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United States Nuclear Regulatory Commission
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NUREG-2212

Standard Review Plan for Applications for 10 CFR PART 70 Licenses for Possession and Use of Special Nuclear Materials of Critical Mass but not Subject to the Requirements in 10 CFR Part 70, Subpart H

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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ABSTRACT

This standard review plan (SRP) contains information intended to provide guidance for submitting applications under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," for possession and use of special nuclear materials (SNM) of critical mass that are not subject to the requirements in 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." Specifically, this NUREG describes the types of information required under 10 CFR 70.22, "Contents of applications," for those that apply for a new (or the renewal or amendment of an existing) materials license for possession and use of special nuclear material (SNM) in quantities exceeding the thresholds for critical mass quantities in 10 CFR 150.11, "Critical mass,"[a] and that, due to the nature of their activities, are not subject to the requirements in 10 CFR Part 70, Subpart H.

The U.S. Nuclear Regulatory Commission (NRC) guidance in this document is intended to be used by the staff to conduct reviews of applications for activities other than those described in 10 CFR 70.60, "Applicability," and that, due to the nature of the activities, do not create significant hazards associated with the use of SNM (such as criticality events) covered under the regulations of 10 CFR Part 70. As such, this subset of 10 CFR Part 70 applicants and licensees is not subject to the requirements in 10 CFR Part 70, Subpart H.

Prior to developing this document, specific guidance at a level appropriate to these applicants and licensees (commonly known as greater than critical mass applicants and licensees) did not exist. Therefore, the NRC prepared NUREG-2212 to assist these applicants, licensees, and facilities in preparing new license or renewal applications for the following activities that are not subject to the requirements in 10 CFR Part 70, Subpart H: (1) experiments using subcritical assemblies, (2) instrument calibration, (3) instruction in radiation detection and measurement, (4) experiments with uranium (U)-235 target foils, (5) low-enriched uranium sources for radiation detection testing, and (6) research and development in homeland security applications.

The SRP provides NRC staff reviewers with guidance that describes methods or approaches that the staff has found acceptable for meeting applicable NRC requirements in 10 CFR Part 70. Implementation of the criteria and guidelines in the SRP by staff members in their review of applications provides assurance that a given design ensures adequate protection of the public health and safety and the environment. This NUREG is intended to improve industry and public stakeholder understanding of the staff's review process. It should be noted that the SRP is not a substitute for NRC regulations, and compliance with the SRP is not required. It also contains related information that applicants and licensees may find useful regarding NRC policy, such as the policy on safety culture (appendix G), the use of discretion on issuing notices of violations (section 2.2.7, "Audit program"), and the NRC Enforcement Policy (section 2.2.7).

[a] For the purpose of this part, SNM in quantities not sufficient to form a critical mass means uranium enriched in the 235 isotope (U-235) in quantities not exceeding 350 grams of contained U-235; U-233 in quantities not exceeding 200 grams; plutonium (Pu) in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: (grams contained U-235/350) + (grams U-233)/200) + (grams Pu/200) $\leq$ 1. For each kind of SNM, determine the ratio between the quantity of that SNM and the quantity specified above for the same kind of SNM. The sum of such ratios for all kinds of SNM in combination shall not exceed unity. For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows: (175 (grams contained U-235/350) + (50 grams U-233)/200) + (50 grams Pu/200) = 1).

TABLE OF CONTENTS

ABSTRACT ..... **iii**
TABLE OF CONTENTS ..... **v**
DEFINITIONS ..... **ix**
LIST OF APPLICABLE REGULATIONS ..... **xv**
ABBREVIATIONS AND ACRONYMS ..... **xvii**
INTRODUCTION ..... **xix**
Purpose of the Standard Review Plan xix
Format of this Guidance Document xxi
Uses of SNM Addressed by this Guidance xxii
Special Considerations Regarding SNM Security Requirements xxii
Applicable Regulations xxiii
Management Responsibility xxiv
How to File xxv
Contents of Initial Applications for a 10 CFR Part 70 License xxvi
Required Fees xxvi
Identifying and Protecting Sensitive Information xxvii
Application Signature xxviii
Amendments and Renewals to a License xxviii
Applications for Exemptions from the NRC's Regulations xxix
Transfer of Control of a License or Bankruptcy of a Licensee xxx
License Terminations xxxi
1 GENERAL INFORMATION **1**
1.1 Applicant's Name and Contact Information 2
1.2 Location and Address of Material Use 3
1.3 Activities for which the Material Is Requested 3
1.4 Period of Time for which the License Is Requested 4
1.5 Radioactive Material for which the License is Requested 4
1.6 Facility Description and Process Overview 4
1.7 Organization and Administration 4
2 RADIATION PROTECTION **7**
2.1 Organizational and Personnel Qualifications 8
2.1.1 Organizational Management 8
2.1.2 Radiation Safety Officer 8
2.1.3 Authorized Users 9
2.1.4 Radiation Safety Training 11
2.2 Radiation Protection Program 12
2.2.1 Alara Program 13
2.2.2 Occupational Dose 14
2.2.3 Public Dose 17
2.2.4 Minimization of Contamination 19
2.2.5 Ventilation and Respiratory Protection 20
2.2.6 Waste Management 22
2.2.7 Audit Program 23
2.3 Facilities and Equipment 25
2.3.1 Radiation Monitoring Instruments 26
2.3.2 Leak Tests 28

2.3.3 Surveys 28
2.4 Commitment to Written Procedures 30
2.5 Operating and Emergency Procedures 31
2.6 Transportation 33
2.7 References 35
3 NUCLEAR CRITICALITY SAFETY 39
3.1 Use of Industry Standards 39
3.2 Criticality Accident Alarm System 40
3.3 Emergency Planning and Response 41
3.4 Subcriticality and Double Contingency Principle 42
3.5 Organization and Administration of the Nuclear Criticality Safety Program 43
3.6 Nuclear Criticality Safety Program Management Measures 45
3.7 Technical Practices for Nuclear Criticality Safety 45
3.8 Calculational Method Validation 46
3.9 Criticality Safety Evaluations 47
3.10 Evaluation and Implementation of Controlled Parameters 48
3.11 Additional Nuclear Criticality Safety Program Commitments 52
3.12 Emergency Plan 53
3.13 References 53
4 CHEMICAL SAFETY 55
4.1 References 57
5 FIRE SAFETY 59
5.1 Facility Design 59
5.2 Fire Protection 60
5.2.1 Fire Protection Systems 60
5.2.2 Employee Training 61
5.2.3 Emergency Response 62
5.3 Process Fire Safety 62
5.4 Combustible Loading and Potential Fire Scenarios 63
5.5 Summary 63
5.6 References 64
6 NATIONAL ENVIRONMENTAL POLICY ACT 65
6.1 Classification of Licensing and Regulatory Actions 65
6.2 References 69
7 MATERIAL CONTROL AND ACCOUNTING 71
7.1 Reports of Loss or Theft or Attempted Theft of Special Nuclear Material 73
7.2 Material Status Reports 73
7.3 Nuclear Material Transaction Reports 74
7.4 Recordkeeping 74
7.5 Written Material, Control, & Accounting Procedures 75
7.6 Physical Inventories 76
7.7 Records Access and Storage 76
7.8 Additional Information 76
7.9 References 76
8 DECOMMISSIONING AND FINANCIAL ASSURANCE 79
8.1 Financial Assurance and Decommissioning Funding Plan 79
8.2 Recordkeeping 79
8.3 References 80

9 PHYSICAL SECURITY 81
9.1 Category II Special Nuclear Material Physical Protection Requirements 82
9.1.1 Applicability 82
9.1.2 General Performance Objectives 82
9.1.3 Physical Protection Requirements at Fixed Sites 83
9.1.4 Physical Protection Requirements in Transit 84
9.2 Category III SNM Physical Protection Requirements 85
9.2.1 Applicability 85
9.2.2 General 86
9.2.3 Physical Protection Requirements at Fixed Sites 86
9.2.4 Physical Protection Requirements in Transit 86
9.3 Plutonium-238 and Plutonium/Beryllium Sealed Sources 87
9.3.1 Applicability 87
9.3.2 General 88
9.3.3 Background Investigations and Access Authorization Program 88
9.3.4 Physical Protection Requirements for Use and Storage 89
9.3.5 Physical Protection during Transit 89
9.3.6 Additional Information 90
9.4 References 91
10 EMERGENCY MANAGEMENT 93
10.1 Emergency Plan 94
10.2 References 96
APPENDIX A TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER A-1
APPENDIX B FACILITIES AND EQUIPMENT CONSIDERATIONS B-1
APPENDIX C RADIATION MONITORING AND INSTRUMENT CALIBRATION PROGRAM C-1
APPENDIX D GUIDANCE FOR MONITORING REQUIREMENTS D-1
APPENDIX E PUBLIC DOSE E-1
APPENDIX F SURVEYS AND MONITORING F-1
APPENDIX G SAFETY CULTURE G-1
APPENDIX H MAJOR U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS H-1
APPENDIX I NUCLEAR CRITICALITY GLOSSARY I-1

DEFINITIONS

The following definitions in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.4, "Definitions," are applicable to greater than critical mass facilities.

Act means the Atomic Energy Act of 1954 (68 Stat 919), including any amendments thereto.

Acute, as used in this part, means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

Agency (Government) means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Agreement State as designated in part 150 of this chapter means any State with which the Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-Agreement State* means any other State.

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material[s] but that the release is not expected to require a response by an offsite response organization to protect persons offsite.

Atomic energy means all forms of energy released in the course of nuclear fission or nuclear transformation.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Common defense and security means the common defense and security of the United States,

Construction means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes.

(2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values.

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas.

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part.

(5) Excavation.

(6) Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility.

(7) Building of service facilities (*e.g., p*aved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines).

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9) Taking any other action that has no reasonable nexus to:
(i) Radiological health and safety, or
(ii) Common defense and security.

Contiguous sites means licensee-controlled locations, deemed by the Commission to be in close enough proximity to each other, that the special nuclear material must be considered in the aggregate for the purpose of physical protection.

Critical mass has two definitions in 10 CFR. The definition in 10 CFR 70.4 is used to identify a limit of SNM above which requires the increased programmatic and regulatory controls in Subpart H for the use of the materials. The definition in 10 CFR 150.11, "Critical mass," however, prescribes an upper limit, below which fewer programmatic controls are required, as stated below:

> 10 CFR 70.4. Critical mass of special nuclear material (SNM), as used in Subpart H, means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.
>
> 10 CFR 150.11, "Critical Mass." For the purposes of this part, special nuclear material in quantities not sufficient to form a critical mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination shall not exceed unity.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or
(2) Release of the property under restricted conditions and termination of the license.

Department and Department of Energy means the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.), to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93–438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95–91. 91 Stat. 565 at 577–578, 42 U.S.C. 7151).

Double contingency principle means that process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Effective dose equivalent means the sum of the products of the dose equivalent to the body organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Effective kilograms of special nuclear material means: (1) For plutonium and uranium-233 their weight in kilograms; (2) For uranium with an enrichment in the isotope U-235 of 0.01 (1%) and above, its element weight in kilograms multiplied by the square of its enrichment expressed as a decimal weight fraction; and (3) For uranium with an enrichment in the isotope U-235 below 0.01 (1%), by its element weight in kilograms multiplied by 0.0001.

Formula quantity means strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula, grams = (grams contained U-235) + 2.5 (grams U-233 + grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

License, except where otherwise specified, means a license issued pursuant to the regulations in this part [10 CFR].

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements.

Person means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Produce, when used in relation to special nuclear material, means (1) to manufacture, make, produce, or refine special nuclear material; (2) to separate special nuclear material from other substances in which such material may be contained; or (3) to make or to produce new special nuclear material.

Research and development means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Sealed source means any special nuclear material that is encased in a capsule designed to prevent leakage or escape of the special nuclear material.

Site Area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Source material means source material as defined in section 11z. of the Act and in the regulations contained in Part 40 of this chapter [10 CFR].

Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material.

Special nuclear material of low strategic significance means:

(1) Less than an amount of special nuclear material of moderate strategic significance as defined in paragraph (1) of the definition of strategic nuclear material of moderate strategic significance in this section, but more than 15 grams of uranium-235 (contained in uranium enriched to 20 percent or more in U-235 isotope) or 15 grams of uranium-233 or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U-235) + (grams plutonium) + (grams U-233); or

(2) Less than 10,000 grams but more than 1,000 grams of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope); or

(3) 10,000 grams or more of uranium-235 (contained in uranium enriched above natural but less than 10 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category III quantity of material.

Special nuclear material of moderate strategic significance means:

(1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation, grams = (grams contained U-235) + 2 (grams U-233 + grams plutonium); or

(2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category II quantity of material.

Special nuclear material scrap means the various forms of special nuclear material generated during chemical and mechanical processing, other than recycle material and normal process intermediates, which are unsuitable for use in their present form, but all or part of which will be used after further processing.

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

Uranium enrichment facility, means:

(1) Any facility used for separating the isotopes of uranium or enriching uranium in the isotope 235, except laboratory scale facilities designed or used for experimental or analytical purposes only; or

(2) Any equipment or device, or important component part especially designed for such equipment or device, capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

Worker means an individual who receives an occupational dose as defined in 10 CFR 20.1003.

LIST OF APPLICABLE REGULATIONS

The following list includes the main requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," that are applicable to licensees authorized (and applicants seeking authorization) to possess special nuclear materials in critical mass quantities not subject to the 10 CFR Part 70, Subpart H, requirements (**Note**: Other 10 CFR Part 70 requirements may apply, as determined by the Commission).

70.9 Completeness and accuracy of information
70.21 Filing, (f)
70.22 Contents of applications, (a)(1), (2), (3), (4), (6), (7), and (8)
70.23 Requirements for the approval of applications, (a)(1), (2), (3), (4), (5), (6), (9) and (10)
70.24 Criticality accident requirements
70.25 Financial assurance and recordkeeping for decommissioning
70.41 Authorized use of special nuclear material, (a)
70.42 Transfer of special nuclear material
70.50 Reporting requirements
70.51 Records requirements
70.52 Reports of accidental criticality
70.55 Inspections
70.56 Tests
70.81 Modification and revocation of licenses
70.91 Violations
70.92 Criminal penalties

ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ALARA	as low as is reasonably achievable
ALI	annual limits on intake
ANSI	American National Standards Institute
AU	authorized user
Be	beryllium
CAAS	criticality accident alarm system
CATEX	categorical exclusion
CFR	*Code of Federal Regulations*
CSE	criticality safety evaluation
DFP	decommissioning funding plan
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
GTCM	greater than critical mass
IN	information notice
ISO	International Organization for Standardization
MC&A	material control and accounting
mGy	milligray
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NCS	nuclear criticality safety
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NIST	National Institute of Standards and Technology
NMMSS	Nuclear Material Management and Safeguards System
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
Pu	plutonium

RIS	reporting identification symbol
RPP	radiation protection program
RSO	radiation safety officer
RWP	radiation work permit
SNM	special nuclear material
SRP	standard review plan
SSD	sealed source and device
Sv	Sievert
TEDE	total effective dose equivalent
U	uranium
ZnS	zinc sulfide

INTRODUCTION

Purpose of the Standard Review Plan

This standard review plan (SRP) describes the types of information required under Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22, "Contents of applications," for applications under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," for receipt, possession, use, and storage of special nuclear material (SNM)[1] in critical mass quantities but not subject to 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." This SNM is intended to be used for conducting activities other than those described in 10 CFR 70.60, "Applicability," and that, due to the nature of their activities, do not create significant hazards associated with the use of SNM (such as criticality events) covered under the regulations of 10 CFR Part 70. As such, this subset of 10 CFR Part 70 applicants and licensees is not subject to the requirements in 10 CFR Part 70, Subpart H.

This group of applicants or licensees, currently referred to as greater than critical mass (GTCM) applicants, licensees, or facilities, are not engaged in SNM enrichment, conversion, or manufacturing activities and yet are similar enough to each other[2] and form a large enough group to consider their own characteristics differently from other users of SNM who use other guidance, such as NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 17, "Program-Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass," or NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," for completing applications for possession and use of SNM.

For the purposes of this NUREG and the associated regulatory analysis, GTCM is any quantity of SNM exceeding (i.e., $>$) the definition of critical mass in 10 CFR 150.11, "Critical mass:"

> (a) For the purposes of this part, special nuclear material[3] in quantities not sufficient to form a critical mass means uranium enriched in the isotope uranium (U) -235 in quantities not exceeding 350 grams of contained U-235; uranium-233 not exceeding 200 grams; plutonium in quantities not exceeding 200 grams [in any form other than plutonium (Pu)/beryllium (Be) neutron sources], or any combination of them in accordance with the following formula[4]:

[1] The regulations in 10 CFR 70.4, "Definitions," define SNM as "(1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the [Atomic Energy Act of 1954, as amended,] determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material."

[2] The safety and risks involved are more akin to those inherent with byproduct materials, which result from nuclear fission and are non-fissile. These cannot be used for atomic weapons, so the material is not at risk for proliferation. Byproduct materials are non-fissile and are not subject to self-sustaining criticality or the risks that are associated with criticality. The U.S. Nuclear Regulatory Commission (NRC) developed this guidance for these specific SNM licensees because, although they use a certain quantity of SNM, they pose little risk of accidental criticality, diversion, or proliferation.

[3] This document uses "SNM," "licensed material," and "radioactive material" interchangeably.

[4] The sum of such ratios for all kinds of SNM, in combination, should not exceed unity. Note that the formula in 10 CFR 150.11 is just an example of specific SNM quantities that, altogether, meet the criteria (i.e., 175 grams of contained U-235 + 50 grams of U-233 + 50 grams of Pu). If the calculated number is greater than 1, then the amount of SNM for which the applicant seeks NRC authorization is a critical mass quantity of SNM.

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

Applicants for a license to receive, possess, use, and store SNM must calculate the ratio among their requested quantities of SNM using this formula. If the result is greater than 1 (i.e., exceeds unity), then the SNM meets the criteria for a critical mass quantity defined in 10 CFR 150.11. The formula determines the appropriate guidance for applicants (i.e., NUREG-1556, Volume 17, for applications for licenses of lower than critical mass versus NUREG-2212 for applications for licenses of GTCM). **NOTE:** Any quantity of SNM exceeding the GTCM threshold in 10 CFR 150.11 falls under NRC-exclusive jurisdiction.

Table 1-1 shows the threshold quantities for SNM to be considered GTCM under 10 CFR Part 70. (**NOTE**: Materials meeting these criteria are not subject to the requirements in 10 CFR Part 70, Subpart H, when used for the specific activities listed under the "Uses of SNM addressed by this guidance" section of this document).

In addition to the limits listed in Table 1-1, the NRC staff developed a limit for Pu/Be sources for when the licensee requests authorization for possession and use of Pu/Be sources only. In these cases, a quantity of more than 2,000 grams of plutonium is treated as GTCM, when the Pu/Be ratio is more than 1,000.[5]

Table 1-1 Radioactive Materials Considered SNM

Special Nuclear Material	Covered by This NUREG	Threshold Quantities Greater Than Critical Mass (g)[6]	Regulatory Authority
Plutonium	Yes	>200	NRC/NMSS
U-235	Yes	≥350	NRC/NMSS
U-233	Yes	≥200	NRC/NMSS

This document describes the type of information needed to develop an application for a specific license for receipt, possession, use, and storage of SNM in GTCM. This guide is not intended to address the following:

- Applications for possession of quantities of SNM equal to or lower than the 10 CFR 150.11 critical mass limits. (**NOTE**: Guidance for applying for a license to possess and use SNM of less than critical mass, as defined in 10 CFR 150.11, is found in NUREG-1556, Volume 17, or in the relevant Agreement State Program guidance.)

[5] The technical basis for treating 2,000 grams of Pu 239 in the form of Pu/Be sealed sources as less than a critical mass is described in "Technical Basis for 2000 Grams of Plutonium Limit in Pu/Be Neutron Source Mass Limit," issued June 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16190A294). The Pu/Be limit will not apply if the request includes possession and use of Pu/Be neutron sources in combination with other types of SNM. If so, then the limits in 10 CFR 150.11(a) apply.

[6] Any quantities of SNM below the thresholds specified on this table fall below Agreement State or NRC regulatory authority under 10 CFR Part 70 in non-Agreement States.

- Applications for possession of quantities of SNM in excess of formula quantities of SNM and for authorization to manufacture and distribute SNM. (**NOTE**: These activities are subject to the requirements in 10 CFR Part 70, Subpart H. The applicable guidance for the review of applications for these activities is NUREG-1520.

This guidance is not intended to be used by the NRC staff for reviewing applications for authorization to engage in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed oxide fuel or fuel assemblies, scrap recovery of SNM, or any other activity that the Commission determines could significantly affect public health and safety. These are subject to the requirements in 10 CFR Part 70, Subpart H.

Format of this Guidance Document

This guidance identifies information that the NRC staff expects to be included in applications for new licenses, renewals, and amendments of specific licenses for receipt, possession, use, and storage of SNM in critical mass quantities, as defined in 10 CFR 150.11, but that are not subject to the requirements in 10 CFR Part 70, Subpart H. Each technical chapter of NUREG-2212 presents guidance in the following format:

(1) Regulatory Requirements—references the applicable regulations

(2) Regulatory Criteria—outlines the criteria the NRC staff uses to evaluate the adequacy of an application

(3) Discussion—provides supplemental information on the technical topic

(4) Regulatory Guidance—identifies the current regulatory guidance that is applicable to the GTCM licensees, not subject to Subpart H, that may be consulted by the staff and applicants

(5) Notes—explain regulatory requirements, identify other relevant NRC guidance, define technical terms, clarify information, provide examples of precedents, or advise when additional information on a topic is not required to be provided

(6) Additional Information—identifies relevant information that facilitates the staff's review of an application and may be included in the license application

(7) References—provides full references to all documents used in the preparation of this guidance report

The guidance in this document is intended to help the NRC staff standardize and streamline its review, but the NRC anticipates applicants will use it to improve the efficiency of the license application process. To facilitate the NRC staff's review, applicants should refer to the requirements in 10 CFR 70.22, follow the guidance in this document (and its appendices), and submit the license application to the NRC. Appendices A through G to this document provide additional, specific guidance relevant to completing an application for a GTCM license.

Uses of SNM Addressed by this Guidance

The staff will use this guidance to standardize and streamline its evaluation of applications for GTCM SNM for the following activities:

- research and development and for educational purposes
- experiments using subcritical assemblies
- instrument calibration
- student instruction in radiation detection and measurement
- U-235 target foils experiments
- the manufacture or fabrication of sealed and unsealed sources containing low-enriched uranium (i.e., enriched to less than 20 percent by weight) that are used in radiation detection testing equipment

Special Considerations Regarding SNM Security Requirements

The NRC categorizes SNM as formula quantity, moderate strategic significance material, and low strategic significance SNM. Chapter 9 of this document provides an in-depth discussion of the physical security requirements applicable to GTCM licensees, according to the category of SNM.

Formula quantity of SNM

Pursuant to the regulations in 10 CFR 70.4, a formula quantity of SNM means the following:

> strategic special nuclear material in any combination in a quantity of 5000 grams or more computed by the formula:
>
> grams = (grams contained U-235) + 2.5 (grams U-233 + grams plutonium)

Formula quantity SNM is sometimes referred to as a Category I quantity of material (see 10 CFR 73.2, “Definitions”).

SNM of moderate strategic significance

SNM of moderate strategic significance is defined in 10 CFR 70.4 as follows:

> (1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of U-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation,
>
> grams = (grams contained U-235) + 2 (grams U233 + grams plutonium); or

(2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

Special nuclear material of moderate strategic significance is sometimes referred to as a Category II quantity of material (see 10 CFR 73.2).

SNM low strategic significance

SNM of low strategic significance is defined in 10 CFR 70.4 as follows:

(1) Less than an amount of special nuclear material of moderate strategic significance…but more than 15 grams of uranium-235 (contained in uranium enriched to 20 percent or more in U-235 isotope) or 15 grams of uranium-233 or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U-235) + (grams plutonium) + (grams U-233); or

(2) Less than 10,000 grams but more than 1,000 grams of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope); or

(3) 10,000 grams or more of uranium-235 (contained in uranium enriched above natural but less than 10 percent in the U-235 isotope).

Special nuclear material of low strategic significance is also referred to as a Category III quantity of material (see 10 CFR 73.2).

The categories of SNM in 10 CFR 73.2 (i.e., material of formula quantity, of moderate strategic significance, or of low strategic significance) determine which physical security and material control and accounting requirements in 10 CFR Part 73, "Physical Protection of Plants and Materials," apply to licensees possessing, handling, and storing different categories of SNM. Chapter 9 of this guidance document provides an in-depth discussion of the physical security requirements applicable to GTCM licensees, according to the category of SNM. For these reasons, NRC staff reviewers and applicants for a GTCM license should be familiar with chapter 9.

Applicable Regulations

Applicants and licensees are responsible for obtaining up-to-date copies of applicable regulations and understanding and complying with the requirements of the regulations applicable to holders of licenses for the possession and use of SNM of GTCM.

The NRC's current regulations can be found at https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html. The following is a list of relevant regulations:

- 10 CFR Part 2, "Agency Rules of Practice and Procedure"
- 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 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material”
- 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions”
- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”
- 10 CFR 70.9, “Completeness and accuracy of information”
- 10 CFR Part 71, “Packaging and Transportation of Radioactive Material”
- 10 CFR Part 73, “Physical Protection of Plants and Materials”
- 10 CFR Part 74, “Material Control and Accounting of Special Nuclear Material”
- 10 CFR 150.11, “Critical mass”
- 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 the NRC”

Copies of the of the NRC’s regulations may be obtained by calling the U.S. Government Publishing Office order desk toll-free at (866) 512-8600; in Washington, DC, at (202) 512-1800; or online at https://bookstore.gpo.gov/catalog/code-federal-regulations-cfrs-print.

A single copy of the above documents may be requested from the NRC’s regional offices (see https://www.nrc.gov/about-nrc/locations.html for addresses and telephone numbers). In addition, 10 CFR Parts 1 through 199 may be downloaded from the NRC’s website at http://www.nrc.gov/reading-rm/doc-collections/ under Regulations (10 CFR).

NRC regulations and amendments may also be accessed from the “NRC Library” link on the NRC’s public website at http://www.nrc.gov. The NRC publishes new and amended regulations in the *Federal Register*.

Management Responsibility

The NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. Compliance with the NRC’s regulations provides reasonable assurance that licensed activities will be conducted safely, and that effective management will result in increased safety and compliance.

How to File

Paper Applications

Applicants for an SNM license should do the following:

- Submit adequate information to satisfy the requirements in 10 CFR 70.22 and 10 CFR 70.23, "Requirements for the approval of applications."
- Provide sufficient detail for the NRC to determine that equipment, facilities, training, experience, the radiation safety program, and all other safety programs are adequate to protect health and safety and minimize danger to life and property.
- Identify and cross-reference the chapter number and its topic on each separate sheet submitted with the application.
- If proprietary information and other sensitive information (e.g., personal privacy and security related) is submitted, the information should be clearly identified per 10 CFR 2.390, "Public inspections, exemptions, requests for withholding" (see chapter 6).
- Ensure applications are signed in accordance with the requirements in 10 CFR 70.22(d).
- Retain one copy of the license application for future reference.

All license applications will be available for review by the general public in the NRC's Public Document Room. If it is necessary to submit proprietary and other sensitive information, follow the procedure in 10 CFR 2.390 for identifying and marking this information. Failure to follow this procedure could result in disclosure of the proprietary or other sensitive information to the public or in substantial delays in processing the application. Applicants should not submit personal information of employees (e.g., home address, home telephone number, social security number, date of birth, radiation dose information), unless the NRC specifically requests it.

The NRC scans paper applications through an optical character reader and converts them to an electronic format. To ensure the smooth transfer of paper documents into an electronic format, applicants should do the following:

- Submit all documents typed, on paper that will feed easily into a document scanner (i.e., legal or letter size).
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura.
- Use an 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure a high contrast between the ink and paper (black ink on white paper is best).

Electronic Applications

Applications may also be submitted in electronic form using the NRC's Electronic Information Exchange by or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's website at http://www.nrc.gov/site-help/e-submittals.html. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

Contents of Initial Applications for a 10 CFR Part 70 License

Note: This section addresses the required contents of a new application. Section IX discusses the required contents of applications for amendments and renewals of licenses.

All items in an application should be in sufficient detail for the NRC staff to determine that the proposed equipment, facilities, training and experience, radiation safety, and other safety programs satisfy the NRC's regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. There is no specific license application form required for GTCM applicants. NRC Form 313, "Application for Materials License," which is used to apply for byproduct material licenses, may also be used to apply for a GTCM SNM license, but it is not required. The NRC describes the information to be provided in a license application in 10 CFR 70.22. The NRC's reviewers will ensure the application contains all required information as part of its acceptance review. The NRC encourages applicants to request preapplication meetings with the staff to discuss regulatory requirements and the licensing review process. The NRC lists filing and other applicable fees in 10 CFR 70.21, "Filing."

Licensees should submit items described in 10 CFR 70.22(b)–(m) on separate sheets of paper. This part of the license application provides the technical basis for the license request. The information should describe the applicable safety programs that will provide adequate assurance of the safety and security of the receipt, use, handling, and possession of SNM. Applicants may organize the license application by using the chapter headings of this NUREG. License applicants that follow the guidance and the model procedures in this NUREG will facilitate the NRC's review.

The grant of 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 a radiation-producing device).

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

Required Fees

The appropriate fee must accompany each application for which a fee is specified. Applicants should refer to 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," to determine the amount of the fee. The regulations at 10 CFR 170.11, "Exemptions," provide information on exemptions from these fees. In accordance with the requirements in 10 CFR 170.12, "Payment of fees," a remittance for the full amount of the fee must accompany each application for which the NRC prescribes a fee. The NRC will not issue a license until it receives the prescribed application fee.

Fees will not be refunded after the NRC staff begins its technical review. The NRC will charge application fees whether or not the Commission approves the application.

The regulations in 10 CFR 171.16, "Annual fees: materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC," provide the annual fee requirements that are applicable to GTCM SNM licensees [see 10 CFR 171.16(d), "Table 2 to paragraph (d)—Schedule of Materials Annual Fees and Fees for Government Agencies Licensed by NRC," Category 1A(2)(a) ("Facilities with limited operations"—Program Codes 21310 and 21320); Category 1F ("Licenses for possession and use of special nuclear materials greater than critical mass, as defined in 10 CFR 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities"—Program Code 22155]; and the Office of Nuclear Materials Safety and Safeguards Program Code Descriptions and Inspection Priorities (ML19322A311, Program Codes 21310, 21320, and 22155). The regulation at 10 CFR 171.16(c) states that reduced annual fees are available for licensees that qualify as "small entities." This regulation describes the process for licensees to apply for certification as a "small entity." In 10 CFR 171.11, the NRC provides information on classes of licensees that are not required to pay annual fees, explains which entities may seek exemptions from such fees, and describes the bases on which the NRC can exempt licensees from those fees.

Applicants should direct all questions about the NRC's fees to the Office of the Chief Financial Officer at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling the NRC's toll-free number, (800) 368-5642, extension 415-7554. The email address is Fees.Resource@nrc.gov.

Identifying and Protecting Sensitive Information

All licensing application materials, except portions that contain sensitive information, will be made available for review in the NRC's Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov/reading-rm.html.

The licensee should identify and mark sensitive information that it believes should not be disclosed to the public. Licensees submitting applications that contain sensitive information should mark them, in accordance with 10 CFR 2.390, before submitting the information to the NRC. The following are examples of sensitive information:

- Proprietary information and trade secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application.

- Personal privacy information: Personal information about employees or other individuals should not be submitted unless the NRC specifically requests it. Examples of private information are social security number, home address, home telephone number, date of birth, and radiation dose information. If private information is submitted, it should be separated from the public portion of the application and clearly marked as follows: "Privacy Act Information—Withhold under 10 CFR 2.390." Further information is available in Regulatory Issue Summary 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, which can be found on the NRC's Generic Communications webpage under Regulatory Issue Summaries: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

- Security-related information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released to the public and are treated as sensitive unclassified information. This includes certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures. Therefore, sensitive security-related information in an application should be marked: "Security Related—Withhold under 10 CFR 2.390." Further information is available in Regulatory Information Summary 2005-31, Revision 1, "Control of Security-Related Sensitive Unclassified Nonsafeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," dated December 26, 2017, which can be found on the NRC's Generic Communications webpage under Regulatory Issue Summaries: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/. Additional information on procedures and any updates are available at http://www.nrc.gov/reading-rm/sensitive-info.html.

Application Signature

All applications and statements must be signed by the applicant or licensee or a corporate officer, as stated in 10 CFR 70.22(d). To ensure adequate management involvement, a duly authorized management representative must sign the submitted application acknowledging management's commitments and responsibilities. Individuals acting in a private capacity are required to date and sign the license application or letter transmitting the license application. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the license application document. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.

Amendments and Renewals to a License

For changes that require preapproval under 10 CFR 70.72(d)(1), the licensee shall submit a license amendment request to the NRC in accordance with 10 CFR 70.34, "Amendment of licenses," and receive the NRC's prior approval before implementing changes to its NRC-regulated programs.[7] If information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment in accordance with 10 CFR 70.34. An administrative change to the license that does not constitute a modification or alteration to the facility or regulated activities also requires a license amendment. The NRC staff reviews and determines whether to grant or deny an amendment request. The proposed change is not in effect until the NRC staff has approved and issued the amendment. In addition, 10 CFR 70.33, "Applications for renewal of licenses," sets out the requirements for the renewal of a license and 10 CFR 70.38(a) provides that a licensee must apply for license renewal at least 30 days before the license expires to continue the license beyond its expiration date.

Licensees are required to request and obtain an amendment to the license before making changes to their radiation safety programs or any other safety programs included in the license

[7] Licensees may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change does not fall within the criteria described in 10 CFR 70.72(c)(1)–(3).

application. The following are examples of changes that require an amendment:

- a change of responsible persons or radiation safety officer (RSO)
- changes in areas of use
- changes in the mailing address
- changes in the address(es) of storage locations
- changes in licensed material, including increases in the possession limit of SNM and the addition of new types of devices

Applicants for a license amendment or license renewal should do the following:

- Submit a letter to the NRC requesting an amendment or renewal.
- Provide the license and docket numbers in the request.
- For renewals, if many outdated documents are referenced or there have been significant changes in regulatory requirements, the NRC's guidance, the licensee's organization, or the licensee's radiation protection program (RPP), provide a complete and up-to-date application. Alternatively, clearly describe the exact nature of the changes, additions, and deletions.

Applications for Exemptions from the NRC's Regulations

Licensees may request exemptions from the NRC's regulations. The exemption request must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest.

Licensees may request specific exemptions from the 10 CFR Part 70 regulations under 10 CFR 70.17, "Specific exemptions." Various sections of the NRC's regulations address requests for exemptions from other regulations. The regulations concerning exemptions state the NRC may grant an exemption, acting on its own initiative or upon an application from a licensee.

Exemptions do not revise regulations, are not intended to apply to large classes of licensees, and are limited to unique situations of limited duration. Exemption requests must be accompanied by descriptions of the following:

- the exemption requested, basis, and justification for the requested exemption
- any proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested

Note: Unless the NRC has granted an exemption from a regulation in writing, full compliance with all applicable regulations is expected and enforced.

Transfer of Control of a License or Bankruptcy of a Licensee

Transfer of Control of a License

The regulation at 10 CFR 70.36, "Inalienability of licenses," states the following:

> (a) No license granted under the regulations in this part and no right to possess or utilize special nuclear material granted by any license issued pursuant to the regulations in this part 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.
>
> (b) An application for transfer of license must include:
>
> (1) The identity, technical and financial qualifications of the proposed transferee; and
>
> (2) Financial assurance for decommissioning information required by 10 CFR 70.25.

Transferring control of a license may be the result of mergers, buyouts, or majority stock transfers. The NRC does not interfere with business decisions of licensees.

NUREG-1556, Volume 15, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," chapter 5,[8] discusses the information that should be included in a request for NRC approval of a proposed transfer of control of a license and the criteria the NRC staff uses to evaluate such a request.

Bankruptcy

The regulations in 10 CFR 70.32, "Conditions of licenses," state the following:

> (a) Each license shall contain and be subject to the following conditions:
>
> (9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:
>
> (A) The licensee.
>
> (B) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the

[8] Applicants for an NRC license are not subject to the NRC's regulations on changes of control of a license unless a change of ownership or management control that would change the information under NRC's review impacts the basis for issuance of the license. In such cases, the applicant must immediately notify the NRC for appropriate action (e.g., withdrawal or rejection of application, termination of licensing review).

estate; or

(C) An affiliate (as that term is defined in 11 U.S.C. 101(a)) of the licensee.

A licensee's (or applicant's) financial condition could affect its ability to control licensed material. Therefore, the NRC must be notified to ensure that appropriate measures to protect the public health and safety are or will be taken. NUREG-1556, Volume 15, chapter 6,[9] includes guidance on the information that should be included in a notification to the NRC of a bankruptcy. NUREG-1556 also describes the criteria the NRC staff used to evaluate the notification of bankruptcy.

License Terminations

In accordance with the requirements in 10 CFR 70.38, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas," licensees may request a termination of the specific license.

- 10 CFR 70.38(a) states the following:

  Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 70.33 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

- 10 CFR 70.38(b) states the following:

  Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

- 10 CFR 70.38(c) states the following:

  Each specific license continues in effect, beyond the expiration date, if necessary, with respect to possession of special nuclear material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

  (1) Limit actions involving special nuclear material to those related to decommissioning; and

[9] Persons who are in the process of applying for an NRC license and who do not already hold one or more other NRC licenses are not required to provide notifications on bankruptcy to the NRC. However, applicants must advise the NRC of bankruptcy issues that result in changes to the financial qualifications information submitted to the NRC.

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements.

- To request license termination under 10 CFR 70.38(d)(1)–(4), licensees must do the following:

  – Notify the NRC, in writing, within 60 days of the occurrence of any of the following:

    (1) expiration of its license

    (2) a decision to cease licensed activities permanently at the entire site

    (3) a decision to cease licensed activities permanently in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements

    (4) no principal activities having been conducted at the entire site under the license for a period of 24 months

    (5) no principal activities having been conducted for a period of 24 months in any separate building or outdoor area, if it contains residual radioactivity making it unsuitable for release according to NRC requirements.

  – Within 12 months of notification of any of the above, submit a decommissioning plan, if required by 10 CFR 70.38(g).

  – Conduct decommissioning, as required by 10 CFR 70.38(h) and 10 CFR 70.38(j).

  – Submit to the appropriate NRC office a 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 leak tests) (see NUREG-1757, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees," Volume 1).

  – Send records important to decommissioning to the appropriate NRC regional office before a license is terminated (see section 3.3 of NUREG-1757, Volume 3, "Financial Assurance, Recordkeeping, and Timeliness"). If licensed activities are transferred or assigned in accordance with 10 CFR 70.42, "Transfer of special nuclear material," and 10 CFR 70.51(b), transfer records important to decommissioning to the new licensee.

In accordance with the requirements in 10 CFR 70.38(k), in part, the Commission will terminate a license following its determination that the following has occurred:

(1) Special nuclear material has been properly disposed.

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) (i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 70.51(a) have been received.

Additional guidance for requesting termination of a license is found in NUREG-1757, Volume 1.[10] However, licensees should also contact the NRC to ensure an understanding of what actions should be taken to initiate and complete the license termination process on a license- or facility-specific basis. The licensee's obligations regarding license termination begin at the time the licensee determines that it will cease operations, or on the date the license is set to expire, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to take any other actions summarized above. A license continues in effect beyond the expiration date, if necessary, until the Commission notifies the licensee in writing that the license is terminated (see 10 CFR 70.38(c). If a licensee abandons a site or refuses to decommission a site, the NRC would consider the case for civil or criminal action, as warranted.

[10] Facilities for which this guidance is intended generally fall under Groups 1 or 2, as described in NUREG-1757, Volume 1.

1 GENERAL INFORMATION

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22, "Contents of applications" [(a)(1)–(4), (6)–(8)], and 10 CFR 70.23, "Requirements for the approval of applications" [(a)(1)–(6), (9), and (10)].

Regulatory Criteria: The regulations in 10 CFR 70.22 describe the information that must be provided in an application for a license under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

- The regulations in 10 CFR 70.22(a)(1) require that an application include information about the individual who can answer questions about the application and a telephone number where the individual may be contacted, as well as the organizational groups that are responsible for managing the proposed activities and the location and address where the material will be handled and stored.

- The regulations in 10 CFR 70.22(a)(2) require that an application identify and describe the activities for which the SNM license is requested, the place where the activities will be conducted, and a facility description and overview.

- The regulations in 10 CFR 70.22(a)(3) require, in part, that an application identify the period of time for which the license is requested.

- The regulations in 10 CFR 70.22(a)(4) require that an application identify the name, amount, and specifications (including the chemical and physical form and, where applicable, isotopic content) of the SNM that the applicant proposes to use.

- The regulations in 10 CFR 70.22(a)(6) require that the application contain the technical qualifications, including training and experience, of the applicant and members of the staff who will engage in the proposed activities.

- The regulations in 10 CFR 70.22(a)(7) require applicants to provide a description of equipment and facilities that will be used by the applicant to protect health and minimize danger to life or property (such as handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems).

- The regulations in 10 CFR 70.22(a)(8) require applicants to discuss their proposed procedures to protect health and minimize danger to life or property (such as procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, and post-criticality accident emergency procedures).

The regulations in 10 CFR 70.23(a) state, in part, that an application for a license will be approved if the Commission determines the following:

(1) The special nuclear material is to be used for the conduct of research or development activities of a type specified in section 31 of the [Atomic Energy Act of 1954, as amended (Act)], in activities licensed by the Commission under section 103 or 104 of the Act, or for such other uses as the Commission determines to be appropriate to carry out the purposes of the Act.

(2) The applicant is qualified by reason of training and experience to use the material for the purpose requested in accordance with the regulations in this chapter.

(3) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property; and

(4) The applicant's proposed procedures to protect health and to minimize danger to life or property are adequate.

(5) Where the nature of the proposed activities is such as to require consideration by the Commission, that the applicant appears to be financially qualified to engage in the proposed activities in accordance with the regulations in this part.

(6) Where the applicant is required to submit a summary description of the fundamental material controls provided in his procedures for the control of and accounting for special nuclear material pursuant to § 70.22(b), the applicant's proposed controls are adequate.

…

(9) Where the applicant is required to submit a plan for physical protection of special nuclear material in transit pursuant to § 70.22(g), of this chapter, the applicant's plan is adequate.

(10) Where the applicant is required to submit a physical security plan pursuant to § 70.22(h), the applicant's proposed plan is adequate;

Discussion: The sections below discuss the regulatory requirements specific to license applications to possess and use special nuclear material (SNM) that exceeds the thresholds in 10 CFR 150.11, "Critical mass," and that are not subject to 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material." The application should provide adequate information identifying the applicant and its characteristics, a general description of the proposed facility and proposed activities, the quantity and form of the SNM, the applicant's technical qualifications, and the time period for which the license is requested. This information will be used by all reviewers, NRC managers, and the general public to understand the proposed facility and its processes, and the individuals responsible for safely operating it.

1.1 Applicant's Name and Contact Information

Under 10 CFR 70.22(a)(1), if the applicant is an individual, the full name, address, age, citizenship, and three personal references shall be provided. An individual may be designated

as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity.

If the applicant is a corporation or institution, name the State where it was incorporated, locations of principal offices, names, addresses, and citizenship of its principal officers. A division or department within a legal entity may not be a licensee. Notify the U.S. Nuclear Regulatory Commission (NRC) of changes in mailing address; these changes do not require a fee.

Of significance to this part of the application is information regarding control of the organization or ownership of any alien, foreign corporation, or government (see 10 CFR 70.36, "Inalienability of licenses"). The NRC must be notified by formal amendment before control of the license is transferred or when ownership changes. Section IX contains more details.

Note: If the applicant is controlled by a foreign entity, the NRC will need to consider foreign ownership, control, and domination. The NRC will need to determine that the applicant, a foreign-owned corporation or entity, will not be a threat to the common defense and security and does not present an unreasonable risk to public health and safety, in accordance with the Act, sections 57c, 63b and 82b. NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 15, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," contains additional information.

1.2 Location and Address of Material Use

The regulations in 10 CFR 70.22(a)(1) require that an applicant specify the street address, city, and State or other descriptive address (e.g., on Highway 28, 7 miles east of the intersection of Highway 18 and State Route 160, Anytown, State) for each facility where the licensed material will be used (see NRC Form 313, "Application for Materials License"). The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable.

An NRC-approved license amendment is required before receiving, using, and storing licensed material at an address or location not included with the application or not already listed on the license.

To conduct operations at temporary job sites (i.e., locations where work is done for limited periods of time), specify "temporary job sites anywhere in the United States where the NRC maintains jurisdiction." The NRC has additional requirements on temporary sites in 10 CFR Part 20, "Standards for Protection against Radiation," Subpart I, "Storage and Control of Licensed Material," and 10 CFR Part 73, "Physical Protection of Plants and Materials."

1.3 Activities for which the Material Is Requested

In accordance with the requirements in 10 CFR 70.23(a)(1), in part, an application for a license will be approved if the Commission determines that the SNM will be used for the conduct of activities licensed by the Commission under section 103 or 104 of the Atomic Energy Act of 1954, as amended, or for such other uses as the Commission determines to be appropriate to carry out the purposes of the Act. In accordance with the requirements in 10 CFR 70.22(a)(2), an applicant shall describe the activity for which the SNM is requested, or in which SNM will be produced, the place at which the activity is to be performed, and the general plan for carrying out the activity (see NRC Form 313). The described uses should contain sufficient information to

enable the reviewers to have a clear understanding of each use and determine the potential for exposure of workers and members of the public to radiation and radioactive materials. The specific uses of each radioisotope requested should be described. The application will include a summary, nontechnical narrative description for each activity or process in which the applicant proposes to acquire, deliver, receive, possess, produce, use, process, transfer, or store SNM. The proposed uses of SNM for the facility must be for uses authorized under the Act.

1.4 Period of Time for which the License Is Requested

In accordance with the requirements in 10 CFR 70.22(a)(3), the applicant should state the period for which licensing is requested. At the outset of applying, this period may not be known. When the period of licensing is unknown, a period for licensing is established based upon the activities of the applicant and the type of license. The applicant will have ample time before licensing to discuss these needs with the NRC staff.

1.5 Radioactive Material for which the License Is Requested

In accordance with the requirements in 10 CFR 70.22(a)(4), the application must clearly state the name, amount, and specifications (chemical and physical form, isotopic content where applicable). The applicant should list each requested radioisotope by its element name and its mass number (e.g., uranium (U)-233). It should be specified whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not required. Applicants requesting an authorization to use volatile radioactive material must provide appropriate facilities, engineering controls, and radiation safety procedures for handling such material.

The anticipated possession limit in milligrams (mg) or grams (g) for each radioisotope should also be specified. Possession limits must cover the total anticipated inventory, including licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half-life greater than 120 days. Chapter 8 discusses these requirements.

1.6 Facility Description and Process Overview

In accordance with the requirements in 10 CFR 70.23(a)(3), an application for a license will be approved if the Commission determines that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. In accordance with the requirements in 10 CFR 70.22(a)(7), the application should describe equipment and facilities to be used by the applicant to protect health and minimize danger to life or property. The applicant should state the general facility and process descriptions involved in the activities for which the license is requested. The application should include a facility layout description; an overview of the different processes at the facility involving licensed material; and a site overview, including a description of the proximity of facility buildings and nearby populations.

1.7 Organization and Administration

The regulations in 10 CFR 70.23(a)(2) state that the Commission will approve an application if it determines that the applicant is qualified by reason of training and experience to use the material for the purpose requested. The regulations in 10 CFR 70.22(a)(6) require an applicant

to provide the technical qualifications, including training and experience of the applicant and members of its staff, to engage in the proposed regulated activities. The applicant should also describe the qualification of its personnel for key management positions in terms of education (i.e., degree and field), training, and experience. Qualification criteria should be described generally, in terms of academic credentials, formal continuing education, and work experience (e.g., “bachelor’s degree in nuclear engineering or related scientific or engineering field, with 5 years of experience managing the radiation protection program in the Department of Nuclear Engineering”).

The regulations in 10 CFR 70.23(a)(4) state that the Commission will approve an application if its proposed procedures to protect health and to minimize danger to life or property are adequate. The regulations in 10 CFR 70.22(a)(8) require applicants to provide information regarding their proposed procedures to protect health and minimize danger to life or property. The applicant should describe the policies and procedures that it will use to manage and closely monitor the facility design, engineering, construction, and modifications to adequately protect public health and safety and the environment. The applicant should describe the relationships among major facility safety functions and programs, such as the radiation safety, nuclear criticality safety, fire safety, chemical safety, environmental monitoring, and emergency planning. The application should discuss the procedures for communications and authority among the organizational units involved in the engineering, health, safety, environmental, and operations functions of the facility.

2 RADIATION PROTECTION

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (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 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance"; 10 CFR 21.21, "Notification of failure to comply or existence of a defect and its evaluation"; and 10 CFR 71.5, "Transportation of licensed material."

Regulatory Criteria: An application for a license to possess special nuclear material (SNM) in critical mass quantities must provide the following radiation protection information, in accordance with the requirements in 10 CFR 70.22(a)(6) and 10 CFR 20.1101, "Radiation protection programs":

- description of the organization and technical qualifications of the applicant and members of his staff to engage in the applicant's proposed activities

- commitment to maintain occupational exposures to radiation as low as is reasonably achievable (ALARA)

- description of the facilities and equipment adequate to protect health and minimize danger to life and property, including that licensees must do the following:

  – possess or have access to radiation monitoring instruments that are necessary to protect health and minimize danger to life or property
  – conduct testing to determine whether there is any radioactive leakage from licensed material
  – conduct surveys of potential radiological hazards in the workplace

- written radiation protection procedures and radiation work permits

- description of the operating and emergency procedures that include the following provisions:

  – instructions to keep radiation doses to workers and members of public ALARA
  – instructions for maintaining security during storage and transportation
  – instructions to maintain accountability during use
  – use of personnel monitoring and radiation survey equipment
  – instructions for packaging and transporting licensed material
  – instructions on whom to contact when an emergency occurs

- description of how the applicant ensures the safe transportation of licensed material

Discussion: The applicant should provide the details of its radiation protection program (RPP) to address the occupational radiation protection measures in 10 CFR Parts 19, 20, 70, and 71. Specifically, applicants must develop, document, and implement an RPP in accordance with 10 CFR 20.1101 to ensure adequate protection for the radiological health and safety of workers.

The content and level of detail in this chapter are generally greater than in other chapters because the criteria are needed to demonstrate compliance with 10 CFR Part 20 requirements.

2.1 Organizational and Personnel Qualifications

2.1.1 Organizational Management

The regulations in 10 CFR 70.22(a)(6) require that an applicant provide the technical qualifications, including training and experience of the applicant, key staff members, and managers. The information in the submittal should identify, by name, the individuals who will be managing the activities described in the license application with sufficient description to convey the training and experience of each of these individuals. Organizational relationships among the individual positions of the staff should be defined and understandable to the reviewer.

The organizational structure and associated administrative program should include administrative policies, procedures and management policies, and qualifications of key management positions. The submittal should describe how these will provide reasonable assurance that the health, safety, and environmental protection functions will be effective.

The applicant should also describe the qualifications regarding education (i.e., degree and field), training, and experience for key management positions. Responsibilities or job descriptions for decision-making individuals (i.e., management positions) should be described for the facility manager, operations manager, shift supervisor, and managers for various safety and environmental disciplines. Alternative named management positions may be proposed. Qualifications should be described generally, in terms of academic credentials, formal continuing education, and work experience.

2.1.2 Radiation Safety Officer

Regulatory Requirements: 10 CFR 20.1101, 10 CFR 70.22(a)(6), and 10 CFR 70.23(a)(2).

Regulatory Criteria: Radiation safety officers (RSOs) must have training and specific experience appropriate for the types and quantities of licensed material to be authorized by the license. The training should be commensurate with the discussion below:

- The applicant shall appoint a suitably educated, experienced, and trained RPP director (typically referred to as the RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. The RSO must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. The applicant should also provide the NRC with the education and experience of the RPP director's staff and identify the relationship between line managers and those responsible for the RPP.

Discussion: The RSO is the individual responsible for the RPP. The RSO should have independent authority to stop operations that may be considered unsafe and should have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Appendix A to this NUREG describes typical RSO duties.

To demonstrate adequate training and experience, the RSO should have: (1) sufficient knowledge of physical, chemical, biological sciences, or engineering; and (2) training and experience commensurate with the scope of proposed licensed activities. Training should include the following subjects:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of SNM to be used)
- regulatory requirements and standards
- hands-on use of radioactive materials

The length of training and experience described will depend upon the type, form, quantity, and proposed use of the licensed material requested. Ultimately, the proposed training and experience should be sufficient to ensure that the RSO can identify and control the anticipated radiation hazards. In addition to having direct access to the plant or facility manager, the RSO should be skilled in the interpretation of data and regulations pertinent to radiation protection, be familiar with the operation of the facility and radiation protection concerns of the site, participate as a resource in radiation safety management decisions, and be responsible for establishing and carrying out the RPP. Appendix A to NUREG-1556, "Consolidated Guidance About Materials Licenses," Volume 17, "Program-Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass," describes some typical RSO duties. This is not an all-encompassing list of radiation safety duties but does identify issues for consideration.

Applicants should provide information about the proposed RSO's training and experience relative to the licensed material requested in the application. Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, and committee and society memberships. Applicants are required to notify the NRC of changes in the designation of the RSO. The applicant must submit to the NRC the name and qualifications of the replacement RSO as part of an amendment request.

2.1.3 Authorized Users

Regulatory Requirements: 10 CFR 19.11, "Posting of notices to workers"; 10 CFR 19.12, "Instruction to workers"; 10 CFR 19.13, "Notifications and reports to individuals"; 10 CFR 20.1101; 10 CFR 70.22(a)(6); and 10 CFR 70.23(a)(2).

Regulatory Criteria: Authorized users (AUs), including radiation workers, must have adequate training and experience to safely possess and use radioactive materials.

Discussion: An AU is a category of staff that the licensee has selected to meet requirements that the NRC has defined, established, and reviewed during the licensing process. An AU is a person who uses or directly supervises the use of licensed material. The AU's primary responsibility is to ensure that radioactive materials are used safely and in accordance with regulatory requirements. The AU is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Some organizations may have multiple AUs or may have multiple uses of material on the license. These individuals must have adequate training and experience with the types, quantities of licensed materials, and activities approved by the license. An AU (also known as "principal investigator/researcher") is a person, other than the RSO, whose training and experience has been reviewed and approved by the applicant or the NRC, or both, and who uses or directly supervises the use of licensed material. The AU is also responsible for keeping occupational doses and doses to members of the public ALARA.

The AUs must have adequate and appropriate training to provide reasonable assurance that the applicant uses licensed material safely; adequately secures, and controls access to, licensed materials; and responds appropriately to events or accidents involving licensed materials to prevent the spread of contamination.

To demonstrate adequate training and experience, the AU should have (1) sufficient knowledge of physical, chemical, and biological sciences, or engineering and (2) training and experience commensurate with the scope of the proposed activities. Training should include the following topics:

- radiation protection principles
- characteristics of ionizing radiation
- units of radiation dose and quantities
- radiation detection instrumentation
- biological hazards of exposure to radiation (appropriate to types and forms of SNM to be used)
- regulatory requirements and standards
- hands-on use of radioactive materials

The type, form, quantity, and proposed use of the licensed material will determine the length of training and experience required.

An AU supervises the use of radioactive materials when directing personnel during operations involving licensed materials. Although the AU may delegate specific tasks to supervised users (e.g., doing surveys, keeping records), the AU is responsible for the safe use of radioactive materials to ensure areas are not contaminated.

Applicants must maintain records of AU training and experience, which must be commensurate with the type and quantity of material the applicant proposes to use. For example, an individual with training and experience only with sealed radioactive sources may not be qualified to use or supervise the use of unsealed licensed material. In addition, an individual with experience using only trace quantities may not understand the risks of working with much larger (e.g., 10 or more times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, an individual experienced with gamma emitters may not have appropriate experience for high energy beta emitters.

2.1.4 Radiation Safety Training

Regulatory Requirements: 10 CFR 19.11; 10 CFR 19.12; 10 CFR 19.13; 10 CFR 37.43, "General security program requirements"; 10 CFR 70.9, "Completeness and accuracy of information"; 10 CFR 70.23(a)(2).

Regulatory Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources) and who, during their employment, are likely to receive an annual occupational dose of radiation greater than 1 millisievert (mSv) (100 millirem (mrem)), must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12. Also, any licensee that possesses an aggregated Category I or Category II quantity of radioactive material (as defined in 10 CFR 37.5, "Definitions") must provide a training program for those individuals implementing the security program. Each individual should also receive periodic (i.e., annual) refresher training.

Discussion: 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) per year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program.

Licensees should not assume that prior employment or academic training has adequately covered safety instructions. Licensees should provide site-specific training for all individuals and should discuss procedures for working with radioactive materials, such as waste processing or transportation. Also, ancillary personnel (e.g., clerical, housekeeping, security), whose duties may require them to work in the vicinity of radioactive material (whether escorted or not), need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately. Additionally, some form of familiarization training or briefing may be necessary for visitors to the site.

Training may be in the form of lectures, demonstrations, videotape, or self-study and should emphasize practical subjects important to the safe use of licensed material. The program should consider both the topics pertinent for each group of workers and the method and frequency of training. The person conducting the training should be a qualified individual (i.e., a person who meets the qualifications for RSO or AU on the license and is familiar with the licensee's program).

Regulatory Guidance: The following regulatory guidance may be helpful in assessing the qualifications of proposed personnel:

- American Nuclear Society/Health Physics Society (ANSI/HPS) N13.36, “Ionizing Radiation Safety Training for Workers,” October 30, 2001

- American Society for Testing and Materials (ASTM) El 168-95, “Radiological Protection Training for Nuclear Facility Workers,” reapproved in 2008

- National Council on Radiation Protection and Measurements (NCRP) Report No. 134, “Operational Radiation Safety Training,” 2000

- Regulatory Guide 1.8, “Qualification and Training of Personnel for Nuclear Power Plants”

- Regulatory Guide 8.13, “Instruction Concerning Prenatal Radiation Exposure”

- Regulatory Guide 8.29, “Instruction Concerning Risks from Occupational Radiation Exposure”

2.2 Radiation Protection Program

Regulatory Requirements: 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 70, 10 CFR 73.67, 10 CFR 21.21, 10 CFR 71.5.

Regulatory Criteria: An application for a license to possess a critical mass of SNM must provide the following information:

- Outline the RPP structure and define the responsibilities of key program personnel.

- Staff the RPP with suitably trained people, provide sufficient resources, and carry out the program.

- Commit to the radiation protection function’s independence from the facility’s operations.

- Review, at least annually, the content and implementation of the RPP, in accordance with 10 CFR 20.1101(c). The review should consider facility changes, new technologies, and other process enhancements that could improve the effectiveness of the overall program.

- Take steps to keep radiation exposures ALARA.

- Describe equipment and facilities adequate to protect personnel, the public, and the environment.

- Ensure conduct of licensed activities by individuals qualified by training and experience.

- Write operating and emergency procedures to address all likely scenarios.

- Describe the organizational structure and the individuals responsible for ensuring implementation of the radiation safety and security program.

- Manage records.

- Implement an audit program to ensure that the licensee reviews the radiation safety and security programs at least annually.

Discussion: The NRC recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. Compliance with NRC regulations provides reasonable assurance that licensed activities will take place safely. Effective management will result in increased safety and compliance.

The RPP must address the occupational radiation protection measures in 10 CFR Parts 19, 20, and 70. The intent of a satisfactory RPP is to safely control the receipt, possession, use, transfer, and disposal of licensed material such that the total dose to an individual does not exceed the standards for protection against radiation prescribed in the regulations. Specifically, licensees must develop, document, and conduct an RPP in accordance with 10 CFR 20.1101.

Regulatory Guidance: The following regulatory guidance discusses methods and procedures that the NRC staff considers acceptable for maintaining radiation exposures to occupational workers and the public ALARA:

- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable"

2.2.1 ALARA Program

Regulatory Requirements: 10 CFR 20.1101(b); 10 CFR 20.1101(d); 10 CFR 20.1402, "Radiological criteria for unrestricted use"; 10 CFR 20.1702(a); 10 CFR 20.2002(d).

Regulatory Criteria: Pursuant to 10 CFR 20.1101, applicants and licensees shall establish a written and comprehensive ALARA program, preparing procedures and policies to ensure that occupational and public radiation exposures, as well as releases to the environment, are maintained ALARA.

Discussion: A central condition to an effective RPP is maintaining exposures to radiation ALARA. There are regulatory limits for occupational and public exposures to radiation and radioactive materials. An ALARA program is established to ensure that the licensee designs its processes and procedures to keep exposures as low as possible and lower than any regulatory limit where possible.

Licensees should make every reasonable effort to maintain radiation exposures as far below the limits specified in that part as practicable. Two basic conditions are considered necessary in any program for keeping occupational exposures as far below the specified limits as is reasonably achievable. The management of the licensed facility should be committed to maintaining exposures ALARA, and the personnel responsible for radiation protection should be continually vigilant in seeking means to reduce exposures. The commitment made by licensee management to minimize exposures should provide clearly defined radiation protection responsibilities and an environment in which the radiation protection staff can do its job properly. Elements of an ALARA program include the following:

- establishing a written, comprehensive, and effective ALARA program

- preparing policies and procedures to ensure that occupational radiation exposures are maintained ALARA

- outlining specific ALARA program goals and establishing an ALARA program organization and structure, including written procedures for its implementation in plant design and operations

- maintaining applicant staff awareness of the commitment of management to ALARA

- ensuring regular assessment by management to understand and evaluate exposures to staff and the public

- overseeing and supervising work to evaluate process improvements resulting in exposure reductions

- training staff in ALARA concepts to engage staff participation

- giving the RSO and health physics staff independent authority to stop work to prevent unnecessary personnel exposures

- regularly reviewing work processes by management to seek improvements

Regulatory Guidance: The following regulatory guidance may be helpful for implementing and maintaining radiation and RPP that ensures exposures to occupational workers and the public are ALARA:

- Regulatory Guide 8.2, “Administrative Practices in Radiation Surveys and Monitoring”

- Regulatory Guide 8.10, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable”

- Regulatory Guide 8.13, “Instructions Concerning Prenatal Radiation Exposure”

- Regulatory Guide 8.15, “Acceptable Programs for Respiratory Protection”

- Regulatory Guide 8.29, “Instructions Concerning Risks from Occupational Radiation Exposure”

2.2.2 Occupational Dose

Regulatory Requirements: 10 CFR Part 20, Subpart C, “Occupational Dose Limits.”

Regulatory Criteria: In accordance with 10 CFR 20.1101, licensees shall establish a written and comprehensive ALARA program and prepare procedures and policies to ensure that occupational and public radiation exposures, as well as releases to the environment, are maintained ALARA.

The regulations in 10 CFR 20.1201, "Occupational dose limits for adults," require licensees to control occupational exposure to adults who are likely to receive an annual dose in excess of any of the following (each evaluated separately):

- 5 rem (0.05 Sv) total effective dose equivalent (TEDE)
- 15 rem (0.15 Sv) eye dose equivalent
- 50 rem (0.5 Sv) shallow-dose equivalent to the skin
- 50 rem (0.5 Sv) shallow-dose equivalent to any extremity

In accordance with 10 CFR 20.1207, "Occupational dose limits for minors," the annual occupational limit for minors is 10 percent of the annual dose limits specified for adult workers:

- 0.5 rem (0.005 Sv) TEDE
- 1.5 rem (0.015 Sv) eye dose equivalent
- 0.5 rem (0.05 Sv) shallow-dose equivalent to the skin
- 0.5 rem (0.05 Sv) shallow-dose equivalent to any extremity

In accordance with 10 CFR 20.1208, "Dose equivalent to an embryo/fetus," for declared pregnant women the dose limit to the embryo/fetus is 0.5 rem (5 mSv) for the entire gestation period.

In accordance with 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under their control and shall supply and require the use of individual monitoring devices by:

- individuals entering a high or very high radiation area
- adults likely to receive in 1 year an intake in excess of 10 percent of the applicable annual limits on intake (ALIs) for ingestion and inhalation
- minors and declared pregnant women likely to receive in 1 year a committed effective dose equivalent in excess of 0.1 rem (1.0 mSv)

Discussion: In accordance with 10 CFR 20.1502, if an adult (individual) is likely to receive in 1 year a dose greater than 10 percent of any applicable limit, monitoring for occupational exposure is required. Employees who regularly work with radioactive materials and have the potential to receive an occupational exposure should be monitored with approved devices as part of their employment. Not every employee on site needs to be monitored. There is typically a variety of work that does not require monitoring, perhaps due to its administrative nature or to the fact that the employee has no access to licensed materials and associated exposure. Monitoring should only be conducted when the work environment calls for it. The licensee may evaluate the dose the individual is likely to receive before allowing the individual to receive the dose, to understand whether this meets the threshold requirement for monitoring. This

documented evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas. Appendix D to this document and Regulatory Guide 8.34, “Monitoring Criteria and Methods To Calculate Occupational Radiation Doses,” contain further guidance on evaluating the need to provide monitoring. This evaluation must be documented and reflect the work processes ongoing. If work processes change, the licensee should consider a reevaluation and, if not done, document the reasons for not doing the evaluation and make them available for review.

If this prospective evaluation shows that an individual’s dose is not likely to exceed 10 percent of any applicable regulatory limit, there are no recordkeeping or reporting requirements regarding the individual’s exposure. For individuals who have received doses at other facilities in the current year, the licensee need not consider the previous dose in this prospective evaluation. When determining the need for monitoring and associated recordkeeping and reporting, only the dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. If it were determined that monitoring was not required, and a subsequent evaluation shows that the 10 percent regulatory threshold has been or will be exceeded, the dose received by an individual when monitoring was not provided should be estimated, recorded, and reported (if required). These estimates can be based on any combination of work location radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a “best estimate” of the actual dose received.

Licensees should use NRC Form 4, “Cumulative Occupational Dose History,” and NRC Form 5, “Occupational Dose Record for a Monitoring Period,” to record the individual dose. 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 “N/A” for “not applicable” in the blocks on NRC Form 4 and NRC Form 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.”

Licensees should also perform prospective evaluations of the doses that may be received by occupationally exposed minors and declared pregnant women. As with individual adult workers, licensees must supply and require the use of individual monitoring devices to monitor external exposures and the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in 10 CFR 20.1502.

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), dosimeters must be processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-accredited processor (10 CFR 20.1501(d)). The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP-accredited processor for its recommendations for exchange frequency and proper use of the dosimeter.

Guidance about methodologies to determine internal occupational dose and summation of occupational dose appears in Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data”; Regulatory Guide 8.34; and Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.”

For all employees for whom it is determined monitoring is required, dosimetry used will be accredited by the NVLAP. In addition, the applicant must maintain records of the occupational exposures of employees working under the license. Documentation may require determination

of any occupational dose received for work under a different license. Certain occupations require annual reporting to the NRC.

Regulatory Guidance:

- American National Standards Institute (ANSI) N13.15-1985, “Radiation Detectors—Personnel Thermoluminescence Dosimetry Systems—Performance”
- ANSI N13.11-2001, “Personnel Dosimetry Performance—Criteria for Testing”
- ANSI N13.22-1995, “Bioassay Program for Uranium”
- ANSI N13.27-1981, “Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters”
- ANSI N13.30-1996, “Performance Criteria for Radiobioassay”
- Regulatory Guide 8.4, “Personnel Monitoring Device—Direct-Reading Pocket Dosimeters”
- Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data”
- Regulatory Guide 8.28, “Audible-Alarm Dosimeters”
- Regulatory Guide 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses”
- Regulatory Guide 8.35, “Planned Special Exposure”

2.2.3 Public Dose

Regulatory Requirements: 10 CFR 20.1003, “Definitions”; 10 CFR 20.1101; 10 CFR 20.1301, “Dose limits for individual members of the public”; 10 CFR 20.1302, “Compliance with dose limits for individual members of the public”; 10 CFR 20.2107, “Records of dose to individual members of the public.”

Regulatory Criteria: Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in a year; that air emissions of radioactive material to the environment, excluding radon-222 and its daughters, will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) TEDE in a year from those emissions; and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations. In addition, licensees must strive to maintain doses to members of the public that are ALARA.

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 and from medical procedures. 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 the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

To the extent practical, procedures and engineering controls based upon sound radiation protection principles are carried out to achieve and maintain doses to members of the public ALARA and in accordance with the following 10 CFR Part 20 requirements:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in 1 calendar year resulting from the licensee's possession or use of licensed materials.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any 1 hour.

- The air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem).

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

Licensees must ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations. In addition, licensees must strive to maintain doses to members of the public that are ALARA.

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.

Pursuant to 10 CFR 20.1302, an applicant is required to demonstrate compliance with the dose restrictions. Appendix E to this document and Regulatory Guide 8.34 contain information on methods to evaluate conditions and demonstrate compliance with the article. This must be a documented, reviewable evaluation. If work processes change such that the potential dose to the public might change, it should be reevaluated.

There are many possible dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into the following three major dose pathway groups:

(1) airborne radioactive material (e.g., inhalation)

(2) waterborne radioactive material (e.g., ingestion)

(3) external radioactive exposure (e.g., source)

The licensee should review these major 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 each licensee's needs. Additional guidance regarding monitoring of effluents appears in section 2.3.3.

Under 10 CFR 20.2107, licensees must maintain records sufficient to demonstrate compliance with the dose limits for members of the public until the Commission terminates the license. Appendix E to this document contains additional guidance regarding compliance with the recordkeeping requirements.

Regulatory Guidance:

- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable"

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

2.2.4 Minimization of Contamination

Regulatory Requirements: 10 CFR 20.1406, "Minimization of contamination."

Regulatory Criteria: Part of an effective ALARA program is planning and consideration for work processes to minimize the spread of contamination. Applicants must 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.

When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination during operation, decontamination and decommissioning efforts, and radioactive waste generation. When submitting new applications, applicants should consider the following:

- implementation of and adherence to good health physics practices in operations

- minimization of areas, to the extent practicable, where licensed materials are used and stored

- maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill

- choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition

- appropriate filtration of effluent streams

- use of nonporous materials, for example, for laboratory bench tops and flooring

- ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction

- use of appropriate plumbing materials with minimal pipe lengths and traps

- minimization of the number of disposal sites (sinks) used for liquid waste disposal

Discussion: Sealed sources and devices (SSDs) that are approved by the NRC or an Agreement State and located and used according to their SSD registration certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD registration certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only SSDs that have not leaked.

This is not an item for an application per se but is addressed here as part of the applicant's commitment to written procedures. It is an integral part of an ALARA program and part of an effective RPP.

Regulatory Guidance:

- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable"

- Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication"

2.2.5 Ventilation and Respiratory Protection

Regulatory Requirements: 10 CFR 20.1101(b), 10 CFR 20.1201(a)(ii), 10 CFR 20.1202(b), 10 CFR 20.1204(a), 10 CFR 20.1502(b), 10 CFR 20.1702(a), 10 CFR 20.1703(a), 10 CFR 20.1703(c).

Regulatory Criteria: Applicants must describe the potential for internal exposure and the measures that will be taken to minimize internal dose. The regulations in 10 CFR 20.1701 require licensees to use process or engineering controls to the extent practical to control the concentration of radioactive material in air. Licensees should use respiratory protection devices only after considering other measures to limit intake.

Discussion: Another consideration for any RPP is the need for respiratory protection or additional ventilation. Work with unsealed material or processes that can cause radioactive materials to become airborne require assessment. Surveys will be part of an effective ALARA program if there is a potential for airborne contamination (see appendix F). Proper engineering controls are carried out for all research involving radioactive materials. Hazard assessments are made and documented, to include dose and dose rates, contamination controls, effluent releases, and an evaluation of the need for ventilation controls. Licensees can use health physics surveys of airborne radioactivity concentration to evaluate process and engineering controls, conduct increased surveillance, determine exposure time limits for workers, and support a program for the use of respiratory protective equipment.

It should be noted that engineering controls are the preferred means of preventing airborne contamination and that thorough justification will be required if an applicant chooses to use respiratory protective equipment to control internal exposure. Respiratory protection will require the need for other occupational safety considerations, such as heat stress. Uncontrolled areas inside a plant may require a survey periodically to ensure there is no effect on the general public. The frequency of routine surveys should be commensurate with the nature of the work; the quantities of material being processed; and the specific protective facilities, equipment, and procedures used to protect workers.

The regulations in 10 CFR 20.1902(d) describe posting requirements for such areas. The use of other precautionary procedures should be considered, such as increased surveillance and limitation of exposure times. The applicant that requires a respiratory protection program needs to address the following:

- Install appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed the occupationally derived air concentration values specified in 10 CFR Part 20, Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” during normal operations.

- Describe management measures, including preventive and corrective maintenance and performance testing, to ensure that the ventilation and containment systems operate when required and are within their design specifications.

- Describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used.

- Describe the frequency and types of tests to measure the performance of ventilation and containment systems, the acceptance criteria, and the actions to be taken when the acceptance criteria are not satisfied.

- Establish a respiratory protection program that meets the requirements of 10 CFR Part 20, Subpart H, “Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas.”

- Prepare written procedures for the selection, fitting, issuance, maintenance, testing, training of personnel, monitoring, and recordkeeping for individual respiratory protection equipment and for specifying when such equipment is to be used.

- Revise the written procedures for the use of individual respiratory protection equipment, as applicable, when making changes to processing, facility, or equipment.

- Maintain records of the respiratory protection program, including training in respirator use.

Appendix B to this document contains further elaboration on respiratory protection.

Regulatory Guidance:

- American Conference of Governmental Industrial Hygienists 2095, "Industrial Ventilation: A Manual of Recommended Practice for Design," 2007

- ANSI Z88.2-1992, "Practices for Respiratory Protection"

- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable"

- Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection"

- Regulatory Guide 8.24, "Health Physics Survey for Enriched Uranium-235 Processing and Fuel Fabrication"

- Regulatory Guide 8.25, "Air Sampling in the Workplace"

2.2.6 Waste Management

Regulatory Requirements: 10 CFR 20.1501, "General"; 10 CFR 20.1904, "Labeling containers"; 10 CFR 20.2001, "General requirements"; 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures"; 10 CFR 20.2003, "Disposal by release into sanitary sewerage"; 10 CFR 20.2004, "Treatment or disposal by incineration"; 10 CFR 20.2005, "Disposal of specific wastes"; 10 CFR 20.2006, "Transfer for disposal and manifests"; 10 CFR 20.2007, "Compliance with environmental and health protection regulations"; 10 CFR 20.2108, "Disposal of certain byproduct material"; 10 CFR 37.11(c); 10 CFR 70.51, "Records requirements"; 10 CFR 71.43, "Lifting and tie-down standards for all packaging."

Regulatory Criteria: Radioactive waste must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained.

Discussion: Radioactive waste is normally generated when performing licensed activities. Such waste may include used or unused radioactive material and unusable items contaminated with radioactive material (e.g., absorbent paper, gloves). Licensees may not receive radioactive waste from other licensees for processing, storage, or disposal, unless the NRC specifically authorizes them to do so.

All radioactive waste must be stored in appropriate containers until its disposal, and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. The NRC requires licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

- transfer to an authorized recipient

- release into sanitary sewerage

- extended interim storage

- prior approval by the NRC of any alternate method

- release in effluents to unrestricted areas, other than into sanitary sewerage

- incineration

Licensees may choose any one or more of these methods to dispose of their radioactive waste. It has been the NRC's experience that many of the facilities dispose of SNM by the first method. Applicants should describe their program for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require licensees to maintain all appropriate records of disposal of radioactive waste.

Regulatory Guidance:

- Regulatory Guide 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning"

2.2.7 Audit Program

Regulatory Requirements: 10 CFR 20.1101; 10 CFR 20.2102, "Records of radiation protection programs"; 10 CFR 21.21(a); 10 CFR 37.33, "Access authorization program review"; 10 CFR 37.55, "Security program review."

Regulatory Criteria: Licensees must review the content and implementation of their RPPs at least annually to ensure the following:

- Compliance with NRC and U.S. Department of Transportation (DOT) regulations (as applicable) is assured, and the terms and conditions of the license are met.

- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101).

- Records of audits and other reviews of program content are maintained for 3 years.

- The access authorization program is effective and complies with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," if required.

- The security program is effective and complies with 10 CFR Part 37, Subpart C, "Physical Protection Requirements During Use," if required.

- Records of audits and other reviews of program content are maintained for 3 years after the record is made.

Discussion: If an audit identifies violations of NRC requirements, the licensee should first 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. Licensees are encouraged to contact the NRC for guidance if there is any uncertainty regarding a reporting requirement. The NRC routinely reviews a licensee's records

to verify if appropriate corrective actions were taken promptly to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take the necessary steps to correct them. The NRC can exercise discretion and may elect not to cite the licensee for these violations if it takes prompt and effective corrective actions. NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions," issued May 2000, contains information on the NRC's use of discretion on issuing a notice of violation.

Additionally, 10 CFR 20.2102 requires licensees to keep records of the RPP, including a description of the program components, audits, and other aspects of program implementation for 3 years from the date of the record. Records of these audits should include the 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. Licensees must maintain these records for NRC inspections. NUREG-1556, Volume 17, Appendix B, "Suggested Format for Providing Information Requested in Items 5 Through 11 of U.S. Nuclear Regulatory Commission Form 313," lists considerations for the audit of an RPP.

The NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As a part of the audit program, licensees should consider including unannounced audits of users of SNM of less than critical mass to determine whether radiation safety procedures are being followed. Licensees should consider providing specialized audit training if staff other than the RSO are used to conduct audits of the performance of licensed materials users. Appendix E to this document contains applicable audit program areas for potential specialized training. It is essential that, once identified, problems are corrected comprehensively and in a timely manner. IN 96-28 provides guidance on this subject. The NRC's Enforcement Policy may be found online at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The NRC Enforcement Manual may be found online at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents at https://www.nrc.gov/reading-rm/doc-collections/enforcement/.

Licensees must maintain records of audits and other reviews of program content and implementation for 3 years from the date of the record, in accordance with 10 CFR 20.2102. The NRC has found acceptable those audit records that contain the following information:

- date of audit
- name of person or persons who conducted the audit
- names of persons contacted by the auditor or auditors
- areas audited
- audit findings and corrective actions
- follow-up

2.3 Facilities and Equipment

Regulatory Requirements: 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR Part 37; 10 CFR 37.5; 10 CFR 37.49, "Monitoring, detection, and assessment"; 10 CFR 37.53, "Requirements for mobile devices"; 10 CFR 70.22(a)(7); 10 CFR 70.23(a)(3); 10 CFR 70.25(g); 10 CFR 70.41(a).

Regulatory Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Facilities and equipment must also provide enhanced physical protection of aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5. Applicants must 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.

Discussion: Consistent with 10 CFR 70.22(a)(7), facilities and equipment must be adequate to protect health and minimize danger to life and property. Applicants must 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. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. 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. These should be identified, as well as radioactive material storage areas.

Licensees should include a description of the area(s) assigned for the receipt, storage, security, preparation, and measurement of radioactive materials. They should submit a diagram showing the locations of the shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Appendix B to this document provides a variety of considerations for facility design and equipment. Not all of these would apply to every licensee but may be helpful in planning.

Modifications to operating and maintenance procedures and to plant equipment and facilities should be made where they will substantially reduce exposures at a reasonable cost.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed in case changes are required. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant cannot possess or use licensed material until after the facilities are approved and completed, equipment is procured and ready for use, and the license is issued.

Section 2.4 of this document includes additional information regarding radiation monitoring, respiratory protection, dosimetry, and bioassay.

Applicants are reminded that records important to decommissioning include the following:

- as-built drawings and modifications of structures and equipment in restricted areas

- as-built drawings and modifications of locations of possible inaccessible contamination, such as buried pipes, that may be subject to contamination

- records of spills and unusual occurrences that may result in contamination of the facility or site

These records are required to be maintained in an identifiable location. Facilities are required to meet NRC criteria before release. Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs needed for decommissioning.

Regulatory Guidance:

- Regulatory Guide 4.7, “General Site Suitability Criteria for Nuclear Power Stations”

2.3.1 Radiation Monitoring Instruments

Regulatory Requirements: 10 CFR 20.1501, 10 CFR 20.2103(a), 10 CFR 70.22(a)(7).

Regulatory Criteria: Pursuant to 10 CFR 20.1501, licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

Discussion: Monitoring of personnel and working areas are essential to an effective ALARA program. Radiation surveys are done for two purposes: (1) to ascertain radiation levels, concentrations of radioactive material, and potential radiological hazards that could be present in the facility, and (2) to detect releases of radioactive material from plant equipment and operations. Radiation surveys will focus on those areas of the plant necessary to show compliance with the dose limits and monitoring requirements of 10 CFR Part 20, Subpart C; Subpart D; and Subpart F.

Licensees shall possess, or have access to, calibrated radiation detection and measurement instruments or licensed services to perform, as necessary, the following:

- package surveys

- contamination surveys

- sealed source leak tests

- air sampling measurements

- bioassay measurements

- effluent release measurements

- unrestricted area dose rate measurements

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (e.g., count rate, dose rate). Most of the radioactive

emissions from SNM are alpha emissions. Specific gamma or x-ray emissions are associated with alpha decay, and a standard Geiger-Mueller detector will give positive confirmation of the presence or absence of loose material. When more information is required for nuclide identification, the applicant should include instrumentation capable of detecting alpha emissions, such as zinc sulfide (ZnS) detectors. Applications should describe the instrumentation available for use and may include instrumentation applicants intend to purchase before starting licensed activities. The description should include the type of instrument and probe and the instrument's intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without calibration with appropriate radioactive sources.

For the purposes of this document, survey instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the survey instruments that may be used to perform the above functions include the following:

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- single or multichannel analyzers
- liquid scintillation counters
- gamma counters
- proportional counters
- ZnS detectors
- neutron detectors
- solid state detectors

The NRC requires that calibrations be made by the instrument's manufacturer or a person specifically authorized by the NRC or an Agreement State unless the applicant specifically requests this authorization. Applicants seeking authorization to do survey instrument calibrations shall submit procedures for review. Records of calibrations shall be retained in accordance with regulatory guidance. Appendix C to this document provides additional guidance.

Regulatory Guidance:

- Regulatory Guide 8.2, "Administrative Practices in Radiation Surveys and Monitoring"

- Regulatory Guide 8.4, “Personnel Monitoring Device—Direct-Reading Pocket Dosimeters”

- Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data”

- Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program”

- Regulatory Guide 8.24, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication”

2.3.2 Leak Tests

Regulatory Requirements: 10 CFR 20.1501; 10 CFR 20.2103, “Records of surveys”; 10 CFR 70.56, “Tests.”

Regulatory Criteria: The NRC requires testing to detect radioactive leakage from the sealed sources. Records of test results must be maintained in accordance with license conditions and NRC regulations. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 becquerel (0.005 microcurie) of radioactivity.

Discussion: Manufacturers, consultants, and other organizations may be authorized by the NRC or an Agreement State either to do the entire leak test sequence for other licensees or to provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the kit supplier’s instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to do the entire leak test sequence themselves. If an applicant chooses to do leak testing, it will submit procedures for review and approval.

Regulatory Guidance:

- Regulatory Guide 8.10, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable”

- Regulatory Guide 8.24, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication”

2.3.3 Surveys

Regulatory Requirements: 10 CFR 20.1101; 10 CFR 20.1501; 10 CFR 20.1906, “Procedures for receiving and opening packages”; 10 CFR 20.2103.

Regulatory Criteria: The regulations in 10 CFR 20.1501 and 10 CFR 20.2103 contain general survey and survey recordkeeping requirements. The regulations in 10 CFR 20.1906 contain general survey requirements for receiving and opening packages.

Discussion: The selection and proper use of radiation detection instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions. The regulations in 10 CFR 20.1003 define a survey 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 regulations in 10 CFR 70.23(a)(4) state that the NRC will approve an application if the Commission determines that the applicant's proposed procedures to protect health and to minimize danger to life or property are adequate. The regulations in 10 CFR 20.1101 require, in general, that applicants develop, document, and implement an RPP commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Therefore, 10 CFR 70.22(a)(7) requires applicants to describe the equipment and facilities that they will use to protect health and minimize danger to life or property, such as handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, and storage facilities. In addition, 10 CFR 70.22(a)(8) requires applicants to describe these proposed procedures to protect health and minimize danger to life or property. To meet regulatory requirements for surveying in 10 CFR 20.1501, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma, and neutrons) and compared to the appropriate limits. Licensees should also use surveys 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, the NRC may require environmental monitoring to demonstrate compliance with 10 CFR Part 20.

The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions. Radiation surveys detect and evaluate contamination of the following:

- facilities
- equipment
- personnel (during use, transfer, or disposal of licensed material)
- restricted and unrestricted areas

The regulations in 10 CFR 20.1501 state that surveys are required when it is reasonable, under the circumstances, to evaluate a radiological hazard and when necessary for the licensee to comply with regulations. Many different types of surveys may need to be done 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, equipment, and packages of radioactive material received or prepared for shipment
- 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, which 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

Appendix F to this document provides additional information. 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. Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any radiation safety program. The regulations in 10 CFR Part 20 do not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be carried out in each work area.

Regulatory Guidance:

- Regulatory Guide 8.10, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable”

- Regulatory Guide 8.24, “Health Physics Survey During Enriched Uranium-235 Processing and Fuel Fabrication”

- Branch Technical Position, “Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Materials,” April 1993

2.4 Commitment to Written Procedures

Regulatory Requirements: 10 CFR 20.1101(b), 10 CFR 70.22(a)(8).

Regulatory Criteria: As required by regulations, the licensee shall use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses to members of the public that are ALARA.

Discussion: Written, approved procedures and engineering controls are required to carry out activities involving material on the application. Processes should be evaluated for workable reductions in exposure through application of ALARA concepts, such as time, distance, and shielding. Use of mockups of work to be performed and prestaging of materials are other ALARA principles that should be considered. The applicant will establish a process for procedure generation, modification, authorization, distribution, and training, such that changes

in technology or practices are communicated effectively and promptly. Part of the process should provide for revising procedures, as necessary, to incorporate facility or operational changes. The RSO, or an individual who has the qualifications of the RSO, should approve all procedures related to radiation protection. The radiation work permits (RWPs) should define the authorized activities, the level of approval required (a radiation specialist, as a minimum), information requirements, period of validity, expiration and termination times, and recordkeeping requirements.

The applicant's commitment to preparing written radiation protection procedures and RWPs is acceptable if the license application provides data and information that meet each of the following commitments:

- Prepare written, approved procedures to carry out activities related to the RPP. Procedures should address applicable radiation protection requirements found in 10 CFR Parts 19, 20, 70, and 71 and any other applicable regulations.

- Establish a process for procedure generation or modification, authorization, distribution, and training, such that changes in technology or practices are communicated effectively and in a timely manner. Review and revise procedures, as necessary, to incorporate any facility or operational changes. The RSO, or an individual who has the qualifications of the RSO, should approve all procedures related to radiation protection.

- Specify written, approved RWPs for activities involving licensed material that are not covered by written radiation protection procedures. The RWPs should define the authorized activities, the level of approval required (a radiation specialist, as a minimum), information requirements, period of validity, expiration and termination times, and recordkeeping requirements.

Regulatory Guidance:

- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable"

2.5 Operating and Emergency Procedures

Regulatory Requirements: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.1801, "Security of stored material"; 10 CFR 20.1802, "Control of material not in storage"; 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 21.21; 10 CFR Part 37, Subpart B, "Background Investigations and Access Authorization Programs"; 10 CFR 37.21(a); 10 CFR 37.45, "LLEA Coordination"; 10 CFR 37.49; 10 CFR 70.22(a); 10 CFR 70.23(a)(4); 10 CFR 70.50, "Reporting requirements."

Regulatory Criteria: Each licensee should develop, implement, and maintain operating and emergency procedures that include the following provisions:

- instructions to keep radiation doses to workers and members of the public ALARA

- instructions for conducting operations to minimize the introduction of residual radioactivity into the site

- instructions for maintaining security during storage and transportation

- instructions for maintaining accountability during use

- instructions for properly storing and disposing of radioactive waste

- use of personnel monitoring and radiation survey equipment

- instructions for packaging and transporting licensed material

- instructions on how to respond and whom to contact when an emergency occurs

- instructions for identifying and reporting to the NRC defects and noncompliance, as required by 10 CFR 21.21

- instructions for maintaining records, in accordance with the NRC regulations and any license conditions

Discussion: There are two important aspects to operating and emergency procedures for applicants. One is for the day-to-day safe use and handling of materials as they apply to the application in intended uses and outcomes. An application must describe procedures for processes that address routine radiation protection and safety matters. A licensee will train its staff in these procedures on a regular basis. Every employee needs to have some level of safety training in this area. The other important aspect in this area is planning for the safety of the public and the environment. An applicant needs to plan its responses if the business of the applicant causes inadvertent effects offsite of the working facility.

The emergency management plan requirements in 10 CFR 70.22(i) state that licenses authorizing radioactive material exceeding certain thresholds must either (1) submit an emergency plan, or (2) submit an evaluation showing that the maximum dose to a person offsite due to a release would not exceed 1 rem effective dose equivalent, or an intake of 2 milligrams of soluble uranium.

Licensees should develop, implement, and maintain operating and emergency procedures to verify that they use all licensed materials in accordance with licensed activities, maintain control and accountability, and ensure radiation doses received by occupational workers and members of the public are ALARA. The operating procedures should describe the operations involving SNM and include a general plan for carrying out the activity. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public. Each licensee must develop, implement, and maintain operating and emergency procedures containing the following elements:

- contamination controls

- personnel and area monitoring (including frequency and limits)

- use of protective clothing and equipment

- recording requirements

- reporting requirements

- waste disposal practices

Licensees should post a copy of the operating and emergency procedures in all laboratory or work areas where radioactive materials are used. If posting of procedures is not practicable, the licensee may post a notice that describes the documents and states where they may be examined. Licensees should also provide copies of operating and emergency procedures to all authorized users. These instructions should describe immediate action to be taken in case of an emergency to prevent release of radioactive material or further contamination of work areas and personnel. Examples of emergency procedures include turning off the ventilation systems, evacuating the area, reentering, and containing spills. The instructions should specifically state the names and telephone numbers of responsible persons to be notified.

The licensee must notify the NRC when licensed material is lost or stolen, or other related conditions occur. The RSO must be proactive in evaluating whether NRC notification is required. Appendix F and the regulations (10 CFR 20.2201–20.2203; 10 CFR 70.50; and 10 CFR 21.21) describe when and where notifications are required.

Regulatory Guidance:

- NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," January 1988

- Regulatory Guide 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning"

2.6 Transportation

Regulatory Requirements: NRC: 10 CFR 20.1101; 10 CFR Part 37, Subpart D, "Physical Protection in Transit"; 10 CFR 70.42, "Transfer of special nuclear material"; 10 CFR 70.51; 10 CFR 71.5; 10 CFR 71.14, "Exemption for low-level materials"; 10 CFR 71.22, "General license: fissile material"; 10 CFR 71.37, "Quality assurance"; 10 CFR 71.38, "Renewal of a certificate of compliance"; 10 CFR 71.47, "External radiation standards for all packages"; 10 CFR 71.63, "Special requirement for plutonium shipments";10 CFR 71.64, "Special requirements for plutonium air shipments"; 10 CFR Part 71, Subpart G, "Operating Controls and Procedures" (except 10 CFR 71.93, 71.99, and 71.100); 10 CFR Part 71, Subpart H, "Quality Assurance." DOT: 49 CFR Parts 171–180 and 49 CFR Parts 390–397.

Regulatory Criteria: The regulations in 10 CFR 71.5(a) require, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. The NRC requires licensees and applicants seeking authorization to transport or ship licensed material, including radioactive waste, to develop, implement, and maintain safety programs for the transport of

radioactive material. An application must describe the transportation program to ensure adequate protection of workers and members of the public from unnecessary exposures to radiation during the transportation of the material and verify compliance with NRC and DOT regulations.

If the NRC authorizes a licensee to possess and use aggregated Category 1 or Category 2, or both, quantities of radioactive materials and to transport or deliver licensed material to a carrier for transporting these materials outside the site of usage, it must comply with the regulations in 10 CFR Part 37. The regulations in 10 CFR 37.75(a) state that each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall do the following:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee.

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(i) Discuss the State's intention to provide law enforcement escorts; and

(ii) Identify safe havens; and

(3) Document the preplanning and coordination activities.

The regulations in 10 CFR 37.75(b) require that each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

The regulations in 10 CFR 37.75(c) require that each licensee who receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

The regulations in 10 CFR 37.75(d) require that each licensee who transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 10 CFR 37.75(b), shall promptly notify the receiving licensee of the new no-later-than arrival time.

The regulations in 10 CFR 37.75(e) require that licensees, as a record, retain for 3 years a copy of the documentation for preplanning and coordination and any revision thereof.

Discussion: The regulations in 10 CFR Part 71 establish the requirements for packaging, preparing for shipment, and transporting licensed material. The regulations in 10 CFR Part 20 describe the requirements for controlling the handling of radioactive material. The regulations in 10 CFR Part 73, "Physical Protection of Plants and Materials," establish the requirements for the physical protection of SNM. Applicants who will transport or ship licensed material, including radioactive waste, must develop, carry out, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and DOT regulations.

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that the 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. The general performance objectives of 10 CFR 73.67(a) require that each licensee possessing, using, or transporting SNM of moderate or low strategic significance shall establish and maintain a physical protection system that will (1) minimize the possibilities for unauthorized removal of SNM consistent with the potential consequences of such actions, and (2) facilitate the location and recovery of missing SNM. Chapter 10 contains more information on physical security requirements. Specific requirements are dependent on the category of SNM possessed, as defined in 10 CFR 70.4, "Definitions."

Shipments of hazardous materials, including radioactive materials and the regulations that govern them, may be complex, regulated by multiple agencies (e.g., the NRC and DOT), and varied in nature. Organizations with little or no experience in transporting or providing radioactive material to a carrier for transport should consult a specialist to address factors such as vehicle restrictions; nuclear safety; package selection; contamination control; and, if needed, physical protection of the material during transit to ensure that materials are shipped safely and securely and in compliance with applicable NRC and DOT regulations.

Appendix H to this document identifies many of the regulatory requirements that should be reviewed in constructing an adequate transportation program.

Regulatory Guidance:

- RAMREG-002/NUREG-1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments," January 1999

- Regulatory Guide 7.7, "Administrative Guide for Verifying Compliance with Packaging Requirements for Shipping and Receiving of Radioactive Material"

- Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material"

2.7 References

American Conference of Governmental Industrial Hygienists 2095, "Industrial Ventilation: A Manual of Recommended Practice for Design," 2007.

American National Standards Institute (ANSI), "Personnel Dosimetry Performance—Criteria for Testing," ANSI N13.11-2001.

ANSI, "Radiation Detectors - Personnel Thermoluminescence Dosimetry Systems Performance," ANSI Ni 3.15-1985.

ANSI, "Bioassay Program for Uranium," ANSI N13.22-1995.

ANSI, "Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters," ANSI N13.27-1981.

ANSI, “Performance Criteria for Radiobioassay,” ANSI N13.30-1996.

ANSI/Health Physics Society (HPS), “Ionizing Radiation Safety Training for Workers,” ANSI/HPS N13.36, October 30, 2001.

ANSI, “Practices for Respiratory Protection,” ANSI Z88.2-1992.

American Society for Testing and Materials, “Radiological Protection Training for Nuclear Facility Workers,” ASTM EI 168-95, reapproved in 2008.

Code of Federal Regulations, Chapter I, Title 10 (10 CFR), “Energy,” 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 Non-compliance.”

10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”

10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.”

10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”

10 CFR Part 73, “Physical Protection of Plants and Materials.”

Code of Federal Regulations, Title 49 (49 CFR), “Transportation,” Parts 171–180 49 CFR Parts 390–397.

National Council on Radiation Protection and Measurements (NCRP), “Operational Radiation Safety Training,” Report No. 134, Bethesda, Maryland, 2000.

U.S. Nuclear Regulatory Commission (NRC), Branch Technical Position, “Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Materials,” April 1993 (Agencywide Documents Access and Management System Accession No. ML103620647).

NRC, “A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees,” NUREG-1140, January 1988.

NRC, “Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass,” NUREG-1556, Volume 17.

NRC, “General Statement of Policy and Procedure for NRC Enforcement Actions,” NUREG-1600, May 2000.

NRC, “U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments,” RAMREG-002/NUREG-1660, January 1999.

NRC, “Qualification and Training of Personnel for Nuclear Power Plants,” Regulatory Guide 1.8.

NRC, “General Site Suitability Criteria for Nuclear Power Stations,” Regulatory Guide 4.7.

NRC, “Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning,” Regulatory Guide 4.21.

NRC, “Administrative Guide for Verifying Compliance with Packaging Requirements for Shipments of Radioactive Material,” Regulatory Guide 7.7.

NRC, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” Regulatory Guide 7.10, Washington, DC.

NRC, “Administrative Practices in Radiation Surveys and Monitoring,” Regulatory Guide 8.2.
NRC, “Personnel Monitoring Device—Direct-Reading Pocket Dosimeters,” Regulatory Guide 8.4.

NRC, “Instructions for Recording and Reporting Occupational Radiation Exposure Data,” Regulatory Guide 8.7.

NRC, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” Regulatory Guide 8.9.

NRC, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,” Regulatory Guide 8.10.

NRC, “Instruction Concerning Prenatal Radiation Exposure,” Regulatory Guide 8.13.

NRC, “Acceptable Programs for Respiratory Protection,” Regulatory Guide 8.15.

NRC, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication,” Regulatory Guide 8.24.

NRC, “Air Sampling in the Workplace,” Regulatory Guide 8.25.

NRC, “Audible Alarm Dosimeters,” Regulatory Guide 8.28.

NRC, “Instruction Concerning Risks from Occupational Radiation Exposure,” Regulatory Guide 8.29.

NRC, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,” Regulatory Guide 8.34.

NRC, “Planned Special Exposure,” Regulatory Guide 8.35.

NRC Enforcement Manual, available online at https://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html#manual.

NRC, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” Information Notice 96-28, May 1, 1996.

3 NUCLEAR CRITICALITY SAFETY

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(4–8); 10 CFR 70.23(a)(2–4); 10 CFR 70.24, "Criticality accident requirements"; 10 CFR 70.50, "Reporting requirements"; 10 CFR 70.52, "Reports of accidental criticality."

Regulatory Criteria: The license application should address the following areas of information to expedite the review of the U.S. Nuclear Regulatory Commission (NRC):

- Evaluate the applicability of Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores."
- Ensure that the application describes the commitments to the criticality accident alarm system (CAAS) requirements in 10 CFR 70.24.
- Make commitments to ensure appropriate emergency planning and response.
- Provide information on the methods it will use to demonstrate that all nuclear processes will be subcritical under normal and credible abnormal conditions with an approved margin of subcriticality for safety.
- Put in place and maintain a nuclear criticality safety (NCS) program and include the commitments associated with the program.

Discussion: As specified in 10 CFR 70.22(2)(8), applicants must describe, in their license application, procedures to protect health and minimize danger to life or property, including procedures to avoid accidental criticality. These requirements are implemented by establishment of an NCS program as described in this chapter. This chapter discusses specific technical and industry terms. Appendix I to this document contains definitions of the terms.

3.1 Use of Industry Standards

Regulatory Guide 3.71 endorses American National Standards Institute (ANSI)/American Nuclear Society (ANS)-8 national standards, with some exceptions and qualifications. The NRC endorsement of these standards means that they provide methods and practices generally acceptable to the NRC staff for the prevention and mitigation of criticality accidents. However, application of a standard is not a substitute for detailed NCS analyses for specific operations.

If an applicant desires to undertake activities to which an NRC-endorsed standard applies, it should address the subjects covered by the standard and the applicable acceptance criteria relevant to the standard as described below.

The license application should contain a commitment to follow the requirements (i.e., "shall" statements) of the standard, subject to any NRC exceptions and qualifications. The application should clearly specify the version of the standard and the specific provisions to which the applicant is committing.

If there are requirements of a standard to which the applicant does not desire to commit, it should provide sufficient information for the staff to determine that the requirement is not

relevant to the applicant's activities, or that the license application contains other commitments that achieve an equivalent safety purpose.

The applicant may also choose to demonstrate compliance with regulatory requirements by committing to following the recommendations (i.e., "should" statements) of a standard, although committing to the recommendations is not required for compliance with a standard.

The applicant should clarify its intent in committing to requirements expressed only as general principles in the standards by making more specific commitments and describing how its license application implements those principles. An applicant should generally use the most current revision of the NRC-endorsed standards in the version of Regulatory Guide 3.71 in effect when it submits the license application. If the applicant commits to a standard or a version of a standard that the NRC has not endorsed, is not the most current endorsed version, or commits to unendorsed portions of an otherwise endorsed standard, the license application should justify the acceptability of these commitments. The use of other than ANS standards (e.g., International Organization for Standardization (ISO) 1709, "Principles of Criticality Safety in Storing, Handling and Processing"; ISO 7753, "Performance and Testing Requirements for Criticality Detection and Alarm Systems") may be acceptable if suitably justified.

The applicant should consult the most current version of Regulatory Guide 3.71 and consider whether newer versions of these standards or new standards should be endorsed and should make note of any exceptions of qualifications. The NRC staff believes that greater than critical mass license applicants should, at a minimum, commit to complying with the base programmatic elements of ANS 8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," and ANS 8.19, "Administrative Practices for Nuclear Criticality Safety," as indicated in Regulatory Guide 3.71. Other standards that should be considered for applicability include ANS-8.3, 8.5, 8.6, 8.7, 8.10, 8.12, 8.14, 8.15, 8.17, 8.19, 8.20, 8.21, 8.22, 8.23, 8.24, and 8.26.

3.2 Criticality Accident Alarm System

The applicant's commitments to 10 CFR 70.24 are acceptable if the applicant has met the following criteria, or if the application has identified and justified an alternative.

The applicant should describe a facility CAAS, or the use of portable instruments and administrative procedures that meet the requirements of 10 CFR 70.24.

The applicant may commit to the current NRC-endorsed version of ANSI/ANS-8.3, "Criticality Accident Alarm System," with exceptions, as noted in Regulatory Guide 3.71, or may propose an acceptable alternative (e.g., ISO 7753) with justification.

An applicant that commits to the specific requirements of ANSI/ANS-8.3 should provide additional details on the CAAS:

- The applicant should describe a CAAS appropriate to the facility for the type of radiation detected, intervening shielding, and magnitude of the minimum accident of concern.

- The applicant's description of its CAAS should include the type of radiation detector and alarm; the detection threshold and minimum accident of concern; the detector logic used to provide dual alarm coverage, minimize false alarms, and detect failure; and the

methods used to determine radius of coverage, placement of alarms, and actions for maintaining and calibrating the system.

- The applicant should commit to designing a CAAS to be resistant to damage from anticipated adverse events such as a fire, explosion, corrosive atmosphere, seismic shock equivalent to the site-specific design-basis earthquake or equivalent value specified by the Uniform Building Code, or other adverse conditions that do not result in the evacuation of the entire facility.

- The applicant should commit to rendering operations safe, by shutdown, evacuation, and quarantine, if necessary, in any area where CAAS coverage has been lost and not restored within a specified number of hours. The number of hours may be determined on a process-by-process basis, because shutting down certain processes, even to make them safe, may carry a larger risk than being without a CAAS for a short time. The applicant should commit to compensatory measures (e.g., limiting access to only personnel with alarming dosimetry compliant with 10 CFR 70.24(a)(1)), halting movement of special nuclear material (SNM) when the CAAS is not functional.

- The applicant should commit to providing emergency power for the CAAS or provides justification for the use of continuous monitoring with portable instruments.

Applicants for a greater than critical mass (GTCM) license often request an exemption from the requirement in 10 CFR 70.24 for a CAAS (e.g., areas where the credible upset, quantities, and forms of SNM make criticality incredible). Exemptions have been justified in the past by commitments to limit activities to storage only in a subcritical configuration or to segregate and control materials so that less than a critical mass would be present in any single isolated building or area. Justification may require acceptable controls to assure handling will only use subcritical mass/geometry or that the specific materials are of a form and geometry such that they are highly stable and subcritical in all credible configurations. If handling or use of materials does occur in areas without a fixed facility CAAS, it may require sufficient alarming portable instrumentation that would serve the same function as a CAAS (i.e., meeting 10 CFR 70.24(a)(1) or its intent) for those individuals in the potentially affected area. Any instrumentation would have to be discussed in sufficient detail that it is clear the instruments are suitable for that function. Any exemption request should use conservative assumptions in the evaluation and meet the requirements of 10 CFR 70.17, “Specific exemptions.”

3.3 Emergency Planning and Response

The applicant should ensure appropriate emergency planning and response by meeting the following criteria or justifying acceptable alternatives:

- The applicant commits to the requirements in ANSI/ANS-8.23, “Criticality Accident Emergency Planning and Response,” as endorsed by Regulatory Guide 3.71.

- The applicant has an emergency plan or satisfies the alternative requirements in 10 CFR 70.22(h)(1)(i).

- The applicant commits to personnel accident dosimeters, or other means of satisfying the requirements of 10 CFR 70.24(b)(1), in areas that require a CAAS.

- These dosimeters, or other radiation instruments, should be readily available to personnel responding to an emergency in accordance with 10 CFR 70.24(a)(3), and there should be a method for prompt onsite dosimeter readout.

The NRC staff review considers that the requirement for an emergency plan for criticality safety is similar to the need for a CAAS. If an exemption from a CAAS is justified, the staff may find that the criticality safety portion of the emergency plan is likewise satisfied with minimal additional detail.

3.4 Subcriticality and Double Contingency Principle

In accordance with the requirements in 10 CFR 70.22(a)(8), an applicant shall provide proposed procedures to protect health and minimize danger to life or property (e.g., procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures). An applicant's commitments to procedures that limit the risk of creating an accidental criticality should describe the method or methods that will be used to demonstrate that all nuclear processes will be subcritical under normal and credible abnormal conditions with an approved margin of subcriticality for safety by meeting the criteria described below or justifying acceptable alternatives.

The applicant should commit to one or more of the following methods for determining subcritical limits on controlled parameters under normal conditions or subcritical values under abnormal conditions:

- using the subcritical values in a currently endorsed standard (e.g., ANSI/ANS-8.1, 8.5, 8.7, 8.12, or 8.15)

- using the subcritical or critical values, with appropriate margin, from widely accepted industry handbooks (e.g., LA-10860-MS, "Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U"; Atlantic Richfield Hanford (ARH)-600, "Criticality Handbook," issued June 1968), experimental data, or peer-reviewed publications

- using industry-accepted hand calculation methods (e.g., areal density, solid angle technique), subject to the limitations of those methods

- using deterministic or probabilistic (e.g., discrete ordinates, Monte Carlo) computer codes to calculate k_{eff} and validating these calculational methods in accordance with the requirements of ANSI/ANS 8.24, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations"

For each method used to demonstrate subcriticality, the applicant should commit to using the method consistent with any limitations, with an appropriate margin of subcriticality and within its area of applicability. The license application should describe the margin of subcriticality and area of applicability.

The applicant should commit to determining safety limits based on one of the methods discussed above. The applicant should commit to evaluating controlled parameters at their safety limits, or more conservatively, and to evaluating parameters that are not controlled at their most reactive credible values.

The applicant should describe a program that ensures compliance with the double contingency principle, where practicable. This principle, as stated in ANSI/ANS-8.1 (and in 10 CFR 70.4, "Definitions"), is as follows:

> Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Note: For GTCM licensees covered by this guidance, the term "process" refers to a discrete system for which a criticality safety analysis is performed; the term "process conditions" means changes in the physical characteristics of such a system capable of resulting in a more reactive system configuration.

Each process that has credible normal or abnormal conditions leading to criticality should have sufficient engineered and administrative controls in place to ensure double contingency protection where applicable.

Additional guidance pertaining to compliance with the double contingency principle appears in appendix 5-A to NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications." Note that the requirements of Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," do not apply to applicants covered by this guidance. However, the expectation is to demonstrate subcriticality under normal and credible abnormal conditions with an approved margin of subcriticality for safety, a fundamental principle of NCS applicable to all 10 CFR Part 70 applicants, along with the double contingency principle, as discussed in ANSI/ANS-8.1. GTCM applicants subject to this guidance should comply with those portions of appendix 5-A pertaining to the subcriticality requirement (also stated in 10 CFR 70.61(d)) and the double contingency principle.

3.5 Organization and Administration of the Nuclear Criticality Safety Program

The applicant's management of the NCS program should meet the following criteria or identify and justify an alternative approach:

- Describing and committing to carrying out and maintaining an NCS program to meet the regulatory requirements in 10 CFR Part 70 and to ensuring adequate protection against the occurrence of accidental criticality. The primary means of doing this should be prevention (i.e., ensuring that processes will be subcritical under normal and credible abnormal conditions).

- Describing NCS program objectives. The applicant's NCS programs may be graded commensurate with the complexity and scope of planned activities but should address all of the program elements listed below in some fashion. For example, applicants that are designated storage only may not need handling procedures, postings, or frequent operational audits. The description should not merely list the program objectives but should describe how the applicant will meet those objectives.

- Performing and documenting criticality safety evaluations (CSEs) for new or changed processes, establishing safety limits and controls as necessary to ensure that processes will remain subcritical under normal and credible abnormal conditions.

- Establishing, as practicable, double contingency protection and defense-in-depth measures and ensuring sufficient margins of safety and subcriticality to provide additional assurance that the likelihood of criticality will be acceptably low.

- Establishing and maintaining a CAAS system and emergency response procedures to protect health and safety in the event criticality occurs.

- Providing technical support to emergency response personnel in responding to and recovering from abnormal conditions and emergencies, up to and including a criticality accident.

- Periodically verifying the adequacy of criticality controls, including observation of operations and verification of equipment configuration.

- Ensuring the adequacy of CSEs through peer reviews, self-assessments, and validation and verification of calculational methods.

- Training and otherwise supporting operations in procedures to ensure the safe handling of SNM.

- Supporting regulatory compliance regarding event reporting (10 CFR 70.50 and applicable portions of 10 CFR Part 70, Appendix A).

The applicant should outline an NCS program structure that is consistent, to the extent practical, with current industry practices (e.g., ANSI/ANS-8.1 and ANSI/ANS-8.19), including establishing the roles and responsibilities of key program personnel (e.g., NCS manager, NCS senior engineers, NCS engineers). The program structure should include the following:

- The applicant should describe the training and qualification of key NCS program personnel.

- The applicant should commit to establishing and maintaining NCS safety limits and operating limits and agree to maintain management measures to ensure their continued reliability and availability.

- The applicant should commit to supporting operations personnel through development of training, preparation of NCS postings, and other appropriate operator aids for key administrative controls and review procedures and operations to ensure instructions and limits or controls are unambiguous, easily understood, and readily achievable.

- The applicant should commit to developing postings and other markings, as well as criticality alarm signals that are distinctive.

- The applicant should evaluate modifications to the facility or safety program to ascertain their effect on criticality safety.

- The applicant should describe an organizational structure in which the NCS organization is independent of operations, to the extent practical.

- Personnel should work in accordance with written, approved procedures when the activity could affect NCS.

- The applicant should establish management policies that reinforce operators' stop-work authority and encourage reporting defective conditions.

Applicants should establish and describe an adequate organization and staffing, in accordance with the requirements in 10 CFR 70.22(a)(6) and 10 CFR 70.23(a)(2), with sufficient staff, resources, and clear responsibilities to allow independent technical reviews of CSEs, periodic assessments of those operations and controls important to criticality safety, and the issuance of stop-work directives separate from operations should an unsafe condition be encountered. In evaluating applicant programs, the NRC staff generally requires that, at a minimum, two individuals who are knowledgeable and qualified in NCS be on an applicant's staff with commensurate responsibilities.

3.6 Nuclear Criticality Safety Program Management Measures

As required by 10 CFR 70.22(a)(6), an applicant must provide information on the technical qualifications, including training and experience of the applicant and members of the staff, to engage in the proposed activities. As such, the application should describe the following management measures associated with the NCS program:

- the requirements of ANSI/ANS-8.19 and ANSI/ANS-8.20, "Nuclear Criticality Safety Training," as they pertain to training, procedures, audits, and assessments

- regarding training—

  – a commitment to training personnel in the areas discussed in section 7 of ANSI/ANS-8.20

  – a commitment to training personnel regarding procedural compliance, stop-work authority, response to alarms, and reporting of defective conditions

- regarding periodic assessments, a commitment to conducting and documenting walkthroughs (i.e., the observation of operations to verify compliance with criticality limits and implementation of criticality controls) for all areas where SNM is used, stored, or handled, such that all areas will be reviewed at some specified frequency

- a graded approach used to justify the schedule for doing walkthroughs, conducting audits, or taking corrective action

3.7 Technical Practices for Nuclear Criticality Safety

The application should describe the following technical practices used to determine and implement NCS safety limits:

- conducting CSEs using industry-accepted and peer-reviewed methods (e.g., in ANSI/ANS-8.1, 8.19, 8.24)

- validating calculational methods used to develop NCS safety limits, in accordance with ANSI/ANS-8.24

- using the code within its validated area(s) of applicability, or, if there are insufficient benchmark experiments over the needed range of variables, ensuring that the area of applicability is extended by making use of trends in the bias, taking the uncertainty due to extrapolation appropriately into account

- demonstrating an adequate margin of subcriticality for safety, by ensuring that the margin is large compared to the uncertainty in the calculated value of k_{eff}

The minimum margin of subcriticality is an allowance for unknown or unquantified uncertainties that have not been accounted for in the validation and is a measure of the degree of confidence that systems calculated to be subcritical are actually subcritical. The minimum margin of subcriticality may be used to define a maximum allowable value of k_{eff} that is considered subcritical, referred to as the upper subcritical limit, as follows:

$$\Delta k_{calc} \leq 1 - \beta - \Delta\beta - \Delta k_{AOA} - \Delta k_m$$

where β = the calculational bias, $\Delta\beta$ = uncertainty in the bias, Δk_{AOA} = margin due to extending the area of applicability beyond the experimental data, and Δk_m = minimum margin of subcriticality.

The applicant's overall margin of subcriticality, which includes the minimum margin of subcriticality and other factors that provide conservatism in the calculation of k_{eff}, should be sufficient to provide reasonable assurance that processes evaluated to be subcritical are actually subcritical. NUREG-1520, appendix 5-B, includes additional guidance on the margin of subcriticality.

3.8 Calculational Method Validation

The applicant should include a summary description of a documented, reviewed, and approved (by the applicant's NCS function and management) validation report for each method that will be used to conduct an NCS analysis. For methods such as experimental data, handbooks, industry standards, and hand calculations, the validation may consist of a demonstration of the method's applicability to the applicant's processes, including specification of any limitations or assumptions needed to ensure their validity. For methods that rely on the explicit calculation of k_{eff}, the validation should evaluate critical benchmark experiments similar in geometry, material composition, and neutron energy spectrum to the systems to be evaluated.

For computer calculation methods, the applicant's criticality code validation should provide reasonable assurance that processes evaluated to be subcritical are actually subcritical. This should include the applicant's selection of benchmark experiments, statistical methodology, and results (determination of the area(s) of applicability and upper subcritical limit(s)). The applicant's validation may be graded commensurate with the amount of subcritical margin, given the forms and quantities of material present. Where normal or abnormal conditions are deeply subcritical, a correspondingly less rigorous validation may be employed. (Additional guidance appears in appendix 5-B to NUREG-1520.) Where there is little benchmark data available to validate an applicant's calculations, additional margin may be employed. However, even with a large margin to criticality, comparison against experimental data is essential. If no experimental

data covering its processes are available, the applicant must use one of the methods other than computer calculation listed in section 3.4.

The applicant's summary description of its validation in the license application should include the following:

- a description of the methodology, including the method used to select benchmark experiments, determining the bias and bias uncertainty, and calculating an upper subcritical limit (including extending the area(s) of applicability, if needed)

- a general description of the physical systems and area(s) of applicability covered by the validation

- a brief description of the benchmark experiment sets used

- the minimum margin of subcriticality and its technical justification

- the calculational system (hardware and software, including nuclear data sets) used

- any limitations on the use of the method

The applicant's commitments to performing validation should include the following:

- a commitment to perform validation consistent with ANSI/ANS-8.24, with any exceptions and qualifications, as stated in Regulatory Guide 3.71, or other widely accepted industry practices, with justification

- a verification process, including verification upon installation and at specified periods; a commitment to evaluate methods for the need for reverification upon changes to the calculational system

- a commitment to assess and document the applicability of the validation to each new calculation

Additional information regarding validation may be found in the current version of NUREG-1520.

3.9 Criticality Safety Evaluations

The application should discuss the commitments regarding doing CSEs:

- The application should describe the written procedures to perform CSEs that incorporate the following principles:

  - The application will establish NCS safety limits based on analyses assuming optimum or the most reactive credible values of parameters (e.g., most reactive conditions physically possible, bounding values limited by regulatory requirements) unless specified controls limit parameters to a particular range of values. If less than the optimum values are used, and corresponding controls are not identified, the CSE will justify the basis.

- The applicant may establish NCS operating limits to ensure that safety limits are unlikely to be exceeded. The application should consider process variability and uncertainty in determining operating limits. Additional conservatism may be applied.

- The application will describe specific controls and management measures necessary to enforce NCS safety limits and will specify operating limits.

- The applicant should commit to providing the technical basis demonstrating subcriticality under normal and credible abnormal conditions and compliance with the double contingency principle in the CSEs.

3.10 Evaluation and Implementation of Controlled Parameters

Parameters available for NCS control are mass, geometry, density, enrichment (or isotopics), reflection, moderation, concentration, interaction (or spacing), neutron absorption (or poison), volume, heterogeneity, physicochemical form, and process variables. The number and names of specific parameters will vary from one applicant to another.

The applicant's commitments to technical practices associated with evaluating and carrying out controlled parameters should either meet the following acceptance criteria or identify and justify acceptable alternatives:

- The applicant should state that the use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet the double contingency principle.

- The applicant should commit to the following preferred hierarchy of controls:

  - the preferred use of passive engineered controls; in particular, passive engineered geometry control

  - the following order of preference for NCS control: (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) simple administrative controls

  - a preference for designating explicit NCS controls over reliance on the natural and credible course of events

  The applicant should commit to a preference for control of two or more parameters over multiple controls on a single parameter. If relying on two or more controls on a single parameter, the applicant commits to a preference for diverse over redundant means of control. These commitments do not mean an applicant will follow the preferred hierarchy of controls in every case. However, an applicant's sets of controls should follow this preference in the majority of cases. In general, for example, where passive controls are readily available, they should be used rather than administrative controls. An applicant should demonstrate how it is meeting these commitments, such as by providing justification when deviating from these criteria.

- The use of each controlled parameter should meet the following general criteria, in addition to the specific criteria for the following individual parameters listed below:

- When a single-parameter limit is used (e.g., minimum critical mass, favorable geometry limit, always-safe concentration), all other parameters are evaluated at their optimum or most reactive credible values. In determining single-parameter limits, it is permissible to specify a particular physicochemical form and isotopic composition.

- Examples are (1) minimum critical mass, based on spherical geometry, optimum moderation, and full water reflection and (2) favorable geometry, based on having equipment filled with optimally moderated material and full water reflection. This is for a specific form of material (e.g., low-enriched uranium dioxide fuel).

- When measurement of a parameter is needed, instrumentation is calibrated.

- When criticality control is based on measuring a single parameter, independent means of measurement (e.g., redundant in-line monitoring, dual independent sampling) are used.

- Safety limits on controlled parameters are established, taking any tolerances and uncertainty into account.

- Controlled dimensions and material properties are verified upon installation, following system changes, and at periodic intervals.

- Criteria for the use of a **controlled parameter** should include the following (additional guidance may be found in the current version of NUREG-1520. If the applicant is not using a particular parameter, it should state it in the application; in such cases, the following commitments are not needed):

  - Criteria for the use of **mass control** should include:

    - Compliance with mass limits is verified by either assuming the entire weight of material is SNM or by measurement to verify the actual weight percent of SNM.

    - Over batching beyond double batching is considered unless it requires multiple independent failures or is precluded by, for example, equipment capacity or quantity of material available.

  - Criteria for the use of **geometry control** should include the following:

    - All credible means of losing geometry control (e.g., corrosion, leakage, bulging, transfer to unfavorable geometry, changes to a more reactive material form) are evaluated for their impact on reactivity.

    - Neutron interaction with other SNM is considered as part of the demonstration of subcriticality unless meeting criteria for being neutronically isolated.

  - Criteria for the use of **density control** should include the following:

    - Controls are established to limit materials to less than theoretical density, and density is confirmed by experimentation or measurement.

- Criteria for the use of **enrichment or isotopics control** (including abundance of individual fissionable isotopes as well as ratios of fissionable elements (e.g., uranium (U)-235 weight percent, plutonium (Pu)-239 weight percent, ratio of Pu/U) should include the following:

  - The facility-wide limit on enrichment or isotopics should be used in calculations, or reliable methods of labeling and segregating such materials should be used.

- Criteria for the use of **reflection control** should include the following:

  - Modeled reflection conditions account for wall thickness, structural materials, and any transient or permanent adjacent reflecting materials. Criteria are established for determining when such materials may be neglected.

  - When reflection is not controlled, reflection equivalent to 30 centimeters (12 inches) of tight-fitting water, or 60 centimeters (24 inches) of tight-fitting concrete are assumed.

  - When reflection is controlled, a minimum equivalent to 2.54 centimeters (1 inch) tight-fitting water reflector is assumed to account for transient incidental reflectors.

  - In the presence of special moderators and reflectors (e.g., deuterium, beryllium, graphite, or high-density hydrocarbons), the adequacy of modeled reflections is justified.

  - When reflection is controlled, the means of limiting personnel intrusion around the individual units is established, preferably by means of rigid barriers.

  - In evaluating arrays of units, the above reflection conditions are applied to the exterior of the array, while interstitial moderation is evaluated as below.

- Criteria for the use of **moderation control** should include the following:

  - A commitment is made to follow ANSI/ANS-8.22, “Nuclear Criticality Safety Based on Limiting and Controlling Moderators,” with any exceptions and qualifications as described in Regulatory Guide 3.71.

  - The preference is for physical barriers to preclude moderator intrusion into SNM (e.g., double roof, double-sleeved piping, exclusion of sprinklers, raised or sloped floors).

  - Moderator controlled areas are conspicuously marked and controls established to preclude the introduction of moderating materials.

  - Firefighting procedures in moderation-controlled areas are evaluated for their impact on reactivity. Any restrictions are included in procedures and training.

- Criteria for the use of **concentration control** should include the following:

  - Controls are established to preclude the inadvertent introduction of precipitating agents (e.g., locking tanks). Credible means of concentrating or precipitating SNM are evaluated.

  - Transfers from favorable to unfavorable geometry are precluded consistent with the double contingency principle; this includes use of dual independent sampling or in-line monitoring, or both.

  - Homogeneity of solutions is justified, with controls established as needed.

- Criteria for the use of **interaction control** should include the following:

  - The preference is for the use of physical barriers (e.g., fixed spacers, cages). If such engineered controls are not feasible, administrative controls with visual aids, such as painted lines and postings, may be used. In all such cases, multiple spacing upsets are required before criticality is possible.

  - The structural integrity of, for example, spacers and storage racks, is sufficient to withstand credible abnormal conditions, including seismic events.

  - Moveable engineered barriers and containers (e.g., birdcage drums, 55-gallon drums) are inspected periodically for deformation.

- Criteria for the use of **neutron absorber control** should include the following:

  - The preference is for the use of fixed absorbers meeting ANSI/ANS-8.21, regardless of whether they are existing structural materials or added specifically for criticality control, with any exceptions and qualifications as described in Regulatory Guide 3.71.

  - When using borosilicate glass Raschig rings, the applicant meets ANSI/ANS-8.5, “Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material,” with any exceptions and qualifications as described in Regulatory Guide 3.71.

  - When using soluble neutron absorbers, the applicant meets ANSI/ANS-8.14, “Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors,” with any exceptions and qualifications as described in Regulatory Guide 3.71.

  - The effective of neutron spectra on absorber effectiveness is considered.

- Criteria for the use of **volume control** should include the following:

  - The preference is for the use of fixed geometry to limit accumulations of SNM to less than a subcritical volume. Irrespective of the shape of such containers, volume control should be based on the most reactive geometry (normally a sphere).

- Criteria for the use of **heterogeneity control** (normally only significant for low-enriched uranium) should include the following:

  - Methods of causing fissile material to become inhomogeneous are evaluated and controls established as needed. If calculations for heterogeneous materials are performed, they should be validated using heterogeneous benchmarks.

  - Assumptions that can affect the physical scale of heterogeneity are justified, and process variables that can affect the scale are controlled.

- Criteria for the use of **physicochemical form control** should include the following:

  - The most reactive credible material form is used in calculations, or controls are established to limit the material to a less reactive form.

  - Abnormal conditions evaluated include both in-situ changes and migration from one area to another.

- Criteria for the use of **process variable control** (e.g., temperature, pressure, acid molarity, electrical load, conductivity, radiation) should include the following:

  - Controls are established to limit process variables within their allowed ranges, and the correlation of the variable to its associated indirectly controlled parameter is established by experiment or measurement.

3.11 Additional Nuclear Criticality Safety Program Commitments

The applicant's description of additional commitments in its NCS program should include the following:

- The applicant should commit to periodically assessing the adequacy of engineered and administrative criticality controls, to promptly detecting any NCS deficiencies, and to taking prompt and effective corrective action to prevent recurrence.

- The applicant should commit to suspending operations or otherwise rendering processes safe upon loss of double contingency protection, until such protection can be restored, and to assessing the adequacy of the affected controls.

- The applicant should commit to retaining records of NCS deficiencies and documenting any corrective actions taken.

- The applicant should commit to identifying all equipment and procedures needed for criticality controls to serve their safety function (i.e., ensure their effectiveness to maintain controlled parameters within subcritical limits) and to maintaining such equipment and procedures as part of its facility management measures, including audits and inspections.

- The applicant should commit to evaluating facility changes for their impact on NCS before implementing them and describe its change review and approval process.

- The applicant should include the criteria applicable to the description of its measures to carry out the event reporting requirements in 10 CFR 70.50 and 10 CFR 70.52.

3.12 Emergency Plan

Prevention is the primary means of protection against the consequences of accidental criticality, but there is still a risk that it will occur. For facilities that require a CAAS in accordance with 10 CFR 70.24, an applicant must either submit an emergency plan or an evaluation demonstrating that an emergency plan is not required, in accordance with the provisions in 10 CFR 70.22(i)(1)(i) and (ii).

A facility CAAS is required if the applicant is authorized to possess a quantity exceeding the mass-based criteria in 10 CFR 70.24(a). If the applicant is required to have a CAAS and submits a request for exemption from the CAAS requirements of 10 CFR 70.24, the exemption should be justified. As stated in ANSI/ANS-8.3, "installation of an alarm system implies a nontrivial risk of criticality." Whenever it is determined that criticality in a given area is credible, and that it has the potential to adversely affect workers or the public, a criticality alarm should be required, unless an exemption is granted pursuant to 10 CFR 70.17, "Specific exemptions." False alarms and evacuations could pose a risk of injury to workers, and maintenance may expose workers who would not otherwise be exposed to occupational or potential criticality doses, so consideration may be given to whether installation of a CAAS results in a net risk benefit.

If a facility CAAS is required, an applicant must establish emergency procedures in response to activation of the alarm, in accordance with 10 CFR 70.24(a). In addition, an applicant must submit either an emergency plan or an evaluation demonstrating that an emergency plan is not required, in accordance with 10 CFR 70.22(i)(1)(i) and (ii). Criteria pertaining to an applicant's emergency procedures and emergency plan, if required, should follow current standards, such as ANSI/ANS-8.3 and 8.23.

3.13 References

American Nuclear Society (ANS) 8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

ANS 8.19, "Administrative Practices for Nuclear Criticality Safety."

American National Standards Institute (ANSI)/ANS-8.3, "Criticality Accident Alarm System."

ANSI/ANS-8.5, "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."

ANSI/ANS-8.14, "Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors."

ANSI/ANS-8.20, "Nuclear Criticality Safety Training."

ANSI/ANS-8.22, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators."

ANSI/ANS-8.23, "Criticality Accident Emergency Planning and Response."

ANSI/ANS 8.24, “Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations.”

Atlantic Richfield Hanford (ARH)-600, “Criticality Handbook,” June 1968.

Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

International Organization for Standardization (ISO) 1709, “Principles of Criticality Safety in Storing, Handling and Processing”; ISO 7753, “Performance and Testing Requirements for Criticality Detection and Alarm Systems.”

Paxton, H.C., and N.L. Pruvost, “Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U,” LA-10860-MS, Los Alamos National Laboratory, 1987.

U.S. Nuclear Regulatory Commission (NRC), “Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores,” Regulatory Guide 3.71.

NRC, “Standard Review Plan for Fuel Cycle Facilities License Applications,” NUREG-1520.

4 CHEMICAL SAFETY

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(6)–(8), 10 CFR 70.23(a)(2)–(4).

Regulatory Criteria: The regulations in 10 CFR 70.22(a)(7) require each application for a license to contain proposed procedures to protect health and minimize danger to life or property (e.g., procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures). Licensees must give reasonable assurance that their facility provides adequate protection against chemical hazards that could affect licensed materials and thus present an increased radiological or chemical risk. Licensees must describe equipment, facilities, and procedures in sufficient detail to reasonably assure the U.S. Nuclear Regulatory Commission (NRC) that it will provide adequate fire safety. To allow the NRC staff to make determinations that the requirements of 10 CFR 70.23(a)(2) through (4), as they relate to chemical safety, are met, the applicant must submit the following, in adequate detail:

- Describe the proposed activities as required by 10 CFR 70.22(a)(2), including the identification of any potential chemical hazards associated with the proposed activities that are within the NRC's regulatory authority.

- Describe the technical qualifications of the applicant and staff as required by 10 CFR 70.22(a)(6). If the proposed operations involve chemical hazards within the NRC's regulatory authority, this description must address the licensee's ability to identify and manage such hazards.

- Describe the equipment and facilities that the applicant or licensee will use to protect health and minimize danger to life or property, as required by 10 CFR 70.22(a)(7). If the proposed operations involve chemical hazards within the NRC's regulatory authority, this description must address the licensee's equipment and facilities that would be used to control such hazards.

- Describe the proposed procedures that would be used to protect health and minimize danger to life or property as required by 10 CFR 70.22(a)(8). If the proposed operations involve chemical hazards within the NRC's regulatory authority, this description must address the licensee's proposed procedures for managing such hazards.

Discussion: Consistent with its statutory authority under the Atomic Energy Act of 1954, as amended (Act), and other legislation, the NRC is responsible for licensing and regulating the nation's civilian use of byproduct, source, and special nuclear material (SNM) to assure the adequate protection of public health and safety, promote the common defense and security, and protect the environment.

This broad statutory authority authorizes the NRC to protect workers and the general public from radiation hazards produced by radioactive materials, chemical hazards produced by radioactive materials, and facility conditions that affect the safety of radioactive materials and thus present an increased radiation risk to workers and the general public. The NRC has a memorandum of understanding with the U.S. Occupational Safety and Health Administration that delineates each agency's regulatory responsibility over chemical hazards (Agencywide Documents Access and Management System (ADAMS) Accession No. ML11354A432).

In accordance with the requirements in 10 CFR 70.4, Definitions," "hazardous chemicals produced from licensed materials" means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials. The NRC staff evaluates chemical safety issues for greater than critical mass facilities pursuant to the requirements in 10 CFR 70.22(a)(8). Applicants (or licensees) for a license to possess and use SNM in critical mass quantities should provide information that allows the NRC staff to determine if the proposed activities involve chemical hazards that are directly associated with NRC-licensed radioactive material. Generally, applicants for a license to possess and use critical mass quantities of SNM do not store or possess large quantities of hazardous chemicals. If large quantities are on site, the applicant needs to demonstrate that there are no chemical hazards associated with the proposed operations or include an analysis that demonstrates that no chemical hazards under the NRC's regulatory authority pose a threat to the safe handling of licensed material. If the applicant possesses hazardous chemicals or intends to handle or mix licensed material with a chemical solution, the application must demonstrate that the chemical safety program is adequately defined and ensures that chemical hazards that are within the NRC's regulatory charter will not threaten the licensee's ability to safely handle the licensed material.

In accordance with the requirements in 10 CFR 70.22(a)(7) and (8), and 10 CFR 70.23(a)(3) and (4), the application must describe the elements of the safety program intended to protect the health and safety of the workers and the public from any chemical hazards. For this reason, the application must include chemical safety-related information including, if appropriate, a description of the chemical safety program. Specific information to be supplied includes the following:

- The description of the proposed activities must include information on any chemicals that would be directly associated with the proposed activities, would be near the proposed activities, or might be produced by the proposed activities. Any restrictions on the chemicals in or near the proposed activities that are used to limit chemical safety hazards must be identified.

- If the proposed activities include hazardous chemicals or the potential to generate hazardous chemicals, the application should present an analysis that demonstrates that accidents involving or producing hazardous or toxic chemicals would not jeopardize the licensee's ability to safely manage the licensed material.

- If there is no analysis or commitments to demonstrate that hazardous or toxic chemicals will not affect the licensee's management of the licensed material, then the description of the technical qualification of the applicant and members of the staff must include the qualifications of personnel who would be responsible for the analysis of chemical hazards of proposed activities, would review and approve such chemical hazards analysis, and would conduct the proposed activities.

- If there is no analysis or commitments to demonstrate that hazardous or toxic chemicals will not affect the licensee's management of the licensed material, the description of the equipment and facilities that will be used to protect health and minimize danger to life or property must include the equipment and facility features that would be used to manage chemical hazards or mitigate the consequences of chemical hazards associated with the proposed activities.

- If no analysis or commitments demonstrate that hazardous or toxic chemicals will not affect the licensee's management of the licensed material, the description should include any procedures used to identify and analyze chemical hazards that are within the NRC's regulatory authority, as well as any procedures used to manage these hazards. The description of proposed procedures should include the following:

  - Describe the method (or methods) used to evaluate chemical hazards associated with the proposed activities and within the NRC's regulatory jurisdiction. The specific method must be appropriate for the nature of the chemical hazard (i.e., chemical toxicity, chemical reactivity). If the proposed activities are defined, the results of the chemical hazards evaluation must be provided.

  - Describe the procedures used for an independent review and acceptance of chemical hazard evaluations.

  - Describe the procedures used to control any chemical hazards associated with the proposed activities identified in the chemical hazards' analysis.

The license application should identify any technical, industry, or professional standards used in the hazards analyses. Appropriate standards include "Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards, Updated Version," by the National Research Council; "Laboratory Safety Guidance" by the Occupational Safety and Health Administration; and "Safety in Academic Chemistry Laboratories" by the American Chemical Society. These standards do not address all aspects of a chemical safety program, particularly if the proposed operations involve the potential for energetic reactions that could release and disperse licensed material. When selecting and using standards, consideration should be given to the findings and recommendations in reports such as the U.S. Chemical Safety and Hazard Investigation Board Case Study, "Texas Tech University Laboratory Explosion," issued 2011.

4.1 References

Occupational Safety and Health Administration, "Laboratory Safety Guidance," (OSHA) 3404-11R, U.S. Department of Labor, Washington, DC, 2011.

Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the Occupational Safety and Health Administration, September 6, 2013 (ML11354A432).

National Research Council of the National Academies, "Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards, Updated Version," The National Academies Press, 2011.

American Chemical Society, "Safety in Academic Chemistry Laboratories," Volume 1, "Accident Prevention for College and University Students," 7th Edition, American Chemical Society Joint Board-Council Committee on Chemical Safety, 2003.

U.S. Chemical Safety and Hazard Investigation Board, "Texas Tech University Laboratory Explosion," Case Study by the U.S. Chemical Safety and Hazard Investigation Board, No 2010-05-I-TX, 2011.

5 FIRE SAFETY

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(6)–(8) and 10 CFR 70.23(a)(3)–(4).

Regulatory Criteria: Applicants must provide reasonable assurance that they will protect health and minimize danger to life or property, which includes providing adequate protection against fires and explosions that could affect licensed materials and thus present an increased radiological or chemical risk. In accordance with the requirements of 10 CFR 70.22(a)(7)–(8), the application must describe equipment, facilities, and procedures in sufficient detail to reasonably assure the U.S. Nuclear Regulatory Commission (NRC) that it will provide adequate protection of health and minimize danger to life or property, which includes fire safety.

Discussion: The application should address all major aspects of a fire safety program, including facility design, fire protection systems, employee training, emergency response, process fire safety, combustible loading, and potential fire scenarios.

5.1 Facility Design

In accordance with the requirements of 10 CFR 70.22(a)(7), an adequate application describes equipment and facilities that the applicant will use to protect health and minimize danger to life or property. Although 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," does not require a separate fire safety program, an application should document commitments pertaining to the fire safety of the equipment and facilities that the applicant will use to protect health and minimize danger to life or property, including a description of building construction, fire area determination, fire-rated walls or opening protection, electrical installation, lightning protection, emergency lighting, life safety and egress, ventilation, and fire water drainage—all facility design characteristics that affect fire safety.

Compliance with applicable National Fire Protection Association (NFPA) standards[1] or the building code may be sufficient to address these areas in the application. The NRC staff recognizes NFPA 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials," as one standard that specifies acceptable facility fire safety design criteria; however, the application may document other nationally recognized codes and standards, if appropriate (e.g., NFPA 45, "Standard on Fire Protection for Laboratories Using Chemicals"). The application should list any relevant code(s) and describe the facility's degree of compliance with that code.

The application should document information on the facility's construction materials and any building codes used during its construction. The NRC staff recognizes NFPA 220, "Standard on Types of Building Construction," as another standard that specifies acceptable facility construction material design criteria. Some building materials (e.g., reinforced concrete and protected steel) are inherently more resistant to fires, while other construction materials (e.g., wood frame) are not as fire resistant. Within the structure, fire barriers may be constructed to divide the building into separate fire areas. Fire barriers are made of fire-resistant materials and are designed to contain a fire to one area until it can be extinguished. Fire barriers are

[1] This guidance document includes references to the NFPA codes because these are standards the NRC staff uses in its licensing review. These various NFPA codes are also referenced throughout chapter 7 of NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications." For example, section 7.4.2 of NUREG-1520 specifically references NFPA 801 as an NRC-accepted standard.

typically walls, although some floor or ceiling assemblies have a fire resistance rating and may be credited as fire barriers.

In a fire barrier, all components of the assembly (i.e., wall, doors, windows, dampers) have a certified fire rating. For openings within the assembly, the rating is meant to indicate the amount of time that the opening protection can resist the fire from penetrating the assembly. All penetrations (e.g., piping, cables, air ducts) should be sealed with a fire-resistant seal or damper. The application should include a description and fire rating of any opening protection, penetration seals, or fire dampers.

The application should describe the facility's electrical system. Nearly all electrical installations in the United States are required by local jurisdictions to comply with NFPA 70, "National Electrical Code." It should confirm this compliance and briefly describe any high voltage equipment in areas where licensed material is present. Furthermore, the application should describe any lightning protection installed at the facility.

Occupant egress (i.e., travel pathway to safety) is an important aspect of life safety that the application should discuss. The NRC staff recognizes NFPA 101, "Life Safety Code," as a standard that specifies acceptable occupant egress design criteria. Maintaining adequate clearances and design of exit access pathways and corridors is a key component of a timely exit strategy. The facility should also provide sufficient emergency lighting and exit signage so that, in the event of a power failure, occupants can still reach a safe area or exit the building.

In accordance with the requirements of 10 CFR 70.22(a)(7), an adequate application describes equipment and facilities that will be used to protect health and minimize danger to life or property, including nuclear safety and environmental issues related to the facility's fire protection design. For example, if a sprinkler system is being used where licensed material is present, the quantity and enrichment level of special nuclear material may dictate the need to address a potential criticality accident. Additionally, if dispersible licensed material is present, water used for firefighting may become contaminated and should be monitored and treated before being released into the sewer system. The same principle applies to ventilation systems, especially when attached to fume hoods or glove boxes where dispersible licensed material is handled. These concerns may not be applicable to all facilities, depending on the type of equipment and nuclear material present.

5.2 Fire Protection

In accordance with the requirements of 10 CFR 70.22(a)(6)–(8), an adequate application describes the technical qualifications, including training and experience, and the equipment, facilities, and proposed procedures that protect health and minimize danger to life or property. Therefore, the application should document the fire protection systems, employee training, and emergency response organizations available for the facilities it includes.

5.2.1 Fire Protection Systems

In accordance with the requirements of 10 CFR 70.22(a)(7), an adequate application describes equipment and facilities used to protect health and minimize danger to life or property, including the fire protection systems that provide adequate protection against fires and explosions in the areas in which licensed material is present. For these areas, the application should describe any fire suppression, detection, or alarm systems, as well as all inspecting, testing, and

maintenance conducted on these systems. Compliance with applicable NFPA standards or the building code may be sufficient to address many of these areas in the application.

A fire suppression system is typically composed of water- or chemical-based agents that are used to put out a fire or contain it until emergency response personnel can arrive. Sprinklers are the most commonly used form of fire suppression. Sprinkler systems are typically designed and installed in accordance with NFPA 13, “Standard for the Installation of Sprinkler Systems” and inspected, tested, and maintained in accordance with NFPA 25, “Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems.” Documenting NFPA code compliance is an acceptable way to describe the design, installation, inspection, testing, and maintenance of sprinkler systems.

It is possible that other forms of fire suppression (i.e., foam or gaseous systems) may be used. In this case, the application should document compliance with any relevant NFPA codes or provide details about the installation of the suppression system. The applicant should provide hand-held fire extinguishers, as required, and train employees who may handle licensed material in how to operate them. The application should indicate the type and placement of these extinguishers, along with all relevant testing, inspections, and training.

Fire detection and alarm systems typically work together to sense a fire in its incipient stages and notify occupants and the fire department. These systems are typically installed, maintained, and tested in accordance with NFPA 72, “National Fire Alarm and Signaling Code.” Some detection systems may be incorporated directly into the ventilation system for when rapid detection is especially important, given the nature of the materials being used. The application should describe the detector and alarm spacing, the type, and the testing and maintenance schedule.

In accordance with the requirements of 10 CFR 70.22(a)(8), an adequate application describes the proposed procedures to protect health and minimize danger to life or property, which includes the inspection, testing, and maintenance of fire protection systems. The NRC assesses the adequacy of an applicant’s fire protection program based on the fire protection features that are available and reliable when called upon. Features that are not properly inspected and maintained can impact the safety of the facility. All fire protection systems should be maintained in accordance with the applicable NFPA or building code, and the application should explain any deviations from the prescribed maintenance plan.

5.2.2 Employee Training

In accordance with the requirements of 10 CFR 70.22(a)(6), an adequate application describes the technical qualifications, including training and experience of the applicant and members of its staff to engage in the proposed activities, including fire safety training for employees that work in areas where licensed material is present. For these areas, the application should describe any emergency training provided to the occupants of the facility. Compliance with applicable NFPA standards may be sufficient to address this area. The application should describe and document examples of employee training such as evacuation exercises (i.e., fire drills), the safe shutdown process, and the use of fire extinguishers, listing all relevant codes and describing the facility’s degree of compliance.

5.2.3 Emergency Response

In accordance with the requirements of 10 CFR 70.22(a)(8), an adequate application describes the proposed procedures to protect health and minimize danger to life or property, which includes the emergency response capabilities for the facility. An adequate application describes the emergency response for areas in which licensed material is present.

The application should describe the emergency organization(s) that would respond to the facility in the event of a fire. This may be a dedicated onsite brigade or the local fire department. If an offsite fire department would respond to a fire, periodic training may be necessary to familiarize the emergency responders with facility access procedures, layout, and pre-fire plans. The application should describe the training and experience that the responders have in handling fires relating to nuclear material. The application should also describe the water supply available for firefighting operations. The application should list any relevant code(s) in describing the response organization's qualifications and capabilities. The applicant and the responding fire department(s) should have a written plan or agreement to define the emergency response.

5.3 Process Fire Safety

In accordance with the requirements of 10 CFR 70.22(a)(7), an adequate application describes equipment and facilities that will protect health and minimize danger to life or property, including the process fire safety within areas where licensed material is present. Process fire safety involves design considerations to prevent an accident or to mitigate the consequences of an accident resulting from the use of process chemicals, combustible metals, flammable and combustible liquids and gases, high-temperature equipment, hot cells and glove boxes, and laboratories. For these areas, the application should identify fire and explosion hazards, along with the fire and explosion parameters of hazardous materials. Compliance with applicable NFPA standards or the building code may be sufficient to address many of these areas (e.g., NFPA 30, "Flammable and Combustible Liquids Code"; NFPA 69, "Standard on Explosion Prevention Systems"; and NFPA 86, "Standard for Ovens and Furnaces"). The application should list any relevant code(s) and describe the facility's degree of compliance.

Hazardous chemicals and processes involving licensed material can contribute to the fire hazard. In areas that have fire hazards that may threaten licensed material, the application should identify any hazardous chemicals, processes, and design standards used to ensure fire safety. The NRC staff recognizes NFPA 801 as one standard that provides acceptable design criteria for radiological process areas that may contain hazardous material, laboratories, high-temperature equipment, hot cells, and glove boxes. However, the applicant may use other nationally recognized codes and standards, if appropriate.

The following are some of the more common material hazards found in laboratories:

- Fluorine reacts violently with organic material or metal powders and water vapor.
- Hydrogen is an explosive and flammable gas used in reduction processes.
- Hydrogen peroxide off-gases hydrogen and oxygen and is incompatible with some extinguishers.

- Nitric acid nitrates organic material, which lowers the ignition temperature of combustibles.

- Sulfuric acid absorbs water from organic material in an exothermic reaction, thereby causing ignition.

- Zirconium is a combustible metal that burns at elevated temperatures.

5.4 Combustible Loading and Potential Fire Scenarios

In accordance with the requirements of 10 CFR 70.22(a)(7), an adequate application describes equipment and facilities to protect health and minimize danger to life or property, including potential fire scenarios for areas in which licensed material is present. For these areas, the application should identify possible ignition sources and the measures that are in place to sufficiently demonstrate reasonable assurance that the facility is protected from fires and explosions. Compliance with applicable NFPA standards or the building code may be sufficient to address many of these areas. The application should identify relevant code(s) and describe any deviations from code compliance.

The application should describe potential combustible loading in each fire area. Combustibles may include materials like chemicals, wood pallets, plastics, paper, or trash. This description should include not only the combustibles that are present in the facility at present but also any that may reasonably be assumed to be present in the future. If there are significant combustibles, the application should consider the credible fire scenarios and document the safety features to prevent potential fires from creating a radiological hazard. Examples of safety features include sprinklers, fire extinguishers, fire barriers, and employee training.

5.5 Summary

In summary, in accordance with the requirements of 10 CFR 70.22(a)(6)–(8), an application should document the following information about the applicant's fire safety program:

- a list of all nuclear material and its location, quantity, and form, as well as a description of any physical barriers separating the material with applicable fire ratings

- a description of the facility's building construction, fire area determination, fire rated walls and opening protection, electrical installation, lightning protection, emergency lighting, life safety and egress, ventilation systems, and fire water drainage

- a description of the facility's fire protection systems (i.e., suppression, alarm, and detection)

- a description of the protection for laboratory equipment that may handle nuclear material (e.g., glove boxes, hot cells, fume hoods)

- a description of the inspection, testing, and maintenance of fire protection systems

- a description of all fire safety training given to employees (e.g., use of fire extinguishers, safe shutdown, evacuation)

- a description of the emergency response capabilities for the facility, including the proximity, qualifications, and training of the responding fire department, including any pre-fire coordination with the fire department (e.g., fire drills, hazardous materials training), and the water supply for firefighting

- a list of all hazardous chemicals or processes that may present a fire hazard in radiological areas

- a description, by fire area, of any potential combustible loading, possible fire scenarios, and safety controls

Compliance with any relevant NFPA or building codes (i.e., NFPA 45 or NFPA 801) may contribute to the discussion of the above items.

5.6 References

Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

NFPA, "Standard for the Installation of Sprinkler Systems," NFPA 13, 2019.

NFPA, "Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems," NFPA 25, 2020.

NFPA, "National Fire Alarm and Signaling Code," NFPA 72, 2019.

NFPA, "Standard on Explosion Prevention Systems," NFPA 69, 2019.

NFPA, "National Electrical Code," NFPA 70, 2020.

NFPA, "Standard for Fire Protection for Facilities Handling Radioactive Materials," NFPA 801, 2020.

NFPA, "Flammable and Combustible Liquids Code," NFPA 30, 2021.

NFPA, "Standard on Fire Protection for Laboratories Using Chemicals," NFPA 45, 2019.

NFPA, "Standard for Ovens and Furnaces," NFPA 86, 2019.

NFPA, "Life Safety Code," NFPA 101, 2021.

NFPA, "Standard on Types of Building Construction," NFPA 220, 2021.

U.S. Nuclear Regulatory Commission, "Standard Review Plan for Fuel Cycle Facilities License Applications," NUREG-1520.

6 NATIONAL ENVIRONMENTAL POLICY ACT

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"; 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review"; and 10 CFR 70.21(f).

Regulatory Criteria: An application for a license to possess a critical mass quantity of special nuclear material (SNM) for the authorized activities listed in 10 CFR 51.22 will be acceptable if it meets the following criteria:

- The application accurately describes the activity for which the license is requested.
- The activity for which the license is requested meets any of the criteria for the categorical exclusion (CATEX) defined in 10 CFR 51.22.

Discussion: The National Environmental Policy Act of 1969, as amended (NEPA), directs that, to the fullest extent possible, (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA, and (2) all agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in 10 CFR Part 51 implement section 102(2) of NEPA in a manner consistent with the domestic licensing and related regulatory authority of the U.S. Nuclear Regulatory Commission (NRC) under the Atomic Energy Act of 1954, as amended (the Act); the Energy Reorganization Act of 1974, as amended; and the Uranium Mill Tailings Radiation Control Act of 1978, and reflect the Commission's announced policy to take account of the regulations of the Council on Environmental Quality published in the *Federal Register* (FR) on November 29, 1978 (43 FR 55978–56007), voluntarily, subject to certain conditions.

The regulations in 10 CFR Part 51 also address the limitations imposed on the NRC's authority and responsibility under NEPA by the Federal Water Pollution Control Act Amendments of 1972, Pub. L. 92-500, 86 Stat. 816 et seq. (33 U.S.C. 1251 et seq.). In accordance with section 511(c)(2) of the Federal Water Pollution Control Act (86 Stat. 893, 33 U.S.C 1371(c)(2)), the NRC recognizes that responsibility for Federal regulation of non-radiological pollutant discharges into receiving waters rests by statute with the U.S. Environmental Protection Agency.

6.1 Classification of Licensing and Regulatory Actions

The NRC licensing actions fall into one of three classifications with respect to NEPA: (1) actions requiring an environmental impact statement as listed in 10 CFR 51.20, "Criteria for and identification of licensing and regulatory actions requiring environmental impact statements, (2) actions requiring an environmental assessment subject to 10 CFR 51.21, "Criteria for and identification of licensing and regulatory actions requiring environmental assessments, or (3) actions that do not require an environmental assessment because they fall under a CATEX in 10 CFR 51.22.

Facilities authorized to use and possess critical mass quantities of SNM (also known as greater than critical mass (GTCM) facilities), which use SNM for research and development purposes, are categorically excluded under 10 CFR 51.22(c)(14)(v). Section 1 gives details on these facilities. Therefore, these facilities are not subject to the requirements to prepare environmental assessments under 10 CFR 51.20 or 10 CFR 51.21.

The NRC anticipates that agency actions associated with GTCM licenses fall into one or more of the categories of actions that are CATEX (mainly under 10 CFR 51.22(c)(14)(v)—use of radioactive materials for research and development and for educational purposes. If an application for a license requests authorization for any of the types of actions described in 10 CFR 51.60, “Environmental report—materials licenses,” or 10 CFR 70.21(f), then the applicant must follow the guidance in NUREG-1748, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs.”

The regulations in 10 CFR 51.22 state that licensing, regulatory, and administrative actions eligible for CATEX shall meet the following criterion: the action belongs to a category of actions which the Commission, by rule or regulation, has declared to be a CATEX, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. The regulations in 10 CFR 51.22(c) list the categories of actions that are CATEX, including, in part, the following:

> (12) issuance of an amendment to a license under parts 50, 52, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction effects. These amendments and approvals are confined to—
>
> (i) Organizational and procedural matters;
>
> (ii) Modifications to systems used for security and/or materials accountability;
>
> (iii) Administrative changes; and
>
> (iv) Review and approval of transportation routes under 10 CFR 73.37.
>
> (14) Issuance, amendment, or renewal of materials licenses issued under 10 CFR Parts 30, 31, 32, 33, 34, 35, 36, 39, 40 or part 70 authorizing the following types of activities:
>
> (v) Use of radioactive materials for research and development and for educational purpose.
>
> (xvi) Any use of source, byproduct, or special nuclear material not listed above which involves quantities and forms of source, byproduct, or special nuclear material similar to those listed in paragraphs (c)(14) (i) through (xv) of this section [category 14].

(15) Issuance, amendment, or renewal of licenses for import of nuclear facilities and materials pursuant to part 110 of this chapter, except for import of spent power reactor fuel.

(17) Issuance of an amendment to a permit or license under parts 30, 40, 50, 52, or part 70 of this chapter which deletes any limiting condition of operation or monitoring requirement based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

(18) Issuance of amendments or orders authorizing licensees of production or utilization facilities to resume operation, provided the basis for the authorization rests solely on a determination or redetermination by the Commission that applicable emergency planning requirements are met.

(20) Decommissioning of sites where licensed operations have been limited to the use of—

(i) Small quantities of short-lived radioactive materials;

(ii) Radioactive materials in sealed sources, provided there is no evidence of leakage of radioactive material from these sealed sources; or

(iii) Radioactive materials in such a manner that a decommissioning plan is not required by 10 CFR 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1), and the NRC has determined that the facility meets the radiological criteria for unrestricted use in 10 CFR 20.1402 without further remediation or analysis.

(21) Approvals of direct or indirect transfers of any license issued by NRC and any associated amendments of license required to reflect the approval of a direct or indirect transfer of an NRC license.

(25) Granting of an exemption from the requirements of any regulation of this chapter, provided that—

(i) There is no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

(iii) There is no significant increase in individual or cumulative public or occupational radiation exposure;

(iv) There is no significant construction impact;

(v) There is no significant increase in the potential for or consequences from radiological accidents; and

(vi) The requirements from which an exemption is sought involve:

(A) Recordkeeping requirements;

(B) Reporting requirements;

(C) Inspection or surveillance requirements;

(D) Equipment servicing or maintenance scheduling requirements;

(E) Education, training, experience, qualification, requalification or other employment suitability requirements;

(F) Safeguard plans, and materials control and accounting inventory scheduling requirements;

(G) Scheduling requirements;

(H) Surety, insurance, or indemnity requirements; or

(I) Other requirements of an administrative, managerial, or organizational nature.

The license or amendment application should do the following:

- Describe the activities for which the applicant is requesting authorization.

- Identify the category or categories of actions into which the authorized activities would fall (i.e., environmental impact statement, environmental assessment, or CATEX).

- Demonstrate that the requested authorization is for activities categorically excluded by addressing the licensing action descriptions for CATEX, as discussed in section 2 of NUREG-1748, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,” issued August 2003. This guidance provides general procedures for the environmental review of licensing actions regulated by the Office of Nuclear Material Safety and Safeguards (NMSS).

To facilitate staff review, applicants and licensees making a proposed CATEX determination should consider the following five review questions listed in appendix B to NUREG-1748:

- Is the action consistent with the Statement of Considerations for the CATEX chosen?

- Is the action likely to significantly affect any aspect of the natural environment?

- Is the action likely to significantly affect any aspect of the cultural environment, including those that might be related to environmental justice?

- Is the action likely to generate a great deal of public interest about any environmental issue?

- Is there a high level of uncertainty about the action's environmental effects?

6.2 References

Code of Federal Regulations, Chapter 1, Title 10 (10 CFR), "Energy," Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," NUREG-1748, August 2003.

7 MATERIAL CONTROL AND ACCOUNTING

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(b); 10 CFR Part 74, "Material Control and Accounting of Special Nuclear Material."

Regulatory Criteria: Applicants or licensees that possess special nuclear material (SNM) must ensure the control and accounting of licensed material.

Discussion: The material control and accounting (MC&A) regulations in 10 CFR Part 74 contain the requirements for the control and accounting of SNM at fixed sites and for documenting the transfer of SNM. The following subparts of 10 CFR Part 74 distinguish among licensees authorized to possess different types and quantities of SNM:

- Subpart B, "General Reporting and Recordkeeping Requirements," applies to each licensee who possesses, receives, or transfers SNM in a quantity of 1 gram or more of contained uranium (U)-235, U-233, or plutonium.

- Subpart C, "Special Nuclear Material of Low Strategic Significance," applies to each licensee authorized to possess and use SNM of low strategic significance, as defined in 10 CFR 74.4, "Definitions," also known as a Category III quantity of SNM (10 CFR 74.31, "Nuclear material control and accounting for special nuclear material of low strategic significance";10 CFR 74.33, "Nuclear material control and accounting for uranium enrichment facilities authorized to produce special nuclear material of low strategic significance").

- Subpart D, "Special Nuclear Material of Moderate Strategic Significance," applies to each licensee authorized to possess and use SNM of moderate strategic significance, as defined in 10 CFR 74.4, also known as a Category II quantity of SNM (10 CFR 74.41, "Nuclear material control and accounting for special nuclear material of moderate strategic significance").

- Subpart E, "Formula Quantities of Strategic Special Nuclear Material," applies to each licensee who is authorized to possess five or more formula kilograms of strategic SNM, as defined in 10 CFR 74.4, also known as a Category I quantity of SNM (10 CFR 74.51, "Nuclear material control and accounting for strategic special nuclear material").

The regulations in 10 CFR 70.22(b), in part, require that each application for a license to possess and use SNM in a quantity exceeding 1 effective kilogram contain a full description of the program for control and accounting of such SNM as will be in the applicant's possession and how compliance with the applicable requirements in 10 CFR 74.31, 10 CFR 74.33, 10 CFR 74.41, and 10 CFR 74.51, as applicable, will be accomplished. However, the requirements in 10 CFR 70.22(b) contain an exclusion for licensees governed by 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," including nonpower reactors (research and test reactors), for uses of SNM as sealed sources, and operations involved in waste disposal. The same exclusions are contained in the MC&A requirements in 10 CFR 74.31, 10 CFR 74.33, 10 CFR 74.41, and 10 CFR 74.51.

Applicants for a license to possess greater than critical mass (GTCM) quantities of SNM, as described in chapter 1 of this document, as sealed sources are subject to the general reporting and recordkeeping requirements under Subpart B but are not subject to the more extensive

MC&A requirements under Subparts C, D, or E of 10 CFR Part 74, which apply to licensees as described above. Applicants for licenses to possess SNM of low or moderate strategic significance, or formula quantities of strategic SNM, as defined in 10 CFR 74.4 that do not meet the exceptions for sealed sources, or the other conditions, as described above, may be subject to the further MC&A requirements of Subparts C, D, or E of 10 CFR Part 74. Applicants and licensees should review the types and quantities of SNM to determine if the more extensive MC&A requirements of Subpart C or D apply.

Guidance on the MC&A requirements for applicants or licensees subject to 10 CFR 74.31 appears in NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities." Guidance on the MC&A requirements for applicants or licensees subject to 10 CFR 74.33 is found in NUREG/CR-5734, "Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities," issued November 1991. NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance," includes guidance for the MC&A requirements in 10 CFR 74.41.

All licensees that possess, receive, or transfer SNM in any form in a quantity of 1 gram or more of contained U-235, U-233, or plutonium are subject to the general reporting and recordkeeping requirements of 10 CFR Part 74, Subpart B. The application should describe how it will accomplish the general reporting and recordkeeping requirements of Subpart B.

The following requirements of Subpart B apply to GTCM applicants:

- 10 CFR 74.11, "Reports of loss or theft or attempted theft or unauthorized production of special nuclear material," requires the licensee to notify the U.S. Nuclear Regulatory Commission (NRC) Operations Center in the event of any lost, stolen, or unlawfully diverted SNM, including attempts, within 1 hour of discovery.

- 10 CFR 74.13, "Material status reports," requires the licensee to prepare material balance reports concerning SNM that the licensee has received, produced, possessed, transferred, consumed, disposed of, or lost.

- 10 CFR 74.15, "Nuclear material transaction reports," requires the licensee who transfers or receives SNM in certain quantities or who adjusts its inventory of SNM to submit a nuclear material transaction report.

- 10 CFR 74.19, "Recordkeeping," requires the licensee to maintain and retain records of the receipt, inventory, acquisition, transfer, and disposal of all SNM. This section also requires certain licensees to establish, maintain, and follow written MC&A procedures that are sufficient to enable the licensee to account for the SNM in its possession under license. This section also requires a licensee possessing certain quantities to take a physical inventory of all SNM in its possession at intervals not to exceed 12 months.

7.1 Reports of Loss or Theft or Attempted Theft of Special Nuclear Material

The regulations in 10 CFR 74.11 require the licensee to notify the NRC Operations Center in the event of any lost, stolen, or unlawfully diverted SNM, including attempts, within 1 hour of discovery.

The applicant should describe how indicators of a possible loss, theft, or diversion of SNM, whether arising from errors or deliberate actions, will be investigated and resolved. The applicant should have well-defined procedures for promptly investigating and resolving indications of possible missing SNM and procedures for promptly determining whether an actual loss of SNM has occurred. Resolving a loss indicator means that the licensee has determined that loss, including possible diversion or theft, has not occurred and is not occurring. Any investigation of an indication of a loss or theft should provide, whenever possible, (1) an estimate of the quantity of SNM involved, (2) the material type of physical form of the material, (3) the type of unauthorized activity or event detected, (4) the time frame within which the loss or activity could have occurred, (5) the most probable cause(s), and (6) recommendations for precluding reoccurrence.

For indications that a loss or theft may have occurred, the resolution process should include (1) thoroughly checking the accountability records and source information, (2) locating the source of the problem, (3) isolating the exact reason for the problem within the area, (4) determining the amounts of SNM involved, and (5) determining that the indication is or is not resolved. If an investigation of an indicator results in a conclusion that the indication is true, such conclusion must be reported to the NRC within 1 hour of its determination in accordance with 10 CFR 74.11. Procedures should identify all documentation requirements associated with the methods for the reporting, investigation, and resolution of missing SNM indicators.

7.2 Material Status Reports

The regulations in 10 CFR 74.13 require licensees to prepare material balance reports and physical inventory listings concerning SNM that the licensee has received, produced, possessed, transferred, consumed, disposed of, or lost. U.S. Department of Energy (DOE)/NRC Form 742, “Material Balance Report,” and DOE/NRC Form 742C, “Physical Inventory Listing,” are the means for submitting reports of material balance and physical inventory listing data to the Nuclear Materials Management and Safeguards System (NMMSS), which is the national database used for tracking certain nuclear material. DOE/Form 742 is used to report a summary of activity for a specified material within a material balance reporting period, as specified in 10 CFR 74.13. The report conveys beginning and ending inventory balances; activities such as shipment and receipts involving other facilities; decay, transmutation; and production calculations. DOE/NRC Form 742C is used to report a facility’s physical inventory listing as of a specified date.

The applicant should generally describe how material status reports are prepared and submitted to NMMSS. Reports must be submitted for each reporting identification symbol (RIS), which can only be obtained after the NRC license is issued. Once the license is issued, the licensee should contact the NRC’s Office of Nuclear Material Safety and Safeguards, Division of Fuel Management, to request an RIS. Processing the request for an RIS will require the NRC license number, the address where the material will be used and stored, the business address of the licensee, and the name and telephone number of a contact person.
The applicant should have well-defined procedures for preparing and submitting reports in a computer-readable format in accordance with the detailed instructions contained in

NUREG/BR-0007, “Instructions for the Preparation and Distribution of Material Status Reports (DOE/NRC Forms 742 and 742C),” and in NMMSS Report D-24, “Personal Computer Data Input for Nuclear Regulatory Commission Licensees.” The procedures should ensure that reports are made and filed within the required time periods, as defined in 10 CFR 74.13. If it will possess U.S. Government-owned material, the applicant should also have procedures in place to ensure that it will meet the DOE-reporting requirements for all receipts, transfers, and inventories of U.S. Government-owned, loaned, or leased material, as specified in NUREG/BR-0007 as well.

If it has materials that are nationally tracked sources, the applicant should have procedures in place to ensure reporting to the National Source Tracking System (NSTS), which is a secure user-friendly web-based database designed to track Category I and II radioactive sources regulated by the NRC and the Agreement States. Applicants that have less than a critical mass and have plutonium sources (less than 16 curies) or plutonium/beryllium sources should report them to the NSTS. Information on NSTS can be found on the NRC public website at http://www.nrc.gov/security/byproduct/ismp/nsts.html.

If the applicant will be subject to the requirements in 10 CFR Part 75, “Safeguards on Nuclear Material—Implementation of Safeguards Agreements Between the United States and the International Atomic Energy Agency,” it should describe how it will submit the required material status reports in accordance with 10 CFR 75.35, “Material status reports.”

7.3 Nuclear Material Transaction Reports

The regulations in 10 CFR 74.15 require a licensee who transfers or receives SNM in certain quantities or who adjusts its inventory of SNM to submit that information to NMMSS. DOE/NRC Form 741, “Nuclear Material Transaction Report,” is the means by which licensees submit transaction data to NMMSS. DOE/NRC Form 741 is used to report physical transfers of nuclear materials between facilities and to report exchanges of foreign obligations on material between facilities even when no physical transfer occurs. The form is also used to report onsite transactions such as inventory corrections that otherwise increase or decrease foreign obligation balances or nuclear material categories within a facility.

The applicant should generally describe how it will track licensed materials from “receipt to disposal” to ensure accurate accounting records and that possession limits listed on the license are not exceeded. The applicant should describe how it prepares nuclear material transaction reports and submits them to NMMSS. The applicant should have well-defined procedures for preparing and submitting reports in a computer-readable format, in accordance with the detailed instructions contained in NUREG/BR-0006, “Instructions for Completing Nuclear Material Transaction Reports (DOE/NRC Forms 741 and 740M),” and in NMMSS Report D-24.If it will possess U.S. Government-owned material, the applicant should also have procedures in place to ensure that it will meet the DOE-reporting requirements for all receipts, transfers, and inventories of U.S. Government-owned, loaned, or leased material, as specified in NUREG/BR-0006 as well. If the applicant will be subject to the requirements in 10 CFR Part 75, it should describe how it will submit the required inventory change reports in accordance with 10 CFR 75.34, “Inventory change reports.”

7.4 Recordkeeping

The regulation in 10 CFR 74.19(a) states that licensees not subject to 10 CFR 74.31, 10 CFR 74.33, 10 CFR 74.41. or 10 CFR 74.51 are subject to the recordkeeping requirements

in 10 CFR 74.19(a)(1)-(4), which require a licensee to maintain records of receipt, inventory, acquisition, transfer, and disposal of all SNM in its possession. Each record relating to MC&A that is required by this regulation or by license condition is to be maintained and retained in accordance with the appropriate regulation or license condition. If a retention period is not otherwise specified, the licensee shall retain the record until the Commission terminates the license.

The applicant should generally describe the recordkeeping system used to maintain records of receipt, use, transfer, and disposal (as waste) of all licensed material. Table 7-1 lists each type of record and how long the record must be maintained. Other records, such as transfer records, could be linked to radioactive material inventory records. Receipt records should also document cases where the licensee found excessive radiation levels or radioactive contamination on packages or containers of material received and describe the action taken.

Table 7-1 Records Maintenance

Type of Record	How Long Record Must Be Maintained
Receipt, Acquisition, or Physical Inventory	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until the NRC terminates the license

Receipt, transfer, and disposal records typically contain the following information:

- radionuclide, quantity, and date of measurement of SNM
- for each sealed source, manufacturer, model number, location, and, if needed for identification, serial number and as appropriate, manufacturer and model number of the device containing the sealed source
- date of the transfer and name and license number of the recipient, and description of the affected radioactive material (e.g., radionuclide, quantity, manufacturer's name and model number, serial number)
- for licensed materials disposed of as waste, the radionuclide, quantity, date of disposal, and method of disposal (e.g., decay, sewer)

7.5 Written Material, Control, & Accounting Procedures

The regulation in 10 CFR 74.19(b) states that each licensee authorized to possess SNM in a quantity exceeding 1 effective kilogram shall establish, maintain, and follow written MC&A procedures that are sufficient to enable the licensee to account for the SNM in its possession under license. If the applicant will possess greater than 1 effective kilogram of SNM, it should generally describe the written procedures established to ensure all the applicable MC&A requirements are met.

7.6 Physical Inventories

The regulation in 10 CFR 74.19(c) states that each licensee not subject to 10 CFR 74.31, 10 CFR 74.33, 10 CFR 74.41, or 10 CFR 74.51 and authorized to possess SNM in a quantity greater than 350 grams of contained U-235, U-233, or plutonium, or any combination thereof, shall make a physical inventory of all SNM in its possession under license at intervals not to exceed 12 months. The applicant should generally describe how it performs physical inventories of its SNM. The applicant should have well-defined procedures for the planning, conducting, assessing, and reporting of the physical inventories. Licensees are required to submit reports regarding the physical inventory in accordance with the requirements in 10 CFR 74.13. The applicant should describe how it maintains and retains inventory records in accordance with 10 CFR 74.19.

7.7 Records Access and Storage

The regulation in 10 CFR 74.19(d) requires licensees to ensure that the recordkeeping system can produce clear and legible copies of records after storage for the period specified by the regulations. The section also states that the licensee shall maintain adequate safeguards against tampering with and loss of records. The applicant should generally describe how it stores records and how it controls its access to records to meet the requirement in 10 CFR 74.19(d).

7.8 Additional Information

As previously noted, GTCM applicants who intend to possess certain amounts and types of SNM that are not in sealed sources may be subject to additional MC&A requirements in 10 CFR Part 74 other than those in Subpart B. A license to possess SNM of low strategic significance (Category III), or SNM of moderate strategic significance (Category II), that is not in sealed sources may be subject to requirements in 10 CFR Part 74, Subparts C and D, respectively. Applicants for licenses to possess such material should contact the NRC for further guidance.

7.9 References

Code of Federal Regulations, Chapter 1, Title 10 (10 CFR), “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

10 CFR Part 74, “Material Control and Accounting of Special Nuclear Material.”

Nuclear Material Management and Safeguards System Report D-24, “Personal Computer Data Input for Nuclear Regulatory Commission Licensees” (http://nnsa.energy.gov/aboutus/ourprograms/nuclearsecurity/nmmsshome/nmmssinfo).

U.S. Nuclear Regulatory Commission (NRC), “Acceptable Standard Format and Content for the Material Control and Accounting Plan Required for Special Nuclear Material of Moderate Strategic Significance,” NUREG-2159.

NRC, “Instructions for Completing Nuclear Material Transaction Reports (DOE/NRC Forms 741 and 740M),” NUREG/BR-0006.

NRC, “Instructions for the Preparation and Distribution of Material Status Reports (DOE/NRC Forms 742 and 742C),” NUREG/BR-0007.

NRC, “Acceptable Standard Format and Content for the Fundamental Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities,” NUREG-1065.

NRC, “Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities,” NUREG/CR-5734, November 1991.

8 DECOMMISSIONING AND FINANCIAL ASSURANCE

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(9); 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning"; 10 CFR 70.51, "Records requirements."

Regulatory Criteria: Pursuant to 10 CFR 70.25(b), a licensee authorized to possess licensed material in excess of the limits specified in 10 CFR 70.25(d) must submit a decommissioning funding plan (DFP) in accordance with the requirements in 10 CFR 70.25(b)(1) or provide a certification of financial assurance for decommissioning in accordance with the requirements in 10 CFR 70.25(b)(2). The requirements in 10 CFR 70.25(e) cover preparing a DFP. Financial instruments must meet the requirements in 10 CFR 70.25(f). In addition, in accordance with the requirements in 10 CFR 70.25(g), all licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Licensees must transfer these records either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 70.51(b)(6), or to the appropriate U.S. Nuclear Regulatory Commission (NRC) regional office before the license is terminated.

Discussion: The NRC regulations requiring certification of financial assurance for decommissioning or a DFP are designed to provide reasonable assurance that the technical and environmental components of decommissioning are carried out and that decommissioning of the facilities is possible at the conclusion or termination of licensed activities. These requirements specify that a licensee either set aside funds for decommissioning activities or provide a guarantee that funds will be available. Criteria for determining whether an applicant is required to submit a DFP or certification of financial assurance under 10 CFR 70.25(b) are set forth in 10 CFR 70.25(d). Applicants should consider encapsulated sources and certain custom sources as unsealed material requiring financial assurance in accordance with 10 CFR 70.25(b).

8.1 Financial Assurance and Decommissioning Funding Plan

The applicant must ensure that decommissioning activities will be carried out in accordance with applicable NRC regulations and that they will be carried out with minimal impact on public and occupational health and safety and the environment (see *Federal Register* (FR), Notice of Final Rule, "General Requirements for Decommissioning Nuclear Facilities," 53 FR 24018, June 27, 1988). There are two parts to 10 CFR 70.25: financial assurance that applies to some licensees (10 CFR 70.25(a)–(d) and (f)), and recordkeeping that applies to all licensees (10 CFR 70.25(g)).

The NRC provides guidance on developing a site-specific DFP and approved wording for each mechanism authorized by the regulation to guarantee or secure funds in NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 3, "Financial Assurance, Recordkeeping, and Timeliness," issued February 2012.

8.2 Recordkeeping

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 70.25(g). Licensees need to maintain permanent records of where licensed material is used or stored while the license is active. 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 or written descriptions of the specific locations or room numbers where SNM is used or stored and any records of spills in or around the licensee's facilities or information relevant to damaged devices or leak tests of radioactive sources. The NRC requires all licensees to maintain these records in an identified location until the site is released for unrestricted use. If the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee before transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. When the license is terminated, these records shall be transferred to the NRC.

Note: No response is needed from most applicants requesting only sealed sources. If financial assurance or a DFP is required, applicants should submit the required documents as described in NUREG-1757, Volume 3.

8.3 References

Code of Federal Regulations, Chapter 1, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission (NRC), Notice of Final Rule, "General Requirements for Decommissioning Nuclear Facilities," 53 FR 24018, June 27, 1988.

NRC, "Consolidated NMSS Decommissioning Guidance—Financial Assurance, Recordkeeping, and Timeliness," NUREG-1757, Volume 3.

9 PHYSICAL SECURITY

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," Subpart I, "Storage and Control of Licensed Material"; 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources"; 10 CFR 70.22(4)(k); 10 CFR Part 73, "Physical Protection of Plants and Materials"; 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

Regulatory Criteria: Applicants or licensees that possess special nuclear material (SNM) must ensure the physical security and control[2] of licensed material.

Discussion: The regulations requiring control, security, and physical protection of SNM are graded based on the risk of the SNM to be used for malicious purposes. Control of all licensed material is covered in 10 CFR Part 20, Subpart I. These regulations require licensees to secure licensed materials in storage from unauthorized removal or access and to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. These basic requirements are largely intended to prevent unintended or inadvertent exposure of the public from gaining access to licensed material during use and storage or from licensed material being lost or uncontrolled in public and are not intended to cover physical protection of licensed material designed to prevent or minimize adversaries from acquiring and using the material maliciously.

The SNM physical protection regulatory requirements designed to prevent or minimize adversaries from acquiring and using the material maliciously at fixed sites and in transit are graded using a material categorization approach. Depending on the type, quantity (i.e., mass) and enrichment of the SNM, the material categorization approach places uranium and plutonium into one of three risk categories: (1) Category I (i.e., formula quantity of strategic SNM), (2) Category II (i.e., SNM of moderate strategic significance), or (3) Category III (i.e., SNM of low strategic significance). The regulations in 10 CFR Part 73 provide SNM physical protection requirements within these categories, which are based primarily on the ability of an adversary to create an improvised nuclear device using SNM. However, the regulations contain exemptions and exceptions to the three-category approach. With respect to 10 CFR Part 73, this guidance addresses Category II and Category III physical protection requirements. In addition to the regulations, following the events of September 11, 2001, the U.S. Nuclear Regulatory Commission (NRC) issued security orders to certain licensees that required additional security measures. New applicants should contact the NRC to determine whether existing security orders are applicable to their facilities. In accordance with 10 CFR 70.22(k), each application for a license to possess or use SNM of moderate strategic significance or 10 kilograms or more of low strategic significance must include a physical security plan that demonstrates how the applicant plans to meet the requirements of 10 CFR 73.67(d), (e), (f), and (g), as appropriate.

In addition to the SNM physical protection requirements in 10 CFR Part 73, certain isotopes and forms of plutonium, as discussed below, must be protected in accordance with the requirements in 10 CFR Part 37, which establish security requirements for the use and transport of Category 1 and Category 2 quantities of radioactive material. These materials are widely used in the United States by industrial, medical, and academic institutions and their theft or diversion

[2] "Control" in this section is used as it relates to 10 CFR Part 20. The use of "control" in this section does not pertain to material control and accountability discussed in chapter 7 of this document.

could lead to their use in a radiological dispersal device or a radiological exposure device. The security of plutonium (Pu)-238 material and plutonium/beryllium encapsulated, or sealed sources, is addressed by 10 CFR Part 37. However, 10 CFR Part 37 does not include other plutonium isotopes (such as Pu-240, Pu-241, or Pu-242) or unsealed materials.

Applicants and licensees should review its types, forms, and quantities of SNM to determine which security or physical protection requirements apply. The discussion below discusses this subject in greater detail.

9.1 Category II Special Nuclear Material Physical Protection Requirements

Regulations in 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance," and 10 CFR Part 73, Appendix E, "Levels of Physical Protection To Be Applied in International Transport of Nuclear Materials," include the physical protection requirements specific to SNM of moderate strategic significance (also known as Category II quantity of material—see 10 CFR 73.2, "Definitions").

9.1.1 Applicability

The definition of SNM of moderate strategic significance in 10 CFR 70.4, "Definitions," is as follows:

> (1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation, grams = (grams contained U-235) + 2 (grams U-233 + grams plutonium), or
>
> (2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

In accordance with 10 CFR 73.67(b)(1), licensees are exempt from the physical protection requirements 10 CFR 73.67 to the extent they possess, use, or transport the following:

> (i) Special nuclear material which is not readily separable from other radioactive material and which has a total external radiation dose rate in excess of 1 gray (100 rad) [100 rem] per hour at a distance of 1 meter (3.3 feet) from any accessible surface without intervening shielding, or
>
> (ii) Sealed plutonium-beryllium neutron sources totaling 500 grams or less contained plutonium at any one site or contiguous sites, or
>
> (iii) Plutonium with an isotopic concentration exceeding 80 percent in plutonium-238.

9.1.2 General Performance Objectives

The general performance objectives in 10 CFR 73.67(a), applicable to fixed sites and transit of SNM, specify that facilities with Category II quantities of SNM must minimize the possibilities for

unauthorized removal of SNM and facilitate the location and recovery of missing SNM. To achieve these objectives, the physical security measures shall provide for (1) early detection and assessment of unauthorized access or activities by an external adversary within the controlled access area containing SNM, (2) early detection of removal of SNM by an external adversary from a controlled access area, (3) assurance of proper placement and transfer of custody of SNM, and (4) response to indications of an unauthorized removal of SNM and then notification of the appropriate response forces of its removal to facilitate its recovery.

In accordance with 10 CFR 70.22(k), each applicant planning to possess or use Category II quantities of SNM must include a physical security plan that demonstrates how it meets the requirements in 10 CFR 73.67(d) and (e), as appropriate. Licensees shall retain a copy of the physical security plan as a record for the period during which the licensee possesses Category II quantities of SNM, and if any portion of the plan is superseded, retain that superseded portion of the plan for 3 years after the effective date of the change. The regulations in 10 CFR 73.67(c) require the licensee to submit the security plan to the NRC for review and approval and then to implement the approved security plan.

Regulatory Guide 5.59, “Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance,” contains additional guidance on developing a Category II physical protection program.

9.1.3 Physical Protection Requirements at Fixed Sites

In accordance with 10 CFR 73.67(d), applicable to fixed sites, licensees shall only use the Category II quantities of SNM in a controlled access area that is illuminated sufficiently to allow detection and surveillance of unauthorized penetration or activities (10 CFR 73.67(d)(1)). A controlled access area is any temporarily or permanently established area that is clearly demarcated, typically with a barrier (e.g., fence or wall), that affords isolation of the material or persons within the controlled access area. The controlled access area shall be monitored with an intrusion alarm or other device or procedures to detect unauthorized penetration or activities (10 CFR 73.67(d)(3)).

Admittance to the controlled access area is controlled to allow only authorized persons (e.g., persons with unescorted access or escorted visitors) who require such access to perform their duties (10 CFR 73.67(d)(6)). Licensees shall screen individuals before granting them unescorted access to the controlled access area to obtain information on which to base a decision to permit such access (10 CFR 73.67(d)(4)). Licensees shall develop and maintain a controlled badging and lock system to identify and limit access to the controlled access areas to authorized individuals (10 CFR 73.67(d)(5)). Licensees shall assure that all visitors to the controlled access areas are under the constant escort of an individual who has been authorized unescorted access to the area (10 CFR 73.67(d)(7)). Vehicles and packages leaving the controlled access area shall be searched on a random basis (10 CFR 73.67(d)(10)). The purpose of the search is to detect unauthorized removal of SNM from the controlled access area.

Within the controlled access area, Category II quantities of SNM shall be stored in a vault-type room, approved security cabinet or equivalent. A vault-type room shall be capable of being locked and shall be protected by an intrusion alarm, which creates an alarm upon the entry of a person anywhere into the room and upon exit from the room or upon movement of an individual within the room. The storage area(s) shall be sufficiently illuminated to allow detection and surveillance of unauthorized penetration or activities (10 CFR 73.67(d)(2)).

Licensees shall establish a security organization to consist of at least one watchman per shift able to assess and respond to any unauthorized penetrations or activities in the controlled access areas (10 CFR 73.67(d)(8)). The security organization shall have the capability to communicate with the appropriate response force, typically local law enforcement (10 CFR 73.67(d)(9)). Licensees shall establish and maintain written response procedures for dealing with threats of thefts or thefts of SNM (10 CFR 73.67(d)(11)). The licensee shall retain a copy of the response procedures for 3 years thereafter. Copies of superseded material must be retained for 3 years after each change.

9.1.4 Physical Protection Requirements in Transit

In accordance with 10 CFR 73.67(e), applicable to transit of SNM, licensees that transport, or deliver to a carrier for transport, Category II quantities of SNM shall provide advance notification to the receiver of any planned shipments specifying the mode of transport, estimated time of arrival, location of the nuclear material transfer point, name of carrier and transport identification. Before beginning the shipment, licensees shall receive confirmation from the receiver that the receiver will be ready to accept the shipment at the planned time and location and acknowledges the specified mode of transport. Before shipment, licensees shall check the integrity of the container and locks or seals (10 CFR 73.67(e)(1)).

In-transit physical protection of Category II quantities of SNM must be arranged by either the shipper or the receiver. The licensee that transports, exports, or delivers to a carrier for transport Category II quantities of SNM shall arrange for the in-transit physical protection of the materials unless the receiver is a licensee and has agreed in writing to arrange for the in-transit physical protection (10 CFR 73.67(e)(1)). The receiver shall arrange for the in-transit physical protection unless the shipper is a licensee and has agreed in writing to arrange for the in-transit physical protection (10 CFR 73.67(e)(2))

In-transit physical protection shall include arranging for telephone or radio communications between the transport and the licensee or its designee. The purpose of this communication is to periodically confirm the status of the shipment, to notify parties of any delays in the scheduled shipment, and to request appropriate local law enforcement agency response in the event of an emergency. Planned communications shall include immediate notification of the arrival of the shipment at its destination, or if the shipment is lost or unaccounted for after the estimated time of arrival at its destination (10 CFR 73.67(e)(3)). Licensees receiving Category II quantities of SNM shall check the integrity of the containers and seals upon receipt of the shipment and notify the shipper of receipt of the material (10 CFR 73.67(e)(2)).

For in-transit physical protection considerations, the routing and transport shall minimize the time that the material is in transit by reducing the number and duration of transfers and by routing the material in the most safe and direct manner. Licensees shall screen all licensee employees involved in the transportation of Category II quantities of SNM to obtain information on which to base a decision to permit them control over the material (10 CFR 73.67(e)(3)). Licensees shall make all shipments of Category II quantities of SNM either in dedicated transports with no intermediate stops to load or unload other cargo and with no carrier or vehicle transfers or temporary storage in-transit, or under arrangements whereby the custody of the shipment and all custody transfers are acknowledged by signature. Licensees shall also maintain Category II SNM under lock or under the control of an individual who has acknowledged acceptance of custody by signature (10 CFR 73.67(e)(4)).

Licensees shall establish and maintain written response procedures for dealing with threats of thefts or thefts of SNM. Response procedures shall include immediate initiation of a trace investigation of any shipment that is determined to be lost or unaccounted for after a reasonable time beyond the estimated arrival time. Response procedures shall also include notification of the NRC Operations Center within 1 hour after the discovery of the loss of the shipment and within 1 hour after recovery of or accounting for such lost shipment (10 CFR 73.67(e)(3)).

The licensee shall retain a copy of required documentation as a record for 3 years after the close of the period for which the licensee possesses the SNM under each license for which the original procedures were developed, and copies of superseded material must be retained for 3 years after each change (10 CFR 73.67(e)(4)).

9.2 Category III SNM Physical Protection Requirements

Regulations in 10 CFR 73.67 and Appendix E to 10 CFR Part 73 include physical protection requirements specific to SNM of low strategic significance (also known as Category III quantity of material—see 10 CFR 73.2).

9.2.1 Applicability

The definition of SNM of low strategic significance (Category III) in 10 CFR 70.4 is as follows:

> (1) Less than an amount of special nuclear material of moderate strategic significance as defined in paragraph (1) of the definition of strategic nuclear material of moderate strategic significance … but more than 15 grams of uranium-235 (contained in uranium enriched to 20 percent…) or 15 grams of uranium-233 or 15 grams of plutonium or the combination of 15 grams when computed by the equation, grams = (grams contained U-235) + (grams plutonium) + (grams U-233); or
>
> (2) Less than 10,000 grams but more than 1,000 grams of U-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope); or
>
> (3) 10,000 grams or more of U-235 (contained in uranium enriched above natural but less than 10 percent in the U-235 isotope).

In accordance with 10 CFR 73.67(b)(1), licensees are exempt from the requirements stated below in 10 CFR 73.67 to that extent that they possess, use, or transport:

> (iv) Special nuclear material which is not readily separable from other radioactive material and which has a total external radiation dose rate in excess of 100 rems per hour at a distance of 3 feet from any accessible surface without intervening shielding, or
>
> (v) Sealed plutonium-beryllium neutron sources totaling 500 grams or less contained plutonium at any one site or contiguous sites, or
>
> (vi) Plutonium with an isotopic concentration exceeding 80 percent in plutonium-238.

9.2.2 General

The general performance objectives in 10 CFR 73.67(a) specify that facilities with Category III quantities of SNM must minimize the possibilities for unauthorized removal of SNM and facilitate the location and recovery of missing SNM. To achieve these objectives, the physical security measures shall provide for (1) early detection and assessment of unauthorized access or activities by an external adversary within the controlled access area containing SNM, (2) early detection of removal of SNM by an external adversary from a controlled access area, (3) assurance of proper placement and transfer of custody of SNM, and (4) response to indications of an unauthorized removal of SNM and then notification to the appropriate response forces of its removal to facilitate its recovery.

In accordance with 10 CFR 70.22(k), each applicant planning to possess or use more than 10 kilograms of Category III quantities of SNM must include a physical security plan that demonstrates how the applicant plans to meet the requirements in 10 CFR 73.67(f) and (g), as appropriate. Applicants or licensees shall retain a copy of the physical security plan as a record for the period during which the licensee possesses Category III quantities of SNM, and if any portion of the plan is superseded, retain that superseded portion of the plan for 3 years after the effective date of the change. The regulations in 10 CFR 73.67(c) require the licensee to submit its security plan to the NRC for review and approval and to carry out the approved security plan. Applicants planning to possess or use less than 10 kilograms of Category III quantities of SNM are still required to carry out the security measures in 10 CFR 73.67(f) and (g) but do not need to develop and submit a security plan to the NRC. In such cases, the applicant may choose to prepare a security plan or use procedures, or both, to carry out the required security measures.

Regulatory Guide 5.59 contains additional guidance on developing a Category III physical protection program.

9.2.3 Physical Protection Requirements at Fixed Sites

In accordance with 10 CFR 73.67(f), applicable to fixed sites, licensees shall only use and store Category III quantities of SNM in a controlled access area (10 CFR 73.67(f)(1)). A controlled access area is any temporarily or permanently established area that is clearly demarcated, typically with a barrier (e.g., fence or wall), which affords isolation of the material or persons within the controlled access area. The controlled access area shall be monitored with an intrusion alarm or other device or procedures to detect unauthorized penetration or activities (10 CFR 73.67(f)(2)).

Licensees shall establish a security organization to consist of at least one watchman per shift able to assess and respond to any unauthorized penetrations or activities in the controlled access areas (10 CFR 73.67(f)(3)). Licensees shall establish and maintain written response procedures for dealing with threats of thefts or thefts of Category III quantities of SNM (10 CFR 73.67(f)(4)). The licensee shall retain a copy of the response procedures for 3 years thereafter. Copies of superseded material must be retained for 3 years after each change.

9.2.4 Physical Protection Requirements in Transit

In accordance with 10 CFR 73.67(g), applicable to transit, licensees that transport or deliver to a carrier for transport Category III quantities of SNM shall provide advance notification to the receiver of any planned shipments, specifying the mode of transport, estimated time of arrival, location of the nuclear material transfer point, name of carrier, and transport identification.

Before beginning the shipment, licensees shall receive confirmation from the receiver that the receiver will be ready to accept the shipment at the planned time and location and acknowledges the specified mode of transport. Before shipment, licensees shall check the integrity of the container and locks or seals. Transport of Category III quantities of SNM shall be in a tamper-indicated sealed container (10 CFR 73.67(g)(1)). Licensees receiving Category III quantities of special nuclear material shall check the integrity of the containers and seals upon receipt of the shipment and notify the shipper of receipt of the material (10 CFR 73.67(g)(2)).

In-transit physical protection of Category III quantities of SNM must be arranged by either the shipper or the receiver. A licensee that transports, exports, or delivers to a carrier for transport of Category III quantities of SNM shall arrange for the in-transit physical protection of the materials unless the receiver is a licensee and has agreed in writing to arrange for the in-transit physical protection (10 CFR 73.67(g)(1)). The receiver shall arrange for the in-transit physical protection unless the shipper is a licensee and has agreed in writing to arrange for the in-transit physical protection (10 CFR 73.67(g)(2)). Arrangements shall include immediate notification of the arrival of the shipment at its destination, or if the shipment is lost or unaccounted for after the estimated time of arrival at its destination (10 CFR 73.67(g)(3)).

Licensees shall establish and maintain written response procedures for dealing with threats of thefts or thefts of SNM. Response procedures shall include immediate initiation of a trace investigation of any shipment that is determined to be lost or unaccounted for after a reasonable time beyond the estimated arrival time. Response procedures shall also include notification of the NRC Operations Center within 1 hour after the discovery of the loss of the shipment and within 1 hour after recovery of or accounting for such lost shipment (10 CFR 73.67(g)(3)). The licensee shall retain a copy of required documentation as a record for 3 years after the close of the period for which the licensee possesses the SNM material under each license for which the original procedures were developed, and copies of superseded material must be retained for 3 years after each change (10 CFR 73.67(g)(3)).

9.3 Plutonium-238 and Plutonium/Beryllium Sealed Sources

9.3.1 Applicability

The regulations in 10 CFR 37.5, “Definitions,” define a Category 1 and a Category 2 quantity of radioactive material as follows:

> *Category 1 quantity of radioactive material* means a quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.
>
> *Category 2 quantity of radioactive material* means a quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this part. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity.

Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

The P-238 quantity in 10 CFR 150.11 (and Pu-238 sources in quantities greater than 16.2 curies), and Pu-239/beryllium sources greater than 16.2 curies, as well, are subject to the requirements in 10 CFR Part 37. These requirements may also apply to applicants or licensees requesting a new license (or renewal of an existing license) to possess byproduct material in addition to SNM.

9.3.2 General

In accordance with 10 CFR Part 37, licensees authorized to possess Category 1 or Category 2 quantities of radioactive material listed in Appendix A, "Category 1 and Category 2 Threshold," to 10 CFR Part 37 (Appendix A lists the radionuclides and the threshold quantities necessary to be subject to 10 CFR Part 37 under Category 1 or 2). The 10 CFR Part 37 regulations require licensees to establish, carry out, and maintain enhanced security procedures that meet increased control requirements to ensure physical protection of the radioactive material.

The Category 1 and 2 radioactive material covered by 10 CFR Part 37 are also subject to the regulations in 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources," which require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking System (NSTS) Transaction Report. The NSTS is a secure, accessible, and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

The NRC provides additional guidance on the development of a 10 CFR Part 37 security program in NUREG-2155, "Implementation Guidance for 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

9.3.3 Background Investigations and Access Authorization Program

In accordance with 10 CFR Part 37, Subpart B, "Background Investigations and Access Authorization Program," licensees must establish an access authorization to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material are trustworthy and reliable. The program must include the following elements:

- Designate reviewing officials after making background investigations, in accordance with 10 CFR 37.23(b)(2), and determine their trustworthiness and reliability, in accordance with 10 CFR 37.23(b)(1). A reviewing official is defined in 10 CFR 37.5 as the individual who shall make the trustworthiness and reliability determination of an individual to decide whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials in the licensee's possession.

- Conduct background investigations of persons to be granted unescorted access, including verification of identity, education, and employment history; criminal records; and fingerprint checks, and document the conclusions, in accordance with 10 CFR 37.23(a).

- Maintain lists of persons who are approved for unescorted access, in accordance with 10 CFR 37.23(e)(5).

- Provide security training, in accordance with 10 CFR 37.23(a)(2).

- Protect personal information against unauthorized disclosure, in accordance with 10 CFR 37.31(a).

9.3.4 Physical Protection Requirements for Use and Storage

In accordance with 10 CFR Part 37, Subpart C, "Physical Protection Requirements During Use," licensees must establish a physical protection program to monitor and immediately detect and respond to any actual or attempted unauthorized access to radioactive material in use or storage. The program must include the following elements:

- a written security plan in accordance with 10 CFR 37.43(a)

- implementing procedures in accordance with 10 CFR 37.43(b)

- security training in accordance with 10 CFR 37.43(c)

- protection of security-related information against unauthorized disclosure in accordance with 10 CFR 37.43(d)

- coordination with local law enforcement authorities in accordance with 10 CFR 37.45

- establishment of security zones that define the area for the physical protection of Category 1 or Category 2 quantities of radioactive material in accordance with 10 CFR 37.47

- establishment of continuous monitoring capability to promptly detect unauthorized entry into security zones in accordance with 10 CFR 37.49(a)

- procedures for prompt assessment and immediate response to any attempted or actual unauthorized entry, including requesting a response from the local law enforcement agency in accordance with 10 CFR 37.43(b)

- notification of local law enforcement agencies and the NRC of security events in accordance with 10 CFR 37.57

- maintenance, testing, and calibration of alarm and communication systems in accordance with 10 CFR 37.51

- physical controls to secure mobile devices against unauthorized removal in accordance with 10 CFR 37.53

9.3.5 Physical Protection during Transit

In accordance with 10 CFR Part 37, Subpart D, Physical Protection in Transit," licensees must provide for physical protection of radioactive material in transit. The requirements apply to

material delivered to a carrier for transport, as well as cases in which the licensee transports material. Normally, the shipping licensee has primary responsibility, but certain requirements involve coordination with the recipient. The physical protection requirements for transport of Category 2 quantities include the following:

- In accordance with 10 CFR 37.71(b), the licensee must verify the validity of the recipient's license authorization, using a license verification system, before transfer.

- In accordance with 10 CFR 37.75(a), the expected arrival times must be verified between the shipper and recipient, and the recipient must notify the shipper when the shipment arrives. In accordance with 10 CFR 37.79(c), the licensee must immediately investigate lost or unaccounted-for shipments.

- In accordance with 10 CFR 37.79(a)(2), a licensee that transports material shall maintain constant control or surveillance over the material and must have the capability for immediate communication to summon a response or assistance.

- In accordance with 10 CFR 37.79(a)(3), if a licensee delivers material to a carrier for transport, the carrier must have an established package tracking system, require an authorized signature for delivery or return, and maintain constant control or surveillance over shipments, with the capability for immediate communication to summon a response or assistance.

- In accordance with the requirements in 10 CFR 37.81, "Reportable safeguards events," the shipping licensee must promptly notify local law enforcement authorities and the NRC in cases of lost shipment or attempted or actual theft or diversion of shipments.

9.3.6 Additional Information

Physical security requirements applicable to SNM vary depending on the category of the SNM to be possessed by an applicant or already possessed by a licensee. Physical security requirements applicable to Category I SNM are not necessarily applicable to Category II or to Category III (i.e., additional requirements apply as the category of SNM increases from III to I). Because of the complexity of determining the physical security requirements that may apply to different applicants requesting an SNM license, an example is provided to demonstrate how an applicant may determine the physical requirements needed to protect the licensed material.

As an illustrative example, assume a greater than critical mass licensee has 800 grams of U-235 enriched to 19.5 percent and 20 grams of Pu-239.

Because the uranium is enriched to less than 20 percent and has a total mass of less than 1 kilogram, it would be below the Category III limits, and thus, would not need additional physical protection beyond the control of licensed material required by 10 CFR Part 20, Subpart I. If the uranium were enriched to greater than 20 percent, it would need to be protected in accordance with 10 CFR 73.67(f).

In this example, 20 grams of plutonium-239 would be a Category III quantity of SNM and would need to be protected in accordance with 10 CFR 73.67(f). As such, the Pu-239 would need to be used and stored in a controlled access area that is monitored with an intrusion alarm or other device or procedures to detect unauthorized penetration or activities. Although a licensee would

not need to submit a security plan to the NRC for approval, it would need to develop, maintain, and carry out response procedures. These procedures should describe the security organization, which would include at least one individual to assess and respond to any unauthorized activities. In general, response efforts would be supplemented by and coordinated with local law enforcement. If the plutonium were Pu-238 (20 grams of Pu-238 equates to 346 curies, which is above the Category II threshold), it would need to be protected in accordance with 10 CFR Part 37.

9.4 References

Code of Federal Regulations, Title 10 (10 CFR), "Energy." Chapter I, Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

10 CFR, Part 73, "Physical Protection of Plants and Materials."

U.S. Nuclear Regulatory Commission (NRC), "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," Regulatory Guide 5.59.

NRC, "Implementation Guidance for 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," NUREG-2155, March 2022.

10 EMERGENCY MANAGEMENT

Regulatory Requirements: Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(i); 10 CFR 70.24, "Criticality accident requirements."

Regulatory Criteria: Applications to possess enriched uranium or plutonium above certain thresholds must contain either (1) an evaluation showing that public doses would not exceed specified limits, or (2) an emergency plan.

Discussion: The regulations requiring emergency planning with respect to possession of special nuclear material (SNM) are contained in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

In accordance with 10 CFR 70.22(i)(1), each application to possess one of the following materials must address this emergency management requirement:

- enriched uranium or plutonium for which a criticality accident alarm is required (10 CFR 70.24(a))

- uranium hexafluoride in excess of 50 kilograms in a single container or 1,000 kilograms total

- more than 2 curies of plutonium in unsealed form or on foils or plated sources

If one of these possession limit thresholds is exceeded, in accordance with the requirements in 10 CFR 70.22(i)(1), the application must contain one of the following:

- an evaluation showing that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent, or an intake of 2 milligrams of soluble uranium, in accordance with the requirements in 10 CFR 70.22(i)(1(i)

- an emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto, in accordance with the requirements in 10 CFR 70.22(i)(1)(ii); if subject to the requirements in 10 CFR 70.24, "Criticality accident requirements," the emergency plan requirements in 10 CFR 70.24(a)(3) also apply

In accordance with the requirements in 10 CFR 70.22(i)(2)(i) through (vi), one or more of the factors stated below may be used to support an evaluation of offsite consequences:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident or to criticality because of the way it is stored or packaged;

(iii) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material;

(iv) The solubility of the material released would reduce the dose received;

(v) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001;

(vi) Operating restrictions or procedures would prevent a release large enough to cause a member of the public offsite to receive a dose exceeding 1 rem effective dose equivalent; or,

(vii) Other factors appropriate for the specific facility.

10.1 Emergency Plan

Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," includes guidance if 10 CFR 70.22(i)(1)(ii) requires an emergency plan. The regulations in 10 CFR 70.22(i)(3) state that an emergency plan must contain the following information:

(i) *Facility description*. A brief description of the applicant's/licensee's facility and area near the site.

(ii) *Types of accidents*. An identification of each type of radioactive materials accident for which protective actions may be needed.

(iii) *Classification of accidents*. A classification system for classifying accidents as alerts or site area emergencies.

(iv) *Detection of accidents*. Identification of the means of detecting each type of accident promptly.

(v) *Mitigation of consequences*. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) *Assessment of releases*. A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) *Responsibilities*. A brief description of the responsibilities of the applicant's personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC [U.S. Nuclear Regulatory Commission]; also, responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination*. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The

applicant/licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than 1 hour after the licensee declares an emergency.[1]

(ix) *Information to be communicated*. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) *Training*. A brief description of the frequency, performance objectives and plans for the training that the applicant/licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) *Safe shutdown*. A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) *Exercises*. Make provisions for quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) *Hazardous chemicals*. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the SNM.

In accordance with the regulations in 10 CFR 70.22(i)(4), an applicant shall allow the offsite response organizations, expected to respond in case of an accident, 60 days to comment on the licensee’s emergency plan before submitting it to the NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

In accordance with 10 CFR 70.32(i), a licensee may change an approved emergency plan without prior Commission approval if the changes do not decrease the effectiveness of the plan and the changes are provided to the Commission within 6 months. Applications including an emergency plan should describe how the applicant will review proposed changes to the emergency plan and the level of management approval the applicant requires before making changes without prior Commission approval.

Chapter 8 of NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," or Regulatory Guide 3.67 provide additional guidance for the development and the review of emergency plans that the regulations in 10 CFR 70.22(i)(1) would require.

10.2 References

Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission (NRC), "Standard Review Plan for Fuel Cycle Facilities License Applications," NUREG-1520.

NRC, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Regulatory Guide 3.67.

APPENDIX A
TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The radiation safety officer (RSO) is responsible for the overall radiation safety at a licensed facility or when the licensee otherwise engages in a licensed activity. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures As Low As Is Reasonably Achievable," discusses methods and procedures that the U.S. Nuclear Regulatory Commission (NRC) staff considers acceptable for maintaining radiation exposures to occupational workers and the public as low as is reasonably achievable (ALARA). This regulatory guide also discusses the applicable regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," and regulatory guidance for implementing an adequate safety program to achieve occupational doses that are ALARA and for adequately protecting the public and the environment from radiation hazards. The regulatory guide also discusses the main responsibilities of the RSO for ensuring radiological safety and compliance with NRC regulations and the conditions of the license.

As discussed in Regulatory Guide 8.10, the RSO's general responsibilities should include the following, among others:

- developing and planning radiological work activities and preparing procedures and other written documentation (e.g., radiation work permits) for achieving ALARA goals and ensuring such procedures are properly followed

- assuring that the proper radiation protection instrumentation, equipment, and supplies are available at workplaces, are in good working order, and are used properly, and that procedures for the use of instrumentation and equipment are available and properly followed

- performing annual audits to review the effectiveness of the ALARA program [**NOTE**: this audit may be performed as an integral part of the reviews performed to meet the requirements in 10 CFR 20.1101(c) for a periodic (at least annual) review of the overall radiation protection program]

- requiring, where practical, modifications to standard operating procedures, equipment, and facilities that will substantially reduce occupational and public exposures

- ensuring that proper focus is given to the source of licensee radiation exposures in the facility or other licensed activity by location, operation, and job category and maintaining awareness of trends in occupational and public exposures

- investigating unexpected exposures to determine the causes, taking steps to reduce the likelihood of similar occurrences in the future, and documenting conclusions and corrective actions

- assessing management of radiological work controls if the planned controls (e.g., radiation work permits, ALARA plans, work order instructions, radiological hold points, and stop work criteria) are not being implemented properly

- routinely reviewing ALARA plans to ensure that they are effective in maintaining both occupational and public doses ALARA

APPENDIX B
FACILITIES AND EQUIPMENT CONSIDERATIONS

This appendix lists the 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 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 nonporous 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 or calculations, or both, demonstrate that any planned or likely effluent will be in accordance with the limits found in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against Radiation,” Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.”

- 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 the 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 buildup. This buildup 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 the 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 (as low as is reasonably achievable). 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 only 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 to prevent the spread of radioactivity.

- Designated areas should be provided for coats and personal belongings, to avoid contamination.

- Areas with 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 buildup.

- Observation of activities done 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 the designated operations.

- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, the provisions of 10 CFR Part 20, Subpart H, “Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas,” need to be followed.

- If waste is compacted, the applicant needs to ensure that facilities are adequate to ventilate the area of compaction and that air sampling for internal exposures is available, if needed, in accordance with 10 CFR 20.1204, “Determination of internal exposure.”

APPENDIX C
RADIATION MONITORING AND INSTRUMENT CALIBRATION PROGRAM

The specifications in Table C-1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility or facilities.

Table C-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
Neutron	Neutron		
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
ZnS	Alpha	All energies	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**
Liquid Scintillation Counting*	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] *The Health Physics & Radiological Health Handbook*, 4th Edition, edited by Thomas E. Johnson and Brian K. Birky, issued 2012 (except for * items).

Calibration

- Calibration must produce readings within ±20 percent 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 state the procedure used and the data obtained. The description of the calibration should include the following:

- 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 did the calibration and the date it was done

The following information should 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

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 American Conference of Governmental Industrial Hygienists' *Air Sampling Instruments for Evaluation of Atmospheric Contaminants*, 9th Edition, issued 2001, provides guidance on total air sample volume calibration methods acceptable to the U.S. Nuclear Regulatory Commission staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should do an acceptable calibration of all airflow or volume metering devices at least annually (see Regulatory Guide 8.25, "Air Sampling in the Workplace").

- Special calibrations should be done 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 done as recommended by the manufacturer.

- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

APPENDIX D
GUIDANCE FOR MONITORING REQUIREMENTS

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," licensees are required to monitor exposures to radiation and radioactive materials at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20, "Standards for Protection against Radiation." According to 10 CFR 20.1502, as a minimum, monitoring is required for individuals likely to receive in 1 year from sources external to the body, a dose in excess of 10 percent of the applicable regulatory limits in 10 CFR 20.1201, "Occupational dose limits for adults." To demonstrate that dosimetry is *not* required, a licensee needs to do a prospective evaluation to demonstrate that its workers are not likely to exceed 10 percent of the applicable annual limits. Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses," provides guidance for prospectively evaluating the need to monitor an individual's occupational radiation dose. If the prospective evaluation shows that an individual is not likely to receive in a year a dose that exceeds the criteria in 10 CFR 20.1502, then monitoring is not required, and the recordkeeping requirement in 10 CFR 20.2106, "Records of individual monitoring results," and the reporting requirements in 10 CFR 20.2206, "Reports of individual monitoring," are not applicable. However, for the individual that already has received greater than the dose criteria in 10 CFR 20.1502 from prior employment in the current monitoring year, the NRC requires subsequent employers to monitor any additional radiation exposure.

The most common way that individuals might exceed 10 percent of the applicable limits is by being involved in the processing of sealed sources or unsealed material, or both (e.g., assembly lines, manufacturing processes and quality control activities). This could include internal radioactive uptake, as well as external radiation exposure. However, for many processes, even these activities result in the individual receiving minimal doses. Before allowing workers to do these tasks, a licensee will need to evaluate the doses that its workers might receive to assess whether dosimetry is required. This is known as a prospective evaluation.

Example

To demonstrate compliance with the occupational dose limits in 10 CFR 20.1201, "Occupational dose limits for adults," a university has estimated the doses to the extremities and whole body of a person doing foil activation experiments using plutonium (Pu)-238/beryllium (Be) sources. Each Pu-238/Be source is authorized to contain up to 352 grams of plutonium. The university based its estimate on observations of individuals doing the recommended procedure according to accepted radiation safety practices. The university had the following types of information:

- time needed to do the entire procedure (e.g., 15 minutes)

- expected dose rate received by the whole body of the individual, associated with the shielded source, and determined using measured or manufacturer-determined data (e.g., 0.02 millisievert (mSv)/h (2 millirem (mrem)/h) at 46 centimeters (18.1 inch) from the shield)

- time the hands were exposed to the shielded source (e.g., 6 minutes)

- expected dose rate received by the extremities of the individual, associated with the shielded source, and determined using measured or manufacturer-determined data on contact with the shield (e.g., 0.15 mSv/h (15 mrem/h)).

From this information, the university estimated that the individual doing each foil activation experiment could receive both of the following:

- less than 0.005 mSv (0.5 mrem) total effective dose equivalent (whole body)

- 0.015 mSv (1.5 mrem) to the hands

In accordance with 10 CFR 20.1201(a)(1)(i), the total effective dose equivalent (whole body) limit for individual adults is equal to 50 mSv (5 rem) per year. Ten percent of that value is 5 mSv (500 millirem) per year. If one of these procedures delivers 0.005 mSv (0.5 mrem), then an individual could do 1,000 of these experiments each year and remain within 10 percent of the applicable limit.

The applicable shallow does equivalent (extremities) is 500 mSv (50 rem) per year and 10 percent of that value is 50 mSv (5 rem or 5,000 millirem) per year. If one of these experiments delivers 0.015 mSv (1.5 mrem), then an individual could do 3,333 of these procedures each year and remain within 10 percent of the applicable limit.

Based on the above specific situation, no dosimetry is required if an individual does fewer than 1,000 foil activation experiments per year since the individual's radiation dose will not exceed the 10 percent of the applicable limit in accordance with the criteria in 10 CFR 20.1502(a)(1).

Guidance to Licensees

Licensees that wish to demonstrate that they are not required to provide dosimetry to their workers need to do prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may not be appropriate for all licensees. In their evaluations, licensees need to use information appropriate to the type(s) of processes they intend to use.

Table D-1 may be helpful in doing a prospective evaluation.

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they are up to date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, use a new sealed source containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to make a new evaluation.

Table D-1 Dosimetry Evaluation

Dosimetry Evaluation for_____
A. Time needed to perform the entire routine procedure, _____ minutes/60 = ____ hours
B. Expected whole body dose rate received by the individual, _____ mrem/h
C. Time the hands were exposed to the radiation source, _____ minutes/60 = ____ hours
D. Expected extremity dose rate received by the individual, determined using the measured or manufacturer-provided data for the radiation source at the typical distance from the hands to the source, _____ mrem/h
Formula: (____ # hours in Row A) x (____ mrem/h in Row B) = (____ mrem per routine procedure) x (____ # of routine procedures each year) = ___ mrem *Whole Body Dose
Formula: (____ # hours in Row C) x (____ mrem/h in Row D) = (____ mrem per routine procedure) x (____# of routine procedures each year) = ____ mrem **Extremity Dose

**Expected whole body doses less than 500 mrem does not require dosimetry.*
***Expected extremity doses less than 5,000 mrem does not require dosimetry.*

APPENDIX E
PUBLIC DOSE

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

To achieve compliance with the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1301, "Dose limits for individual members of the public," licensees must conduct operations to ensure the following:

- To the extent practical, procedures and engineering controls based upon sound radiation protection principles are put in place to achieve doses to members of the public that are as low as reasonably achievable (ALARA), in accordance with 10 CFR 20.1101(b).

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) (100 millirem (mrem)) in 1 calendar year resulting from the licensee's possession or use, or both, of licensed materials, in accordance with 10 CFR 1301(a)(1).

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any 1 hour, in accordance with 10 CFR 1301(a)(2).

- The air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1 mSv (10 mrem), in accordance with 10 CFR 1101(d).

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

Doses to Members of the Public	
INCLUDES doses from:	DOES NOT INCLUDE 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	• Sanitary sewerage discharges from licensees • Natural background radiation • Medical administration of radioactive material • Voluntary participation in medical research

Unrestricted areas, as defined in 10 CFR 20.1003, "Definitions," are areas to which access is neither limited nor controlled by the licensee. These may include offices, shops, laboratories (where licensed material is not used or stored), areas outside buildings, property, and storage areas. The licensee is not required to control access to these areas to control the exposure of workers to radiation or radioactive materials. The regulations in 10 CFR 20.1003 also define "Controlled Area," in part, as an area to which access can be limited (i.e., controlled) by the licensee for any reason (e.g., security).

Simple Method

The licensee may use any acceptable method from either 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2) for determining compliance with the annual dose limits in 10 CFR 20.1301, “Dose limits for individual members of the public.” The method described in 10 CFR 20.1302(b)(2) limits the worst-case dose to 1 mSv (0.1 rem). Under this method, the maximum concentration of radionuclides permitted at the unrestricted area boundary would result in a dose to an individual of 0.5 mSv (0.05 rem), and the dose from external radiation to an individual who is always present to receive the dose would be 0.5 mSv (0.05 rem). This method provides licensees with an easy way to demonstrate compliance without considering occupancy factors or summing of internal and external doses.

Calculation Methods

The licensee may also show compliance with 10 CFR 20.1301 by using the method described in 10 CFR 20.1302(b)(1). This method allows the licensee to take into account the length of time an individual is receiving the dose from external sources and the concentration of radionuclides in gaseous and liquid releases at the location of the individual. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation. For example, if the actual dose to an individual from external sources plus the maximum possible dose from gaseous and liquid releases is below the public dose limit, the licensee may choose to use this “theoretical” value rather than try to evaluate the exact concentration of radionuclides at the individual’s location. If the former calculation is over the limit, the licensee can show compliance by doing the more difficult calculation. If appropriate, the licensee also has the option, with prior U.S. Nuclear Regulatory Commission (NRC) approval, of adjusting the dose to take into account the physical and chemical characteristics of its effluent.

Because, in accordance with 10 CFR 20.1302(b)(1), licensees shall demonstrate by measurement or calculation that the total effective dose equivalent (TEDE) limit to the individual who is likely to receive the highest dose from the licensed operation does not exceed the annual dose limit, dose calculations need to take into account the worst case scenario in which an individual would be located at the areas of greatest internal and external exposures. The calculation could use an occupancy factor of 1, which means the individual was continuously present 24 hours a day, 365 days a year. If this result shows that the limit is not exceeded, then there is no need for further calculations. If the limit is exceeded with an occupancy factor of 1, the licensee would have to make realistic assumptions about how many hours in a 24-hour day an individual would be present at the points of highest internal and external exposures. To obtain the occupancy factor, the licensee would take the number of hours of predicted occupancy in a day and divide it by 24 hours, (e.g., 8 hours of predicted occupancy divided by 24 hours would give an occupancy factor of 8/24, or 1/3). Some licensees will require in-depth reviews of their use of radioactive material to obtain appropriate assumptions for the external (and internal) dose rates and occupancy factors.

Survey and Monitoring

In accordance with 10 CFR 60.132(c)(2), in part, effluent monitoring programs shall be designed to measure the amount and concentration of radionuclides released. Dose rates vary, depending upon the nature of the source and its condition. It may be necessary to provide continuously operating dose-rate meters, or if the source is predictable, it may be adequate to integrate dose rates over periods of time. The mode of discharge of airborne and waterborne effluents will vary from facility to facility. Airborne effluents are most frequently discharged

continuously during operations, but the operation itself may be discontinuous, whereas 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 monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of radionuclides, for example, it may be necessary to obtain information on the chemical form, concentration, and flowrate of the discharge as well as meteorological and hydrological data and other information relating to the receiving environment.

Records

The regulations in 10 CFR 20.2107, "Records of dose to individual members of the public," require licensees to maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public until the NRC terminates the license. The regulations in 10 CFR 20.2102, "Records of radiation protection programs," and 10 CFR 20.2103, "Records of surveys," contain additional requirements for maintaining records.

Records related to the radiation protection program must be appropriate to each licensed operation or activity. Therefore, the reviewer and the applicant need to become familiar with the requirements in 10 CFR Part 20, "Standards for Protection against Radiation," Subpart L, "Records," that would be relevant to the proposed or licensed facility operations.

Regulatory Guide 8.21, "Health Physics Surveys for Byproduct Material at NRC Licensed Processing and Manufacturing Plants," and Appendix I, "Radiation Safety Survey Topics," to NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 17, "Program-Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass," provide guidance on survey records required under 10 CFR 20.2103.

In general, records of radiation survey results should include the identification (make, model, and serial number) of the instrument(s) used, date of the survey, name of the surveyors, specific location where the survey was performed, items and equipment surveyed, reason for the survey, background levels, and survey results (i.e., contamination levels with appropriate units). The unique identification of the survey instrument allows it to be linked to its calibration and maintenance records. Radiation survey records should also include a description or diagram of the area surveyed, administrative action levels for controlling exposures and evaluations of the effect of measured radiation levels, and documentation of any corrective action taken. The radioactive material release records required pursuant to 10 CFR 20.2103(b)(4) should contain adequate information to allow reasonable offsite dose assessments to be made in the future. In addition, records should include information on quantities of specific radionuclides and the estimated uncertainty in activity release values, if known.

The regulations in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," require surveys of radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public (i.e., 1 millisievert per year (mSv/yr) (100 millirems per year (mrem/yr))). Furthermore, 10 CFR 20.2103(b)(4) requires that records of measurement results and calculations used to evaluate the release of radioactive effluents be maintained until the NRC terminates the license requiring the record. Radionuclide releases may be determined by effluent monitors or by effluent sampling and subsequent laboratory analysis. For those facilities that use sampling as the primary quantification method, appropriate records for laboratory counting systems should be kept (e.g., calibration, minimum detectable activity determinations, chi square, resolution). In

summary, the information maintained in the records discussed in this section should include the following, as applicable:

- type and energy of radiation involved
- physical, chemical, and isotopic description of the radioactive material (i.e., gaseous, liquid or particulate), the chemical compound and particle size distribution, if known
- total activity released and the method of determination
- time and date of the start and end of the release
- dilution volume of the effluent stream
- identification of the release point (i.e., roof vent, facility stack, drain to the sewer system)
- location, identification, and function of the facility surveyed
- time and date of surveys
- location at which measurements were made, or where liquid and air samples were obtained, either by written description or by sketches
- methods and instruments used in measurements (i.e., the method of obtaining the air or water samples)
- results of the measurements, with the quantities and in the units in which they were obtained (e.g., Sv/h, mSv, R/h, mrem/h, or count/min)
- dose or activity calculations, including occupancy factors and the assumptions made
- statement of conclusions from the survey and whether the findings comply with the regulations
- recommendations regarding remedial actions and resurvey
- name of the persons doing surveys

Note: Regulatory Guide 4.16, “Monitoring and Reporting Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Facilities,” provides guidance on the development and implementation of effluent monitoring programs described in license applications and for monitoring and reporting effluent data.

Constraint on Releases of Airborne Radioactive Materials to the Environment[1]

The regulations in 10 CFR 20.1302(b) state the following:

> A licensee shall show compliance with the annual dose limit in 10 CFR 20.1301 by (1) 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 dose limit; or (2) demonstrating that (i) the annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of Appendix B to 10 CFR Part 20 ["Standards for Protection Against Radiation"] and (ii) if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

In addition, 10 CFR 20.1101(d) states the following:

> To implement the ALARA requirements of 10 CFR 20.1101(b), and notwithstanding the requirements in 10 CFR 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees other than those subject to 10 CFR 50.34(a), such that the 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 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203 ["Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits"] and promptly take appropriate corrective action to ensure against recurrence.

[1] Further information regarding guidance on compliance with the Constraint Rule appears in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors."

APPENDIX F
SURVEYS AND MONITORING

This appendix provides applicants and licensees with information for meeting the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," Subpart F, "Surveys and Monitoring."

Ambient Radiation Level Surveys

- Dose-rate surveys and monitoring, at a minimum, should be conducted in locations where individual adults, including workers, are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits in 10 CFR 20.1201, "Occupational dose limits for adults" (see also 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose").

- Dose-rate surveys, at a minimum, should be conducted in locations where members of the public could receive a total effective dose equivalent of 1 millisievert (mSv) (100 millirem (mrem)) in a year, or the dose in any unrestricted area from external sources could exceed 0.02 mSv (2 mrem) in any 1 hour (see 10 CFR 20.1301(a)(2)).

- Dose-rate surveys should be done in a manner and frequency that is representative of the use of radioactive materials. At a minimum, these surveys should be done daily in areas of radioactive material use, where exposures to workers could reasonably occur, (e.g., generator storage or elution and dose preparation stations). Other areas where radiological conditions are not expected to change appreciably from day to day should be surveyed weekly (e.g., radioactive waste storage areas).

Contamination Surveys

The U.S. Nuclear Regulatory Commission (NRC) regulations in 10 CFR 20.1501(a)(1) require, in part, that licensees make, or cause to be made, surveys that may be necessary to comply with the regulations in 10 CFR Part 20. The regulations in 10 CFR 20.2103, "Records of surveys," require that each licensee maintain records showing the results of surveys and calibrations called for by 10 CFR 20.1501, "General," and 10 CFR 20.1906(b) (see 10 CFR 20.2103(a)). In accordance with the regulations in 10 CFR 70.25(g), licensees shall keep records of information important to the decommissioning of a facility. The regulations in 10 CFR 70.25(g)(1) require that licensees keep records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.

Licensees' contamination surveys should be sufficient to identify areas of contamination that might result in unacceptable levels of exposure 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 wipe tests, which should be analyzed using an appropriate counting instrument. Fixed contamination may be measured directly at the surface of the contamination with the appropriate instrument detector held at close proximity to the surface without direct contact. Table C-1 in appendix C to this document gives examples of appropriate instruments to be used in contamination surveys and monitoring.

Contamination surveys shall be conducted as follows:

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, or equipment

- after any spill or contamination event

- to evaluate contamination of users and the immediate work area at the end of each day when licensed material is used

- in unrestricted areas at frequencies consistent with the types and quantities of materials in use

- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

Survey Frequency

The regulation at 10 CFR 20.1501 requires that licensees make, or cause to be made, radiation surveys that may be necessary for the licensee to comply with the NRC regulations. The regulation at 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," states "(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301."

In general, surveys should be performed before the facility begins operation to establish a baseline of background radiation levels and radioactivity from natural sources. These baseline surveys should be performed under various conditions expected during routine plant operation. Surveys should be conducted during the test operation of any new process or protective equipment, during significant changes in input materials or workload, and during routine plant operations with all potentially involved persons present and carrying out their functions. Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," provides guidance on the types and frequencies of surveys that the NRC staff considers acceptable for the protection of workers in facilities licensed by the NRC to process special nuclear materials. Appendix B to Regulatory Guide 8.24 presents minimum acceptable frequencies for meeting the requirements in 10 CFR 20.1501.

Personnel should survey for contamination in locations where radioactive materials are used or handled, including areas where radioactive materials are eluted, prepared, assayed, dispensed, or packaged for transport. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. The frequency of routine surveys should be commensurate with the specific operations and nature of the work being conducted; the quantities of material being processed; and the specific protective facilities, equipment, and procedures used to protect workers from external radiation and the intake of radioactive materials.

Contamination in Unrestricted Areas

Unrestricted areas inside a facility should be surveyed and smeared periodically for surface contamination to ensure that contamination is adequately confined in the controlled areas. Licensees should use uniform methods for surveying and collecting and analyzing smear samples. When contamination is found, licensees should immediately decontaminate the unrestricted areas to background levels.

A standardized method for smear testing of a relatively uniform area should be used over extended periods of time to aid in comparing contamination at different times and places and to evaluate trends. A smear taken from an area of about 100 square centimeters (cm^2) is acceptable to indicate levels of removable contamination.

When it is not possible to return an area to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in table F-1[1]. **Note:** The contamination levels in table F-1 are not to be used for releasing facilities for unrestricted use or termination of the license pursuant to 10 CFR Part 20, Subpart E, "Radiological Criteria for License Termination." In particular, the contamination levels for most alpha emitters in table F-1 exceed the occupational dose levels in 10 CFR Part 20, Subpart E. Table F-1 levels can continue to be used for release of equipment and material from licensed material facilities during operational activities before license termination (see 63 FR 64132, November 18, 1998).

[1] Table F-1 is incorporated into draft NUREG-2212 from "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," issued April 1993 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML103620647). See also Appendix A, "Acceptable Surface Contamination Levels," to Regulatory Guide 8.24 (ML110400305). Table F-1 contamination levels can be used to determine whether equipment and materials used in facilities licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," can be released during operational activities and before license termination (see 63 FR 64132, November 18, 1998).

Table F-1 Acceptable Surface Contamination Levels

Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
U-nat, U-235, U-238, and associated decay products	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)
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, 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)
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131,I-133	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)
U-nat, U-235, U-238, and associated decay products	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)
Other alpha emitters[7]	8.33 Bq/100 cm^2 (500 dpm/100 cm^2)	25 Bq/100 cm^2 (1,500 dpm /100 cm^2)	1.67 Bq/100 cm^2 (100 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)

[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, disintegrations per minute (dpm) 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 a 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.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirads per hour (mrad/h) at 1 centimeter and 1.0 mrad/h at 1 centimeter, respectively, measured through not more than 7 milligrams per cm^2 of total absorber.

[7] Surface contamination levels were derived using one order of magnitude less than the values for beta-gamma emitters.

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Table F-1 provides the maximum acceptable residual levels for contaminated equipment that is to be released for unrestricted use. The NRC provides additional guidance on the release of equipment into unrestricted use in NUREG-1575, Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)," Appendix E, "Disposition Criteria," issued January 2009. Table F-1 values are acceptable criteria to assess contamination in facilities during operation. Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," and Regulatory Guide 8.30, "Health Physics Surveys in Uranium Recovery Facilities," provide additional guidance on surveys and contamination control in unrestricted areas.

Survey Record Requirements

The NRC's recordkeeping requirements do not specify the information that must be included in a survey record. However, the information to be recorded should be commensurate with the specific operations and nature of the activities being conducted and must be in sufficient detail to meet the requirements in 10 CFR 20.2103, "Records of surveys." In general, each survey record should include, at a minimum, the following:

- diagrams of the areas identifying specific locations surveyed
- 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 the date
- corrective actions taken for elevated levels identified and results of repeated survey

The regulations at 10 CFR 70.25(g) require that licensees keep records of surveys and information important to the decommissioning of a facility. The regulations in 10 CFR 70.25(g)(1) require that licensees keep records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.

Reports Under 10 CFR 20.2203

The regulations at 10 CFR 20.2203(a) require that for reportable events, in addition to the notification required by 10 CFR 20.2202, "Notification of incidents," each licensee must submit a written report within 30 days after learning of any of the following occurrences, as stated below in 10 CFR 20.2203(a)(1)-(4):

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in § 20.1201; or
(ii) The occupational dose limits for a minor in § 20.1207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or
(iv) The limits for an individual member of the public in § 20.1301; or
(v) Any applicable limit in the license; or
(vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(3) Levels of radiation or concentrations of radioactive material in—

(i) A restricted area in excess of any applicable limit in the license; or
(ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301); or

(4) For licensees subject to the provisions of EPA's [U.S. Environmental Protection Agency's] generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

The regulations at 10 CFR 20.2203(b)(1) require that a report describe the extent of exposure of individuals to radiation and radioactive material and include the following, as appropriate:

- estimates of each individual's dose
- the levels of radiation and concentrations of radioactive material involved
- the cause of the elevated exposures, dose rates, or concentrations
- corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA [as-low-as-is-reasonably achievable] constraints, generally applicable environmental standards, and associated license conditions

The regulations in 10 CFR 20.2203(b)(2) require that the report include the name, social security account number, and date of birth for each occupationally overexposed individual (or declared pregnant woman).

Air Sampling

Air sampling 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 material

Regulatory Guide 8.25, “Air Sampling in the Workplace,” and NUREG-1400, “Air Sampling in the Workplace,” contain further guidance on air sampling.

Air Effluent Monitoring

Airborne radioactive effluents should be monitored at the release points (e.g., stack) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration of equipment and checks of filtration to ensure their reliability.

Regulatory Guide 4.20, “Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,” issued December 1996, and Regulatory Guide 4.20, provide guidance on methods acceptable (calculation or COMPLY code) to the U.S. Nuclear Regulatory Commission (NRC) for compliance with the constraint on air emissions to the environment.

Effluent monitoring systems should be designed in accordance with American National Standards Institute/Health Physics Society (ANSI/HPS) 13.1-2011, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” and ANSI N42.18-2004, “Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents.”

Sanitary Sewerage 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, “Dose limits for individual members of the public,” and 10 CFR 20.2003, “Disposal by release into sanitary sewage,” respectively.

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 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:

- presence of unusually high levels of facial or nasal contamination

- 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

References

American National Standards Institute (ANSI)/Health Physics Society, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," ANSI/HPS N13.1-2011, March 30, 2011.

ANSI, "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents," ANSI N42.18-2004, 2004.

Code of Federal Regulations, Chapter I, Title 10 (10 CFR), "Energy," 20.1201, "Occupational dose limits for adults."

10 CFR 20.1301, "Dose limits for individual members of the public."

10 CFR 20.1302, "Compliance with dose limits for individual members of the public."

10 CFR 20.1501, "General."

10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose."

10 CFR 20.1906, "Procedures for receiving and opening packages."

10 CFR 20.2103, "Records of surveys."

10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning."

U.S. Nuclear Regulatory Commission (NRC), *Federal Register* Notice, "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," 63 FR 64132, November 18, 1998.

NRC, "Air Sampling in the Workplace," NUREG-1400.

NRC, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)," NUREG 1575, Supplement 1.

NRC, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," Regulatory Guide 4.20.

NRC, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," Regulatory Guide 8.24.

NRC, "Air Sampling in the Workplace," Regulatory Guide 8.25.

NRC, "Health Physics Surveys in Uranium Recovery Facilities," Regulatory Guide 8.30.

APPENDIX G
SAFETY CULTURE

Individuals and organizations undertaking regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to U.S. Nuclear Regulatory Commission (NRC) authority.

"Nuclear safety culture" is defined in the NRC's safety culture policy statement (76 FR 34773; June 14, 2011) as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety).

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, the NRC's safety culture policy statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, in the handling of special nuclear material, licensees should have a policy for reporting safety concerns to ensure safety culture is maintained. When safety has become embodied in their culture, the staff should report a safety concern without any fear of retaliation.

The NRC's safety culture policy statement can be found at https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html. More information on NRC activities relating to safety culture appears at https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html.

APPENDIX H
MAJOR U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

The following are the major areas in the U.S. Department of Transportation regulations that are most relevant for the transportation of licensed material shipped as Type A[1] quantities:

- Carriage by Public Highway—General Information and Regulations, Subpart A, Title 49 of the *Code of Federal Regulations* (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.

- 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.

- Hazardous Materials Table, 49 CFR 172.101, "Purpose and use of hazardous materials table," Appendix A, "List of Hazardous Substances and Reportable Quantities," Table 2: "Radionuclides."

- 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.

- 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 packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging.

- 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.

- Radiation Protection Program for Shippers and Carriers, Subpart I, 49 CFR 172.801, 49 CFR 172.803, 49 CFR 172.805: Applicability of the radiation protection program, radiation protection program, record keeping, and notifications.

- Shipping Papers, 49 CFR 172.200–204: General entries, description, additional description requirements, shipper's certification.

- Training, Subpart H, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements.

[1] Type A quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material, or A2, for normal form radioactive material, where A1 and A2 are given in Table A-1 of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," or may be determined by procedures described in Appendix A, "Determination of A1 and A2," to 10 CFR Part 71.

- 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 before each shipment, approval of special form radioactive materials.

APPENDIX I
NUCLEAR CRITICALITY GLOSSARY

This glossary defines technical and industry terms that are used in Chapter 3 of this document.

Abnormal condition. An event or condition not intended as a desirable or regularly occurring condition in the facility or process design but which is anticipated as a contingency in criticality safety evaluations. A condition that is reached by exceeding the safety limit(s) of one or more controlled parameters.

Administrative control. Human actions, whether required or prohibited, relied on to prevent or mitigate a specific accident sequence or to maintain subcriticality, and established in formal plant procedures.

Area(s) of applicability. The range of physical parameters (e.g., isotopic abundance, moderation, neutron energy, absorbers) characterizing a fissile material system over which a given calculational method has been validated; the range of such parameters covered by the chosen benchmark experiments and for which a bias has been determined.

Benchmark. A critical experiment that is widely accepted and whose physical characteristics and their uncertainties have been well characterized, so that it is suitable for validation.

Bias. The numerical difference between the calculated and experimental values of k_{eff} for a set of benchmark experiments covering a particular area of applicability (often expressed as a function of system parameters).

Concurrent. In the context of double contingency, two changes in process conditions are concurrent if the effect of the first change persists until the second change occurs. This does not mean simultaneous (where both upsets occur at the same time) but rather that the system is affected by both changes during some time interval.

Consequence. (1) Occurrence of an accidental criticality, (2) the energy released in an accidental criticality, normally expressed in terms of the number of fissions or dose to workers.

Contingency. In the context of double contingency, a change in process conditions or loss of a criticality control that could result in one or more parameters exceeding their safety limits.

Control. Structures, systems, components, devices, equipment, or human actions relied on to prevent or mitigate an accident sequence, or to maintain subcriticality by limiting a parameter within specified limits and established and identified as such in formal plant safety basis documentation.

Control system. A set of controls that function together to prevent or mitigate one or more accident sequences, or to maintain subcriticality by limiting one or more parameters within specified limits.

Controlled parameter. A parameter of a system that is maintained within a specified range to ensure subcriticality.

Credible abnormal condition. As used in meeting Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61(d), one of the abnormal conditions that must be considered in the context of demonstrating compliance with the double contingency principle. Conditions resulting from credible single failures and related sequences of events up to those that must be considered in meeting the double contingency principle (see NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," Appendix 5-A, for more information).

Critical. (1) Having an actual k_{eff} value greater than 1; (2) having a calculated k_{eff} value greater than the upper subcritical limit.

Critical mass.[1] For this document's purpose, a critical mass of special nuclear material (SNM) means uranium enriched in the isotope uranium (U)-235 in quantities exceeding 350 grams of contained U-235; or U-233 in quantities exceeding 200 grams; or plutonium in quantities exceeding 200 grams; or any combination of them in accordance with the following formula: (grams contained U-235/350) + (grams U-233)/200) + (grams plutonium (Pu)/200) > 1.

Criticality control. A control used to ensure subcriticality.

Criticality safety evaluation. A structured analysis demonstrating criticality safety for a given process, including a demonstration that processes will be subcritical under normal and credible abnormal conditions, and the specification of controls and limits to achieve that goal (also often referred to, for example, as a *nuclear criticality safety evaluation*, *analysis*, or *assessment*).

Degraded. A control, control system, or controlled parameter is considered to be degraded when the parameter is maintained within its safety limit but has reduced reliability and availability, such that the possibility of those limits being exceeded is no longer unlikely.

Double contingency principle. Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Double contingency protection. The condition of requiring at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Engineered control. Structures, systems, components, devices, or equipment relied on to prevent or mitigate a specific accident sequence or to maintain subcriticality and established in formal design documents.

Event. (1) A change in process conditions that has the potential to adversely affect safety; (2) one of several occurrences that constitute an accident sequence.

Favorable geometry. Characteristic of structures, systems, devices, or equipment such that fissile material maintained within specified dimensions will be subcritical under the most reactive credible conditions (defined for a given isotopic composition and physicochemical form).

[1] As used in 10 CFR Part 70, a critical mass of SNM means SNM in a quantity exceeding 700 grams of contained ^{235}U; 520 grams of ^{233}U; 450 grams of plutonium; 1,500 grams of contained ^{235}U, if no uranium enriched to more than 4 percent by weight of ^{235}U is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

Independent. In the context of double contingency, two changes in process conditions are independent if the occurrence of one does not cause, or affect the probability of occurrence of, the other; if the probability that both occur is independent of the order in which they occur; and if there are no identifiable common-mode failures that can lead to criticality.

Isolated. (1) The condition whereby the flow of matter and energy between a system and surrounding systems can be neglected for the purpose of doing a safety analysis; (2) being separated by a sufficient distance from other systems or materials such that their presence has a negligible effect on the system's k_{eff}.

Lost. A control, control system, or controlled parameter is considered to be lost when the measures that maintain the parameters within their safety limits cease to function as designed, or cannot be verified to function as designed, whether or not the affected parameters actually exceed their safety limits.

Management measures. Measures employed by plant management to ensure continued safe operation of nuclear processes and continued effective operation of the nuclear criticality safety (NCS) program, such as operator training, NCS engineer qualification, audits and assessments, and administrative and operating procedures.

Margin of safety. The difference between the actual value of a parameter and the value of the parameter at which the system is expected to be critical (taking bias and bias uncertainty into account).

Margin of subcriticality. (1) The difference between the actual value of k_{eff} and the value at which the system is expected to be critical (taking bias and bias uncertainty into account); (2) the difference between the calculated value of k_{eff} (including uncertainties) and the value at which the system is expected to be critical (taking bias and bias uncertainty into account), plus any margin in k_{eff} resulting from conservative modeling of system parameters.

Minimum margin of subcriticality. Margin in k_{eff} beyond the bias and uncertainty in the bias, to allow for any unknown or difficult to quantify uncertainties in calculating k_{eff} (frequently referred to as the *arbitrary margin* or *administrative margin*).

Normal condition. A condition specifically anticipated or allowed for as part of the normal operation of the facility. A condition in which all controlled parameters are within their safety limits.

Operating limit. The value of a controlled parameter to which actual operations are restricted, with sufficient margin to ensure that exceeding the safety limit is unlikely.

Optimum. The value of a parameter that produces the highest k_{eff}.

Parameter. The measurable or observable characteristic of a system that affects the value of k_{eff}. The parameters normally are mass, geometry, density, enrichment/isotopics, reflection, moderation, concentration, interaction, absorption, volume, heterogeneity, physicochemical form, and process variables.

Process condition. In the context of double contingency, the set of all characteristics or attributes of a process important to safety (a change in the value of a parameter, or loss or degradation of a control affecting the ability to maintain a parameter, for example).

Reactivity. Loosely used synonymously with k_{eff}. Used most frequently in "most reactive credible," to mean the physical conditions that produce the highest credible value of $k_{eff.}$

Research and development. (1) Theoretical analysis, exploration, or experimentation, or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Safe mass. The quantity of fissile material that is safely subcritical under the most reactive credible conditions (defined for a given isotopic composition and physicochemical form), including allowance for over batching.

Safe process condition. The defined range of acceptable values of one or more controlled parameters and other process conditions.

Safety control. The same as "control."

Safety limit. The value of a controlled parameter established by a criticality safety evaluation to which the process will be controlled. This can be equal to the subcritical limit but can include additional margin due to uncertainty and variability in the process (also referred to as the "analytical limit").

Safety margin. The same as "margin of safety."

Sealed source. Any SNM encased in a capsule designed to prevent SNM leakage or escape.

Special nuclear material. (1) Plutonium, U-233, uranium enriched in the isotope U-233 or in the isotope U-235, and any other material which the Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be SNM but does not include source material, or (2) any material artificially enriched by any of the foregoing but does not include source material.

Subcritical. Demonstrated not to be critical; having a value of k_{eff} not greater than the upper subcritical limit.

Subcritical limit. (1) The bounding value of a controlled parameter that has been demonstrated to maintain a system subcritical in plant criticality safety evaluations; (2) the upper subcritical limit.

Subcritical margin. The same as "margin of subcriticality."

System. Discrete part of a fissile material operation that can be separated from other systems for the purpose of doing a safety analysis and that is the subject of a criticality safety evaluation.

Unlikely. In the context of double contingency, (1) expected to occur rarely, if at all, during the lifetime of a facility, or (2) judged to have a probability of occurrence less than 10^{-2} per year per event.

Upper subcritical limit. The maximum value of k_{eff} that is considered to be subcritical with an acceptable degree of confidence (taking bias and bias uncertainty into account and including a minimum margin of subcriticality).

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This Standard Review Plan contains information intended to provide program-specific guidance for Title 10 of the Code of Federal Regulations (10 CFR) Part 70, “Domestic Licensing of Special Nuclear Material,” applications for materials licenses of critical mass of special nuclear materials (SNM) that are not subject to the requirements in 10 CFR Part 70, Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material” (also known as greater than critical mass applicants or licensees). Specifically, NUREG-2212 describes the types of information required under 10 CFR 70.22, “Contents of applications,” to apply for a new (or renew an existing) materials license for possession and use of special nuclear material in quantities exceeding the thresholds for critical mass quantities of SNM specified in 10 CFR 150.11, “Critical mass,” but that, due to the nature of their activities, are not subject to the requirements in 10 CFR Part 70, Subpart H.

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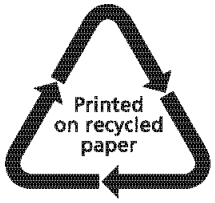

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