.32(h); 10 CFR 30.34(b); 10 CFR 30.35; 10 CFR 30.36(e); 10 CFR 30.36(g)(4)(v); 10 CFR 30.51(d); 10 CFR 30.51(e); 10 CFR 30.51(f); 10 CFR 40.31(i); 10 CFR 40.36; 10 CFR 40.42(e); 10 CFR 40.42(g)(4)(v); 10 CFR 40.61(d); 10 CFR 40.61(e); 10 CFR 40.61(f); 10 CFR 70.22(a)(9); 10 CFR 70.25; 10 CFR 70.38(e); 10 CFR 70.38(g)(4)(v); 10 CFR 70.51(b)(6); and 10 CFR 70.51(b)(7).

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 must meet the requirements for decommissioning financial assurance. All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site, or any area, is released for unrestricted use. Licensees must transfer these records either to the new licensee, when licensed activities are transferred or assigned, or to the appropriate Nuclear Regulatory Commission (NRC) Regional office when the license is terminated.

Discussion: NRC wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance that applies to some licensees and recordkeeping that applies to all licensees.

NRC decommissioning financial assurance regulations are designed to provide reasonable assurance that the decommissioning of 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. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Applicants are required to provide financial assurance when the possession of radioactive material of half life (T1/2) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a decommissioning funding plan (DFP) or has an option of

submitting either a DFP or a Certification of Financial Assurance are stated in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25. A DFP contains a site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.

Acceptable financial assurance includes prepayment options (trusts, escrow accounts, government funds, certificates of deposit or deposits of government securities); surety, insurance, or other guarantee methods (letters of credit, surety bonds, lines of credit, parent company guarantees, insurance policies), and statements of intent for Government entities. Criteria for parent company guarantees and self-guarantees can be found in 10 CFR 30, Appendix A, Appendix C, Appendix D, and Appendix E.

Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, 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. A revision to RG 3.66 will incorporate new guidance related to self-guarantees. RG 3.66 also describes the information required to be submitted for a DFP. NUREG-1337, Revision 1, "Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated August 1989, also provides guidance for decommissioning financial assurance reviews.

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 30.35(g), 10 CFR 40.36(f), and 10 CFR 70.25(g). All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. Careful recordkeeping of radionuclides used, including form, amount, and area used, will facilitate area release and license termination. In the event that the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee when the transfer of the licensed activities takes place. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records must be transferred to NRC.

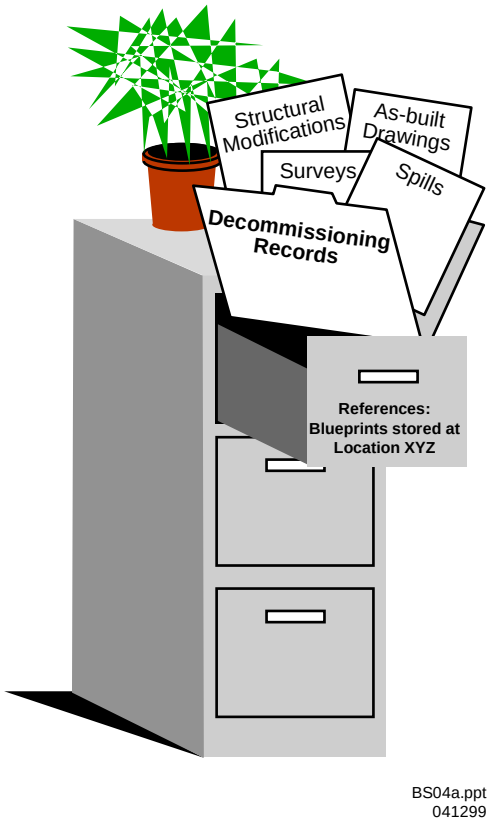


Figure 8.1 Types of Records that Must be Maintained for Decommissioning.

10 CFR 30.35(g), Requirements for Disposition of Records Important to Decommissioning

- Before licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer to the new licensee

OR

- Before the license is terminated, transfer records to the appropriate NRC Regional office.

Response from Applicant: If a DFP or certification of financial assurance is required, submit the required documents as recommended in RG 3.66.

8.6 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: 10 CFR 30.4; 10 CFR 30.32(d); 10 CFR 30.33(a)(1); 10 CFR 33.11; and 10 CFR 33.17.

Criteria: Requested radioisotopes must be used for purposes authorized by the Atomic Energy Act of 1954, as amended. Sealed sources and devices containing licensed material must be used only for the purpose for which they are designed and according to the manufacturer's (distributor's) instructions and recommendations for use as specified in the SSD Registration Certificate. Sealed sources or devices containing sealed sources that are intended for use solely under broad scope licenses, and that will not be transferred to another licensee, need not be evaluated by the NRC prior to use if the licensee is authorized to possess the requested quantity of radioactive material in unsealed form and the licensee performs its own safety evaluation. Applicants desiring activities disallowed by 10 CFR 33.17(a) should apply for specific authorization.

Discussion: The applicant should describe in general terms the purposes for which the licensed material will be used. New applicants should describe why a broad scope license is needed rather than amendments to an existing limited scope license. The uses should be consistent with prior licensed activities. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for exposure of workers and members of the public to radiation and radioactive materials. The information provided regarding "Purpose of Use" is understood by the NRC staff as a self-imposed limitation contained within the application. If a broad scope licensee desires to initiate a use other than those described in its application and committed to in its license, the licensee must submit an amendment to the license to modify or expand the "purpose."

The exclusions stated in 10 CFR 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad licenses will not do any of the following:

- Conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users)
- Receive, acquire, own, possess, use, transfer, or import devices containing 3.7×10^{15} becquerels (Bq) (100,000 curies) or more of byproduct material in sealed sources for irradiation of materials
- Conduct activities for which a specific license issued by the NRC under 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"; or 10 CFR Part 35, "Medical Use of Byproduct Materials," is required
- 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.

Applicants desiring these activities should review the appropriate base NUREG (i.e., that volume of NUREG-1556 that most closely applies) and request specific authorization in accordance with the guidance contained therein. For example, broad scope licensees who wish to perform

industrial radiography should review NUREG-1556, Volume 2, "Program-Specific Guidance About Radiography Licenses," and provide necessary information, as specified.

Response from Applicant: Describe in general terms the purposes for which the licensed material will be used.

8.7 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Executive management, the Radiation Safety Committee (RSC), if required, and the Radiation Safety Officer (RSO) and his or her staff, as necessary, work as a team to oversee the broad scope program. Each plays a critical role within its area of responsibility. The roles and responsibilities of executive management, the RSC, the RSO, and the radiation safety office staff are discussed in the sections that follow.

Note: NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of executive management, the RSC, and the RSO at medical facilities but contains information pertinent to all broad scope programs.

8.7.1 EXECUTIVE MANAGEMENT

Regulations: 10 CFR 20.1101(c); 10 CFR 33.13(c); 10 CFR 33.14(b); and 10 CFR 33.15(c).

Criteria: The applicant must have administrative controls and provisions relating to organization and management and management review necessary to assure safe operations.

Discussion: Executive management is the individual at the senior management level who is responsible for oversight of the facility's radiation safety program and has the ultimate responsibility for the license and the activities associated with the license. Executive management has an important role in implementing and managing the radiation safety program. NRC expects executive management to be knowledgeable of the program.

Due to the various structures of different organizations, NRC recognizes that executive management may need to delegate certain responsibilities to other managers for the day-to-day oversight of the program. For example, a large company may have several licenses issued to it for different facilities or for different activities. In this case, a company may choose to establish a senior level manager with responsibility for all of the licenses issued to that company, with the day-to-day responsibility for each license designated to the facility senior manager or program area senior manager. There are numerous ways in which an applicant may wish to structure its management oversight to meet the needs of the organization. However, there must still be one

level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

In a Type A broad scope program, executive management or her/his delegate is a vital member of the RSC and should attend Committee meetings. In all licensed programs, executive management should be knowledgeable of the results of periodic audits and the annual review of the licensed program, to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner. Annual reviews and audits are discussed in more detail in Section 8.10.1 of this guidance document.

The licensee should consider several factors when selecting executive management for the radiation safety program. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. This individual must be available to facilitate effective and immediate action on behalf of management, the RSC (for Type A broad scope programs), and the RSO, particularly in the event of an emergency. Executive management must have the authority to make prompt decisions without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license.

Executive management is involved in selecting the chairperson and members of the RSC (for Type A broad scope) and the RSO (for Type A and Type B broad scope), and defines the role, duties and responsibilities of each. Executive management should support the RSC and the RSO, creating an atmosphere of cooperation and professionalism such that individuals feel comfortable raising radiation safety concerns. Authority will be enhanced if authorized users clearly understand that there is strong management support for, and participation in, the licensed program. Many problems can be avoided if management takes proactive steps before radiation safety problems escalate. Individuals should understand management's expectations regarding internal enforcement of program requirements and the consequences for non-compliance.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 1, describes the role of executive management at medical facilities, but it also contains information pertinent to all broad scope programs.

Response from Applicant: The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to assure safe operations. It is recommended that the applicant submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).

8.7.2 RADIATION SAFETY COMMITTEE

Regulations: 10 CFR 33.13(c)(1) and 33.13(c)(3)(iii).

Criteria: Type A broad scope licensees must establish a Radiation Safety Committee (RSC), which works with executive management and the Radiation Safety Officer (RSO) in implementing the radiation safety program. Type B and Type C broad scope licensees are not required to establish an RSC.

Discussion: An applicant for a Type A broad scope license must establish a RSC pursuant to 10 CFR 33.13(c)(1). The RSC works with executive management and the RSO in implementing the radiation safety program, and will be involved in establishing policies and procedures for managing the radiation safety program. The RSC, through the executive management, must have the authority and flexibility necessary so that it may effectively fulfill its role in managing the radiation safety program.

The RSC for a Type A broad scope program is composed of such persons as the RSO, executive management, and persons trained and experienced in the safe use of byproduct materials. Each area of use under the license should be represented on the RSC.

A chairperson for the committee should be selected. There are several factors to consider when selecting a chairperson for the RSC. An individual with a knowledge of radiation safety issues, good leadership abilities, the authority and credibility by virtue of their position within the facility, and a desire to serve as chairperson will facilitate the effectiveness of the RSC. Additionally, the individual chosen as the chairperson must have the time to devote to the position in addition to other responsibilities he or she might have within the facility. Executive management should delegate a level of authority to the position so that the chairperson is effective. In general, the RSO should not be appointed as the chairperson of the Committee, since the RSO is responsible for the day-to-day operation of the radiation safety program and may be too closely involved with the licensed activities to be objective.

The RSC should establish a quorum for RSC meetings. A quorum consisting of the chairperson of the committee (or his/her designee), the RSO, the executive management (or his/her alternate), a representative from each area of use from which specific issues will be discussed, and any other member whose field of expertise is necessary for the discussion is considered acceptable.

The meeting frequency for RSC meetings for broad scope programs is not specified in 10 CFR Part 33. The RSC should meet as often as needed to ensure the radiation safety program is operating in compliance with the license, established procedures and the regulations. For most programs, quarterly RSC meetings are needed to adequately oversee the program.

The RSC should maintain minutes of its meetings. The minutes should include the date of the meeting, the members present and absent to demonstrate a quorum was present, a summary of the discussions, recommendations and the results of votes. The RSC should also document its review of new users, uses, and program changes. The minutes should also include information related to the ALARA program reviews and the annual audit review.

Duties and Responsibilities

The committee is responsible for reviewing personnel dosimetry data, discussing the results of required radiation surveys, and any significant incidents, including spills, contamination, misadministrations, etc. The RSC is also required to review the program for maintaining doses ALARA and providing any necessary recommendations to ensure doses are ALARA. The overall compliance status for authorized users should be thoroughly reviewed. The RSC, working with the executive management, shares responsibility with the RSO for conducting periodic audits of the radiation safety program. Additionally, the Committee reviews any consultant's audit findings and acts upon those findings. The RSC also reviews the results of the annual audit of the radiation safety program. Possible trends should be analyzed, and suggestions for timely and corrective action should be made. Problems should be clearly defined and reviewed in the future as open items. An assessment of the effectiveness of corrective actions is also helpful in deterring or eliminating future problems and violations.

One of the primary responsibilities of the RSC for a broad scope program is to evaluate new users and new uses of byproduct material. The RSC needs to consider all available information in making decisions. This includes evaluating the training and experience of applicants who request authorization to use radioactive material at the facility, using criteria developed by the RSC. The RSC members should be aware of the regulatory training and experience criteria that apply to each type of use at their institution. For example, 10 CFR Part 35 contains the training and experience required for authorized users in medical programs. The criteria developed by the committee should include such things as the requester's training and experience, the proposed facilities, the protocol for using radioactive material to ensure that all procedures are in accordance with good radiation safety practices, and waste disposal.

For Type A broad scope licensees or applicants for a Type A broad scope license who desire the flexibility to make certain program changes and changes to certain procedures as discussed in Section 1 of this document, the RSC, along with executive management and the RSO, will review and approve program and procedural changes in accordance with criteria developed and approved by the RSC. The criteria for reviewing and approving such changes should include provisions for training staff before implementing new procedures and ensure that the proposed changes will not degrade the effectiveness of the currently approved program. Additionally, the audit program should include an evaluation process that will assure that changes have been properly implemented by the staff and will determine the effectiveness of changes made in achieving program goals.

NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," Chapter 2, describes the role of the radiation safety committee at medical facilities, but contains information pertinent to all broad scope programs.

For medical broad scope programs, the requirements of 10 CFR Part 35 must be met. Broad scope licensees should review other base NUREGs that may apply to their licensed program,

such as NUREG-1556,Volume 9, "Program Specific Guidance About Medical Use Licenses," for licensees who possess radioactive material for medical use.

Response from Applicant: Applicants for a Type A broad scope license should submit the following:

- Description of the duties and responsibilities of the RSC.
- Criteria used for selecting members of the RSC, including what members and the number of members constituting a quorum. Members should be indicated by position title, rather than by name.
- Criteria used by the RSC and RSO for approving new users and new uses.

In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license should submit the following:

- A description of the duties and responsibilities of the RSC, including:
  - — review and approval of permitted program and procedural changes prior to implementation;
  - — implementation of program and procedural changes;
  - — audit of licensed operations to determine compliance; and
  - — taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

- A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

8.7.3 RADIATION SAFETY OFFICER

Regulations: 10 CFR 30.33(a)(3); 10 CFR 33.13(c)(2); 10 CFR 33.14(b)(1); 10 CFR 34.42; 10 CFR 35.21; and 10 CFR 36.13(d).

Criteria: Type A and Type B broad scope licensees must have a Radiation Safety Officer (RSO) who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters. The RSO's training and experience must include the types and quantities of licensed material to be authorized on the license. While

regulation does not require Type C broad scope licensees to have an RSO, 10 CFR 33.15 requires that the licensee establish administrative controls and provisions relating to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to assure safe operations. Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, such as an RSO.

Discussion: Each Type A and Type B program in which byproduct materials are used must appoint an RSO who is responsible for radiation safety and compliance with the regulations for the use of byproduct material. Each Type C broad scope program should appoint an individual who is responsible for the day-to-day operation of the radiation safety program. In a Type A broad scope license the RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met. The RSO should have full access to all activities involving the use of byproduct material and the authority to terminate any activity in which health and safety appear to be compromised without consulting with executive management or the RSC, if required. The applicant should submit a "Radiation Safety Officer Delegation of Authority" signed by executive management. Appendix J contains a model "Delegation of Authority" that is acceptable to NRC.

In a Type A broad scope licensed program, the RSO typically performs a preliminary review of proposed new uses and users, prior to formally discussing the proposal with the RSC. The RSC grants the formal approval of new users and uses in a Type A broad scope license. The task of reviewing and approving proposed uses and users in a Type B broad scope licensed program is the responsibility of the RSO. In a Type C broad scope program, individuals are qualified as users if they meet the training and experience criteria described in 10 CFR 33.15(b). While no licensee Committee or individual is required by regulation to make the determination that an individual is qualified to use the material possessed under the Type C broad scope license, or that a particular use of byproduct material is safe, licensee management is ultimately responsible for assuring safe operations.

The RSO performs audits of all areas of use and individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and user permit conditions. Specific duties and responsibilities of the RSO include:

- Monitoring and surveys of all areas in which radioactive material is used
- Oversight of ordering, receipt, surveys, and delivery of byproduct material
- Packaging, labeling, surveys, etc., of all shipments of byproduct material leaving the institution

- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits
- Training of all personnel
- Waste disposal program
- Inventory and leak tests of sealed sources
- Decontamination
- Investigating any incidents and responding to any emergencies
- Maintaining all required records.

The responsibilities of the RSO may not be transferred to other individuals. Many tasks and duties associated with managing the program may be assigned or delegated to other qualified individuals; however, the responsibility for these tasks and duties is with the RSO. NRC does recognize that a qualified individual will have to fill in for the RSO when the RSO will be away for short periods of time for professional conferences, vacation, or illness. However, this should not occur for extended or indefinite periods of time. Consideration should also be given to how this individual would be contacted in the event of an emergency.

When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, select an individual who is qualified to serve as the RSO. The RSO will need a basic technical knowledge sufficient to understand, in general, the majority of the work being done with byproduct materials under his or her responsibility. NRC recognizes that an RSO cannot be an expert in all areas that might be involved in a broad scope program. The RSO should be qualified by training and experience to perform the duties required for the position. Executive management should ensure that enough time is allocated to the individual selected as the RSO to carry out the responsibilities of the position.

The applicant should review the Radiation Safety Officer guidance provided in the base NUREG corresponding to the particular type of licensed program. For example, NUREG-1556, Volume 7, “Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,” contains guidance that is appropriate for broad scope licensees who are involved in research and development.

The applicant should also be aware of specific regulatory requirements for the RSO which may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for an RSO in a medical program. However, an individual who qualifies as a medical RSO is not necessarily qualified to be RSO in a broad scope program.

Chapters 3 and 4 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," describes the role of the RSO and selection of the RSO at medical facilities but it also contains information pertinent to all broad scope programs.

Response from Applicant:

For Type A and Type B Applicants:

- Submit the name of the proposed RSO
- Describe the training and experience for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license
- Submit a statement delineating the RSO's duties and responsibilities
- Submit a Radiation Safety Officer Delegation of Authority signed by the licensee's executive management.

For Type B Applicants, submit the criteria used by the RSO to approve of new users and uses of byproduct material.

For Type C Applicants, submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program, e.g., the RSO, who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee, as required by 10 CFR 30.32(c).

Applicants should provide specific information about the proposed RSO's training and experience which is relative to the licensed material requested in the application. Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, etc. This only serves to slow down the review process.

Note: It is important to notify NRC, as soon as possible, typically within 30 days, of changes in the designation of the RSO. The name and qualifications of the replacement RSO must be submitted to NRC as part of an amendment request. Applicants should review the regulations for specific program areas, such as medical uses, that have specific requirements regarding changes in the RSO.

8.7.4 RADIATION SAFETY OFFICE STAFF

Criteria: Licensees should provide sufficient staff to assist the Radiation Safety Officer in implementing the radiation safety program.

Discussion: The licensee should provide the RSO with a sufficient staff of professional and administrative support personnel. The number of staff and their qualifications will vary depending on the scope of the program. For small programs, the RSO may not require any assistance. Licensees should evaluate the licensed program and ensure that the RSO has adequate resources to effectively manage the program.

Chapters 6 and 7 of NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," discusses the subjects of radiation safety program resources and the use of consultants and service companies at medical facilities, but contains information pertinent to all broad scope programs.

Response from Applicant: No response is required.

8.8 ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO OCCUPATIONAL WORKERS AND ANCILLARY PERSONNEL)

Regulations: 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 30.33(a)(3); and 10 CFR 30.34(e).

Criteria: Before beginning work with or in the vicinity of licensed material, all individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training.

Discussion: 10 CFR 19.12(a) describes the training that licensees are required to provide individuals who, in the course of their employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). 10 CFR 19.12(b) requires that the licensee, in determining which individuals are subject to the training requirements of 19.12(a), consider assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during the life of a licensed facility. While many licensees can demonstrate that it is not likely during a normal situation for a laboratory worker, manufacturing technician, hospital technologist, or environmental services worker at their facility to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these individuals and others could reasonably be expected to receive this level of exposure during abnormal situations (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Practical, site-specific training should be provided for all

individuals prior to beginning work with or in the vicinity of licensed material. Periodic refresher training should also be provided. Topics covered should, at a minimum, include those described in 10 CFR 19.12(a). The training may take any form. Many licensees utilize video tapes or interactive on line or off line computer programs to provide training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual who is familiar with the licensee's program.

Retraining should be performed whenever there is a change in duties or the work environment and at a frequency sufficient to ensure that all staff are adequately trained.

Applicants should review the model training program described in the appropriate base NUREG corresponding to the particular type of licensed program. For example, NUREG-1556, Volume 7 describes a training program that is acceptable to NRC for licensees who are involved in research and development, and Volume 9 describes a training program that is acceptable to NRC for licensees who possess radioactive material for medical use.

The applicant should also be aware of additional specific training requirements that may apply to their licensed program. For example, 10 CFR Part 35 contains specific requirements for the training of individuals who will work under the supervision of medical authorized users.

Response from Applicant:

- Submit a description of the radiation safety training program developed for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training; or
- Identify the model training program described in the appropriate base NUREG corresponding to your particular type of licensed program and submit a statement that this training program will be implemented.

In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety training program without amendment of the license as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement your submitted training program.

8.9 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 20.1101(b); 10 CFR 20.1101(d); 10 CFR 20.1406; 10 CFR 30.33(a)(2); 10 CFR 30.34(e); 10 CFR 30.35(g); 10 CFR 33.13; 10 CFR 33.14; and 10 CFR 33.15.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. They must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants for all broad scope licenses need to demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and its employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the types and quantities of radioactive materials to be used. Facilities and equipment designed to control exposure can range from a vial that contains licensed material, to buildings, fences, or exclusion areas that are between the source and the maximally exposed member of the public. These facilities not only reduce the exposure from the source but may also limit access to the source. The licensee should list and describe these facilities for the following purposes:

- To show compliance with a regulation
- To demonstrate the use of the material will be within the ALARA concept
- To meet emergency response requirements.

Licensees should consider controlling exposures through available engineering options, as well as through limiting the releases of effluents to the environment. The licensee should describe all facilities and equipment essential to achieving these goals. The licensee will also need to describe the criteria that will be used by the RSC and/or RSO, as appropriate, to review and approve of proposed facilities. Facilities and equipment used for special applications where the impact upon workers or the public could be significant if radioactive material were released accidentally, need to be specifically described. These would include, for example, room irradiators, specialized iodination/tritiation facilities, alpha laboratories, radioactive waste processing facilities (including incinerators, compactors, liquid reclamation processors, etc.), radioactive waste storage facilities (including decay-in-storage locations), individual laboratories processing 3.7 gigabecquerels (GBq) (100 millicuries) or more of radioactive materials per experiment or process, nuclear pharmacies, specially designed therapy rooms, and sealed source storage areas. Significant modifications affecting facilities and equipment should have prior RSO review and RSC approval before commencement of such modifications.

Also note that if radioactive materials will be used in or on animals, a description of the animal handling and housing facilities will need to be discussed. Appendix H of NUREG-1556, Volume 7, “Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,” provides guidance on the information that should be addressed concerning the use of radioactive materials in animals.

In your discussion of the criteria used to evaluate your facilities and equipment, you should include a discussion on how a laboratory or facility classification scheme relates to toxicity and quantity of radioactive material and your facility and equipment requirements. For example, the

International Atomic Energy Agency (IAEA), as well as other health physics and industrial hygiene professional organizations, has developed classification schemes used in assessing minimum needs (e.g., equipment and facilities, user training, personnel monitoring, surveys) that consider the hazard and quantity of byproduct materials to be used (IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition.") Applicants may consider the development of such a classification scheme since it can be correlated with all aspects of the radiation safety program. Each applicant's scheme should be based upon the types and quantities of radioactive material anticipated to be used. The criteria used to develop the classification scheme should be provided to each RSC member for use when evaluating requests to use licensed materials.

Appendix K provides the radionuclide toxicity and laboratory classification information excerpted from IAEA, which is acceptable to the NRC staff. This table is not all inclusive and is meant to be used as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt. Your application will need to describe the minimum facilities and equipment requirements for each laboratory classification.

Appendix L provides additional guidance regarding facilities and equipment used to handle radioactive materials in a laboratory setting.

Response from Applicant: Describe the criteria your RSC and/or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). Your description will need to include your method of classifying laboratories based on type, toxicity and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme that take into consideration shielding, the proximity of radiation sources to unrestricted areas and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems including pertinent airflow rates, pressures, filtration equipment and monitoring systems. For special application facilities, such as those facilities described above, you will need to specify their locations (i.e. buildings and room numbers) and special considerations that your RSC and/or RSO will use in authorizing byproduct material use. Also describe your procedures for control, review, and approval of significant facilities or equipment modifications.

8.10 ITEM 10: RADIATION SAFETY PROGRAM

8.10.1 AUDIT PROGRAM

Regulations: 10 CFR 33.13(c); 10 CFR 33.14(b); 10 CFR 33.15(c); 10 CFR 20.1101; and 10 CFR 20.2102.

Criteria: Applicants for Type A, Type B, and Type C broad scope licenses are required by 10 CFR 33.13(c), 33.14(b), and 33.15(c) respectively, to establish administrative controls and provisions relating to management review necessary to ensure safe operations.
10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation, periodically (at least annually). Licensees are required by 10 CFR 20.2102 to maintain records of the radiation protection program, including: (1) the provisions of the program; and (2) audits and other reviews of the program contents and implementation.

Discussion:

Management and Radiation Safety Committee Audits

The application for a Type A, B, or C broad scope license should discuss executive management oversight of the licensed program and the mechanisms they will use to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program. This oversight may include independent audits of the program, frequent meetings with the RSC and/or RSO as appropriate, and periodic tours of selected facility areas.

In a Type A broad scope program, the RSC assists executive management in performing this oversight function. Detailed written procedures should be developed and implemented for the operation of the RSC to ensure that appropriate oversight is provided. The RSC should be fully aware of the operations and activities of the Radiation Safety Office. The RSC should conduct periodic interactive management audits and evaluations of the Radiation Safety Program's performance, including: non-conformance reports; corrective action; status reports and audits; incident investigation reports; ALARA program development and implementation; effluent releases; qualification and radiological safety training; and performance of the RSO. Results of the RSC's audit and program reviews should be reported to executive management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions.

Appendix M contains a model audit program that is acceptable to NRC for use in the review of most non-medical broad scope programs.

10 CFR 20.1101(c) requires the licensee to review the radiation program content and implementation periodically (at least annually). Generally, these audits are conducted at least once every 12 months.

Internal Audits

The application should describe the audit mechanism implemented by the RSO and her or his staff, or other individual who is responsible for the day-to-day operation of the licensed program, to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health

physics practices. The audit program should include routine unannounced inspections of each user's facility and practices to supplement and audit the routine monitoring performed by the user. Facility inspections should include:

- Review of user inventory and survey records
- Evaluation of user and technician training through discussion and observation of work practices
- Performance of independent surveys of user work areas
- Evaluation of compliance with NRC regulations, the conditions of the license, the RSC/RSO permit and safety manual requirements
- Provision for performance-based instruction to users and technical-level staff.

The types and frequencies of monitoring performed by the RSO should be indicated. The intervals of surveys and audits should be frequent enough to ensure close communications and proper surveillance of individual radioactive material users. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high use facilities and users of volatile radioactive materials may be audited weekly or biweekly, intermediate use facilities may be audited monthly, and low-level facilities may be audited quarterly).

If an audit identifies violations of NRC requirements, the licensee should evaluate the safety significance of each violation to set priorities and identify resources to correct these violations. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. Certain identified problems or potential violations may require notification or a report to the NRC. For information on NRC's reporting requirements, refer to "Guide to NRC Reporting and Recordkeeping Requirements," NUREG-1460, Revision 1, dated July 1994. NUREG-1460, Revision 1, was compiled from requirements in Title 10 of the U.S. Code of Federal Regulations as codified on December 31, 1993. Appendix N of this document describes the more common NRC reporting requirements. Licensees are encouraged to contact NRC for guidance if there is any uncertainty regarding a reporting requirement. NRC routinely reviews licensees' records to verify if appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. NRC can exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. For information on NRC's use of discretion in issuing a notice of violation, refer to the current version of NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

The NRC's emphasis in inspections is for applicants to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced

audits of byproduct material users to determine if, for example, safe use of radionuclide procedures and emergency procedures are available and are being followed.

Recordkeeping

10 CFR 20.2102 requires that licensees maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record. Records of audits should include: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspection by the NRC.

Response From Applicant:

- Describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised. In addition, if you are upgrading your limited scope license to a Type A broad scope license or you are renewing your Type A broad scope license, describe the RSC's involvement in these oversight mechanisms.
- The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101 to the NRC for review during the licensing phase. The adequacy of this audit program will be reviewed during NRC inspection.
- Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health physics practices.

In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license as discussed in Sections 1 and 8.7.2 of this document, describe the process you will use to revise and implement your audit program.

References: See the Notice of Availability on the inside cover of this report to obtain copies of NUREG-1460, Revision 1, "Guide to NRC Reporting and Recordkeeping Requirements," dated July 1994; NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions;" and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action." The current version of NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions," is available electronically at <http://www.nrc.gov/OE>. INs are available in the "Reference Library" on NRC's Home Page at <http://www.nrc.gov>.

8.10.2 RADIATION MONITORING INSTRUMENTS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103(a); 10 CFR 30.33(a)(2); 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15; 10 CFR 34.25; and 10 CFR 35.51.

Criteria: Licensees must, pursuant to 10 CFR 20.1501, possess and periodically calibrate radiation monitoring instruments that are necessary to protect health and minimize danger to life or property.

Discussion: Licensees must possess an adequate number of radiation detection and measurement instruments as necessary and ensure they are calibrated periodically for the radiation being measured. For purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. The choice of instrument needs to be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.).

The applicant should submit the criteria used in determining what radiation detection and monitoring equipment will be required for each type of use by authorized users and the availability of a sufficient quantity of these instruments to both the radiation safety office and authorized users (e.g., ion-chambers, G-Ms, air samplers, liquid scintillation counters).

NRC requires that survey instruments used to determine compliance with regulatory requirements be calibrated periodically by the instrument manufacturer or persons specifically authorized by NRC or an Agreement State. Survey instruments should be calibrated at least annually (every 12 months), unless otherwise specified by regulation or license condition. Licensees seeking authorization to perform their own survey instrument calibrations will need to submit calibration procedures for review. The licensee may wish to review available industry standards for calibration of instruments such as ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Appendix O of this document provides useful information about instrument specifications and model calibration procedures that are acceptable to NRC.

Some instruments may only need to be checked periodically for operability and response to radiation rather than receive full calibration. For example, Geiger-Mueller (G-M) type survey instruments used to identify contamination in laboratories may only need to be checked for ability to detect low level contamination.

Applicants will need to submit their method for assuring that instruments are checked and/or calibrated at proper frequencies.

Response from Applicant:

- Provide the criteria used by your RSC and/or RSO, as appropriate, to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities.

- Discuss how the RSC and/or RSO, as appropriate, will assure that instruments are properly calibrated at prescribed frequencies.
- Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor who is licensed by NRC or an Agreement State to perform instrument calibrations. Licensees who want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix O of this document.

In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your instrument specifications and procedure for calibration of instruments without amendment of the license as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement these submitted procedures.

Note: If you wish to perform instrument calibration as a commercial service, you will need to either amend your existing broad scope license or apply for a new NRC license authorizing commercial calibration service.

8.10.3 MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1501(a); 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2001; 10 CFR 20.2108(b); 10 CFR 20.2201; 10 CFR 30.34(e); 10 CFR 30.35(g); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 33.13; 10 CFR 33.14; and 10 CFR 33.15.

Criteria: Licensees must, pursuant to 10 CFR Parts 20, 30, and 33, develop, implement, and maintain written procedures for all of the following:

- Purchasing and receipt of radioactive material
- Safely receiving and opening packages
- Ensuring control and accountability of licensed material.

The licensee must also maintain records of receipt, utilization, transfer, and disposal of licensed material.

Discussion: Applicants for a broad scope license are required to establish appropriate administrative controls and provisions that are necessary to assure safe operations including procedures to assure the control of procurement and use of byproduct material. Administrative procedures must assure that only authorized individuals receive radioactive materials and that individuals receive only the types and quantities of radioactive material that they are authorized to receive.

Applicants for a broad scope license are strongly encouraged to develop an administrative procedure to control procurement and use of radioactive material that emphasizes centralized purchasing and receipt. NRC has found centralized purchasing and receipt to be effective in controlling licensed materials entering the licensed institution through normal commercial channels, particularly for larger institutions. Procedures must also be established to control licensed materials obtained outside of the normal channels, e.g., through the loan or transfer of materials without purchase or through surplus. Appendix P of this document describes a model procedure for controlling procurement and use of radioactive material that is acceptable to NRC.

Licensees are required to develop, implement, and maintain written procedures for safely receiving and opening packages in accordance with 10 CFR 20.1906. Appendix P of this document describes a model procedure for safely receiving and opening packages containing licensed materials that is acceptable to NRC.

Applicants for a broad scope license are required to establish appropriate administrative controls and provisions relating to material control and accounting that are necessary to assure safe operations. Licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay of unsealed licensed material (e.g., computer programs, manual ledgers, log books, etc.). These methods help to assure that licensee and individual authorized user possession limits are not exceeded. Licensees who possess sealed sources are required to perform periodic inventories. The frequency of these inventories is normally established by license condition as every 6 months; however, regulation may specify a different inventory frequency (e.g., sealed sources used for medical therapy are required to be inventoried every 3 months).

Licensed material is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory being in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the NRC Regional Office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage. Applicants for broad scope licenses must establish policies and procedures to ensure compliance with security requirements.

Licensees must maintain records of receipt, use, transfer, and disposal of all licensed material. Table 8.1 below lists each type of record and how long the record must be maintained.

Table 8.1 Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Information about locations where licensed material is used or stored are among the records important to decommissioning and required by 10 CFR 30.35(g). See also the section on "Financial Assurance and Recordkeeping for Decommissioning."

Response from Applicant:

- Describe your administrative procedures to assure control of procurement and use of byproduct material.
- While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. These procedures will be reviewed during inspection.
- Describe your administrative controls and provisions relating to materials control, accounting and security.

In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your administrative procedures to assure control of procurement and use of byproduct material and your administrative controls and provisions relating to material control, accounting and security, without amendment of your license as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be utilized by your Radiation Safety Committee to revise these administrative procedures, controls, and provisions.

8.10.4 OCCUPATIONAL DOSE

Regulations: 10 CFR 20.1201; 10 CFR 20.1202; 10 CFR 20.1203; 10 CFR 20.1204; 10 CFR 20.1207; 10 CFR 20.1208; 10 CFR 20.1501; 10 CFR 20.1502; 10 CFR 20.1703; 10 CFR 20.2106; and 10 CFR 20 Appendix B.

Criteria: The use of individual monitoring devices for external dose is required, pursuant to 10 CFR 20.1502(a), for:

- Adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 0.005 Sv (0.5 rem) deep-dose equivalent.
  - 0.015 Sv (1.5 rems) eye dose equivalent.
  - 0.05 Sv (5 rems) shallow-dose equivalent to the skin.
  - 0.05 Sv (5 rems) shallow-dose equivalent to any extremity.

- Minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately):
  - 1.0 mSv (0.1 rem) deep-dose equivalent.
  - 1.5 mSv (0.15 rem) eye dose equivalent.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to the skin.
  - 0.005 Sv (0.5 rem) shallow-dose equivalent to any extremity.

- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.
- Individuals entering a high or very high radiation area.

Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for:

- Adults likely to receive in 1 year an intake in excess of 10% of the applicable Annual Limit of Intake (ALI) for ingestion and inhalation.
- Minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

Discussion: If an adult is likely to receive in 1 year a dose greater than 10% of any applicable limit, monitoring is required. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that the individual is not likely to exceed 10% of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. For individuals who received exposure at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining

the need for monitoring, and therefore, recordkeeping and reporting requirements. If it is determined that monitoring is not required and a subsequent evaluation shows that the 10% threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations or other estimates to produce a "best estimate" of the actual dose received.

If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "NR" for "Not Required" in the blocks on NRC Forms 4 and 5 to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "Not Detectable."

If the prospective evaluation shows that the individual is likely to exceed 10% of an applicable limit, then monitoring, and reporting of the results of monitoring performed regardless of the actual dose received, is required. If air sampling or bioassay is required, discussion of air sampling or bioassay should provide enough detail that the NRC staff is assured that appropriate steps will be taken to manage and monitor such exposure.

Table 8.2 Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay that may be Applicable

Regulatory Guide 8.7, Revision 1	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20	Applications of Bioassay for I-125 and I-131
Regulatory Guide 8.21	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants
Regulatory Guide 8.23	Radiation Safety Surveys at Medical Institutions
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Doses
Regulatory Guide 8.35	Planned Special Exposures
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
Regulatory Guide 8.37	ALARA Levels for Effluents from Materials Licensees
NUREG-0938	Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure
NUREG-4884	Interpretation of Bioassay Measurements
ANSI N13.30-1996	"Performance Criteria for Radiobioassay," dated 1996

Additional References for Further Reading:

1. U.S. Department of Energy DOE G 441.1-2, "Occupational ALARA Program Guide," March 17, 1999.

2. U.S. Department of Energy DOE G 441.1-3, "Internal Dosimetry Program Guide," March 17, 1999.

3. U.S. Department of Energy DOE G 441.1-4, "External Dosimetry Program Guide," March 17, 1999.

4. U.S. Department of Energy DOE G 441.1-8, "Air Monitoring Guide," March 17, 1999.

5. U.S. Department of Energy DOE G 441.6-1, "Evaluation and Control of Radiation Dose to the Embryo/Fetus," April 1998.

Response from Applicant: Submit a description of the method used to demonstrate compliance with the referenced regulations or submit a statement that an evaluation disclosed that individuals do not require monitoring.

In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise your personnel dosimetry program without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement your submitted personnel dosimetry program.

8.10.5 PUBLIC DOSE

Regulations: 10 CFR 20.1003; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; and 10 CFR 20.2107.

Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed in such a way that the total effective dose equivalent (TEDE) to members of the public will not exceed more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour.

Discussion: Public dose is defined in 10 CFR Part 20 as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 10 CFR 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 10 CFR 20.2003. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on whether the individual is in a restricted area, a controlled area, or an unrestricted area when the dose is received.

There are both external exposure components and internal exposure components of public dose. The licensee should review all possible internal and external exposure pathways and decide which are applicable to its operations.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1302(b). The extent and frequency of monitoring will depend upon the nature of the licensee's operations, potential releases, exposures and pathways to cause public dose or environmental contamination. For additional guidance regarding monitoring of effluents, refer to section entitled "Radiation Safety Program - Surveys."

10 CFR 20.2107 requires that licensees maintain survey and monitoring records that demonstrate compliance with the dose limits for members of the public until the Commission terminates the license.

Response from Applicant: No response is required from the applicant, but records and written materials documenting compliance will be examined during inspection. During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public.

For guidance about accepted methodologies for determining doses to members of the public, see Appendix Q of this document.

8.10.6 SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 30.32(i); 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 30.72; 10 CFR 33.13; 10 CFR 33.14; and 10 CFR 33.15.

Criteria: Licensees are required, pursuant to the regulations stated above, to:

- Keep radiation doses to workers and members of the public ALARA
- Ensure security of licensed material
- Make required notifications to NRC of events.

Discussion: Licensees are responsible for developing and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who may not be knowledgeable about radioactive materials cannot be exposed to or contaminated by the material, and individuals cannot take the material. When any licensed materials are in use in controlled or unrestricted areas, they must be under constant surveillance so that the radiation worker can prevent others from becoming contaminated by or exposed to the material, or prevent persons from removing the material from the area.

Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include:

- Storage and use of licensed materials only in restricted areas;
- Limiting access to an entire facility or building or portion of the building only to radiation workers;
- Providing storage areas that can be locked to prevent access to the material; and
- Implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use.

You should develop procedures that clearly state acceptable methods to secure licensed material at your facility. Particular attention may be required at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities, and waste processing facilities. Your security procedures may be in a separate document or included in the "General Safety Procedures."

Applicants should develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. General safety guidelines are described in Appendix R of this document. Licensees are encouraged to use these guidelines in developing procedures for the safe use of radioisotopes.

Licensees need to identify all areas that require posting in accordance with 10 CFR 20.1902, unless they meet the exemptions listed in 10 CFR 20.1903. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 10 CFR 20.1904, unless they meet the exemptions in 10 CFR 20.1905.

Applicants need to establish written procedures to handle emergencies ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, individual users should have a clear understanding of their limitations in an emergency, with step-by-step instructions and clear direction of whom to contact. Model Emergency Procedures that are acceptable to NRC are described in Appendix R of this document.

Emergency spill kits should be strategically placed in well marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished, as necessary. The licensee should also consider establishing an Emergency Response Team composed of individuals experienced in various emergency response functions (e.g., radiological, medical, emergency management, security, and fire protection).

10 CFR 20.2201-20.2203, 10 CFR 21.21 and 10 CFR 30.50 require certain incidents and emergencies be reported to NRC. Appendix N of this document provides examples of some events that require notification and/or reports. Note that Appendix N is not all inclusive, as there are other notification and/or reporting requirements that may apply to your specific program (i.e. 10 CFR Parts 34, 35, 36, 39 etc.). NUREG-1460, Revision 1, "Guide to NRC Reporting and Recordkeeping Requirements," is a compilation of requirements based on regulations codified as of December 31, 1993.

If you plan to possess quantities of material in excess of the applicable amounts listed in 10 CFR 30.72, Schedule C, then you may also be required to submit an "Emergency Response Plan for Responding to a Release." See Section 8.5.1 for specific information related to this requirement.

Response from Applicant: Submit your procedures for safe use of radionuclides and emergencies. Your submission should include procedures for maintaining security of licensed radioactive materials. As an alternative, you may state "We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license, and you want the flexibility to revise your safe use and emergency procedures without amendment of the license as described in Sections 1 and 8.7.2 of this document, discuss the process that will be used to revise and implement your submitted safe use and emergency procedures.

8.10.7 SURVEYS

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 30.53; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15; 10 CFR 34.27(c)(2); 10 CFR 34.67; 10 CFR 35.59(d); 10 CFR 36.81(h); and 10 CFR 39.35(a).

Criteria: Licensees are required, pursuant to the regulations listed above, to make surveys of potential radiological hazards in their workplace. NRC requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak test results must be maintained.

Discussion: Survey is defined as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. These evaluations may be measurements (e.g., radiation levels measured with a survey instrument or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The licensees must interpret and evaluate such measurements and calculations to take appropriate action. The selection and proper use of

appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public. In certain cases, environmental monitoring may be required to demonstrate compliance with 10 CFR Part 20.

Surveys are required when it is necessary for the licensee to comply with the regulations or to evaluate a radiological hazard. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material or where licensed material is or could be released to unrestricted areas.
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer.
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement, *in vivo* counting, or by analysis and evaluation of material excreted or removed from the human body.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

10 CFR Part 20 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area.

Appendix S of this document describes survey procedures that are acceptable to NRC.

NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. Also, NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM),"

dated December 1997, should be reviewed by licensees who have large facilities to decommission.

Leak Test

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by NRC or an Agreement State and specified by the Sealed Source and Device (SSD) Registration Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerels (Bq) (0.005 microcuries) of radioactivity.

Leak tests are not required if:

- Sources contain only hydrogen-3 (tritium)
- Sources contain only byproduct material with a half-life of less than 30 days
- Sources contain only a radioactive gas
- Sources contain 3.7 megabecquerels (MBq) (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kilobecquerels (kBq) (10 microcuries) or less of alpha-emitting material
- Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see Appendix T of this document.

Response from Applicant:

- Surveys

  Submit procedures to evaluate radiological hazards, both external and internal. If you wish, you may state "we will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, Volume 11, 'Program-Specific Guidance About Licenses of Broad Scope.'"

- Leak Testing

  Submit your leak test procedures. As an alternative, you may state, "we will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, 'Program-Specific Guidance About Licenses of Broad Scope.'"

In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license, and you want the flexibility to revise your survey or leak test program without

amendment of the license, as described in Sections 1 and 8.7.2 of this document, discuss the process that will be used to revise and implement your submitted survey and leak test program.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985.

8.10.8 TRANSPORTATION

Regulations: 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 33.13; 10 CFR 33.14; 10 CFR 33.15; 10 CFR 34.35; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.47; 10 CFR 71.87; and 49 CFR Parts 171-178.

Criteria: Broad Scope licensees who will transport or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with NRC and U.S. Department of Transportation (DOT) regulations.

Discussion: Department of Transportation regulations (49 CFR) were written to help assure that transportation of hazardous materials in *commerce* were transported uniformly and safely. NRC licensees who transport byproduct material (hazardous material) in commerce would, therefore, be required to comply with all applicable regulations found in DOT. However, many NRC licensees routinely transport byproduct material that is not in commerce. In 1979, 10 CFR 71.5 was codified to ensure that all NRC licensees who transport byproduct material, in commerce or not, transport byproduct material in a uniformly safe manner. Some broad scope licensees have applied for certain exemptions to 10 CFR 71.5; however, those exemption requests to 10 CFR 71.5 were not granted. NRC's position regarding the transportation regulations in 49 CFR is that they already allow for flexibility and are thus considered to be performance-based requirements rather than prescriptive requirements. For example, packages shipped by broad scope licensees frequently meet the "Limited Quantity" criteria as described in 49 CFR 173.421 and are therefore excepted from certain DOT requirements provided certain other less restrictive requirements are met. Appendix U of this document provides an overview of the transportation requirements commonly affecting NRC licensees. Licensees may also wish to review NUREG-1660, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," published jointly by NRC and DOT in November 1998.

Knowing how 10 CFR 71.5 and 49 CFR interrelate is very important to broad scope programs. Therefore, it is imperative that your radiation safety staff be thoroughly familiar with 10 CFR 71.5 and 49 CFR in order to comply and to take full advantage of the flexibility inherent in DOT requirements.

Licensed material, including radioactive waste, must be packaged and transported in accordance with NRC and DOT requirements if the transportation involves the use of public highways. In addition, broad scope licensees need to develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if such transportation does not involve the use of public highways.

Licensees also need to consider the safety of all individuals who may handle or may come in contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that the radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of 10 CFR 71.47, but are ALARA.

Licensees shipping radioactive waste for disposal must prepare appropriate documentation as specified in 10 CFR 20, Appendix G.

Response from Applicant: No response is needed from applicants during the licensing phase. Compliance with transportation requirements will be reviewed during NRC inspections.

Reference: "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1983 revision)" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training, at (202) 366-4900. The Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) is available from NRC upon request.

8.11 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1501; 10 CFR 20.2001; 10 CFR 20.2002; 10 CFR 20.2003; 10 CFR 20.2004; 10 CFR 20.2005; 10 CFR 20.2006; 10 CFR 20.2007; 10 CFR 20.2108; and 10 CFR 30.51.

Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements, and appropriate records of waste disposal must be maintained.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal unless specifically authorized by NRC.

The U.S. Environmental Protection Agency (EPA) issued guidance for developing a comprehensive program to reduce hazardous waste. This guidance was transmitted to licensees

by the NRC in IN-94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Program," dated March 1994. The 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, etc.).

The following methods of waste disposal may be considered and should be addressed in the application as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with 10 CFR 20.2001(a). Each shipment must comply with all applicable NRC and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Decay-In-Storage (DIS) and Extended Interim Storage

The NRC has concluded that materials with half-lives of less then or equal to 120 days are appropriate for DIS and interim storage. The minimum holding period for decay is ten half-lives of the longest lived radioisotope in the waste. Such waste may be disposed of as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

The NRC does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, 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," dated February 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW.

A model procedure for DIS is contained in Appendix V of this guidance document.

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents. Applicants who are considering release of radioactive material into air and water should review Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents, and references documents containing acceptable methods of effluent monitoring.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. 10 CFR 20.2003 authorizes disposal of licensed material by release into a public sanitary sewerage system if certain conditions are met. Licensees are responsible for demonstrating that licensed materials discharged into the public sewerage system are readily soluble in water or are biological materials that are readily dispersible in water. NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides the criteria for evaluating solubility of waste. Licensees should carefully consider the possibility of reconcentration of radioisotopes that are released into the sewer. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewerage systems in IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage meet the criteria stated in 10 CFR 20.2003 and do not exceed the monthly and annual limits specified in regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage. A model procedure for disposal of radioactive waste via sanitary sewer and maintenance of records is described in Appendix V of this guidance document.

If your facility maintains a private sewerage treatment system, a septic system, or leach fields, the regulations of 10 CFR 20.2003 are not applicable for releases to these systems (see 10 CFR 20.1003, definition of "sanitary sewerage"). You may make releases of liquids to private sewerage systems, septic systems, or leach fields as effluents released to unrestricted areas pursuant to 10 CFR 20.1302(b)(2)(i).

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in Item 8.10.7 of your application. Contaminated sludges will be required to be disposed of as radioactive waste using one of the methods described in this Section. Applicants may obtain approval of alternative disposal methods through application to the Commission, as described in 10 CFR 20.2002.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004. 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 or transferred to a specific licensee. Policy and Guidance Directive PG 8-10, "Disposal of Incinerator Ash as Ordinary Waste," dated January 1997, provides guidance relative to the disposal of ash. A model procedure for incineration of waste is described in Appendix V of this guidance document.

Applicants who are considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Waste Volume Reduction

Waste volume reduction operations that could create a radiological hazard to licensee employees or the general public must be described in detail in the application. A model procedure for waste compaction is described in Appendix V of this guidance document.

Disposal of Specific Waste as If it Were Not Radioactive

The following radioactive wastes may be disposed of as non-radioactive waste:

- Liquid scintillation medium containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram of the medium; and
- Animal carcasses or animal tissue containing no more than 1.85 kBq (0.05 microcuries) of H-3 or C-14 per gram averaged over the weight of the entire animal.

Applicants should have procedures that will ensure that the above limits are not exceeded and that the disposal of animal tissue or carcasses containing licensed material is in a manner that will not permit their use either as food for humans or animals. Applicants must maintain accurate records of these disposals.

Burial

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.

Other Methods Specifically Approved by the NRC Pursuant to 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

The 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% to 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.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Response from Applicant:

Provide procedures for waste collection, storage, and the disposal by any of the authorized methods described in this section. Applicants should contact appropriate Regional Office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.

Note: Applicants do not need to provide information to NRC if they plan to dispose of LLW via transfer to an authorized recipient or to dispose of liquid scintillation media or animals containing low levels of H-3 or C-14, as authorized by 10 CFR 20.2005.

8.12 ITEM 12: FEES

The next two items on NRC Form 313 are to be completed on the form itself.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.13 ITEM 13: CERTIFICATION

Representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. NRC will return all unsigned applications for proper signature.

Note:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date.

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests, applicants must do the following:

- Be sure to use the most recent information concerning your program in preparing an amendment or renewal request.
- Submit in duplicate, either an NRC Form 313 or a letter requesting amendment or renewal.
- Provide the license number.
- For renewals, provide a complete and up-to-date application. Licensees should not reference previously submitted documents; rather, these documents should be resubmitted.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31; 10 CFR 20.2301, 10 CFR 30.11; 10 CFR 34.111; 10 CFR 35.19; 10 CFR 36.17; and 10 CFR 39.91.

Criteria: Licensees may request exemptions to regulations. The licensee must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

Discussion: Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11(a)). These regulations state that NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests must be accompanied by descriptions of the following:

- Exemption and justification of why it is needed
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested
- Alternative methods for complying with the regulation and why compliance with the existing regulation is not feasible.

Until NRC has granted an exemption in writing, NRC expects strict compliance with all applicable regulations.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b); 10 CFR 30.35(g); 10 CFR 30.36(d); 10 CFR 30.36(g); 10 CFR 30.36(h); 10 CFR 30.36(j); 10 CFR 30.51(f); 10 CFR 20.1401; 10 CFR 20.1402; 10 CFR 20.1403; 10 CFR 20.1404; 10 CFR 20.1405; and 10 CFR 20.1406.

Criteria: Pursuant to the regulations described above, the licensee must do the following:

- Notify NRC, in writing, within 60 days of:
  - — the expiration of its license
  - — a decision to permanently cease licensed activities at the *entire site* (regardless of contamination levels)
  - — a decision to permanently cease licensed activities in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements
  - — no principal activities having been conducted at the *entire site* under the license for a period of 24 months
  - — no principal activities having not been conducted for a period of 24 months in *any separate building or outdoor area*, if they contain residual radioactivity making them unsuitable for release according to NRC requirements.
- Submit decommissioning plan, if required by 10 CFR 30.36(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and 10 CFR 30.36(j).
- Submit, to the appropriate NRC Regional Office, completed NRC Form 314, "Certificate of Disposition of Materials" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: As discussed above in "Criteria," before a licensee can decide whether it must notify NRC, the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

The permanent cessation of principal activities in an individual room or laboratory may require the licensee to notify NRC if no other licensed activities are being performed in the building.

This also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

Draft Regulatory Guide DG-4006, "Demonstrating Radiological Criteria For License Termination," issued July 8, 1998 and NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. Appendix B of the Handbook contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission. An acceptable screening computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is D and D, Version 1; this was issued on August 20, 1998. Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the Federal Register (Volume 63, Number 222, Page 64132-64134) on November 18, 1998. This includes the following acceptable license termination screening values of common radionuclides for building surface contamination.

Table 11.1 Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination

Radionuclide	Symbol	Acceptable Screening Levels*
hydrogen-3 (tritium)	^{3}H	1.2×10^{8}
carbon-14	^{14}C	3.7×10^{6}
sodium-22	^{22}Na	9.5×10^{3}
sulfur -35	^{35}S	1.3×10^{7}
chlorine-36	^{36}Cl	5.0×10^{5}
manganese-54	^{54}Mn	3.2×10^{4}
iron-55	^{55}Fe	4.5×10^{6}
cobalt-60	^{60}Co	7.1×10^{3}
nickel-63	^{63}Ni	1.8×10^{6}
strontium-90	^{90}Sr	8.7×10^{6}
technetium-99	^{99}Tc	1.3×10^{6}
iodine-129	^{129}I	3.5×10^{4}

Radionuclide	Symbol	Acceptable Screening Levels*
cesium-137	^{137}Cs	2.8×10^4
iridium-192	^{192}Ir	7.4×10^4

* Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100% of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10% to 100% range) may calculate site-specific screening levels using D and D Version 1, based on site-specific resuspension factor. For Unrestricted Release (dpm/100 cm^2) Units are disintegrations per minute per 100 square centimeters (dpm/100 cm^2). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in 10 CFR 20.1402. For radionuclides in a mixture, the "sum of fractions" rule applies; see 10 CFR Part 20, Appendix B, Note 4. Refer to NRC Draft Guidance DG-4006 for further information on application of the values in this table.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then any necessary decommissioning activities must be undertaken, NRC Form 314 or equivalent information must be submitted, and other actions must be taken as summarized in the Criteria.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional Offices. (See Figure 2.1 for addresses and telephone numbers).

Appendix A

List of Documents Considered in Development of this NUREG

List of Documents Considered in Development of this NUREG

Table A.1 List of Documents Considered in Development of this NUREG

Document	Incorporated	Superceded
Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope," dated October 1994	Yes	Yes
Regulatory Guide 10.5, "Applications for Type A Licenses of Broad Scope," dated December 1980	Yes	Yes
Proposed Revision 2 to Regulatory Guide 10.5, "Guide for the Preparation of Applications for Type A Licenses of Broad Scope," dated February 1985	Yes	Yes
Draft Regulatory Guide DG-4006, "Demonstrating Radiological Criteria for License Termination," issued July 8, 1998	Yes	No
Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," dated January 1992	Yes	No
Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under Parts 30, 40, 70, and 72," dated June 1990	Yes	No
Draft Regulatory Guide FC 412-4, "Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services," dated June 1985	Yes	No
Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996	Yes	No
Policy and Guidance Directive FC 85-07, "Standard Review Plan for Applications for Type A Licenses of Broad Scope," dated June 1994	Yes	Yes
Policy and Guidance Directive FC 84-20, "Impact of Revision of 10 CFR Part 51 on Materials License Actions," dated March 9, 1994	Yes	No
Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses."	Yes	No
Policy and Guidance Directive FC 408-4, "Guide for the Preparation of Applications for Type A Licenses of Broad Scope (Proposed Revision 2 to Regulatory Guide 10.5)"	Yes	Yes

Document	Incorporated	Superceded
FC 92-02, "Guidance on Licensing Medical Facilities with Broad Scope Programs," dated June 1992.	Yes	Yes
Policy and Guidance Directive FC 84-21, "Incineration by Materials Licensees," dated December 5, 1984	Yes	No
NRC Inspection Manual, Inspection Procedure 87100	Yes	No
NUREG-1516, "Management of Radioactive Material Safety Programs at Medical Facilities," dated May 1997	Yes	No
NUREG-1460, Revision 1, "Guide to NRC Reporting and Recordkeeping Requirements," dated July 1994	Yes	No
NUREG-1337, Revision 1, "Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated August 1989	Yes	No
NUREG-1660, "U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," published November 1998	Yes	No
NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997	Yes	No
NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997	Yes	No
IAEA Safety Standard, Safety Series 1, "Safe Handling of Radionuclides," dated 1973	Yes	No
ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments"	Yes	No
ANSI N13.30-1996, "Performance Criteria for Radiobioassay"	Yes	No
Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewerage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)"	Yes	No
Information Notice 90-09, "Extended Interim Storage of Low Level Radioactive Waste by Fuel Cycle and Materials Licenses"	Yes	No
Information Notice 97-30, "Control of Licensed Material During Reorganizations, Employee-Management Disagreements and Financial Crises"	Yes	No

Document	Incorporated	Superceded
Information Notice 89-25 (Rev. 1), "Unauthorized Transfer of Ownership or Control of Licensed Activities"	Yes	No
Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"	Yes	No
Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20"	Yes	No
Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Minimization Programs"	Yes	No
Administrative Letter 96-05, Compliance with the Rule "Timeliness in Decommissioning of Material Facilities," dated November 5, 1996	Yes	No
Staff Memorandum dated August 12, 1997, from John Hickey, Chief, Low-Level Waste and Decommissioning Projects Branch, Division of Waste Management, NMSS, concerning "Implementation of 10 CFR 30.36(d)."	Yes	No
"All Agreement States Letter," SP-96-022, dated February 16, 1996	Yes	No
Administrative Letter 96-05 (Rev. 1), Compliance with the Rule "Timeliness in Decommissioning of Material Facilities," dated July 14, 1998	Yes	No

Appendix B

United States Nuclear Regulatory Commission Form 313

United States Nuclear Regulatory Commission Form 313

Replace this page with NRC Form 313.

Appendix C

Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313

Suggested Format for Providing Information Requested in Items 5 Through 11 of NRC Form 313

Item No.	Suggested Response	Yes	Description Attached
5.	**RADIOACTIVE MATERIAL** **Unsealed and/or Sealed Sources** Applicants for a Type A broad scope license should request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. The applicant should separately list individual radionuclides needed in much larger quantities or in much smaller quantities than that described in the atomic number 1-83 request. The maximum quantities of nuclides with atomic numbers above 83 also should be listed separately. A separate listing should also be submitted for sealed sources needed in larger quantities than described in the atomic number 1-83 request. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an Sealed Source and Device (SSD) Registration Certificate or specifically approved on a license. This information need not be submitted if the licensee is authorized to possess the requested quantity of radioactive material in unsealed form and the licensee performs the required safety evaluation of the source and device.		

Item No.	Suggested Response	Yes	Description Attached
5.	**RADIOACTIVE MATERIAL *(Cont'd)*** **Unsealed and/or Sealed Sources *(Cont'd)*** Possession requests should be categorized into general areas of use, e.g., research and development activities, routine gauging activities, self-shielded irradiators, instrument calibrators, and medical applications. Licensees who possess radioactive materials in excess of the quantities listed in 10 CFR 30.72 must provide with the application either of the following: (1) an evaluation showing that the maximum off-site dose due to a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid; or (2) an emergency response plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3). Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in 10 CFR 33.100, Schedule A. Type B licensees should request the quantity of material specified in 10 CFR 33.11(b). Type C licensees should request the quantity of material specified in 10 CFR 33.11(c). **Financial Assurance and Recordkeeping for Decommissioning** Applicants requesting authorization to possess licensed material in excess of the limits specified in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 must submit a decommissioning funding plan (DFP) or certification of financial assurance for decommissioning.		
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED** Describe in general terms the use or purpose of each requested radioisotope.		

Item No.	Suggested Response	Yes	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM** **Executive Management** The applicant must describe administrative controls and provisions relating to organization and management and management review necessary to assure safe operations. It is recommended that the applicant submit an organizational chart describing the management structure, reporting paths, and the flow of authority between executive management, the RSC (for Type A broad scope), and the RSO (For Type A and Type B broad scope).		

Item No.	Suggested Response	Yes	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM *(Cont'd)*** **Radiation Safety Committee** Applicants for a Type A broad scope license should submit the following: • Description of the duties and responsibilities of the RSC. • Criteria used for selecting members to the RSC, including what members and number of members constitutes a quorum. Members should be indicated by position title, rather than by name. • Criteria used by the RSC and RSO for approving new users and new uses. In addition, applicants for a Type A broad scope license who are requesting the flexibility to make some program changes and revise some procedures previously approved by the NRC without amendment of the license, as described in Section 1 of this document, should submit the following: • A description of the duties and responsibilities of the RSC, including: – review and approval of permitted program and procedural changes prior to implementation; – implementation of program and procedural changes; – audit of licensed operations to determine compliance; and – taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence. • A description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.		

Item No.	Suggested Response	Yes	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM *(Cont'd)*** **Radiation Safety Officer** For Type A and Type B applicants: • Submit the name of the proposed RSO; • Describe the training and experience for the proposed RSO that demonstrates the individual is qualified to perform the duties required under the license; • Submit a statement delineating the RSO's duties and responsibilities; and • Submit a "Radiation Safety Officer Delegation of Authority" signed by the licensee's executive management. For Type B applicants: • Submit the criteria used by the RSO to approve new users and uses of byproduct material. For Type C applicants: Submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program, e.g., Radiation Safety Officer, who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee as required by 10 CFR 30.32(c).		

Item No.	Suggested Response	Yes	Description Attached
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO WORKERS)** Submit a description of the radiation safety training program developed for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training; or identify the model training program described in the appropriate base NUREG corresponding to your particular type of licensed program and submit a statement that this training program will be implemented. In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your radiation safety training program without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement your submitted training program.		
9.	**FACILITIES AND EQUIPMENT** Describe the criteria your RSC and/or RSO, as appropriate, will use to review and approve facilities and equipment. Your description will need to include your method of classifying laboratories based on type, toxicity and quantity of byproduct material being requested. Sample diagrams should be provided for each classification scheme. These should take into consideration shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When reviewing facilities where radioactive materials may become airborne, sample diagrams should take into consideration description of the ventilation systems, including pertinent airflow rates, pressures, filtration equipment and monitoring systems. For special application facilities, you will need to specify their locations, (i.e. buildings and room numbers) and special considerations that your RSC and/or RSO will use in authorizing byproduct material use. Also describe your procedures for control, review and approval of significant facilities or equipment modifications.		

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM** **Audit Program** Describe the mechanisms used by executive management to ensure that adequate oversight of the program is exercised. In addition, if you are upgrading your limited scope license to a Type A broad scope license or you are renewing your Type A broad scope license, describe the RSC's involvement in these oversight mechanisms. The applicant is not required to, and should not, submit its program for conducting the annual audit required by 10 CFR 20.1101 to the NRC for review during the licensing phase. The adequacy of this audit program will be reviewed during NRC inspection. Describe the audit mechanism implemented by the RSO or other responsible individual to determine user compliance with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC or RSO-approved permits (as appropriate), and good health physics practices. In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise the audit mechanism implemented by the RSO without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process you will use to revise and implement your audit program.		

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Instruments** Provide the criteria used by your RSC and/or RSO, as appropriate, to review and approve radiation monitoring instrumentation to assure that appropriate radiation monitoring equipment will be used during licensed activities. Discuss how the RSC and/or RSO, as appropriate, will assure that instruments are properly calibrated at prescribed frequencies. Submit procedures for instrument calibration or state that instruments will be calibrated by a vendor who is licensed by NRC or an Agreement State to perform instrument calibrations. Licensees who want authorization to calibrate their own survey instruments may commit to implementing the model procedures published in Appendix O of this document. In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your instrument specifications and procedure for calibration of instruments without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement these submitted procedures.		

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Material Receipt and Accountability** Describe your administrative procedures to assure control of procurement and use of byproduct material. While the applicant is required to develop and implement safe opening procedures for packages containing radioactive material, the applicant need not submit the procedures during the licensing process. These procedures will be reviewed during inspection. Describe your administrative controls and provisions relating to materials control, accounting and security. In addition, if you are a Type A broad scope licensee or applicant, and you want the flexibility to revise your administrative procedures to assure control of procurement and use of byproduct material and your administrative controls and provisions relating to material control, accounting and security, without amendment of your license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be utilized by your Radiation Safety Committee to revise these administrative procedures, controls, and provisions. **Occupational Dose** Submit a description of the method for demonstrating compliance with the referenced regulations or a statement that an evaluation has disclosed that individuals do not require monitoring. In addition, if you are a Type A broad scope licensee or applicant and you want the flexibility to revise your personnel dosimetry program without amendment of the license, as discussed in Sections 1 and 8.7.2 of this document, describe the process that will be used to revise and implement your submitted personnel dosimetry program.		

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Public Dose** No response is required from the applicant, but records and written materials documenting compliance will be examined during inspection. During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. For guidance about accepted methodologies for determining doses to members of the public, see Appendix Q of this document. **Safe Use of Radionuclides and Emergency Procedures** Provide your procedures for safe use of radionuclides, including security of materials and emergencies. As an alternative, you may state, 'We will adopt the procedures for the safe use of radionuclides and emergencies as published in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."' In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license, and you want the flexibility to revise your safe use and emergency procedures without amendment of the license, as described in Sections 1 and 8.7.2 of this document, discuss the process that will be used to revise and implement your submitted safe use and emergency procedures.		

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION SAFETY PROGRAM *(Cont'd)*** **Surveys** Submit procedures to evaluate radiological hazards, both external and internal. If you wish, you may state, "we will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope." Submit your leak test procedures, or, as an alternative, you may state, "we will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope." In addition, if you are a Type A broad scope licensee or you are applying for a Type A broad scope license, and you want the flexibility to revise your survey or leak test program without amendment of the license, as described in Sections 1 and 8.7.2 of this document, discuss the process that will be used to revise and implement your submitted survey and leak test program. **Transportation** No response is needed from applicants during the licensing phase.		
11.	**WASTE MANAGEMENT** Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact appropriate Regional Office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in this section.		

Appendix D

Sample License - Type A

Sample License - Type A

A Type A Sample License appears on the following pages.

MATERIALS LICENSE

Amendment No. 1

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, 36, 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 the application dated September 8, 1994
1. Sample Research and Development Broad-Type A FA required /DFP not required	3. License Number 99-03610-01 is amended in its entirety to read as follows:
2. 12345 Crystal Road Ballybran, New Jersey 03610	4. Expiration Date October 31, 1999
	5. Docket No. 030-03610 Reference No.

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 1 through 83 with half-lives less than 120 days	A. Any	A. 100 millicuries per radionuclide and 5 curies total
B. Hydrogen 3	B. Any	B. 200 millicuries
C. Carbon 14	C. Any	C. 50 millicuries
D. Calcium 45	D. Any	D. 2 millicuries

9. Authorized Use

A. through D. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 12345 Crystal Road, Ballybran, New Jersey.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, G. Lanszecki Chairperson.

B. The Radiation Safety Officer for this license is Killashandra Ree, Ph.D.

12. Licensed materials shall not be used on human beings.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific conditions of this license.

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

15. This license does not authorize commercial distribution of licensed material.

16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

    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 be exceed three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, 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 and detector cells 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 material; 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 transfer 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

F. The 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Director, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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

18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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

22. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such 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. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's application dated June 30, 1994.

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

25. 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 July 30, 1994
    B. Letter dated September 8, 1994

For the U.S. Nuclear Regulatory Commission

Date: _____ By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix E

Sample License - Type A with Increased Flexibility

Sample License - Type A with Increased Flexibility

A Type A with Increased Flexibility Sample License appears on the following pages.

MATERIALS LICENSE

Amendment No. 1

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, 36, 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 the letter dated September 8, 1994,
1. Sample Research and Development Broad-Type A FA required/DFP not required	3. License number 99-03610-01 is amended in its entirety to read as follows:
2. 12345 Crystal Road Ballybran, New Jersey 03610	4. Expiration Date October 31, 1999
	5. Docket No. 030-03610 Reference No.

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 1 through 83 with half-lives less than 120 days	A. Any	A. 100 millicuries per radionuclide and 5 curies total
B. Hydrogen 3	B. Any	B. 200 millicuries
C. Carbon 14	C. Any	C. 50 millicuries
D. Calcium 45	D. Any	D. 2 millicuries

9. Authorized Use

A. through D Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 12345 Crystal Road, Ballybran, New Jersey.

11 A. Licensed material shall be used by or under the supervision of individuals designated in writing by the Radiation Safety Committee, G. Lanszecki Chairperson.

B. The Radiation Safety Officer for this license is Killashandra Ree, Ph.D.

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

15. This license does not authorize commercial distribution of licensed material.

16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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 three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, 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 and detector cells 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 an/or gamma emitting material or not more than 10 microcuries of alpha emitting material; 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 transfer 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 an/or contamination.

F. The 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Director, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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

18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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

22. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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 such 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

23. Radioactive waste generated shall be stored in accordance with the statements, representations and procedures included with the waste storage plan described in the licensee's application dated June 30, 1994.

24. 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. Notwithstanding the requirements of License Condition 26, the licensee is authorized to make program changes and changes to procedures specifically identified in the application dated June, 30, 1994, and letter dated September 8, 1994, which were previously approved by the commission and incorporated into the license without prior Commission approval as long as:
    (A) the proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;
    (B) the revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;
    (C) the licensee's staff is trained in the revised procedures prior to implementation; and
    (D) the licensee's audit program evaluates the effectiveness of the change and its implementation.

26. 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 licencee's application and correspondence are more restrictive than the regulations.

    A. Application dated June 30, 1994
    B. Letter dated September 8, 1994

For the U.S. Nuclear Regulatory Commission

Date: _____

By: _____
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Amendment No. 1

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, 36, 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.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

Appendix F

Sample License - Type B

Sample License - Type B

A Type B Sample License appears on the following pages.

MATERIALS LICENSE

Amendment No. 1

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, 36, 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 the application dated September 4, 1994.
1. Sample Research and Development Broad-Type B FA required/DFP not required	3. License Number 99-03610-01 is amended in its entirety to read as follows:
2. 11111 Crystal Court Ballybran, New Jersey 03611	4. Expiration date October 31, 1999
	5. Docket No. 030-03610 Reference No.

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. As specified in Section 33.100, schedule A of 10 CFR 33 (Type B Broad License)	A. Any	A. See condition 12.

9. Authorized Use

A. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 11111 Crystal Court, Ballybran, New Jersey.

A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Officer.

B. The Radiation Safety Officer for this license is Lars Dahl, Ph.D.

11. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column 1. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, schedule A, Column 1, for that radionuclide. The sum of the ratios for all radionuclides possessed under the licence shall not exceed unity.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column 1, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	10 curies
Krypton 85	10 curies
Iodine 129	10 millicuries
Any byproduct material other Than alpha emitting byproduct Material not listed in 10 CFR 33.100 Schedule A	10 millicuries

12. Licensed material shall not be used in or on human beings.

13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific conditions of this license.

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

15. This license does not authorize commercial distribution of licensed material.

16. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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 three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, 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 and detector cells 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 material; or

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

(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 transfer 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 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Director, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the rest results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

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

18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

20. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

21. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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

22. 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:

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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 such 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. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's application dated July 3, 1993.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03610-01

Docket or Reference Number
030-03610

Amendment No. 1

25. 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.

Z. Application dated July 3, 1993
AA. Letter dated February 8, 1994
BB. Letter dated September 4, 1994

For the U.S. Nuclear Regulatory Commission

Date: _____ By _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix G

Sample License - Type C

Sample License - Type C

A Type C Sample License appears on the following pages.

MATERIALS LICENSE

Amendment No. 1

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, 36, 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 the letter dated May 6, 1994,
1. Sample Research and Development Broad-Type C No FA required/DFP not required	3. License Number 99-03612-01 is amended in its entirety to read as follows:
2. 99999 Crystal Street Ballybran, New Jersey 03612	4. Expiration Date October 31, 1999
	5. Docket No. 030-03612 Reference No.

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. As specified in Section 33.100, Schedule A, of 10 CFR 33 (Type C Broad License)	A. Any	A. See Condition 12

9. Authorized Use

A. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 99999 Crystal Street, Ballybran, New Jersey

11. A. Licensed material shall be used by, or under the supervision of, individuals who satisfy the requirements of 10 CFR 33.15.

B. The Radiation Safety Officer for this license is C.H. Ramble.

12. A. If only one radionuclides is possessed, the possession limit is the quantity specified for that radionuclides in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclides, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclides. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03612-01

Docket or Reference Number
030-03612

Amendment No. 1

B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100 Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	100 millicuries
Krypton 85	100 millicuries
Iodine 129	100 microcuries
Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	100 microcuries

13. Licensed material shall not be used in or on human beings.

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

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

16. This license does not authorize commercial distribution of licensed material.

17. A. Sealed sources and detector cells containing licensed material shall be tested for leakage an/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

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

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, 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 and detector cells need not be leak tested if:

(I) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) they 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 material; or

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03612-01

Docket or Reference Number
030-03612

Amendment No. 1

(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 transfer 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 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 and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Director, Division of Nuclear Materials Safety, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission of an Agreement State to perform such services.

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

19. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.

20. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

21. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.

22. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
99-03612-01

Docket or Reference Number
030-03612

Amendment No. 1

23. 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. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives

    B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument 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 such 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.

24. 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. 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 January 2, 1993
    B. Letter dated March 4, 1994
    C. Letter dated May 6, 1994

For the U.S. Nuclear Regulatory Commission

Date: _____

By: _____
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix H

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control Application

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license; some licensees refer to this as "transferring the license." Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. The new name of the licensed organization. If there is no change, the licensee should so state.

2. The new licensee contact and telephone number(s) to facilitate communications.

3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.

4. An indication of whether the transferor will remain in non-licensed business without the license.

5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.

6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).

7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.

8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.

9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.

10. Confirmation that all records concerning the safe and effective decommissioning of the facility, pursuant to 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.

11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?

12. A description of any decontamination plans, including financial assurance arrangements of the transferee, as specified in 10 CFR 30.35, 40.36, and 70.25. Include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.

13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to NRC by the transferor. These include, but are not limited to: maintaining decommissioning records required by 10 CFR 30.35(g); implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

    With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before transferring control.

    With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program to ensure compliance with the license and regulations.

References: The information above is contained in IN 89-25, Revision 1, "Unauthorized Transfer of Ownership or Control of Licensed Activities." See the Notice of Availability (on the inside front cover of this report) to obtain copies.

Appendix I

Information Needed for Field Use of Byproduct Material

Information Needed for Field Use of Byproduct Material

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 that remain in the wild). These types 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).

If you desire to perform field studies in which licensed material is deliberately released to the environment for the purposes of studies, please provide the following information:

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. 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 J

Model Delegation of Authority for Radiation Safety Officer

Model Delegation of Authority for Radiation Safety Officer

MODEL DELEGATION OF AUTHORITY
RADIATION SAFETY OFFICER

Memorandum To: All Employees

From: Chief Executive Officer

Subject: Delegation of Authority for Radiation Safety Officer

_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of byproduct material. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of byproduct material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.

Appendix K

Radionuclides Classified According to Relative Toxicity (Excerpted from (IAEA Safety Standard, Safety Series No. 1, “Safe Handling of Radionuclides, 1973 Edition”)

Radionuclides Classified According to Relative Toxicity (Excerpted from (IAEA Safety Standard, Safety Series No. 1, "Safe Handling of Radionuclides, 1973 Edition")

This table is ***not*** all inclusive and is meant to be used as an example only. Based on chemical/physical form, need and quantities, your classification scheme may differ from that of the IAEA excerpt.

Table K.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 Radiotoxicity

^{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 Radiotoxicity

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

Group 4: Low Radiotoxicity

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

Table K.2: Limitations on Activities in Various Types of Working Place or Laboratory[3]

Radiotoxicity of Radionuclides	Minimum Quantity	Type of Working Place or Laboratory Required		
	μCi	Type C	Type B	Type A
1. very high	0.1 (3.7 kBq)	<10 μCi (<370 kBq)	10 μCi (370 kBq)	10 μCi or more (>370 kBq)
2. high	1.0 (37 kBq)	<100 μCi (<3.7 MBq)	100 μCi (3.7 MBq)	100 μCi or more (>3.7 MBq)
3. moderate	10 (370 kBq)	<1 mCi (<37 MBq)	1 mCi - 1 Ci (37 MBq - 37 GBq)	1 Ci or more (>37 GBq)
4. low	100 (3.7 MBq)	<10 mCi (<370 MBq)	10 mCi - 10 Ci (370 MBq - 370 GBq)	10 Ci or more (>370 GBq)

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

Appendix L

Facilities and Equipment Considerations

Facilities and Equipment Considerations

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each topic in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside closed systems discussed below. Surfaces should be smooth and non-porous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods or glove boxes with controlled, and possibly filtered, exhaust systems.

  Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be required in the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 10 CFR 20, Appendix B.

  Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and ductwork should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.

- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Similarly, shielding of low atomic number material, such as high-density plastic, may be used to reduce the exposure from high-energy beta-emitting materials. Shielded shipping containers are frequently used for continued storage after receipt of materials.
- A particular sink should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on number of users and distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas and away from areas frequently occupied by personnel. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed, such that, in the event of an accident, they can be shut down and isolated to contain radioactivity.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with the lowest possible background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of 10 CFR Part 20, Subpart H.

Appendix M

Sample Audit Program - Non-Medical

Sample Audit Program - Non-Medical

The following audit form may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before an NRC inspection). This form is not intended to be all inclusive. During an audit, the auditor needs to keep in mind not only the requirements of NRC's regulations, but also the licensee's commitments in its applications and other correspondence with NRC. Licensees are encouraged to modify the audit form as needed to include items specific to their licensed program. The auditor should also evaluate whether the licensee is maintaining exposures to workers and the general public as low as is reasonably achievable (ALARA) and, if not, make suggestions for improvement. References are included at the end of this audit form.

1. MANAGEMENT OVERSIGHT:

(Management support to radiation safety; RSC; RSO; program audits, including annual reviews of program and ALARA reviews; control by authorized users; appropriate follow up on events and previous audit/inspection findings)

2. AMENDMENTS AND PROGRAM CHANGES:

(Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition).

3. FACILITIES:

(Facilities as described in license; uses; control of access; engineering controls; calibration facilities; shielding; air flow)

4. EQUIPMENT AND INSTRUMENTATION:
(Operable and calibrated survey equipment; procedures; 10 CFR Part 21)

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

7. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users)

8. RADIATION PROTECTION:

(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

9. RADIOACTIVE WASTE MANAGEMENT:

(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method)

10. DECOMMISSIONING:

(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

11. TRANSPORTATION:

(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

12. NOTIFICATIONS AND REPORTS:

(Reporting and followup of theft, loss, incidents and overexposures. Notification of change in RSO and/or authorized user. Radiation exposure reports provided to individuals.)

13. POSTING AND LABELING:

(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

14. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with staff's results and regulations)

15. AUDIT FINDINGS:

REFERENCES

A. Management Oversight

1. Radiation Safety Committee

   Applicable license conditions.

2. Radiation Safety Officer

   Applicable license conditions.

3. Audits, Reviews, or Inspections

   10 CFR 20.1101 Radiation protection programs.
   10 CFR 20.2102 Records of radiation protection programs.
   Applicable license conditions.

4. ALARA

   10 CFR 20.1101 Radiation protection programs.

5. Authorized Users

   Applicable license conditions.

B. Amendments and Program Changes:

   Applicable license conditions.

C. Facilities

1. Access Control

   10 CFR 20.1601,1602 Control of access to high/very high radiation areas.
   10 CFR 20.1801 Security of stored material.
   10 CFR 20.1802 Control of material not in storage.
   Applicable license conditions.

2. Engineering Controls

   10 CFR 20.1101 Radiation protection programs.
   10 CFR 20.1701 Use of process or other engineering controls.
   Applicable license conditions.

D. Equipment and Instrumentation

1. Survey Instruments

10 CFR 20.1501	General.
10 CFR 20.1701	Use of Process or Other Engineering Controls.
10 CFR 20.2103	Records of Surveys.

Applicable license conditions.

2. Safety Component Defects

10 CFR 21.21	Notification of failure to comply or existence of a defect and its evaluation.

E. Material Use, Control, and Transfer

1. License and applicable license conditions.

2. Security and Control

10 CFR 20.1003	Definitions (restricted area and unrestricted area).
10 CFR 20.1801	Security of stored material.
10 CFR 20.1802	Control of material not in storage.

3. Receipt and Transfer of Licensed Material

10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1906	Procedures for receiving and opening packages.
10 CFR 20.1501	Surveys.
10 CFR 20.2103	Records of surveys.
10 CFR 30.41	Transfer of byproduct material.
10 CFR 30.51	Records of receipt and transfer.

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area Surveys

10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2107	Records of dose to individual members of the public.

Applicable license conditions.

2. Leak Tests and Inventories

Applicable license conditions.

G. TRAINING AND INSTRUCTIONS TO WORKERS

1. General

10 CFR 19.12	Instruction to workers.

Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.
Applicable license conditions.

H. RADIATION PROTECTION

1. Radiation Protection Program

a. Exposure evaluation

10 CFR 20.1501	General.

b. Programs

10 CFR 20.1101	Radiation protection programs.

2. Dosimetry

   a. Dose Limits

10 CFR 20.1201	Occupational dose limits for adults.
10 CFR 20.1202	Compliance with requirements for summation of external and internal doses.
10 CFR 20.1207	Occupational dose limits for minors.
10 CFR 20.1208	Doses to an embryo/fetus.

   b. External

10 CFR 20.1203	Determination of external dose from airborne radioactive material.
10 CFR 20.1501	General.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.
	Applicable license conditions.

   c. Internal

10 CFR 20.1204	Determination of internal exposure.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.
10 CFR 20, Subpart H	Respiratory protection and controls to restrict internal exposure in restricted areas.

3. Records

10 CFR 20.2102	Records of radiation protection programs.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2104	Determination of prior occupational dose.
10 CFR 20.2106	Records of individual monitoring results.

I. RADIOACTIVE WASTE MANAGEMENT

1. Disposal

10 CFR 20.1904	Labeling containers.
10 CFR 20.2001	General requirements.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.
10 CFR 20.2003	Disposal by release into sanitary sewerage.

2. Effluents

a. General

Applicable license conditions

b. Release to septic tanks

10 CFR 20.1003	Definitions (sanitary sewerage).
10 CFR Part 20, App. B, Table 2	Effluent Concentrations.

c. Incineration of waste

10 CFR 20.2004	Treatment or disposal by incineration.

d. Control of air effluents and ashes

10 CFR 20.1201	Occupational dose limits for adults.
10 CFR 20.1301	Dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.1701	Use of process or other engineering controls.

Applicable license conditions

3. Waste Management

a. General

10 CFR 20.2001	General requirements.
Information Notice (IN) 90-09	Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees.

b. Waste compacted

Applicable license conditions.

c. Waste storage areas

10 CFR 20.1801	Security of stored material.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1904	Labeling containers.

Applicable license conditions.

d. Packaging, Control, and Tracking

10 CFR Part 20, Appendix F	Requirements for Low-Level Waste Transfer for Disposal at Land Disposal Facilities and Manifests.
10 CFR 20.2006	Transfer for disposal and manifests.
10 CFR 61.55	Waste classification.
10 CFR 61.56	Waste characteristics.

e. Transfer

10 CFR Part 20, Appendix F	Requirements for Low-Level Waste Transfer for Disposal at Land Disposal Facilities and Manifests.
10 CFR 20.2001	General requirements.
10 CFR 20.2006	Transfer for disposal and manifests.

f. Records

10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.

J. DECOMMISSIONING

10 CFR 30.35	Financial assurance and recordkeeping for Decommissioning.
10 CFR 30.36	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

K. TRANSPORTATION

1. General

10 CFR 71.5	Transportation of licensed material.

2. Shippers - Requirements for Shipments and Packaging

a. General Requirements

49 CFR Part 173, Subpart I	Class 7 (radioactive) materials.
49 CFR 173.24	General requirements for packaging and packages.
49 CFR 173.448	General transportation requirements.
49 CFR 173.435	Table of A1 and A2 values for radionuclides.

b. Transport Quantities

10 CFR 71.4	Definitions.

i. All quantities

10 CFR 71.4	Definitions.
49 CFR 173.410	General design requirements.
49 CFR 173.431	Activity limits Type A and Type B
49 CFR 173.441	Radiation level limitations.

49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of Class 7 (radioactive) materials.
49 CFR 173.476	Approval of special form Class 7 (radioactive) materials.

ii. Limited quantities

49 CFR 173.421	Excepted packages for limited quantities of Class 7 (radioactive) materials.
49 CFR 173.422	Additional requirements for excepted packages containing Class 7 (radioactive) materials.

iii. Type A quantities

49 CFR 173.412	Additional design requirements for Type A packages.
49 CFR 173.415	Authorized Type A packages.
49 CFR 178.350	Specification 7A; general packaging, Type A.

iv. Type B quantities

49 CFR 173.416	Authorized Type B packages
49 CFR 173.467	Package testing

v. LSA material and SCO

49 CFR 173.403	Definitions.
49 CFR 173.427	Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

c. HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.
49 CFR 172.300-338	Marking.
49 CFR 172.400-450	Labeling.
49 CFR 172.500-560	Placarding.
49 CFR 172.600-604	Emergency response information.

3. HAZMAT Training

49 CFR 172.702	Applicability and responsibility for training and testing.
49 CFR 172.704	Training requirements.

4. Transportation by Public Highway

49 CFR 171.15	Immediate notice of certain hazardous materials incidents.
49 CFR 171.16	Detailed hazardous materials incident reports.
49 CFR 177.800	Purpose and scope of this part and responsibility for compliance and training.
49 CFR 177.816	Driver training.
49 CFR 177.842	Class 7 (radioactive) material.

L. NOTIFICATIONS AND REPORTS

10 CFR 19.13	Notifications and reports to individuals.
10 CFR 20.2201	Reports of theft or loss of licensed material.
10 CFR 20.2202	Notification of incidents.
10 CFR 20.2203	Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
10 CFR 30.50	Reporting requirements.

M. POSTING AND LABELING

10 CFR 19.11	Posting of notices to workers.
10 CFR 21.6	Posting requirements.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1903	Exemptions to posting requirements.
10 CFR 20.1904	Labeling containers.
10 CFR 20.1905	Exemptions to labeling requirements.

Appendix N

Reporting Requirements

Reporting Requirements

Typical NRC Notifications And/Or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(I)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(I)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(I)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii)
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	10 CFR 20.2203(a)(2)(I)
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	10 CFR 20.2203(a)(2)(iv)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(I)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550, except as noted.

Appendix O

Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program

Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program

Radiation Monitoring Instrument Specifications

The specifications in Table O.1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table O.1 Typical Survey Instruments[1] (instruments used to measure radiological conditions at licensed facilities).

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

[1] Table from *The Health Physics & Radiological Health Handbook*, Revised Edition, edited by Bernard Shleien, 1992 (except for * items).

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel performing survey instrument calibration
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments will:

- Approximate a point source
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^{-6} coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^{2} megabecquerels (21 mCi) of cobalt-60

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20% and 80% of full scale. The instrument's readings shall be within ± 15% of the conventionally true values for the lower point and ± 10% for the upper point.
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10% of the full decade value.
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.
- Readings above 2.58×10^{-4} coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation.
- The inverse square and radioactive decay law should be used to correct changes in exposure rate due to changes in distance or source decay.

Surface Contamination Measurement Instruments[4]

- Survey meters' efficiency must be determined by using radiation sources with similar energies and types of radiation that the survey instrument will be used to measure.

---

[4] ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration."

- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80% of full scale, and the reading at approximately 20% of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within ±20% of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments will do the following:

- Approximate the geometry of the samples to be analyzed
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration must produce readings within ± 20% of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters will include quench correction.

Calibration Records

Calibration records, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration should include:

- The owner or user of the instrument
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- For instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument

- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
- The exposure rate or count rate from a check source, if used
- The name of the person who performed the calibration and the date it was performed.

The following information will be attached to the instrument as a calibration sticker or tag:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use)
- For each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- The date of calibration and the next calibration due date
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample must be determined. Accurate determination of the volume of air sampled requires standard, reproducible, and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication entitled "Air Sampling Instruments" found in the 7th Edition, American Conference of Governmental Industrial Hygienists, 1989, provides guidance on total air sample volume calibration methods acceptable to NRC staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods of calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard.

The following are significant errors associated with determining the total air volume sampled:

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[5]

E_S: Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading.)

E_t: The percentage error in measurement of sampling time that should be kept within 1%.

E_V: The most probable value of the cumulative percentage error in the determination of the total air volume sampled. E_V can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_V = [E_S^2 + E_C^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_V, in the determination of total volume, should be less than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor, and sample time are ± 4, 2, and 1%, respectively, and there are no other significant sources of error, the cumulative error would be:

$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\%$ or approx. 5%

[5] The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$Vs = V1 * (P1/760) * (273/T1)$

where V_s = volume at standard pressure and temperature (760 mm Hg and 273°K
V_1 = volume measured at conditions P_1 and T_1
T_1 = temperature of V_1 in K
P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed, and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of:

1. Draft Regulatory Guide FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," June 1985.

2. Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," June 1992.

3. NUREG-1400, "Air Sampling in the Workplace," September 1993.

Additional References:

4. The Health Physics & Radiological Health Handbook, 3rd Ed. Edited by Bernard Shleien, Lester A. Slaback, Jr., and Brian Kent Birky, 1998.

5. ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.

6. "Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 7th Edition, 1989.

7. DOE G 441.1-7, “Portable Monitoring Instrument Calibration Guide,” U.S. Department of Energy, March 1999.

8. DOE G 441.1-8, “Air Monitoring Guide,” U.S. Department of Energy,” March 1999.

Appendix P

Material Receipt and Accountability

Material Receipt and Accountability

Sample Model Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material, quantities, manufacturer, and model are authorized by the license and that the possession limits are not exceeded.
- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the Radiation Safety Office (or designated receiving area).
- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below:

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

If the package appears to be damaged, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

Any packages containing radioactive material that arrive between (state times, e.g., 4:30 p.m. and 7:00 a.m. or on Saturdays or Sundays) shall be signed for by the security guard (or other designated trained individual) on duty and taken immediately to the designated receiving area. Security personnel (or other designated trained individual) should unlock the door, place the package in the designated secured storage area, and re-lock the door.

Radiation Safety Officer (RSO): _____

Office Phone: _____

Home Phone: _____

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package to remain until monitored by the RSO.

Outside of normal working hours (e.g., nights, weekends, and holidays), deliveries will usually be handled by security personnel (or other trained individuals), as described in the above procedures. Since certain packages of licensed material will have detectable external radiation, they should be sent immediately to a designated storage area, where they will be checked for contamination and external radiation level as soon as practical. They should not be allowed to remain in the receiving area any longer than necessary, as they may be a source of exposure for receiving personnel.

If the instructions are not clear, or if there are questions regarding receiving packages containing radioactive material, please contact:

Name _____

Phone _____

For additional information on worker training, see the section entitled Training for Individuals Working In or Frequenting Restricted Areas.

Materials Possessed Under a General License, or Received from a General Licensee

Individuals at your facility may receive and use material pursuant to a general license as authorized in 10 CFR Part 31. Generally licensed materials are distributed by manufacturers authorized by the NRC to distribute materials directly to the persons who will use them under a general license. Some common items include nickel-63 sources in electron capture detectors in certain gas chromatographs, tritium gas contained in self-luminous EXIT signs, calibration sources in liquid scintillation counters, and uranyl acetate used for staining electron microscope samples. You should develop a policy for how your institution will require responsible use and tracking of this material.

Generally licensed material may also be received when a general licensee transfers a generally licensed item to a specific license that is authorized to possess the material. However, when

received by the specific licensee (your facility), the item must now be considered as specifically licensed and should be tracked with other specifically licensed material.

Sample Model Procedure for Safely Opening Packages Containing Licensed Materials

For packages received under the specific license, authorized individuals shall implement procedures for opening each package, as follows:

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, so shipment does not exceed license possession limits.
- Monitor the external surfaces of a labeled package according to specifications in Table 8.4, Section 13.14, Item 10.
- Open the outer package (following supplier's directions if provided) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). Check again that the shipment does not exceed license possession limits. If you find anything other than expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels prior to discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final carrier and by telephone, telegram, mailgram, or facsimile, the Administrator of the appropriate NRC Regional Office listed in 10 CFR 20, Appendix D when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(I); or external radiation levels exceed the limits of 10 CFR 71.47.

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or laboratory or AU's control to another should have prior approval from the RSO. A written transfer procedure should be developed by the RSO to ensure that transfers are done in accordance with the conditions of the

license. All transfers shall be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material shall not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers/shipments must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service Regulations, whichever is applicable.

Gifts

On occasion, licensees may be offered or have donated licensed materials by other individuals as gifts (e.g., a retiring medical practitioner donating his cesium needles to the university medical center). All such gifts of radioactive materials must be transferred to the licensee and handled in accordance with NRC requirements and the conditions of the license. In any case, the RSO should approve the gift prior to the transfer.

Additional References:

1. DOE G 441.13-1, “Sealed Radioactive Source Accountability and Control,” U.S. Department of Energy,” April 1998.

Appendix Q

Methodology for Determining Public Dose

Methodology for Determining Public Dose

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 millirem (mrem)] in one calendar year resulting from the licensee's possession and/or use of licensed materials.
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.
- Air emissions of radioactive materials do not result in doses greater than 0.1 mSv (10 mrem) TEDE.

Members of the public include persons who live, work, study, or may be near locations where byproduct material is used or stored and employees whose assigned duties do not include the use of byproduct material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public	
INCLUDES doses from: • Radiation and/or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials • Licensed material in transportation or storage at the licensee's facility	DOES NOT INCLUDE doses from: • Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

Typical unrestricted areas may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials, but the licensee may control access to these areas for other reasons, such as security.

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem).

- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in Table 2 of Appendix B to Part 20; and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year.

In order to perform a dose assessment, the licensee should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport, and storage of radioactive material at the facility. The licensee must then take radiation measurements or perform calculations to demonstrate compliance.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources.
- Measurements of radionuclides in air and water effluent.

The method used to measure dose will depend on the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when volatile materials are used, such as during iodinations, but the discharge itself is usually not continuous since volatile materials are often used periodically rather than continuously. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee must determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. An extremely conservative calculation would assume that the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see Table Q.1). If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in Table Q.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table Q.1 Standard Occupancy Factors

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas
1/4	Corridors, lounges, elevators using operators, unattended parking lots
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public, until the Commission terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Appendix R

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes and Model Emergency Procedures

General Topics for Safe Use of Radioisotopes

Each laboratory or area where radioactive material is used or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low-background area.
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink or personal effects in areas where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.
- Never pipette by mouth.
- Store radioactive solutions in clearly labeled containers.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

Radionuclides-specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-125 or iodine-131, special safety instructions should be provided to users, including the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use
- Bioassay procedures for individuals working with millicurie quantities of radioiodine
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures.
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of phosphorus-32, special safety instructions should be provided to users, including the following:

- The use of low-density plastic shielding in order to keep bremsstrahlung radiation to a minimum
- A mandatory radiation survey and wipe test for radioactive contamination after each use
- The use of extremity monitors for procedures that involve one millicurie or more
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures
- The use of eye protection for procedures that involve 10 millicuries or more.

Model Procedures for Handling Emergencies

General Safety Procedures to Handle Spills

- Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:
  - — Disposable gloves
  - — Housekeeping gloves
  - — Disposable lab coats

- — Disposable head coverings
- — Disposable shoe covers
- — Roll of absorbent paper with plastic backing
- — Masking tape
- — Plastic trash bags with twist ties
- — "Radioactive Material" labeling tape
- — Marking pen
- — Pre-strung "Radioactive Material" labeling tags
- — Box of Wipes
- — Instructions for "Emergency Procedures"
- — Clipboard with a copy of the Radioactive Spill Report Form for the facility
- — Pencil
- — Appropriate survey instruments, including batteries (for survey meters).

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident specific variables, such as the number of individuals affected; other hazards present; the likelihood of spread of contamination; and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay. The applicant should establish criteria for determining when the major spill procedure and minor spill procedure should be utilized.

Minor Spills of Liquids and Solids

- Instructions to Workers
  - — Notify persons in the area that a spill has occurred.
  - — Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
  - — Clean up the spill, wearing disposable gloves and using absorbent paper.
  - — Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
  - — Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing, and shoes for contamination.

- — Report the incident to the Radiation Safety Officer (RSO) promptly.
- — Allow no one to return to work in the area unless approved by the RSO.
- — Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
- — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - — Follow up on the decontamination activities and document the results.
  - — As appropriate, determine cause and corrective actions needed; consider bioassays, if there is a potential for internal contamination.
  - — If necessary, notify NRC.

Major Spills of Liquids and Solids

- Instructions to Workers
  - — Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
  - — Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
  - — Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
  - — Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
  - — Notify the RSO immediately.
  - — Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - — Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
  - — Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results.
  - — Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.
  - — If necessary, notify NRC.

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases

- Instructions to Workers
  - — Notify all personnel to vacate the room immediately.
  - — Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.
  - — Vacate the room. Seal the area, if possible.
  - — Notify the RSO immediately.
  - — Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area.
  - — Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO.
  - — Promptly report suspected inhalations and ingestions of licensed material to the RSO.
  - — Decontaminate the area only when advised and/or supervised by the RSO.
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

- Reminders to RSO

- — Supervise decontamination activities.
- — Perform air sample surveys in the area before permitting resumption of work with licensed materials
- — Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
- — Consider need for medical exam and/or whole body count before permitting involved individuals to return to work with licensed material.
- — Determine cause and corrective actions needed; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- — If necessary, notify NRC.

Minor Fires

- Instructions to Workers
  - — Immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present.
  - — Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department (as instructed by RSO).
  - — Once the fire is out, isolate the area to prevent the spread of possible contamination.
  - — Survey all persons involved in combating the fire for possible contamination.
  - — Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.
  - — In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area.
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - Supervise decontamination activities.

- — If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- — Consult with fire safety officials to assure that there are no other possibilities of another fire starting.
- — Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.
- — If necessary, notify NRC.

Fires, Explosions, or Major Emergencies

- Instructions to Workers
  - — Notify all persons in the area to leave immediately.
  - — Notify the fire department.
  - — Notify the RSO and other facility safety personnel.
  - — Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water, etc.
  - — Cooperate with the RSO and/or the RSO's staff (e.g., investigation of root cause, provision of requested bioassay samples).
  - — Allow no one to return to work in the area unless approved by the RSO.
  - — Follow the instructions of the RSO and/or the RSO's staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

- Reminders to RSO
  - — Coordinate activities with facility's industrial hygienist or environmental health & safety office, and with local fire department.
  - — Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.
  - — Once the fire is extinguished, advise the firefighters not to enter potentially contaminated areas or areas where radioactive sources may be present until a thorough evaluation and

survey are performed to determine the extent of the damage to the licensed material use and storage areas.

— Perform thorough contamination surveys of the firefighters and their equipment before they leave the controlled area and decontaminate, if necessary.

— Supervise decontamination activities.

— Consider bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document incident.

— If necessary, notify NRC.

Copies of emergency procedures should be provided to all users. Post a current copy in each laboratory or other area where radioactive material is used.

Procedures for Collecting Bioassay Samples

In the event of an emergency where an individual may become contaminated and radioactive material was taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. The following items should be considered in developing your procedures:

- the type of bioassay that must be performed (direct or indirect)
- the number of samples or data points to be collected
- the frequency of sampling (hourly, daily, weekly, once?, etc.)
- the size of the sample to be collected (24-hour urine collection?)
- the ease/difficulty of sample collection
- the need for written instructions to be provided to the sample collector, who may be the contaminated individual.

Appendix S

Radiation Safety Survey Topics

Radiation Safety Survey Topics

This Appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits, and bioassays.

Training

Before allowing an individual to perform surveys, the RSO (or for Type C broad scopes, the individual designated as responsible for the day-to-day operation of the radiation safety program) will ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples, and analyzing samples
- Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low-background area.
- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv (2.5 mrem/hr) or more (50 mSv/year divided by 2,000 hr/year).
- 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any one hour.

Contamination Surveys

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
- After any spill or contamination event
- When procedures or processes have changed
- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use but not less frequently than quarterly
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10% of the smallest annual limit on intake (ALI) (either the inhalation or ingestion ALI) listed for that Radionuclides in 10 CFR Part 20. These surveys should be done at a frequency appropriate to the types and

quantities of radioactive materials in use, but at a minimum quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that Radionuclides in 10 CFR Part 20, detailed, documented surveys should be performed at least monthly.

Table S.1 contains suggested contamination survey frequency from Regulatory Guide 8.23 (See Tables S.2, S.3, and S.4 for alternate survey frequencies).

Table S.1 Suggested Frequency of Contamination Surveys from Regulatory Guide 8.23

Areas Where RAM Has Been Used	Frequency
Areas where > 7.4 MBq (200 μCi) is used at any one time	Weekly
Areas where < 7.4 MBq (200 μCi) is used at any one time	Monthly

Alternate Survey Frequency

Classification of Laboratories

Table S.2 Survey Frequency Category

Group	Low	Medium	High
1	< 370 kBq (10 μCi)	370 kBq (10 μCi) to 37 MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	> 370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

Proportional fractions are to be used for more than one isotope.

Table S.3 Survey Frequency Category Modifiers

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1

Modifying Factors	Factors
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory. To do this, multiply the activity range under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of μCi ranges for LOW, MEDIUM, and HIGH survey frequency.

Survey Frequency:

- Low - Not less than once a month
- Medium - Not less than once per week
- High - Not less than once per normal working day.

Table S.4 Isotope Groups

Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249

Group 3	Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 P-33 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-131m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-131 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171, Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-l91 Pt-193 Pt-197 Au-196 Au-198 Au-l99 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239
Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-9lm Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table S.5.

Table S.5 Acceptable Surface Contamination Levels

Nuclide[1]	Average[2, 3]	Maximum[2, 4]	Removable[2, 5]
I-125, I-129	1.7 Bq/100 cm^2 (100 dpm/100 cm^2)	5.0 Bq/100 cm^2 (300 dpm/100 cm^2)	0.3 Bq/100 cm^2 (20 dpm/100 cm^2)
I-126, I-131, I-133, Sr-90	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)	50.0 Bq/100 cm^2 (3,000 dpm/100 $cm^{2)}$	3.3 Bq/100 cm^2 (200 dpm/100 cm^2)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm^2 (5,000 dpm/100 cm^2)	250 Bq/100 cm^2 (15,000 dpm /100 cm^2)	16.7 Bq/100 cm^2 (1,000 dpm/100 cm^2)

Nuclide[1]	Average[2, 3]	Maximum[2, 4]	Removable[2, 5]

[1] Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

[2] As used in this table, dpm (disintegration per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[4] The maximum contamination level applies to an area of not more than 100 cm^2.

[5] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure that they meet these limits.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed
- A list of items and equipment surveyed
- Specific locations on the survey diagram where wipe test was taken
- Ambient radiation levels with appropriate units
- Contamination levels with appropriate units
- Make and model number of instruments used
- Background levels
- Name of the person making the evaluation and recording the results and date.

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals

involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- Determine whether the confinement of radioactive materials is effective
- Measure airborne radioactive material concentrations in the workplace
- Estimate worker intakes of radioactive material
- Determine posting requirements
- Determine what protective equipment and measures are appropriate
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays.

Refer to Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993, for further guidance on the air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to NRC for compliance with the constraint on air emissions to the environment.

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur anytime unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas, the number of procedures performed, or other appropriate methods. The unmonitored effluents should not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found on column 1 of Table 2 in 10 CFR Part 20, Appendix B, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," and ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in 10 CFR 20.1301 and 20.2003, respectively.

The topic of sanitary sewerage releases is more fully discussed in Appendix X.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual
- Retention and excretion characteristics of the radionuclides
- Sensitivity of the measurement technique
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10% ALI criterion is consistent with 10 CFR 20.1502(b), which requires licensees to monitor intakes and

assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting, urinalysis, etc.) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity since the most recent bioassay measurement is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than 2 hours should be excluded from the evaluation, since external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program because of change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual

intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination
- Entry into airborne radioactivity areas without appropriate exposure controls
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- Known or suspected incidents of a worker ingesting radioactive material
- Incidents that result in contamination of wounds or other skin absorption
- Evidence of damage to or failure of a respiratory protective device.

References:

1. Regulatory Guide 4.20, “Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,” dated December 1996.

2. Regulatory Guide 8.9, Revision 1, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” dated July 1993.

3. Regulatory Guide 8.23, Revision 1, “Radiation Safety Surveys at Medical Institutions,” dated January 1981.

4. Regulatory Guide 8.25, Revision 1, “Air Sampling in the Workplace,” dated June 1992.

5. Regulatory Guide 8.32, “ Criteria for Establishing a Tritium Bioassay Program,” dated July 1988.

6. Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” dated July 1993.

7. NUREG-1400, “Air Sampling in the Workplace,” dated September 1993.

8. NUREG/CR- 4884, “Interpretation of Bioassay Measurements,” dated July 1987.

9. ANSI N13.1 (1969), “Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,” dated 1991.

10. ANSI N13.30-1996, “Performance Criteria for Radiobioassay,” dated 1996.

11. ANSI N42.18, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents,” 1991.

12. NCRP Commentary No. 3, “Screening Techniques for Determining Compliance with Environmental Standards,” published in January, 1989, and the addendum published in October, 1989.

13. U.S. Department of Energy, DOE G 441.1-8, “Air Monitoring Guide,” March 17, 1999.

14. U.S. Department of Energy, DOE G 441.1-3, “Internal Dosimetry Program Guide,” March 17, 1999.

15. U.S. Department of Energy, DOE G 441.1-4, “External Dosimetry Program Guide,” March 17, 1999.

16. U.S. Department of Energy, DOE G 441.1-2, “Occupational ALARA Program Guide,” March 17, 1999.

Appendix T

Model Leak Test Procedures

Model Leak Test Procedures

This appendix provides applicants and licensees with model leak test procedures and sample calculations for determining activity on a wipe test sample.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD Registration Certificate.

Procedure for Performing Leak Testing and Analysis

For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclide, and activity.

- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclide and ensure that its calibration is current.
- Using the selected instrument, count and record background count rate.
- Calculate efficiency of the detector. A sample calculation is shown in the next box.
- Count the sample.

For example: $\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$

where: cpm = counts per minute
std = standard
bkg = background
Bq = becquerels

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

For example: $\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{efficiency in cpm/Bq}} = \text{Bq on wipe sample}$

- Sign and date the list of sources, data and calculations. Retain records for 3 years (10 CFR 20.2103(a)).
- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly.
- Also notify NRC.

Appendix U

Transportation Requirements

Transportation Requirements

The major areas in the DOT regulations that are most relevant for transportation of licensed material shipped as Type A quantities are as follows:

- Hazardous Materials Table, 49 CFR 172.101, App. A, list of hazardous substances and reportable quantities (RQ), Table 2: Radionuclides
- Shipping Papers 49 CFR 172.200-204: General entries, description, additional description requirements, shipper's certification
- Package Markings 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, specifications for RADIOACTIVE placards
- Emergency Response Information, Subpart G, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements
- Shippers - General Requirements for Shipments and Packaging, Subpart I, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.412, 49 CFR 173.415, 49 CFR 173.431, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.448, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, additional design requirements for Type A packages, authorized Type A packages, activity limits for Type A… packages, requirements for determining A_1 and A_2, table of A_1 and A_2 values for radionuclides, radiation level limitations, contamination control, general transportation requirements, quality control requirements prior to each shipment, approval of special form radioactive materials.
- Carriage by Public Highway - General Information and Regulations, Subpart A, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Hazard Communications for Class 7 (Radioactive) Materials

DOT Shipping Papers (49 CFR 172.200-205)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Entries Always Required Unless Excepted	Additional Entries Sometimes Required	Optional Entries
! The basic description, In sequence: **Proper Shipping Name**, **Hazard Class (7),** **U.N. Identification Number** ! 24 hour **emergency response telephone number** ! Name of **shipper** ! Proper page numbering (Page 1 of 4) ! Except for empty and bulk packages, the **total quantity** (mass, or volume for liquid), in appropriate units (lbs, mL....) ! If not special form, **chemical and physical form** ! The **name of each Radionuclides** (95% rule) and total package activity. The activity must be in SI units (e.g., Bq, TBq), or both SI units and customary units (e.g., Ci, mCi). ! For each labeled package: - The **category of label** used; - The **transport index** of each package with a Yellow-II or Yellow-III label ! Shipper's **certification** (not required of private carriers)	Materials-Based Requirements: ! If hazardous substance, "RQ" as part of the basic description ! The LSA or SCO group (e.g., LSA-II) ! "Highway Route Controlled Quantity" as part of the basic description , if HRCQ ! Fissile material information (e.g., "Fissile Exempt," controlled shipment statement [see §172.203(d)(7)]) ! If the material is considered hazardous waste and the word waste does not appear in the shipping name, then "waste" must precede the shipping name (e.g., Waste Radioactive Material, nos, UN2982) ! "Radioactive Material" if not in proper shipping name Package-Based Requirements: ! Package identification for DOT Type B or NRC certified packages ! IAEA CoC ID number for export shipments or shipments using foreign-made packaging (see §173.473) Administrative-Based Requirements: ! "Exclusive Use-Shipment" ! Instructions for maintenance of exclusive use-shipment controls for LSA/SCO strong-tight or NRC certified LSA (§ 173.427) ! If a DOT exemption is being used, "DOT-E" followed by the exemption number	! The type of packaging (e.g., Type A, Type B, IP-1, ...) ! The Technical/chemical name may be in included (if listed in §172.203(k), in parentheses between the proper shipping name and hazard class; otherwise inserted in parenthesis after the basic description) ! Other information is permitted (e.g., functional description of the product), provided it does not confuse or detract from the proper shipping name or other required information ! For fissile radionuclides, except Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may be used *in place of* activity units. For Pu-238, Pu-239, and Pu-241, the weight in grams or kilograms may optionally be entered *in addition to* activity units [see § 172.203(d)(4)] ! Emergency response hazards and guidance information (§§ 172.600-604) may be entered on the shipping papers, or may be carried with the shipping papers [§ 172.602(b)]

Some Special Considerations/Exceptions for Shipping Paper Requirements

! Shipments of Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from shipping papers. For limited quantities (§173.421), this is only true if the limited quantify is not a hazardous substance (RQ) or hazardous waste (40 CFR 262)

! Shipping papers must be in the pocket on the left door, or readily visible to person entering driver's compartment and within arm's reach of the driver

! For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, be designated by an "X" (or "RQ") in the hazardous material column, or be highlighted in a contrasting color

Hazard Communications for Class 7 (Radioactive) Materials

Marking Packages (49 CFR 172.300-338)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Markings Always Required Unless Excepted

Non-Bulk Packages

- Proper shipping name
- U.N. identification number
- Name and address of consignor or consignee, *unless*:
  - highway only and no motor carrier transfers, or
  - part of carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee [see §172.301(d)]

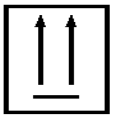
Bulk Packages (i.e., net capacity greater than 119 gallons as a receptacle for liquid, or 119 gallons and 882 pounds as a receptacle for solid, or water capacity greater than 1000 lbs, with no consideration of intermediate forms of containment)

- U.N. identification number, on orange, rectangular panel (see §172.332) - some exceptions exist

Additional Markings Sometimes Required

Materials-Based Requirements:

- If in excess of 110 lbs (50 kg), Gross Weight
- If non-bulk liquid package, underlined double arrows indicating upright orientation (two opposite sides) [ISO Std 780-1985 marking]



- If a Hazardous substance in non-bulk package, the letters "RQ" in association with the proper shipping name

Package-Based Requirements:

- The package type if Type A or Type B (½" or greater letters)
- The specification-required markings [e.g., for Spec. 7A packages: "DOT 7A Type A" and "Radioactive Material" (see §178.350-353)]
- For approved packages, the certificate ID number (e.g., USA/9166/B(U), USA/9150/B(U)-85, ...)
- If Type B, the trefoil (radiation) symbol per Part 172 App. B [*size*: outer radius ≥ 20 mm (0.8 in)]

- For NRC certified packages, the model number, gross weight, and package ID number (10 CFR 71.85)

Administrative-Based Requirements:

- If a DOT exemption is being used, "DOT-E" followed by the exemption number
- If an export shipment, "USA" in conjunction with the specification markings or certificate markings

Optional Markings

- "IP-1," "IP-2," or "IP-3" on industrial packaging is recommended
- Both the name and address of consignor and consignee are recommended
- Other markings (e.g., advertising) are permitted, but must be sufficiently away from required markings and labeling

Some Special Considerations/Exceptions for Marking Requirements

- Marking is required to be: (1) durable, (2) printed on a package, label, tag, or sign, (3) unobscured by labels or attachments, (4) isolated from other marks, and (5) be representative of the HAZMAT contents of the package
- Limited Quantity (§173.421) packages and Articles Containing Natural Uranium and Thorium (§173.426) must bear the marking "radioactive" on the outside of the inner package or the outer package itself, and are excepted from other marking. The excepted packages shipped under UN 2910 must also have the accompanying statement that is required by §173.422.
- Empty (§173.428) and Radioactive Instrument and Article (§173.424) packages are excepted from marking
- Shipment of LSA or SCO required by §173.427 to be consigned as exclusive use are excepted from marking except that the exterior of each nonbulk package must be marked "**Radioactive-LSA**" or "**Radioactive-SCO**," as appropriate. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52.
- For bulk packages, marking may be required on more than one side of the package (see 49 CFR 172.302(a))

Hazard Communications for Class 7 (Radioactive) Materials

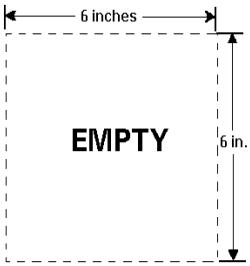
Labeling Packages (49 CFR 172.400-450)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Placement of Radioactive Labels

- Labeling is required to be: (1) placed near the required marking of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in contrast with its background, (4) unobscured by markings or attachments, (5) within color, design, and size tolerance, and (6) representative of the HAZMAT contents of the package
- For labeling of radioactive materials packages, two labels are required on opposite sides excluding the bottom

Determination of Required Label

Size: *Sides:* ≥ 100 mm (3.9 in.) *Border:* 5-6.3 mm (0.2-0.25 in.)	 49 CFR 172.436	 49 CFR 172.438	 49 CFR 172.440	 49 CFR 172.450
Label	**WHITE-I**	**YELLOW-II**	**YELLOW-III**	**EMPTY LABEL**
Required when:	Surface radiation level < 0.005 mSv/hr (0.5 mrem/hr)	0.005 mSv/hr (0.5 mrem/hr) < surface radiation level ≤ 0.5 mSv/hr (50 mrem/hr)	0.5 mSv/hr (50 mrem/hr) < surface radiation level ≤ 2 mSv/hr (200 mrem/h) [Note: 10 mSv/hr (1000 mrem/hr) for exclusive-use closed vehicle (§173.441(b)]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to **§173.428**. It must cover any previous labels, or they must be removed or obliterated.
Or:	**TI = 0** [1 meter dose rate < 0.0005 mSv/hr (0.05 mrem/hr)]	**TI ≤ 1** [1 meter dose rate < 0.01 mSv/hr (1 mrem/hr)]	**TI ≤ 10** [1 meter dose rate < 0.1 mSv/hr (10 mrem/hr)] [Note: There is no *package* TI limit for exclusive-use]	
Notes:	! Any package containing a Highway Route Controlled Quantity **(HRCQ) must bear YELLOW-III label** ! Although radiation level transport indices (TIs) are shown above, **for fissile material**, the TI is typically determined on the basis of criticality control			

Content on Radioactive Labels

! RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
(1) The radionuclides in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
(2) The activity in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis.
(3) The Transport Index (TI) in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label *may* not be required on opposite sides, and must not display the hazard class number
- Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are excepted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classed for that hazard. Hazard communication requirements for the other class are required
- Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
- The “Cargo Aircraft Only” label is typically required for radioactive materials packages shipped by air [§ 172.402(c)]

Hazard Communications for Class 7 (Radioactive) Materials

Placarding Vehicles (49 CFR 172.500-560)

NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Visibility and Display of Radioactive Placard

- Placards are required to be displayed:
  - on four sides of the vehicle
  - visible from the direction they face, (for the front side of trucks, tractor-front, trailer, or both are authorized)
  - clear of appurtenances and devices (e.g., ladders, pipes, tarpaulins)
  - at least 3 inches from any markings (such as advertisements) which may reduce placard's effectiveness
  - upright and on-point such that the words read horizontally
  - in contrast with the background, or have a lined-border which contrasts with the background
  - such that dirt or water from the transport vehicle's wheels will not strike them
  - securely attached or affixed to the vehicle, or in a holder.
- Placard must be maintained by carrier to keep color, legibility, and visibility.

Conditions Requiring Placarding

- Placards are required for any vehicle containing package with a RADIOACTIVE Yellow-III label
- Placards are required for shipment of LSA or SCO required by §173.427 to be consigned as exclusive use. Examples of this category are domestic, strong-tight containers with less than an A_2 quantity, and domestic NRC certified LSA/SCO packages using 10 CFR 71.52. Also, for bulk packages of these materials, the orange panel *marking* with the UN Identification number is not required.
- Placards are required any vehicle containing package with a Highway Route Controlled Quantity **(HRCQ)**. In this case, the placard must be placed in a square background as shown below (see §173.507(a))

Radioactive Placard

Size Specs:

Sides: ≥ 273 mm (10.8 in.)

Solid line Inner border: About 12.7 mm (0.5 in.) from edges

Lettering: ≥ 41 mm (1.6 in.)

Square for HRCQ: 387mm (15.25 in.) outside length by 25.4 mm (1 in.) thick

49 R CF 17 2.556

RADIOACTIVE PLACARD (Domestic)

Base of yellow solid area: 29 ± 5 mm (1.1 ± 0.2 in.) above horizontal centerline

I A 6 AE SS (19 85) paras. 443-444

RADIOACTIVE PLACARD (International)

S 4 ee 9 CFR 172.527 AND 556

RADIOACTIVE PLACARD FOR HIGHWAY ROUTE CONTROLLED QUANTITY
(either domestic or international placard could be in middle)

Some Special Considerations/Exceptions for Placarding Requirements

- Domestically, substitution of the UN ID number for the word "RADIOACTIVE" on the placard is prohibited for Class 7 materials. However, some import shipments may have this substitution in accordance with international regulations.
- Bulk packages require the orange, rectangular panel marking containing the UN ID number, which must be placed adjacent to the placard (see §172.332) [NOTE: except for LSA/ SCO exclusive use under §173.427, as above]
- If placarding for more than one hazard class, subsidiary placards must not display the hazard class number. Uranium Hexaflouride (UF_6) shipments ≥ 454 kg (1001 lbs) require both RADIOACTIVE and CORROSIVE (Class 8) placarding
- For shipments of radiography cameras in convenience overpacks, if the overpack does not require a RADIOACTIVE - YELLOW III label, vehicle placarding is not required (regardless of the label which must be placed on the camera)

Minimum Required Packaging For Class 7 (Radioactive) Materials
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Quantity:	< 70 Bq/g (< 0.002 :Ci/g)	Limited Quantity (§173.421)	A_1/A_2 value (§173.435)	1 rem/hr at 3 m, unshielded (§173.427)

Non-LSA/SCO:	**Excepted**	**Type A**	**Type B** [3]
Domestic or International LSA/SCO: LSA-I solid, (liquid)[1] SCO-I	**Excepted**	**IP-I**	**Type B** [3]
LSA-I Liquid LSA-II Solid, (liquid or gas)[1] (LSA-III)[1] SCO-II		**IP-II**	**Type B** [3]
LSA-II Liquid or Gas LSA-III		**IP-III**	**Type B** [3]
Domestic (only) LSA/SCO: LSA-I, II, III; SCO-I, II	**Excepted**	**Strong-tight** [2] / **DOT Spec. 7A Type A**	**Type B** [3] **NRC Type A LSA** [3,4]

1. For entries in parentheses, exclusive use is required for shipment in an IP (e.g., shipment of LSA-I liquid in an IP-I packaging would require exclusive use consignment)
2. Exclusive use required for strong-tight container shipments made pursuant to §173.427(b)(2)
3. Subject to conditions in Certificate, if NRC package
4. Exclusive use required, see §173.427(b)(4). Use of these packages expires on 4/1/99 (10 CFR 71.52)

Package and Vehicle Radiation Level Limits (49 CFR 173.441) [A]
This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

Transport Vehicle Use:	**Non-Exclusive**	**Exclusive**		
Transport Vehicle Type:	Open or Closed	Open (flat-bed)	Open w/Enclosure [B]	Closed
Package (or freight container) **Limits:**				
External Surface	2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**	10 mSv/hr **(1000 mrem/hr)**
Transport Index (TI) [C]	10	no limit		
Roadway or Railway Vehicle (or freight container) **Limits:**				
Any point on the outer surface	N/A	N/A	N/A	2 mSv/hr **(200 mrem/hr)**
Vertical planes projected from outer edges		2 mSv/hr **(200 mrem/hr)**	2 mSv/hr **(200 mrem/hr)**	N/A
Top of…		load: **(200 mrem/hr)**	enclosure: 2 mSv/hr **(200 mrem/hr)**	vehicle: 2 mSv/hr **(200 mrem/hr)**
2 meters from. . .		vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	vertical planes: 0.1 mSv/hr **(10 mrem/hr)**	outer lateral surfaces: 0.1 mSv/hr **(10 mrem/hr)**
Underside		2 mSv/hr **(200 mrem/hr)**		
Occupied position	N/A [D]	0.02 mSv/hr **(2 mrem/hr)** [E]		
Sum of package TI's	50	no limit [F]		

A. The limits in this table do not apply to excepted packages - see 49 CFR 173.421-426
B. Securely attached (to vehicle), access-limiting enclosure; package personnel barriers are considered as enclosures
C. For nonfissile radioactive materials packages, the dimensionless number equivalent to maximum radiation level at 1 m (3.3 feet) from the exterior package surface, in millirem/hour
D. No dose limit is specified, but separation distances apply to Radioactive Yellow-II or Radioactive Yellow-III labeled packages
E. Does not apply to private carrier wearing dosimetry if under radiation protection program satisfying 10 CFR 20 or 49 CFR 172 Subpart I
F. Some fissile shipments may have combined conveyance TI limit of 100 - see 10 CFR 71.59 and 49 CFR 173.457

Package and Vehicle Contamination Limits (49 CFR 173.443)

This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials

NOTE: All values for contamination in DOT rules are to be averaged over each 300 cm^2
Sufficient measurements must be taken in the appropriate locations to yield representative assessments

&(means the sum of beta emitters, gamma emitters, and low-toxicity alpha emitters
" means the sum of all other alpha emitters (i.e., other than low-toxicity alpha emitters)

The Basic Contamination Limits for All Packages: 49 CFR 173.443(a), Table 11	**General Requirement: Non-fixed (removable) contamination must be kept as low as reasonably achievable (ALARA)**
	&(: **0.4 Bq/cm^2 = 40 Bq/100 cm^2 = 1x10^{-5} :Ci/cm^2 = 2200 dpm/100 cm^2**
	": **0.04 Bq/cm^2 = 4 Bq/100 cm^2 = 1x10^{-6} :Ci/cm^2 = 220 dpm/100 cm^2**

The following exceptions and deviations from the above basic limits exist:

Deviation from Basic Limits	**Regulation 49 CFR §§**	**Applicable Location and Conditions Which must Be Met:**
10 times the basic limits	173.443(b) and 173.443(c) Also see 177.843 (highway)	On any external surface of a package in an **exclusive use shipment, during transport** including end of transport. Conditions include: (1) Contamination levels at beginning of transport must be below the basic limits. (2) Vehicle must not be returned to service until radiation level is shown to be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any accessible surface, and there is no significant removable (non-fixed) contamination.
10 times the basic limits	173.443(d) Also see 177.843 (highway)	On any external surface of a package, at the beginning or end of transport, if a closed transport vehicle is used, solely for transporting radioactive materials packages. Conditions include: (1) A survey of the interior surfaces of the empty vehicle must show that the radiation level at any point does not exceed 0.1 mSv/hr (10 mrem/hr) at the surface, or 0.02 mSv/hr (2 mrem/hr) at 1 meter (3.3 ft). (2) Exterior of vehicle must be conspicuously stenciled, **"For Radioactive Materials Use Only"** in letters at least 76 mm (3 inches) high, on both sides. (3) Vehicle must be kept closed except when loading and unloading.
100 times the basic limits	173.428	**Internal** contamination limit for **excepted package-empty packaging**, Class 7 (Radioactive) Material, shipped in accordance with 49 CFR 173.428. Conditions include: (1) The basic contamination limits (above) apply to **external** surfaces of package. (2) Radiation level must be ≤ 0.005 mSv/hr (0.5 mrem/hr) at any external surface. (3) Notice in §173.422(a)(4) must accompany shipment. (4) Package is in unimpaired condition & securely closed to prevent leakage. (5) Labels are removed, obliterated, or covered, and the "empty" label (§172.450) is affixed to the package.

In addition, **after any incident** involving spillage, breakage, or suspected contamination, the modal-specific DOT regulations (§177.861(a), highway; §174.750(a), railway; and §175.700(b), air) specify that vehicles, buildings, areas, or equipment have "no significant removable surface contamination," before being returned to service or routinely occupied. The carrier must also notify offer or at the earliest practicable moment after incident.

Example Certificate Enclosed In/or on Package, Included with the Packing List or Otherwise Forwarded with the Package

This package conforms to the conditions, and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or articles, UN2910.

_____

(Signed) Radiation Safety Officer

Appendix V

Model Waste Management Procedures

Model Waste Management Procedures

General Guidelines

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal into ordinary "non-radioactive" waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind workers that nonradioactive waste such as leftover reagents, boxes, and packaging material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.

5. Waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.

6. Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or to radiation.

Model Procedure for Disposal by Decay-in-Storage (DIS)

Applicants should assure that adequate space and facilities are available for the storage of waste for DIS. Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

1. Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

2. Short-lived waste should be segregated from long-lived waste.

3. Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

4. Liquid and solid wastes must be stored separately.

5. When the container is full, it should be sealed. The sealed container should be identified with a label affixed or attached to it.

6. The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, date when ten half-lives of the longest-lived radioisotope will have transpired, and the initials of the individual who sealed the container. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives that persons performing surveys should be aware of the potential for measurable radiation.

7. The contents of the container should be allowed to decay for at least ten half-lives of the longest-lived radioisotope in the container.

8. Prior to disposal as ordinary trash, each container should be monitored as follows:

    a. Check the radiation detection survey meter for proper operation.

    b. Survey the contents of each container in a low background area.

    c. Remove any shielding from around the container.

    d. Monitor all surfaces of the container.

    e. Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity, i.e. surface readings are indistinguishable from background.

    f. If the surveys indicate residual radioactivity, return the container to DIS area and contact the RSO for further instructions.

9. If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. Syringes/needles placed into sealed waste containers for decay do not need the labels removed, provided that the following is done: waste barrels are sealed prior to delivery to the waste disposal firm and delivered directly from the licensee's facility; labels are removed from the waste barrels/containers; and that the waste is incinerated, not placed in a landfill; and the waste disposal firm is cautioned not to open the container prior to incineration.

Model Procedure for Disposal of Liquids Into Sanitary Sewerage

1. Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

2. Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.

3. Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in 10 CFR 20, Appendix B.

4. Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR 20, Appendix B, Table 3 (records for individual users/laboratories).

5. If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

6. Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 Gbq (1 Ci) of all other radioisotopes combined.

7. Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.

8. Liquid waste should be discharged only via designated sinks or toilets.

9. Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.

10. Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces. Decontaminate as appropriate.

11. Decontaminate all areas or surfaces if found to be contaminated.

12. For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and its quantity and concentration that is released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial waste disposal, i.e., incineration of a licensee's own waste. 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 level concentrations in liquid scintillation media and animal tissue may be disposed of without regard to radioactivity. After you review your program and confirm that you have waste that requires specific NRC approval for incineration, please provide the following information.

1. Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.

2. Describe the waste that is proposed to be incinerated, to include: the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged and labeled for transfer from the generation site to the incinerator; the name of the radioisotope; concentration of radioactivity averaged over the weight of the material to be incinerated (microcuries per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year. Describe procedures for ensuring that these frequencies and activities will not be exceeded.

3. Describe the procedures for packaging, handling, securing and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.

4. Describe your method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe your procedures for collection, handling and disposal of the ash residue.

5. Describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations.

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

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

8. Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR 20.

9. Provide a written commitment that the applicant has coordinated with appropriate State and local authorities and that such permits and other authorizations as may be necessary have been obtained.

10. Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations and for monitoring all effluent generated by the incineration process. The procedures must ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant must describe how any ash generated exceeding regulatory limits will be disposed of.

Model Procedure for Compaction

The following information should be provided from licensees who propose to compact waste.

1. Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs, etc.).

2. Describe the type, quantities, and concentrations of waste to be compacted.

3. Provide an analysis of the potential for airborne release of radioactive material during compaction activities.

4. State the location of the compactor(s) within the 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 the procedures for monitoring filter blockage and exchange.

5. Discuss the methods used to monitor worker breathing zones and/or exhaust systems.

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

7. Discuss 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.

Appendix W

Addendum: Summary of Comments Received on Draft NUREG-1556, Vol. 11, and Other Changes

Addendum: Summary of Comments Received on Draft NUREG-1556, Vol. 11, and Other Changes

Comments Provided by the California Chapter of the American College of Nuclear Physicians (ACNP-CA), Dated December 2, 1998

Location	Subject	Comment
Entire Document	Document ignores recommendations of the Institute of Medicine	All of these documents (NUREG-1556 Volumes 9 and 11 the proposed revision of 10 CFR Part 35) ignore and fail to implement the recommendations in the report from the Institute of Medicine (IOM) of the National Academy of Sciences.
NRC Staff Response: The Institute of Medicine recommendations concerned the regulation of the medical uses of byproduct, source and special nuclear material. ACNP-CA's comment appears to apply to the proposed revision of Part 35 and NUREG-1556 Volume 9, not Volume 11. NUREG-1556 Volume 11 is intended to provide guidance for broad scope licensees, including medical broad scope licensees. Therefore, there are occasional references to 10 CFR Part 35 and NUREG-1556 Volume 9 in Volume 11 to alert licensees to the presence of additional or different requirements for broad scope licensees who use byproduct material for medical purposes. NUREG-1556 Volume 11 makes no attempt to establish additional requirements and/or guidance for medical licensees.		
Entire Document	Document is not risk related and performance based.	The NRC promised that both the revised Part 35 and the NUREGs would be risk related and performance based. They are neither!
NRC Staff Response: We believe that NUREG-1556, Volume 11, is risk related and performance based. NRC recognizes the low risk associated with many licensed activities and the ability of broad scope licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 11 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. In addition, Volume 11 establishes a method for Type A broad scope licensees who have developed an adequate oversight program to make substantial changes to many procedures previously approved by NRC without amendment of the license. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspection.		

Location	Subject	Comment
Entire Document	Document reveals an increase in regulations and other requirements and increased costs.	The NRC also stated that regulatory activity and costs would be decreased, but a review of the proposed Part 35 and the two latest NUREGs reveals an increase in regulations and other requirements and increased costs.
NRC Staff Response: We do not believe that NUREG-1556, Volume 11, reveals an increase in regulations and other requirements and increased costs. Volume 11 does not create any regulations and the only new requirements are established for Type A broad scope licensees who want the flexibility to revise procedures previously approved by NRC without amendment of the license. However, these additional requirements do not apply to Type A broad scope licensees who do not want this added flexibility or to Type B and Type C broad scope licensees. While these additional requirements would incur some cost if added program flexibility was implemented, we believe that these costs would be balanced by the elimination of the need for many license amendments. The decision is made by the licensee.		
Entire Document	NRC limited areas of public comment.	The NRC had promised to have an open and unbiased review of these documents, but they again violated their trust by limiting the areas of public comment only to the questions unilaterally framed by the NRC.
NRC Staff Response: Public comment on NUREG-1556, Volume 11 was requested, and desired, in all areas. There was no limiting of the areas for public comment.		
Comment not applicable to NUREG-1556, Volume 11	The proposed revision of Part 35 is based on flawed premises.	The California Chapter of ACNP responded to the proposed revision of Part 35 with an overall critique of its many deficiencies. We could not in good conscience comment regulation by proposed regulation because we can not accept the flawed premises on which any of these regulations- are based.
NRC Staff Response: This comment appears to apply only to the proposed revision of Part 35 and NUREG-1556, Volume 9. As previously stated, NUREG-1556, Volume 11, only references Part 35 and NUREG-1556, Volume 9, and makes no attempt to establish additional requirements and/or guidance for medical licensees.		

Location	Subject	Comment
Entire Document	Insufficient comment period established by NRC.	We and other organizations had requested a one year delay in order to permit time for an honest discourse between the NRC and interested parties in order to resolve these many important problems. Instead, I was recently informed that the NRC has extended the comment period for only one month. This is apparently not a month for discussion of outstanding problems, but merely another month to comment on these flawed documents.

NRC Staff Response: NRC would have preferred to extend the comment period so that more individuals, including NRC staff, could have reviewed the document and provided comment. Nevertheless, the comment period was open for four months and NRC believes that it is important to finalize the document so that it can be used. NRC believes that significant additional comment will be provided as licensees and license reviewers gain experience using the document. These comments will be incorporated into the document during a planned revision in 2002.

Location	Subject	Comment
Not applicable to NUREG-1556, Volume 11	Request that Commission review the determinations published in the Federal Register that: (1) NRC has responsibility for controlling the practices of nuclear medicine and nuclear pharmacy in order to ensure patient radiation safety; and (2) the Commission cannot use concepts of relative risk in its risk assessment because it is forbidden to do so by the Atomic Energy Act.	At the public meeting on the Proposed Part 35 and NUREG-1556 Volume 9, which was held at the NRC on Oct. 21 and 22, 1998, a representative from SNM and ACNP put two critical questions to the NRC Commissioners, not the NRC staff or management, and asked for rapid resolution. Commissioner McGaffigan was present and the request was directed to him, as no other Commissioners were present. Neither question has been answered. The first question dealt with the apparent determination by the Commission that the Atomic Energy Act had been misinterpreted for over 40 years and that in fact NRC has responsibility for controlling the practices of nuclear medicine and nuclear pharmacy in order to ensure "patient radiation safety". NRC's newly-found power apparently now extends to determining which radiopharmaceuticals are allowed to be given to patients, in what doses, and for what medical conditions, and extends as well to how the drugs are prepared. That is, NRC has now published in the Federal Register that it has the power to practice medicine and pharmacy in 50 states without a license and without even seeing the patients. The SNM/ACNP found this arrogant pronouncement to be outrageous, and asked that the Commissioners review what they signed and verify whether or not they really believe this. The second question dealt with the fact that the Commission has determined that it cannot use concepts of relative risk in its risk assessment because it is forbidden to do so by the Atomic Energy Act. The SNM/ACNP representative clearly explained that all of medicine is an exercise in relative risk, and that absolute risk is a logically impossible way to consider the risk of using byproduct material in medicine. Put another way, it is theoretically impossible to have a "risk informed" rule in medicine if relative risk is not considered. Again, this was published in the Federal Register, and the Commissioners were asked to review what they signed and verify whether or not it accurately reflects their beliefs.

Location	Subject	Comment
NRC Staff Response: As previously stated, NUREG-1556, Volume 11, only references Part 35 and NUREG-1556, Volume 9, and makes no attempt to establish additional requirements and/or guidance for medical licensees. These comments appear to apply to the proposed revision of Part 35 and NUREG-1556, Volume 9.		
Entire Document	Request one-year delay for review	Again, we urge a one-year delay for a reconsideration of Part 35, as well as NUREG-1556, Volumes 9 and 11.
NRC Staff Response: For the reasons stated above, NRC Management has decided that NUREG-1556, Volume 11, will be issued without further delay.		

Comments Provided by Mallinckrodt, Inc. (St. Louis, MO), Dated December 7, 1998

Location	Subject	Comment
Executive Management	Executive Management	Specifically, we are seeking a clarification for Section 8.7.1, Executive Management. In particular, as referenced in the NUREG-1516, Management of Radioactive Material Safety Programs at Medical Facilities, an individual at the senior management level is responsible for the oversight of a licensee's radiation safety program. Some large companies may have several broad scope licenses. Even though an individual at a senior management level (e.g., senior vice president or vice president and general manager of a group/division) may have the ultimate responsibility for several licenses, the oversight of each of the radiation protection program may be delegated to the facility's senior management representative (e.g., the Facility Director). In these cases, the Facility Director is the vital member of the Radiation Safety Committee (RSC), and has the authority to commit the necessary resources. In other cases, depending upon the organizational structure, the oversight for the facility's radiation safety program may be delegated to two individuals - one for fiscal resources and one for programmatic resources. In other words, even though senior management has the ultimate responsibility, the guidance should be revised to provide flexibility in delegating the oversight responsibility, depending upon the company's organizational structure.

NRC Staff Response: This section is modified to clarify that there is flexibility in delegating the oversight responsibility, depending upon the company's organizational structure. However, the document still requires that there is still one level of management, as the licensee's representative, with ultimate responsibility for the radiation safety program.

Comments Provided by UCLA School of Medicine, Harbor - UCLA Medical Center, Department of Radiology (Torrence, CA), Dated December 21, 1998

Location	Subject	Comment
Chapter 11	Termination of Activities	I read with interest the NRC's "acceptable license termination screening values of common radionuclides for building surface contamination", which appear in Table I of Fed. Reg. 63 (222) 64134, attached. These actually appear to have been based on science. Compare these with NRC's "acceptable surface contamination levels in unrestricted areas", found in Table R. 3, p. R-4 of draft "Program-Specific Guidance About Medical Use Licensees", NURFG-1556 Vol. 9, attached. For the same radionuclide, the medical licensee limits are about 3-10,000 times more restrictive than for decommissioned licensees. Why is that? I would think they would be the same or less restrictive for medical licensees. If there is some reason why they are not the same, what is that reason and why is there not a constant factor rather than an enormous range of factors between the two?

NRC Staff Response: The Federal Register Notice providing supplemental information on the implementation of the final rule on radiological criteria for license termination was not published at the time this NUREG was issued for comment. Dr, Marcus' comments are noted and the new guidance has been incorporated.

Comments Provided by Michigan State University, Dated December 21, 1998

Location	Subject	Comment
Appendix L (Appendix K in Final)	IAEA Table	45 Ca, a high radiotoxicity radionuclide, is excluded from the table and needs to be in because it is used by most research and development licensees. It targets bone, so is therefore high radiotoxicity. Also, the betas are more ionizing than gammas in tissue.

NRC Staff Response: The NRC staff agrees with this comment; however, it is not the intent of the NRC to modify the table presented in the 1973 IAEA document. The staff recognizes that there are many radionuclides that are used on a regular basis in R&D laboratories that are not included in the table referenced in Appendix L, of Draft NUREG 1556, Volume 11 (Appendix K of the Final document). The table was not intended be used as an all inclusive reference in a broad scope license. The table is provided as guidance showing how a toxicity table may look.

Location	Subject	Comment
Appendix L (Appendix K in Final document)	IAEA Table	125 I is listed as a high radiotoxicity radionuclide. It is low, due to many things, as described below. 125 I is very low energy, low ionizing potential (no mass and no charge), low specific gamma ray constant, short half life, not a high risk target organ. (The effective half life is 45 days in thyroid, meaning the clearance is fast if a dose is incurred.) Most of the uses of 125 I are in a form bound to protein so it does not volatilize in the bound form, and is not utilized well by the human body when bound to a protein. Also, 131 I, with much higher energies, and more gammas of significance, is given orally to or injected in humans every day all over the world as a diagnostic and therapeutic regimen, in tens of millicurie amounts, with little to no health risk. There is slightly more risk in iodinations with 125 I, as I have mentioned. But even that risk is low in actual practice, where they use a hood and other precautions and have required thyroid bioassays after each use; thyroid uptakes are almost unheard of these days. Classifying 125 I as a high risk nuclide will have a major impact upon our programs as they are currently licensed and operated. We request that the radiotoxicity be reclassified in the NUREG doc to a low radiotoxicity. This is in keeping with current biological risk and scientific knowledge and regulations, such as the 10 CFR 20 App B information.

NRC Staff Response: The NRC staff acknowledges these comments. Again, it is not the intent of the NRC staff to change the 1973 excerpt of the IAEA table. During the licensing process, NRC Broad scope licensees may propose how they will classify radionuclide toxicity based on chemical/physical form, quantity and type of use. If the proposed classification scheme has a sound scientific basis, it would be acceptable to the NRC. The NRC licensing and/or inspection staff may challenge a proposed classification scheme or one that may be in use; however, it is not the intent of the NRC to provide an all inclusive classification table.

Location	Subject	Comment
Appendix L (Appendix K in Final document)	IAEA Table	I am recommending that the NRC incorporate our entire classification scheme as part of the NUREG 1556 Vol 11 guidance document. It gives licensees a NRC-endorsed method of managing risk categories.
The NRC staff acknowledges the offer to incorporate the commentor's NRC-approved classification scheme; however, we must decline. The fact that the NRC approved your toxicity classification table does not mean that the NRC has endorsed the table. The NRC licensing staff approved this licensee's proposed table based on need and proposed use of the licensee which may not fit the needs of other licensees. However, the NRC staff encourages licensees (both NRC and Agreement State) to share information among themselves.		

Comments Received from the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) on December 3, 1998

Location	Subject	Comment
Entire Document	Licensing flexibility should be uniform for NRC and Agreement States	CORAR recommends that broad scope licensing flexibility should be uniform for NRC and Agreement State licensees. The NRC should make statements to this effect in NUREG 1556 and/or in the Federal Register.
NRC Staff Response: NRC is developing the NUREG-1556 series of guidance documents for use by applicants for NRC license, NRC licensees, and NRC license reviewers. As with all NRC guidance documents, they are available for adoption by Agreement States for use within their own regulatory programs; however, NRC does not have the authority to impose this guidance on Agreement State Programs and their licensees.		
Section 1, page 1-4, paragraph 3, lines 3-4	Purpose of Draft Report	"NRC has permitted broad scope licensees, on a case by case basis, to build in limited program flexibility during the licensing process". The Council on Radionuclides and Radiopharmaceuticals (CORAR) encourages the NRC to continue to permit program flexibility for broad scope licensees. This is necessary to promote the continuous improvement of licensee programs as new technologies become available.
NRC Staff Response: It is NRC's intent to continue to permit this program flexibility.		
Section 1, page 1-5, paragraph 1	Purpose of Draft Report	"Type A Broad Scope License Condition Used to Grant Additional Flexibility". This license condition should be reasonable for most applicable licensees.
NRC Staff Response: Comment acknowledged. NRC will modify the condition if experience shows it to be inadequate to achieve the desired result.		
Section 8.7.1, page 8-12	Executive Management	NRC appears to be assuming that one individual shall have oversight of a licensee's radiation safety program. However, in practice, it might be necessary to divide this function between several individuals to ensure the necessary expertise is engaged. The purpose is for the licensee to be able to demonstrate effective oversight. The NRC should empower the licensee to determine the best way to carry out this function.

Location	Subject	Comment
NRC Staff Response: The document was revised to include an explanation in response to another comment received on the NUREG.		
Section 8.7.3, page 8-16, paragraph 7, lines 1 and 2	Radiation Safety Officer	…broad scope licensees must have a Radiation Safety Officer who is responsible for implementing the radiation safety program." CORAR disagrees that this statement applies to all broad scope licensees. Appropriate job duties of an RSO will depend critically on the nature of the facility, operations, organization and culture. For large manufacturing licensees involving hundreds of radiation workers, it is commonly most effective to assign line supervision responsible for implementing the radiation safety program. In such programs the best use of the RSO's expertise is in assuring that the safety program is adequate. This can be most effectively achieved by the RSO being designated the authority and resources to independently and continuously audit the radiation protection program and report findings to supervisors, RSC and management for their action. CORAR does recognize that, in small licensees with infrequent use of radioactive materials, the RSO might well be the best person to implement the radiation safety program. However, CORAR recommends that licensees should be given the flexibility to determine RSO's job functions and show how they would satisfy the needs of the program.
NRC Staff Response: The language has been changed to the language specified in 10 CFR Part 33, which requires the appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters. NRC does recognize that a radiation safety officer at a large facility will not be able to perform each specific function required of this position. This is discussed in the fourth paragraph of the Discussion.		

Location	Subject	Comment
Section 8.7.3, page 8-17, paragraph 3, line 3	Radiation Safety Officer	"Specific duties and responsibilities of the RSO include…" In a major manufacturing facility where hundreds of radiation workers continuously handle radioactive materials it is not possible for an RSO to individually complete all the tasks listed. It might be practical to assign an RSO to supervise a team responsible for carrying out all or some of these duties. Alternatively the RSO could be assigned responsibility for auditing these functions. Licensees should be given the flexibility to determine appropriate duties and responsibilities to assign to the RSO.
NRC Staff Response: As stated in the comment above, the NRC does recognize that a radiation safety officer at a large facility will not be able to perform each specific function required of this position. As discussed in the fourth paragraph of the Discussion, tasks and duties may be assigned or delegated to other individuals; however, the responsibility for such tasks and duties is with the radiation safety officer.		
Section 8.10.4, page 8-30, paragraph 8 and page 8-31, paragraph 2	Occupational Dose	"Minors who are likely to receive an annual dose in excess of any of the following… -0.5 mSv (0.05 rem) deep dose equivalent" and "Declared pregnant women who are likely to receive an annual dose from occupational exposure in excess of 0.5 mSv (0.05 rem) deep dose equivalent." The dose limit for requiring the use of dosimeters for minors and declared pregnant women was changed from 0.5 mSv (0.05 rem) deep dose equivalent to 1 mSv (0.1 rem) deep dose equivalent earlier this year to be compatible with public dose limits.
NRC Staff Response: Comments acknowledged and corrections made.		

Location	Subject	Comment
Section 8.11, page 8-40, paragraph 5	Waste Management	"The NRC has concluded that materials with half lives of less than or equal to 120 days are appropriate for [decay in storage] and interim storage". CORAR agrees with this conclusion and recommends that all licensees be permitted to store radionuclides with half-lives up to 120 days. Also NRC should consider allowing decay in storage for radionuclides with greater half lives on a case by case basis.
NRC Staff Response: Radionuclides with a half life of 120 days or less may be routinely submitted and approved for decay in storage. The licensee can, with appropriate justification, request decay in storage for radionuclides with greater half lives on a case by case basis.		
Appendix H, page H-1, paragraph 4	Information Needed for Transfer of Control Application	"3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation)…" In large manufacturing companies, officers of the corporation do not typically have radiation protection expertise or concern themselves with licensed activities. CORAR recommends that prior written consent be required from the NRC only for changes in individuals named in the license.
NRC Staff Response: This comment relates to Appendix H, "Information Needed for Transfer of Control Application." Section 30.34 of 10 CFR Part 30 specifically prohibits the transfer of a license, either voluntarily or involuntarily, unless the Commission finds that the transfer is in accordance with the provisions of the Act and gives its consent in writing. NRC needs to know of any changes in personnel having control over licensed activities in order to fully evaluate any planned transfers of licensed operations. This is necessary to ensure that: (1) radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses; (2) materials are properly handled and secured; (3) persons using these materials are competent and committed to implementing appropriate radiological controls; (4) a clear chain of custody is established to identify who is responsible for disposition of records and licensed material; (5) the transferee has the financial resources to decommission the license if necessary; and (6) public health and safety are not compromised by the use of such materials. This information regarding a change in the officers of a corporation is needed only if there is a transfer of control of the license. NRC does not require notification of a change in the senior level management responsible for the license if there is no transfer of control of the license.		

Location	Subject	Comment
Appendix L, page L-1, Table 1 (Appendix K in Final document)	Radionuclides Classified According to Relative Toxicity	This table would be more useful if it listed all commonly used radionuclides including 33-P, 90-Sr, 99-Mo, 131-I, and 153- Sm.
NRC Staff Response: The NRC agrees with this comment; however, NRC does not wish to modify the table as presented in the referenced IAEA Safety Standard. This table was not meant to be all inclusive but instead was presented as an example of a scheme which has served the industry well for many years. Licensees are encouraged to develop their own schemes. Section 8.9 was revised to explain that the IAEA table is an example and is not meant to represent an all inclusive toxicity table.		
Appendix Q, page Q-4, paragraph 8 and 9 (Appendix O in Final document)	Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program	"Survey meters' efficiency must be determined by using radiation sources… "…Readings shall be within 20% of the conventially true value." These paragraphs are confusing. Instruments used to quantitate contamination are calibrated by exposing them to a calibrated source of radioactive material that is selected to emulate the type of and energy of radiation and the monitoring geometry. It is not possible to obtain calibration sources that will provide true readings to 20%, 50% and/or 80% of scale for numerous instruments. Hence this specified procedure is not viable and NRC should remove it and provide a procedure that can be implemented.
NRC Staff Response: The procedure for calibrating surface contamination measurement instruments was taken from ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration." It is the proper method for calibrating instruments used to measure surface contamination. That said, for most purposes, it is acceptable to calibrate the instrument in the way that you describe.		

Location	Subject	Comment
Appendix R, page R-2, paragraph 4 (Appendix P in Final document)	Material Receipt and Accountability	"Check DOT … label or packing slip for activity of contents, so shipment dose not exceed license possession limits." Most licensees do not know at what point in time a received package is considered accepted by the licensee and included in the site inventory that must be within license possession limits. CORAR recommends that a procedure be included that describes what a licensee must do when being offered a package which, if accepted, will exceed license possession limits.
NRC Staff Response: NRC believes that it is more appropriate to place the information you requested in the text rather than Appendix R (Appendix P in the Final document). Section 8.10.3, "Material Receipt and Accountability," has been revised to specify that licensed material is considered part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material in excess of license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the NRC Regional Office and request issuance of an expedited license amendment. The materials must not be used until the license amendment is granted.		
Appendix S, page S-1 (Appendix Q in Final document)	Methodology for Determining Public Dose	For completeness, this table should include doses to the public from licensed material in transportation.
NRC Staff Response: Comment noted and suggested change made to document.		

Location	Subject	Comment
Appendix S, page S-2, paragraph 1, lines 10-12 (Appendix Q in Final document)	Methodology for Determining Public dose	"…the licensee … with prior NRC approval ... [can] take into account the physical and chemical characteristics of its effluent." CORAR recommends that the NRC should grant prior approval to account for the physical and chemical characteristics of effluents to all licensees who maintain or contract with an RSO who is qualified to make such calculations. NUREG 1556 Vol. 11 should include an example statement that could be added to such licenses permitting the RSO to use best methods to determine the potency of effluents.
NRC Staff Response: NRC cannot, through guidance, grant prior approval to account for the physical and chemical characteristics of effluents to licensees who have a qualified RSO. This would have to be accomplished by rulemaking. 10 CFR 20.2002 states that if a licensee or applicant for license wants to dispose of licensed material in a manner not otherwise authorized by Part 20, the licensee or applicant may apply to the Commission for approval of proposed procedures. 10 CFR 20.2002(a) requires, in part, that the application include the physical and chemical properties important to risk evaluation.		
Appendix T, page T-4, paragraph 2, lines 3-4 (Appendix R in Final document)	General Topics for Safe Use of Radioisotopes and Model Emergency Procedures	"…consider bioassays if licensed material may have been ingested". Instead of "Ingested", generalize this statement to include all potential intakes of radioactive material.
NRC Staff Response: Comment noted and suggested change made.		

Location	Subject	Comment
Appendix T, page T-7, paragraphs 2 and 3 (Appendix R in Final document)	General Topics for Safe Use of Radioisotopes and Model Emergency Procedures	"Allow no one to return to work in the areas unless approved by the RSO." "Once the fire is extinguished, do not allow firefighters to enter the radiation area until a thorough…" In many towns and states when a building fire occurs and firefighters are called to respond, local regulations assign authority over the building to the firechief. This status continues until the firechief has ordered the building to be entered and confirmed that the fire is extinguished. Hence it is the fire chief who is legally responsible for allowing personnel to enter the building not the RSO. These statements should be rewritten to indicate that the RSO should advise the firefighters concerning entry into the building and disposition of sources of radiation.
NRC Staff Response: Comments acknowledged and changes made.		
Appendix U, page U-1, paragraph 2 (Appendix S in Final document)	Radiation Safety Survey Topics	"Before allowing an individual to perform surveys, the RSO will ensure that he or she has sufficient training and experience to perform surveys independently". Type C broad scope licensees do not necessarily have a RSO. Add to or replace "RSO" with "qualified designee".
NRC Staff Response: A statement was added: "(or for Type C broad scope licensees, the individual designated as responsible for the day-to-day operations of the radiation protection program)."		
Appendix U, page U-2 (Appendix S in Final document)	Radiation Safety Survey Topics	CORAR recommends that the NRC needs to include recommendations of methods a licensee could use to demonstrate compliance with public dose limits when ambient dose rates in unrestricted areas from licensed operations are greater than 12 μrem/h and less than 2 mrem in any one hour.
NRC Staff Response: The methodologies for determining public dose are addressed in Appendix S (Appendix Q in Final document). Appendix U (Appendix S in Final document) is intended for more general radiation safety survey topics.		

In their December 3, 1998 letter, CORAR also recommended that NRC review comments they submitted to NRC on February 4, 1997, in response to the proposed revision of 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material" and NRC Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope."

In that document, CORAR stated that their main concern was that NRC was proposing to prescribe how licensees were to structure their organization and how to design duties and responsibilities within the organization. CORAR maintained that such suggestions should be presented in a Regulatory Guide, as examples of how to organize a radiation protection program, rather than in a regulation. In addition, CORAR provided the following comments:

(1) regulations for broad scope licensees should be performance based;

(2) prescriptive requirements should be avoided in the regulations, and when necessary, applied on a case-by-case basis as license conditions;

(3) most of the prescriptive requirements in this proposed rule would be more effectively conveyed to licensees in a Regulatory Guide if presented as examples of acceptable ways to structure a radiation protection program;

(4) it is impractical for any regulatory agency to prescribe organization structure and specific duties and responsibilities for the great range of broad scope licensee practices and conditions;

(5) broad scope licensees have access to sufficient expertise and resources to enable them to make their own decisions on developing and maintaining a radiation protection program and should be given the authority to do this to meet regulatory performance standards;

(6) 10 CFR 33 should include a section that specifically permits licensees to define their own radiation protection program and related organization, responsibilities and duties in the license application to meet regulatory requirements;

(7) broad scope licensees should be allowed to make timely and appropriate improvements to their radiation protection program and related information described in license applications without the delays and burden of intensive documentation and NRC notifications and approvals; and

(8) the proposed rule is: (1) too prescriptive and is often counterproductive for major manufacturing licensees and (2) has content that would serve the licensee, the regulator and the public more effectively if reshaped and issued as guidance rather than regulation.

NRC agreed with the comments expressed by CORAR in their February 4, 1997 submission. Comments from CORAR and similar comments provided by others resulted in the withdrawal of the proposed revision of 10 CFR Part 33. NRC believes that NUREG-1556 Volume 11 addresses all of the concerns addressed by CORAR in their February 4, 1997 submission.

Comments Provided by Illinois Department of Nuclear Safety, Dated December 11, 1998

Location	Subject	Comment
Section 1, page 1-1, paragraph 2	Purpose of Draft Report	In Section 1, page 1-1, paragraph 2, please include the number of years experience that a specific licensee should have prior to applying for a broad scope license. The Department generally requires specific licensees to have safely operated for 5 years prior to applying for a broad scope.
NRC Staff Response: Previous NRC guidance documents have specified 5 years of operational experience under a limited scope license as a "normal" prerequisite before a broad scope license would be granted. In drafting NUREG-1556, Volume 11, we decided to be somewhat less specific and discuss the fact that a broad scope license "is not normally issued to a new licensee" and that an applicant for a broad scope license "typically has several years of experience operating under a limited scope license." We did this because we believed that the license reviewer should have greater latitude in deciding, on a case-by-case basis, whether or not the applicant for broad scope license has adequate experience. Five years of experience may not be considered adequate if the applicant desires a Type A broad scope license and their experience was with a minimal or inactive limited scope program. Conversely, two or three years of experience may be considered adequate if the experience was with a large and dynamic limited scope licensee. Also consider that the guidance will be used for all broad scope licensees and there should be a difference in the amount of limited scope experience required for an applicant for a Type A broad scope program versus that needed for a Type B or Type C broad scope program.		
Section 1, page 1-1, paragraph 4	Purpose of Draft Report	In paragraph 4, page 1-1, we, have been discussing the possibility of deleting Types B and C broad scopes from our rules. The Department believes that the licensee should have the experience and the management in place to establish a (Type A) broad scope or they should be limited only to a specific (limited scope) license for the activities requested. It has been our experience that limited broad scopes (Type B and Type C) have not gained much from these types of licenses. (Information in parentheses was added for clarification following a telephone discussion with Mr. Gibb Vinson of the Department of Nuclear Safety on January 14, 1999.)

Location	Subject	Comment

NRC Staff Response: 10 CFR Part 33 describes Type A, Type B and Type C broad scope licenses. To eliminate Type B and Type C broad scope authorizations, NRC would need to revise Part 33 through rulemaking. In 1996, NRC proposed rulemaking which, in part, would have eliminated Type B and Type C broad scope authorizations from Part 33. Negative public comment resulted in the termination of this rulemaking.

Location	Subject	Comment
Section 1, pages 1-4 and 1-5	Purpose of Draft Report	We agree with your program flexibility policy in Section 1, pages 1-4 and 1- 5. The condition listed could be very useful. We also authorize this type of latitude including changes to instruments of equivalent specifications and vendor services with equivalent qualifications licensure. We would not allow the licensee to change to a less restrictive survey frequency/procedure as indicated in paragraph 2, page 1-5, since most broad Scopes prefer to default to the most extreme survey frequencies if given the opportunity.
NRC Staff Response: NRC intends to allow licensees who have been granted additional flexibility through license condition to make program changes and changes to procedures as long as the licensee meets the requirements stipulated in the license condition. One stipulation is that the change will not decrease the effectiveness of the Radiation Safety Program. If the licensee changes to a less restrictive survey frequency or procedure, as in your example, a determination will be made during an inspection whether the change decreased the effectiveness of the Program. If the inspector finds that after changing the survey procedure, the licensee failed to identify contamination which resulted in significant personnel exposure or the spreading of contamination into unrestricted areas, and the failure to identify contamination can be attributed to the procedure change, the inspector will likely make the determination that the change decreased the effectiveness of the Program. If, on the other hand, the inspector finds no increase in the spread of contamination or personnel exposures, or finds that the procedure change was not responsible for the increases that were identified, a determination will likely be made that the change did not decrease the effectiveness of the Program. Performance assessments, rather than assessments of compliance, will be the focus of NRC inspections.		
Section 3, page 3-1, paragraph 2	Management Responsibility	In NRC's application form 313, we are not sure of the mechanism in place which binds the licensees to the management responsibilities outlined in Section 3, page 3-1, paragraph 2, through the signatory on the form.
NRC Staff Response: The mechanism in place which binds the licensee to the management responsibilities outlined in Section 3, page 3-1, paragraph 2, is the NRC Form 313 certification (see Item 13 of NRC Form 313). Item 13 requires certification that: (1) the applicant understands that all statements and representations made in the application are binding upon the applicant; (2) the application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30, 32, 33, 34, 35, 36, 39, and 40; and (3) all of the information contained in the application is true and correct to the best of the applicant's knowledge and belief. Section 3, Management Responsibility, is an attempt to simplify and highlight for licensee management the major responsibilities encompassed by the NRC Form 313 certification.		

Location	Subject	Comment
Section 8.3	Address(es) where licensed material will be used or possessed	In Section 8.3, we are not sure how prescriptive you wish your licensees to be with their facility descriptions/diagrams. As a rule we require a campus diagram delineating locations of specific buildings. We require detailed descriptions only of waste storage, irradiator, calibration facilities, etc.
NRC Staff Response: In Item 8.3, an applicant need not identify each facility at a particular address where byproduct material will be used. A statement that byproduct material will be used at the main campus of ABC University located in Anytown, Anystate, is sufficient. If material is to be used off campus at a particular facility, that facility's address should be specified. Concerning special use areas, i.e. waste storage, irradiator, etc., the NRC agrees with the commenter that the location of these areas should be identified either by building number or by other means. Concerning detailed descriptions and/or diagrams of special use areas, Section 8.9 describes the type of information the NRC expects to receive. As discussed in Section 8.9, broad scope applicants need to describe and provide diagrams which represent typical laboratories and special use laboratories, i.e., low use, high use, iodination laboratories, waste handling facilities, etc. and discuss the type of equipment that will be required for use in each type of laboratory. The NRC staff determined that no changes to Item 8.3 were necessary.		
Section 8.7.2, page 8-14	Radiation Safety Committee	A specific list of duties and responsibilities should be provided for the radiation safety committee (RSC). It would also be useful to include as an appendix to this section a sample application form/permit to be used by authorized users when applying to the RSC for permission to use radioactive materials.
NRC Staff Response: There is a general discussion of the duties and responsibilities of the Radiation Safety Committee in Section 8.7.2. The team did not include a specific list of duties and responsibilities for the Radiation Safety Committee because duties and responsibilities might vary from program to program. Broad scope licensees should have the flexibility to develop the duties and responsibilities for their Committee based on the needs of the organization. For the same reason, the team did not provide a sample application form or permit for authorized users to use when applying to the Radiation Safety Committee for permission to use radioactive materials.		

Location	Subject	Comment
Section 8.7.4	Radiation Safety Office Staff	The applicant should provide the number and qualifications of support staff for the radiation safety office. All too often a program cannot function because of insufficient funding or staff for radiation safety.
NRC Staff Response: Because of the range of broad scope programs, NRC cannot specify the number or qualification of the Radiation Safety Office support staff. The licensee is best equipped to make this decision. NRC regulations only require that a licensee have adequate equipment and facilities to protect public health and minimize danger to life or property; that a licensee be qualified by training and experience to use the materials for the purpose requested; and that a licensee establish administrative controls and provisions relating to the organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations. The adequacy of the Radiation Safety Office support staff becomes a performance issue. During an inspection, the inspector will evaluate the adequacy of the licensee's program. If deficiencies in the licensed program are identified, the inspector will attempt to determine the root cause of the deficiencies. One aspect which will be considered is the number and qualification of Radiation Safety Office support staff.		
Section 8.8, page 8-20	Training	We agree with your statement that an untrained worker could represent a hazard to themselves and others resulting in a dose in excess of the 100 mrem/yr action level for training. We therefore are still at a loss as to the relationship established in IOCFR19.12(a) between training and dose. We believe he intent of this rule should be revisited as it could be used by licensees to circumvent training.
NRC Staff Response: The relationship established in 10 CFR 19.12(a) between training and dose is qualified in 19.12(b) where it requires that, in determining those individuals subject to the requirements of 19.12(a), licensees must take into consideration assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. Our statement is intended to emphasize the requirements of 10 CFR 19.12(b) and the importance of providing training to all individuals who, through their actions, could create a hazard to themselves and others resulting in a dose in excess of 100 millirem.		

Location	Subject	Comment
Sections 8.10.1 and 8.10.7	Audit Program and Surveys	There should be a discussion about responsibility for performing routine audits versus surveys. At many institutions, this responsibility is not clearly defined for the RSO staff and the authorized users. Please clarify.

NRC Staff Response: An audit is conducted to evaluate the work performed by another individual or group. Audits are traditionally performed by or for persons who have program oversight responsibility such as the RSO and his/her staff. On occasion we have seen programs where the authorized user audits the work performed by his/her subordinate users or where a group of authorized users is tasked with the performance of a program audit. Surveys are the evaluation of a real or potential radiological condition and are subject to audit. Surveys are traditionally performed by radioactive material users although some licensees task the RSO and his/her staff with the performance of surveys.

The responsibility for conducting surveys and conducting audits is a decision that is made by each individual licensee according to what works best for their program. NRC does not intend to interfere with this decision. The licensee needs to make certain that, whatever the decision, the responsibility is clearly communicated to the responsible individuals.

Section 8.10.2, page 8-27, paragraph 4	Radiation Monitoring Instruments	Regarding Section 8.10.2, page 8-27, paragraph 4, we generally require a full calibration of detection instruments used to demonstrate compliance. Operability checks require less documentation and are difficult to verify in many cases.

NRC Staff Response: NRC also requires a full calibration of instruments used to demonstrate compliance with a regulation or license requirement. However, if an instrument is only used to check a work area for contamination or to check for personal contamination on hands or clothes, it is more important that the instrument used responds to low levels of the type of contamination that may be present. It is not important that the quantity of material present be accurately quantified. If contamination is noted, a properly calibrated instrument can be used to further evaluate the extent of the problem, if necessary. NRC does not necessarily require documentation of operability checks nor would we necessarily attempt to verify that an operability check was performed. Inspectors simply tour facilities and physically test equipment found in the laboratories to see if the equipment responds to the type of radioactive material used in the laboratory and if the instrument is sensitive enough to detect levels of radioactive material contamination below that where one would be concerned about safety. This inspection technique is also used to evaluate instrumentation which is required to undergo full calibration. Rarely would a calibration record be reviewed as it is much more important that the instrument function properly when it is used.

Location	Subject	Comment
Section 8.10.2	Radiation Monitoring Instruments	In Section 8.10.2, we require that the applicant submit a list of instrumentation that will be provided initially with the inclusion of a statement that allows substitution of instruments with equivalent specifications.
NRC Staff Response: The adequacy of the licensee's instrumentation will be evaluated during inspection.		
Section 8.10.5	Public Dose	In Section 8, 10.5, we require the licenses to submit calculations demonstrating compliance with doses, to restricted and unrestricted areas from sources of radiation and effluent releases. This should be discussed in this section.
NRC Staff Response: The licensee's ability to comply with the public dose limits will be evaluated during inspection.		
Section 8.11, page 8-41	Waste Management	In Section 8. 11, page 8-41, a reference to the document SP-97-056 should be, included here regarding solubility of sewer releases.
NRC Staff Response: Comment noted; however, SP-97-056 was not included as it only provides limited information related to inspection findings at two nuclear laundries.		

Location	Subject	Comment
Section 8.11, Par 1	Waste Management	Also In Section 8.11, page 8-42, paragraph 1, you have referenced Regulatory Guide 8.37. The guidance states that 10% to 20% should be the ALARA level for effluent released as a result of incineration. Considering how Regulatory Guides are used, the result is a de facto lowering of the release limits. This does not allow for an evaluation of the applicant's specific technical circumstances where distance, building wake effects, etc. may further reduce any potential dose as a result of meeting regulatory limits at the incinerator exit stack. The Department believes that the effluent from an incinerator stack should have the same restrictions imposed as any other gaseous release point unless technical considerations warrant otherwise. If the Commission insists this matter is of such importance, the lowering of the release limits to 10% of 10 CFR 20 should go through the rulemaking process as a change to 10 CFR 20 where additional information can be presented by the Commission to support these limits.

NRC Staff Response: 10 CFR 20.1302(b)(2) describes the regulatory limit for radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area. This does allow for an evaluation of the applicant's specific technical circumstances you described (distance, building wake effects, etc.) if necessary; however, because the releases from most materials licensees are far below the regulatory limits and it is easier for licensees to quantify effluent releases at the outfall, such as at the incinerator stack, licensees frequently demonstrate compliance using the measured radioactive material concentrations at the outfall rather than calculating or measuring concentrations at the boundary of the unrestricted area.

Regulatory Guide 8.37 does not establish a new regulatory limit, it simply establishes some ALARA goals. Please note that 10 CFR 20.1101(d) establishes a "constraint" on air emissions such that an individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 0.1mSv (10 millirem). This "constraint" effectively lowers the gaseous release limit to 20% of that described in 10 CFR 20.1302(b)(2).

Appendix K	Consideration for Laboratory Animal and Veterinary Medicine Uses	In Appendix K, additional discussion for the use of volatile radiopharmaceuticals such as radioiodine should be included not only for the protection of veterinary staff but also for animals released to the public.

NRC Staff Response: NRC believes that these subjects have already been adequately addressed in other sections of this document.

Location	Subject	Comment
Appendix M	Facilities and Equipment Considerations	In Appendix M, these facility descriptions appear too detailed for broad scope facilities to include as part of the application. This should be included as part of the review by the, RSC in the internal permitting process for authorized users. There are also duplicates of page M-1 here.

NRC Staff Response: The NRC staff agrees that Appendix M contains a large amount of detail; however, as stated in paragraph 1 of Appendix M, not every applicant will need to address each topic in its application. The NRC staff also agrees with the commentor that topics in Appendix M should be included as part of the review by the RSC in the internal permitting process for authorized users and feels that this has been accomplished throughout the document.