U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUREG-1556
Volume 22

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Possession Licenses for Fusion Machines

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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Draft Report for Comment

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Office of Nuclear Material Safety and Safeguards

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number NUREG-1556, Volume 22 in your comments and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

Addresses: You may submit comments by any one of the following methods. Please include Docket ID NRC-2023-0071 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC website and on the Federal rulemaking website http://www.regulations.gov.

Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2023-0071.

Email comments to: Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

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For any questions about the material in this report, please contact: Allyce Bolger, Intergovernmental Liaison Project Manager, at 301-415-0855 or by e-mail at Allyce.Bolger@nrc.gov.

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for fusion machine possession licenses. In particular, the report describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License." This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

Paperwork Reduction Act

This NUREG contains voluntary guidance for the mandatory information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0001; 3150-0008; 3150-0009; 3150-0014; 3150-0017; 3150-0020; 3150-0021; 3150-0035; 3150-0044; 3150-0120; 3150-0123; and 3150-0214. Send comments regarding this information collection to the Information Services Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollects.Resource@nrc.gov, and to the OMB Office of Information and Regulatory Affairs (3150-0001; 3150-0008; 3150-0009; 3150-0014; 3150-0017; 3150-0020; 3150-0021; 3150-0035; 3150-0044; 3150-0120; 3150-0123; and 3150-0214) Attention: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503.

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FOREWORD

The NRC's NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, NRC and Agreement State license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator
22	Program-Specific Guidance About Possession Licenses for Fusion Machines

The current document, NUREG–1556, Volume 22, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Fusion Machines," is intended for use by applicants, licensees, and NRC staff.

This report takes a risk-informed, performance-based, and technology-inclusive approach to licensing fusion machines. A team composed of staff from NRC Headquarters, NRC Regional Offices, and Agreement States prepared this document, drawing on the experience with licensed facilities conducting fusion research and development, staff's collective experience with radiation safety and environmental protection in general and specifically with known fusion machines currently under development.

NUREG–1556, Volume 22, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable if they include a basis for the staff to make the determinations needed to issue or renew a license.

The comments received during the public comment period for NUREG–1556, Volume 22, were summarized and addressed in a document that can be located on the NRC's Agencywide Documents and Management System (ADAMS) under [TBD]. Access to ADAMS is available on the public website at: https://www.nrc.gov/reading-rm/adams.html. The comments received by NRC included editorial corrections and comments on a variety of issues, including [TBD].

Dafna Silberfeld, Director
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ACKNOWLEDGMENTS

The NRC's Office of Nuclear Material Safety and Safeguards thanks the individuals listed below for assisting in the preparation of the report. All participants provided valuable insights, observations, and recommendations.

The core team for the fusion machine rulemaking would like to thank the staff in the regional offices of the NRC and all of the States who provided comments and technical information that assisted in the development of this report.

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ABBREVIATIONS

ACI	American Concrete Institute
ADAMS	Agencywide Documents Access Management System
AISC	American Institute of Steel Construction
ALI	annual limit on intake
ANSI	American National Standards Institute
AU	authorized user
bkg	background
Bq	Becquerel
CFR	*Code of Federal Regulations*
Ci	Curie
cm	centimeter
cm^2	square centimeter
cpm	counts per minute
CSI	Criticality Safety Index
DAC	derived air concentration
DFP	decommissioning funding plan
DIS	decay in storage
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
FA	financial assurance
FR	*Federal Register*
FRN	*Federal Register* notice
g	gram
GBq	gigabecquerel
h	hour
H-3	tritium
HAZMAT	hazardous material
HRCQ	highway route-controlled quantity
HT	tritiated gas
HTO	tritiated water
IAEA	International Atomic Energy Agency
IATA	International Air Transportation Association
ICAO	International Civil Aviation Organization
IMO	International Maritime Organization
IN	information notice
kBq	kilobecquerel
kg	kilogram
L/C	license condition
LLW	low-level radioactive waste
LSA	low specific activity
LSC	liquid scintillation counting
MARSAME	Multi-Agency Radiation Survey and Assessment of Materials and Equipment
MARSSIM	Multi-Agency Radiation Survey and Sited Investigation Manual
MBq	megabecquerel
mCi	millicurie
mGy	milligray
MDA	minimum detectable activity

mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OMB	Office of Management and Budget
OSL	optically stimulated luminescence
PHMSA	U.S. Pipeline and Hazardous Materials Safety Administration
PII	personally identifiable information
QA	quality assurance
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RQ	reportable quantity
R&D	research and development
RSL	radiation surface level
RSO	radiation safety officer
SA	State Agreement
SCO	surface contaminated objects
SI	International System of Units (abbreviated SI from the French, Le Système internationale d'unités)
SNM	special nuclear material
SSD	sealed source and device
std	standard
Sv	Sievert
TBq	terabecquerel
TEDE	total effective dose equivalent
TI	Transportation Index
TLD	thermoluminescent dosimeter
U.S.C.	United States Code
µC	microcoulomb
µCi	microcurie
µGy	microgray
UN	United Nations
WAC	waste acceptance criteria

1 PURPOSE OF REPORT

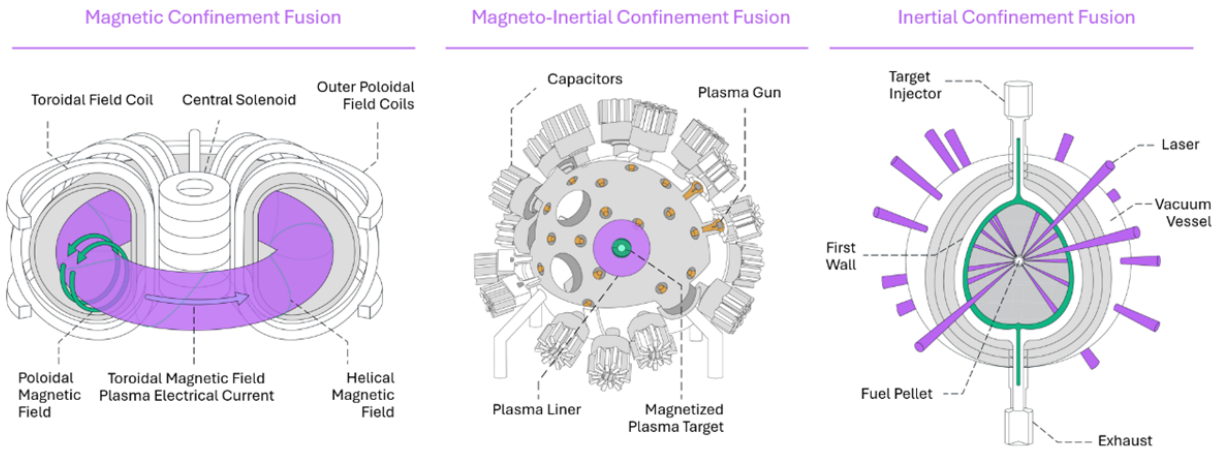
This report provides guidance to applicants applying for a byproduct material possession license for fusion machines under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and it provides the NRC staff with criteria for evaluating such applications to ensure the protection of public health and safety and the environment. This NUREG is not intended to address the technical development or the commercial aspects of manufacturing, distributing, and servicing of fusion machines. The focus of this NUREG is to ensure the radioactive material used in research and development, or commercial fusion machines is controlled, confined, and shielded to ensure adequate protection of public health and safety, and the environment.

The Accelerating Deployment of Versatile, Advance Nuclear for Clean Energy (ADVANCE) Act of 2024 amended the Atomic Energy Act of 1954, as amended (AEA), by adding a new definition for "fusion machine" and amending the definition of "byproduct material." The regulations in 10 CFR Parts 20 and 30 were amended to reflect these changes. "Fusion machine" means "a machine that is capable of—(1) transforming atomic nuclei, through fusion processes, into different elements, isotopes, or other particles; and (2) directly capturing and using the resultant products, including particles, heat, or other electromagnetic radiation." The term "fusion machine" is also incorporated in the definition of byproduct material in 11e(3)(ii) of the AEA as follows: "any material that—(A) has been made radioactive by use of a particle accelerator, including by use of a fusion machine; and (B) if made radioactive by use of a particle accelerator that is not a fusion machine, is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity."

This NUREG identifies the information needed to complete NRC Form 313, "Application for Material License," for the possession and use of byproduct material. If the applicant requires any other type of license, such as a broad-scope license, other applicable guidance documents in this NUREG–1556 series are available at https://www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr1556/. As a guidance document intended to assist a wide variety of fusion machine design applicants, this NUREG contains a considerable amount of information about how licensees may choose to implement their programs to meet NRC regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the regulations in 10 CFR. This NUREG is intended to cover a spectrum of fusion machine designs and fuels, and as such, not all sections may be applicable to a particular applicant. For example, designs that will not have a tritium breeding blanket will not need to provide information regarding that component. This NUREG provides detailed guidance on what information may need to be submitted in an application to satisfy NRC requirements. However, the information contained within the NUREG is also not an exhaustive list of what information may be necessary for a fusion machine applicant to demonstrate compliance with NRC requirements. NRC encourages early discussions with staff to facilitate support the applicant's submittal of a complete application, for a smoother licensing review process.

This report addresses the variety of radiation safety issues associated with fusion machines of various designs of which there are three primary regimes: magnetic confinement, inertial confinement, and magneto-inertial confinement. Magnetic confinement fusion uses strong

magnetic fields to confine, shape, and heat a long-lived plasma in which the fusion reaction takes place. Conversely, inertial confinement uses powerful lasers to compress a target comprised of deuterium and tritium to initiate a fusion reaction that releases a burst of energy. Lastly, magneto-inertial confinement uses a combination of the other two regimes to produce and contain short-lived plasmas.



Graphic courtesy of Oxford Sigma

Figure 1-1 Primary Fusion Machine Designs

2 AGREEMENT STATES

2.1 Jurisdiction Determination

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source, and special nuclear material (SNM) in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive federal jurisdiction within an Agreement State, NRC continues to be the regulatory authority.

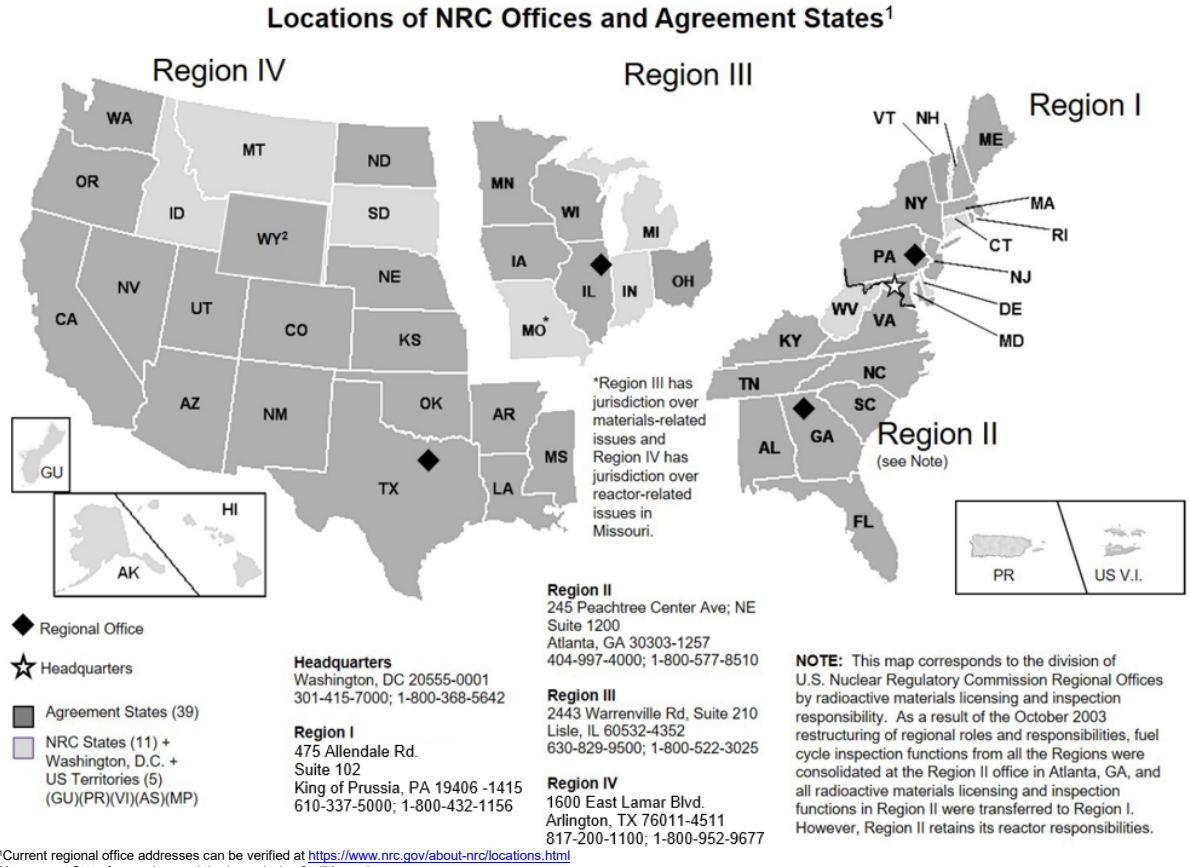


Figure 2-1 U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian Tribes.[1] The NRC has regulatory authority over land determined to be exclusive federal jurisdiction, while the Agreement State may have jurisdiction over nonexclusive federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement (SA) series, SA-500, "Jurisdiction Determination," which is available at https://www.nrc.gov/reading-rm/doc-collections/nmss-procedures/state-agreement.html.

Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2-1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency, regardless of location [except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.12, "Persons using byproduct material under certain U.S. Department of Energy and U.S. Nuclear Regulatory Commission contracts"]	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory, or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-Federal entity on federally recognized Indian Tribal land	NRC*
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State	Agreement State
Non-Federal entity in Agreement State	Agreement State**
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State**
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC

[1] For the purposes of this guidance, an "Indian Tribe" is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe, pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at www.bia.gov.

Table 2-1 Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State conducting industrial radiography at a Part 50 or 52 reactor site, including construction, preoperational, and operational phases	Agreement State

*The NRC can exercise jurisdiction as the regulatory authority on Tribal land of a federally recognized Indian Tribe. Section 274b. agreements do not give States the authority to regulate nuclear material in these areas. However, there may be States that exercise regulatory authority over these areas, based on treaties or agreements with specific Tribes. Companies owned or operated by federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on Tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the Tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

**Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of SNM. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific Atomic Energy Act radioactive materials they intend to possess or use.

A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available at https://www.nrc.gov/agreement-states.html#agreement-states.

2.2 Reciprocal Recognition of Specific Licenses

Performing licensed activities in other jurisdictions is possible through reciprocal recognition of specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit NRC licensees to perform licensed activities under circumstances when an Agreement State is the regulatory authority (see Section 2.1 of this NUREG). NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority, as indicated in Section 2.1 of this NUREG. To ensure compliance with an Agreement State's reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State radiation control program office well in advance of the scheduled use of licensed material.

Agreement State licensees that wish to conduct licensed activities in areas under NRC jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate NRC regional office for the Agreement State that issued their license. Failure to file for reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can result in NRC enforcement action, which may include civil penalties. The reciprocity filing must be renewed annually.

Specific guidance regarding NRC licensees filing for reciprocity in Agreement States and Agreement State licensees filing for reciprocity with the NRC or another Agreement State are provided in NUREG–1556, Volume 19, "Consolidated Guidance About Materials Licenses: Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)."

3 MANAGEMENT RESPONSIBILITY

The NRC recognizes that effective management of radiation safety programs is vital to achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely, and that effective management will result in increased safety, security, and compliance.

> "Management," as used in this volume, refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

3.1 Commitments and Responsibilities

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.32(c), each application must be signed by the applicant or licensee or a person duly authorized to act for and on the behalf of the applicant or licensee. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the applicant's or licensee's commitments and responsibilities for the following:

- radiation safety, security, and control of radioactive materials and compliance with regulations,
- completeness and accuracy of the radiation safety records, and all information provided to the NRC (10 CFR 30.9, "Completeness and accuracy of information"),
- knowledge about the contents of the license and application,
- compliance with current NRC and U.S. Department of Transportation regulations, the licensee's operating, emergency, and security procedures, and NRC license commitments,
- commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and compliance with regulations is maintained,
- commitment to report defects, noncompliances, or reportable events, in accordance with regulations,
- selection and assignment of a qualified individual to serve as the radiation safety officer (RSO) for licensed activities and confirmation that the RSO has independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities,
- commitment to ensure that radiation workers have adequate training,

- prevention of discrimination against employees engaged in protected activities (10 CFR 30.7, "Employee protection"),

- commitment to provide information to employees about the employee protection and deliberate misconduct provisions in 10 CFR 30.7, "Employee protection," and 10 CFR 30.10, "Deliberate misconduct,"

- notification of the appropriate NRC regional administrator, in writing, immediately following the filing of a petition for voluntary or involuntary bankruptcy [10 CFR 30.34(h)], as discussed further in Section 8.2.1, "Notification of Bankruptcy Proceedings," of this NUREG, and

- commitment to obtain NRC's prior written consent before transferring control of the license (see Section 9.1, "Timely Notification of Transfer of Control," of this NUREG).

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the current version of the NRC's Enforcement Policy and Inspection Procedures, available in the NRC's online library at https://www.nrc.gov/reading-rm.html.

3.2 Safety Culture

Individuals and organizations performing 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 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 a 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. Safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, performance of maintenance on irradiated components, if done improperly, can cause high doses to extremities and high contamination levels. An individual performing this task must review and prepare to conduct the task carefully beforehand, observing ambient radiation and contamination levels and any interferences, such as cables and other components that are energized, that could pose a non-radiological hazard.

The need to evaluate the safety of existing conditions, survey, if necessary, review the procedure, and reposition as many interferences as possible before attempting to remove the irradiated component may correspond with the safety culture trait specified in Table 3-1 as "Work Processes" (the process of planning and controlling work activities is implemented so that safety is maintained). Licensees should be aware that this is just an example, however, and should consider reviewing their radiation safety programs to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions. More information on NRC activities relating to safety culture can be found at https://www.nrc.gov/about-nrc/safety-culture.html.

Table 3-1 Traits of a Positive Safety Culture

Leadership Safety Values and Actions	**Problem Identification and Resolution**	**Personal Accountability**
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues with a potential impact on safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety -conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities to identify discrepancies that might result in error or inappropriate action.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up--to--date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (10 CFR) contain NRC regulations applicable to possession, production, or use of radioactive material in a fusion machine. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

- 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 30 "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 32 "Specific Domestic licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- 10 CFR Part 40 "Domestic Licensing of Source Material"
- 10 CFR Part 51 "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 10 CFR Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste"
- 10 CFR Part 71 "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 170 "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, As Amended"
- 10 CFR Part 171 "Annual Fees for Reactor 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"

The current versions of these parts can be found under the "Basic References" link at the NRC's online library at https://www.nrc.gov/reading-rm/doc-collections/cfr/ or at https://www.ecfr.gov/current/title-10/chapter-I. Regulations are periodically amended, and the NRC (as well as all other federal agencies) is required to publish notice of such amendments in the *Federal Register* (https://www.federalregister.gov/).

5 HOW TO FILE

5.1 Application Preparation

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313, Items 1 through 4, 12, and 13, on the form itself.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages or use Appendix A of this NUREG.
- Provide sufficient detail as requested in this NUREG for the NRC to determine that the equipment, facilities, training, experience, and radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- Other than NRC Form 313 and Appendix A pages, as applicable, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information. If submitted, proprietary, personal privacy, security-related, and other sensitive information should be clearly identified according to Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding" (see Chapter 6, "Identifying and Protecting Sensitive Information," of this NUREG).

5.2 Where to File

Applicants wishing to possess or use licensed material in any state, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC's four regional offices and their respective areas for licensing purposes and the Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites or federally recognized Indian Tribal lands in Agreement States, applicants must first determine the jurisdictional status of the land to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, "Agreement States," of this NUREG for additional information.

5.3 Application Submission

Electronic applications are preferrable and can be submitted by following the instructions on NRC Form 313.

If an applicant chooses to submit applications by paper; to ensure a smooth transfer to an electronic format, applicants should do the following:

- submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner,
- choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura,
- use an 11-point or larger font,
- avoid stylized characters, such as script or italics,
- ensure that the print is clear and sharp, and
- ensure that there is high contrast between the ink and paper (black ink on white paper is best).

Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c) (see Section 8.13, "Certification," of this NUREG).

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in the NRC Public Document Room and electronically at the NRC Library. For more information on the NRC Library, visit www.nrc.gov.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked as indicated below, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, before the information is submitted to the NRC. Key examples are as follows:

- 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. Appendix B of this NUREG provides a checklist for requests for withholding information from public disclosure.

- Personally Identifiable Information: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice (IN) 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" and "INs," respectively at https://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 that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive, unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities and associated security measures are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain sensitive security-related information and the top of every page of a document that contains such information should be clearly marked: "Security-Related Information—Withhold under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see RIS 2005-31, Rev. 1, "Control of Security-Related Sensitive Unclassified Non-Safeguards 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 Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates is available at https://www.nrc.gov/reading-rm/sensitive-info.html.

The regulations list various forms of information that can be protected from public disclosure. These include:

- trade secrets and commercial or financial information,
- interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC,
- certain records or information compiled for law enforcement purposes,
- geological and geophysical information and data, including maps or information concerning wells, and
- personnel, medical, or other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure. This regulation is available electronically on the Commission's Web site at https://www.nrc.gov/reading-rm/doc-collections/cfr.

Except for personal privacy information, which is not subject to the affidavit requirement, if NRC determines that the application or affidavit is deficient (i.e., does not contain the required information as outlined in 10 CFR 2.390), the applicant will be notified that additional information is needed and that the review will continue when the required information is received.

If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to withdraw the information or application, NRC will notify the applicant, in writing, that the request for withholding has been denied and that NRC will disregard any references concerning the proprietary status of the information.

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified in writing that NRC plans to honor the request. Management Directive 12.6 is available electronically on the NRC Web site at https://www.nrc.gov/reading-rm/doc-collections/management-directives/.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

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7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (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 NRC will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review of an application has begun, no fees will be refunded. Application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "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." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities." Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide proper certification of this status to the NRC each year along with its annual fee payment.

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC at Fees.Resource@nrc.gov.

8 CONTENTS OF AN APPLICATION

The following information applies to the indicated items on NRC Form 313.

All items in the application should be completed in enough detail for the NRC to determine whether the proposed equipment, facilities, training and experience, and radiation safety and security program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should be given, when developing the application, to the concepts of keeping exposures consistent with 10 CFR Part 20 minimizing contamination, and maintaining control of radioactive materials.

The focus of this NUREG is to control, confine, and shield radioactive material in a fusion machine. Since this guide will apply to a wide range of fusion machine designs, some radioactive material, components, and safety systems discussed in this guide may not be applicable (e.g. not all applicants will have a breeder blanket). The applicant only needs to provide information applicable to radioactive material present used, stored, or produced as part of their fusion operations.

Title 10 of the *Code of Federal Regulations* Part 20 contains requirements for radiation protection standards, dose management and minimization of contamination.

The application should include information on how the licensee will implement the security requirements in 10 CFR 20.1801, “Security of stored material,” and 10 CFR 20.1802, “Control of material not in storage.”

Refer to Appendix C of this NUREG for guidance regarding the definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants and licensees before the NRC has concluded its environmental review of the proposed licensing action, if required. The issuance of a license for a fusion machine will require an environmental review in accordance with 10 CFR 51.60(b)(viii) unless the fusion machine is strictly used for research and development or educational purposes and meets the criteria for a categorical exclusion. Additional information on the development of an environmental review for a fusion machine can be found in Section 8.5.3 of this NUREG.

All supplemental information should be provided as an attachment to the applicant’s signed and dated NRC Form 313. Appendix A of this NUREG are provided to help applicants in submitting information required in Items 5 through 11 of NRC Form 313.

Several appendices in this report present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on NRC Form 313 appear under “Response from Applicant” in this guide.

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 inspection.

8.1 Item 1: License Action Type

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

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

Check Box A for a new license request. Note that a pre-licensing site visit may be required prior to issuance of the license.

Check Box B for an amendment to an existing license and provide the license number.

Check Box C for a renewal of an existing license and provide the license number.

See "License Amendments and Renewals" in Chapter 9 of this NUREG.

8.2 Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over the production and handling of the radioactive material. A division or department within a legal entity may not be a licensee. 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. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address.

Notify the NRC of changes in the mailing address, bankruptcy proceedings, or transfers of control. These changes do not require a fee.

8.2.1 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

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

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

bankruptcy actions are completed. The NRC may request that the U.S. Department of Justice represent the NRC's interests in the bankruptcy proceeding.

Response from Applicant: No response is required, licensees must immediately notify the NRC, in writing, following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

Reference:

- NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"

8.2.2 Timely Notification of Transfers of Control

Regulation: 10 CFR 30.34(b).

Criteria: Licensees must provide all supporting information and obtain the NRC's *prior, written consent* before transferring control of the license, also referred to as a "change of ownership" or "transferring the license."

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

- radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses,
- materials are properly handled and secured,
- persons using these materials are capable, competent, and committed to implementing appropriate radiological controls,
- a clear chain of custody is established to identify who is responsible for disposition of records and licensed material,
- public health and safety are not compromised by the use of such materials,
- adequate financial assurance (FA) is provided for compliance with the applicable NRC requirements, if required, and
- the transferee has the financial resources to decommission the license, if necessary.

Refer to NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses" for more information about transfer of control.

Response from Applicant: No response is required.

Reference:

- NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"
- Regulatory Issue Summary (RIS) 2014-08, Revision 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licensees," dated May 5, 2016

8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be produced, used, handled, or stored. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable. In addition, applicants are encouraged to provide global positioning system coordinate, as appropriate, for each facility where licensed materials will be stored or used.

If licensed material is to be possessed or used at more than one location, give the specific address of each location. Applicants for a broad-scope license need not identify each facility at a particular address where licensed material will be possessed or used. For example, broad-scope applicants can specify that licensed material will be possessed or used on the manufacturing campus of ABC Corporation located on Presidential Avenue in Anytown, State.

Applicants should identify all facilities designed or established for special uses (e.g., interim or long-term waste storage facilities and tritium handling and storage). A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive materials, the applicant should mark these documents as "Security-Related Information—Withhold under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," of this NUREG for more details.

Response from Applicant: Provide the specific address of each location where licensed material will be used, produced, handle, or stored.

8.4 Item 4: Person To Be Contacted About This Application

Identify the individual who can answer questions about the application and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses. This individual, usually the RSO, will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, their position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if their telephone number, cell phone number, or

e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

> As indicated on NRC Form 313, Items 5 through 11 should be submitted on separate pages. Applicants may use Appendix A of this NUREG for this purpose and should note that using the suggested wording of responses and committing to use the model procedures in this NUREG will facilitate the NRC's review.

8.5 Item 5: Radioactive Material

8.5.1 Unsealed and Sealed Byproduct Material

Regulations: 10 CFR 30.4, 10 CFR 30.6, 10 CFR 30.9, 10 CFR 30.11, 10 CFR 30.32, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 30.36, 10 CFR 30.37, 10 CFR 30.38, 10 CFR 32.210, 10 CFR Part 51.

Criteria: A specific license is required, describing and authorizing the production, use, and handling of radioactive materials. Applicants must submit information specifying each radionuclide that will be used and produced, the form of the radionuclide(s), and the maximum activity to be possessed at any one time. The list of radionuclides should also include incidentally activated radionuclides that are produced during fusion machine operations.

Discussion: Licensees will need to determine the amount of all licensed materials that will be possessed and included on the license as maximum authorized possession limits. The quantity of unsealed radioactive material used and produced by the fusion machine is important for ensuring compliance with FA consideration, emergency preparedness planning, and security requirements in accordance with 10 CFR 20.1802. For example, licensees are required by 10 CFR 30.35(e)(2) to update their decommissioning funding plan (DFP) or FA at intervals not to exceed 3 years or at the time of renewal to account for a number of factors including changes in the authorized possession limits. Additional information on DFP and FA can be found in Section 8.5.2.

Since several fusion machine designs are likely to have tritium present, the applicant should be aware of the amount of tritium throughout the fusion machine for protection of the workers and the public. It is important to note the radiation dose for tritiated water[2] (HTO) is significantly greater than gaseous tritium[3] (HT). However, for the purposes of the possession limit required in Section 8.6 of this NUREG, the applicant should specify the total amount of tritium from all chemical forms. For unsealed radioactive material, applicants should specify whether the radionuclides produced will be in volatile or nonvolatile form (i.e., irradiated metal), since additional safety precautions are required when handling volatile material.

[2] HTO is a symbol for a water molecule in which a tritium atom (T) is present in place of a normal hydrogen atom (H).

[3] A molecule of hydrogen gas contains two hydrogen atoms. Either one of these atoms may be replaced with T to form HT, or two T atoms may combine to form T2 gas.

If components are exposed to neutrons, activated products will also need to be included in the license possession limits. For incidentally activated radionuclides, the applicant should request authorization to possess and use byproduct material with atomic numbers from 3 through 83 (3-83). The applicant should consider incidentally activated nuclides that are expected to be produced. The applicant should indicate the total cumulative quantity for all radionuclides to be possessed at any one time, and the maximum quantity for any one of the radionuclides within atomic numbers 3-83. The total cumulative possession should be commensurate with the applicant's needs. If certain incidentally activated radionuclides will be produced in much larger quantities (more than 1 Ci) than described in the atomic number 3-83 request and the radionuclides have a half-life greater than 120 days, the applicant should list these separately, rather than increase the possession limit for all radionuclides.

To determine the quantity and type of activation products to be expected from specific planned operating conditions, the applicant should work with their suppliers. Note that it is important to carefully select the type of material and shielding used throughout the fusion machine to minimize the amount and type of incidentally activated radionuclides.

If needed, an applicant may request authorization to possess byproduct materials with atomic numbers greater than 83 (e.g., atomic numbers 84 through 96). For this request, the applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides. For an example of how to present this information, see Table 8-1, "Sample Format for Providing Information About Requested Radionuclides." Note that authorization to possess byproduct materials with atomic numbers 84 through 96 does not authorize the possession of uranium, thorium, or plutonium because, even though these elements have atomic numbers within the range of 84 through 96, these materials are either source material or SNM and not byproduct material. It is understood that tritium is frequently transported and stored on depleted uranium beds so the total amount of depleted uranium used for this purpose should be separately listed in the authorization to possess table. Each authorized radionuclide is listed on an NRC license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

Applicants and licensees should also determine whether they possess, or will possess, sealed sources or devices, including check, calibration, transmission, and reference sources. Applicants must request authorization to possess specifically licensed sealed source(s) or device(s), in accordance with 10 CFR 30.32(g). If the manufacturer and distributor are no longer in service, a copy of the Sealed Source and Device (SSD) registration certificate may be requested from the NRC or the issuing Agreement State. Sealed sources and devices that were produced before October 23, 2012, may not have received radiation evaluations and may not have been registered by the NRC or Agreement State. If the applicant possesses these types of sources or devices, the applicant must submit all available information identified in 10 CFR 32.210(c) concerning the source, and if applicable, the device, and sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a leak test. For calibration and reference sources of less than 1 millicurie beta/gamma and less than 10 microcuries alpha, the applicant need only submit the manufacturer, model number, radionuclide, and quantity.

The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The

safety evaluation is documented in an SSD registration certificate. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining NRC's prior permission in a license amendment. For additional guidance relating to sealed sources and devices, see also NUREG–1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration."

The applicant must either: (i) provide a range of atomic numbers for the requested radionuclides; or (ii) list each requested radionuclide by its element name and its mass number in Item 5 on NRC Form 313, specifying whether the material will be acquired, produced, and used in unsealed or sealed form. The name of the specific chemical compound that contains the radionuclide is not generally required.

The anticipated possession limit for each radionuclide should also be specified in becquerels (Bq), although the curie (Ci) value may be provided, in addition. The amount of tritium can also be provided in grams. Possession limits must include 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. For fusion machines that will produce tritium in breeding beds or similar components where the tritium will be recovered and reused as fuel, the applicant should specify a tritium inventory commensurate with the system operating in a steady state condition.

Under 10 CFR 30.9(a), "Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations … shall be complete and accurate in all material respects." Under 10 CFR 30.34(c), each person licensed under 10 CFR Parts 30 through 36 and 39 "shall confine his [sic] possession and use of the byproduct material to the locations and purposes authorized in the license."

Applicants should need to meet the requirements in 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radionuclide with a half-life greater than 120 days. These requirements are discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," of this NUREG.

Response from Applicant:

For Unsealed Materials:

- Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced.

- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored, and waste materials.

Note*:* For incidentally activated radionuclides in shielding and fusion machine components, the applicant should request authorization to possess and use any form of byproduct material with atomic numbers 3-83 and indicate the total cumulative quantity for these radionuclides to be possessed at any one time. The applicant should also identify individual incidentally activated radionuclides with long half-lives (greater than120 days) that will be produced in larger quantities, that is, quantities in excess of 1Ci.

For Sealed Radioactive Materials and Discrete Sources:

- Identify each radionuclide (element name and mass number) that will be used in each source.

- Provide the manufacturer or distributor's name and model number for each sealed source, device, or source/device combination requested. If the manufacturer and distributor are no longer in service, a copy of the SSD registration certificate may be requested from the NRC or the issuing Agreement State.

- Confirm that each sealed source, device, or source/device combination is registered as an approved sealed source or device by NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.

- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certification of registration issued by the NRC or by an Agreement State.

- Provide all available information identified in 10 CFR 32.210(c) if the sealed source, device, or source/device combination is not registered and was manufactured before October 23, 2012. Provide sufficient additional information to demonstrate under 10 CFR 30.32(g)(2)(ii) that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of its radiation safety features, the intended use and associated operating experience with the source, device, or source/device combination, and the results of a leak test.

- Provide the manufacturer, model number, radionuclide, and quantity for calibration and reference sources with less than 1 mCi beta/gamma and 10 µCi alpha. (10 CFR 30.32(g)(3)).

- Licensees who request a possession limit in excess of the quantities specified in 10 CFR 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must perform an evaluation of potential offsite doses. If the offsite dose from an accidental release of radioactive material exceeds 10 mSv (1 rem), the applicant must submit an emergency plan, as specified in 10 CFR 30.32(i).

Note*:* When responding to this section, licensees should follow the guidance in "Identifying and Protecting Sensitive Information," to determine if their response includes sensitive security-related information that needs to be marked accordingly.

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 20.2108, 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.51(f).

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in 10 CFR 30.35 must submit a DFP or provide a certification of FA for decommissioning. It is expected that a fusion machine licensee will need to prepare a DFP given the quantities of

tritium and activation products possessed. Even if a DFP or certification of FA is not required, licensees are required under 10 CFR 30.35(g) to maintain, in an identified location until the site is released for unrestricted use, decommissioning records related to leaking sources and structures, equipment, and the site where radioactive materials are used or stored. Also, before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), licensees must transfer records important to decommissioning to the proposed new licensee in accordance with 10 CFR 30.35(g). Furthermore, before a license is terminated, the licensee must send records important to decommissioning that are required by 10 CFR 30.35(g) to the appropriate NRC regional office in accordance with 10 CFR 30.51(f).

Discussion: The NRC seeks to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. Most fusion machine facilities that produce radioactive materials will be required to comply with the FA requirements because of the tritium and incidentally activated materials produced during operations.

NRC regulations requiring a DFP or FA are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner, and that licensees will provide adequate funds to cover all costs associated with decommissioning in accordance with 10 CFR 30.35. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee, through a third party, that funds will be available to decommission and release the site for unrestricted use. Applicants are required to submit a DFP or provide FA when they possess radioactive material with a half-life greater than 120 days that exceeds certain limits. Regulations in 10 CFR 30.35 set forth criteria for determining if an applicant is required to submit a DFP or has the option of submitting either a DFP or a certification of FA.

A DFP contains a site-specific cost estimate and a certification by the licensee that it has provided FA in the amount of the cost estimate for decommissioning prior to the issuance of the license. The DFP must also contain a signed original of this financial instrument, which must satisfy the requirements of 10 CFR 30.35(f). Paragraph (f) establishes the methods by which any FA instrument, such as a prepayment, surety bond, insurance, or sinking fund, must be provided. As an alternative to developing a DFP, some licensees may be eligible under 10 CFR 30.35(b)(2) to submit a certification of FA in an amount corresponding to the table of possession limits set forth in 10 CFR 30.35(d). Note that a certification of FA instrument must meet the same 10 CFR 30.35(f) requirements as a DFP.

NUREG–1757, Volume 3, “Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness,” Revision 1, provides guidance acceptable to NRC staff on the information to be provided for establishing FA for decommissioning and a standard format for presenting the information. (See Figure 8-1 for some acceptable forms of FA.)

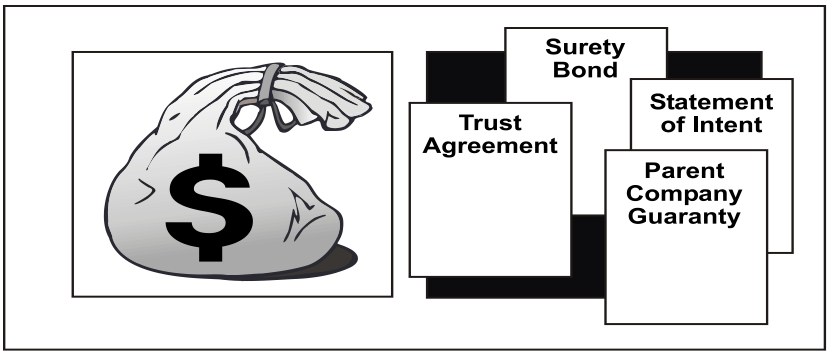


Figure 8-1 Financial Assurance for Decommissioning

The requirements for maintaining records important to decommissioning, including the type of information required, are stated in 10 CFR 30.35(g). These requirements also apply to licensees that are not required to submit a DFP or certification of FA. Under this provision, "records important to decommissioning" include:

- Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of tritium migration into fusion machine components and structural materials such as concrete. These records must include any known information identifying involved nuclides, quantities, forms, and concentrations.

- As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and stored, and of locations of possible inaccessible contamination, such as buried pipes, that may be subject to contamination. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

- Except for areas containing only sealed sources (provided the sources have not leaked, or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years of the following:

    - all areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003, "Definitions,"

    - all areas outside of restricted areas that require documentation under 10 CFR 30.35(g)(1),

    - all areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108, and

    - all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR Part 20 (Subpart E), "Radiological Criteria for License Termination," or apply for approval for disposal under 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures."

- Records of the cost estimate performed for the DFP or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used. It is also important to note that under 10 CFR 30.35(e)(2), the DFP must be updated at the time of license renewal and at intervals not to exceed 3 years, to account for changes in costs and the extent of contamination. The updated DFP must also specifically consider the decommissioning cost impacts of:

    - spills of radioactive material producing additional residual radioactivity in onsite subsurface material,
    - waste inventory increasing above the amount previously estimated,
    - waste disposal costs increasing above the amount previously estimated,
    - facility modifications,
    - changes in authorized possession limits,
    - actual remediation costs that exceed the previous cost estimate, and
    - onsite disposal.

The regulations in 10 CFR 30.35(g) also require that licensees maintain records important to decommissioning in an identified location until the site is released for unrestricted use. In accordance with 10 CFR 30.35(g), licensees must transfer records important to decommissioning to any new proposed licensee before licensed activities can be transferred or assigned according to 10 CFR 30.34(b). Furthermore, under 10 CFR 30.51(f), before license termination, each licensee will forward the records required by 10 CFR 30.35(g) to the appropriate regional office. Recipients of existing licenses in accordance with 10 CFR 30.34(b) are also responsible for maintaining these records until the license is terminated or transferred to another party. Careful recordkeeping of radionuclides possessed and used, including their form, amount, and the size of the area(s) where they have been used, will facilitate license termination and release of the area(s) for unrestricted use.

Response from Applicant:

- State the following: “Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.52(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office or assign the records to the appropriate NRC regional office before the license is terminated.”

AND

- If FA is required, submit a DFP and evidence of FA following the guidance of NUREG-1757, Volume 3.

Reference:

- NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness"

8.5.3 Environmental Review

Regulations: 10 CFR 30.32(f), 10 CFR 51.20(b)(14), 10 CFR 51.45, 10 CFR 51.60(b)(1).

Criteria: For a fusion machine, other than for research and development and for educational purposes, the applicant must provide an environmental report under the provisions of 10 CFR 51.60(b)(1)(viii). The environmental report must be prepared in accordance with the requirements in 10 CFR 51.45, "Environmental report."[4]

Discussion: The existing categorical exclusions in 10 CFR 51.22(c)(14) for material uses are based on known quantities and forms of byproduct, source, and SNM. New material uses that fall within the current scope of categorical exclusions could fall under the same categorical exclusion. For example, there is a categorical exclusion for any radioactive material use for research and development and for education purposes in accordance with 10 CFR 51.22(c)(14)(v).

For fusion machines for commercial purposes, the quantities and forms of radioactive material are currently not expected to be within the scope considered for other material uses. Thus, such fusion machines would not meet the categorical exclusion for material uses under 10 CFR 51.22(c)(14). The NRC would then need to consider addressing the licensing of a fusion machine under an environmental assessment or an environmental impact statement. The NRC considers the submission of an environmental report important to better understand the scope of impacts, particular for new designs, for evaluating environmental impact with an environmental assessment or an environmental impact statement.

The environmental review is performed following the guidance in NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." The NRC's completion of an environmental assessment or environmental impact statement, based on the level of complexity, can require several months up to 2 years to review, approve, and publish. The applicant is encouraged to meet with NRC staff early in the licensing process prior to submitting an application to ensure that complete information required for the environmental report is included to facilitate the NRC's review. Early engagement will help to minimize delays for the submission of an application and construction of the fusion facility. See Appendix C of this NUREG for additional guidance on construction activities that can take place prior to the submission of the environmental review.

Pursuant to 10 CFR 30.32(f) and subpart A of 10 CFR part 51, for a commercial fusion machine, the license application and an environmental report shall be filed at least 9 months prior to commencement of construction of the facility. For a licensed R&D fusion machine that is transitioning to commercial operations, the licensee should submit an amendment to their

[4] The regulations under 10 CFR Part 51 are related to the National Environmental Policy Act of 1969, as amended, and are only federal obligations. However, other environmental requirements, whether local, State, or another Federal agency (e.g., U.S. Army Corps of Engineers) may still be required as appropriate with related/required environmental evaluations.

license for commercial operations and provide the appropriate environmental information. The licensee is encouraged to meet with NRC staff to facilitate the application review and environmental report to ensure timely processing and approval of the application.

Response from Applicant: For fusion machines not subject to a categorical exclusion, an environmental report is required. All other fusion machine applicants should submit the environmental report following the format in NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs."

Reference:

- NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs"

8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used

Regulations: 10 CFR 30.4, 10 CFR 30.32(k), 10 CFR 30.33(a)(1).

Criteria: An application for a license will be approved if the proposed activity is authorized by the Atomic Energy Act of 1954, as amended, and radioactive material and devices will be used only for the purposes for which they are authorized in the license. For this license, the materials will be used and produced in a fusion machine. The radioactive material produced will be possessed and stored as necessary. Also, inadvertently activated components will be handled during maintenance, repair, and disposal activities.

Discussion: Applicants should specify that the radioactive material requested for a fusion machine in Item 5 will be possessed, produced, used, handled, and stored, in accordance with NRC regulations. The applicants should also specify if the fusion machine will be used for research and development and for educational purposes, or for a commercial purpose. Commercial uses of a fusion machine could include the generation of electricity, heat, and/or manufacturing of isotopes.

Applicants may use the format given in Table 8-1 to provide the requested information.

Table 8-1 Sample Format for Providing Information About Requested Radionuclides

Byproduct Material Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
Any byproduct material with atomic numbers 3 through 83 (half-life equal to or less than 120 days)	Any	___ gigaBecquerels (GBq) [milliCuries (mCi)] per radionuclide and ___ GBq (Ci) total	Possession and storage of incidentally activated products from fusion activities

Table 8-1 Sample Format for Providing Information About Requested Radionuclides

Byproduct Material Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
Any byproduct material with atomic numbers 3 through 83 (half-life greater than 120 days)	Any	___ gigaBecquerels (GBq) [milliCuries (mCi)] per radionuclide and ___ GBq (Ci) total	Possession and storage of incidentally activated products from fusion activities
Any byproduct material with atomic numbers 84 through 96 (if needed)	Any	___ GBq (mCi) per radionuclide and ___ GBq (Ci) total	Possession and storage of incidentally activated products from fusion activities
Hydrogen 3	Any	___ TBq (Ci) or grams	Possession, storage, production, and use
Manganese 54	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities
Nickel 59	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities
Cobalt 60	Sealed sources (*insert manufacturer and model number*)	Not to exceed ___ GBq (mCi) per source and ___ GBq (mCi) total	Calibration and check of instruments
Cobalt 60	Any	___ GBq (Ci)	Possession and storage incident to production activities
Nickel 63	Sealed source (*insert manufacturer and model number*)	Not to exceed ___ GBq (mCi) per source and ___ GBq (mCi) total	Calibration and check of instruments
Niobium 94	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities

Table 8-1 Sample Format for Providing Information About Requested Radionuclides

Byproduct Material Radionuclide	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
Cesium 137	Sealed sources (*insert manufacturer and model number*)	Not to exceed ___ GBq (mCi) per source and ___ GBq (mCi) total	Calibration and check of instruments
Europium 152	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities
Europium 154	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities
Polonium 210	Any	___ GBq (Ci)	Possession and storage of incidentally activated products from fusion activities
Depleted Uranium	Metal	___ kilograms (kg)	Storage of tritium

Note: Types of activation products will vary from this table depending on the design and materials used in the fusion machine. The table above include examples of activation products in concrete (europium 152 and europium 154), steel (manganese 54, nickel 59, cobalt 60, niobium 94), and lithium-lead breeding beds (polonium 210).

Response from Applicant:

- Provide the following statement: “Radioactive materials used in the fusion machine will be possessed, used, produced, and stored in accordance with NRC regulations.”

- Provide a complete list of radioactive material that will be possessed specific to the fusion process (including irradiated materials incident to the fusion reaction) that includes the radionuclide, chemical form, maximum possession limit, and proposed use. For all other material that is not used specific to the fusion process, specify its proposed use (e.g., calibration of instruments).

- Specify if the fusion machine will be used for research and development or educational purposes, or for commercial operation. If commercial operation, the applicant should specify what type of commercial operation (e.g., electricity, heat, or isotope production).

Note*:* Using a table with the format in Table 8-1 will facilitate the review of the application.

8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

8.7.1 Radiation Safety Officer

Regulations: 10 CFR 30.32(k), 10 CFR 30.33.

Criteria: The RSO's training and experience should be applicable to and generally consistent with the types and quantities of licensed material listed on the license for which the individual's authorization as an RSO is requested.

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations considered to be unsafe. The RSO should have sufficient time and commitment from management to fulfill the duties and responsibilities of the position to ensure that (i) radioactive materials are used in a safe manner; (ii) approved radiation safety procedures are being implemented; and (iii) the required records of licensed activities are maintained. This management support includes resource allocation. The licensee must notify the NRC and obtain a license amendment before making changes in the designation of the RSO listed on the license.

Typical RSO duties are illustrated in Figure 8-2 and described in Appendix D of this NUREG. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows they have been designated as RSO.

Appendix D of this NUREG also provides a model delegation of authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (designees). Licensees may also appoint alternate RSOs (ARSO) who may "step in" as the point of contact when the RSO is unavailable. Such designees or ARSOs do not need to meet all RSO qualifications, but these individuals should be qualified, experienced authorized users who have adequate knowledge of the activities to which they are assigned. These individuals are typically AUs (see following section). Designees and ARSOs should have the same management support and decision-making authority as the RSO necessary to accomplish the tasks to which they have been assigned, but they are not required to have a delegation of authority from management.

Please note that only the primary RSO is named on an NRC license.

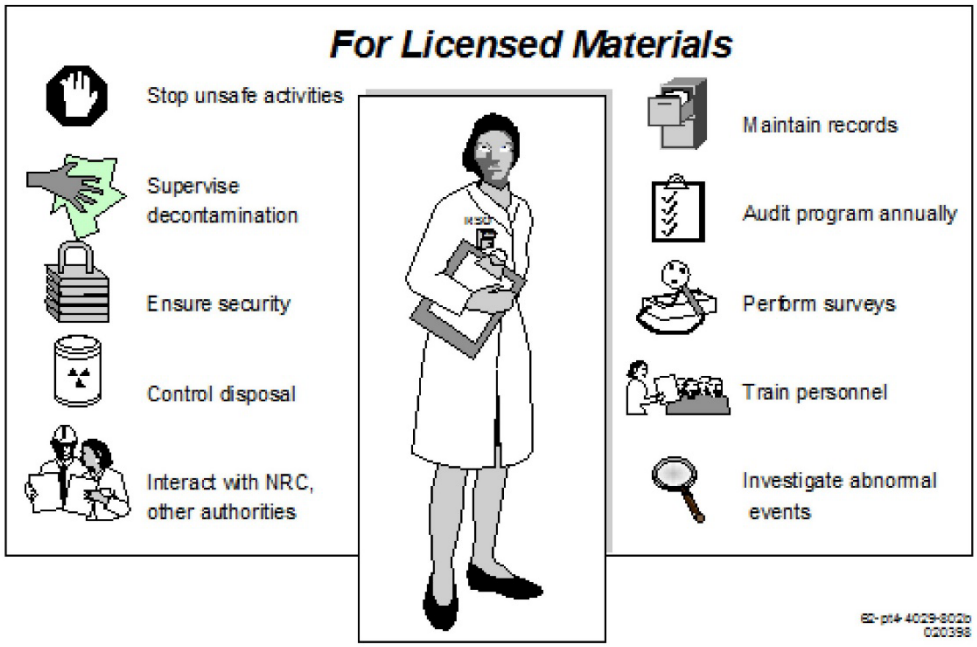


Figure 8-2 Typical Duties and Responsibilities of RSOs

The RSO should have at a minimum, (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed activities.

Training should include the following subjects:

- radiation protection principles,
- characteristics of ionizing radiation,
- units of radiation dose and quantities,
- radiation detection and measurement instrumentation,
- biological hazards of exposure to radiation (appropriate to types and forms of byproduct material to be used),
- NRC regulatory requirements and standards commensurate with the uses proposed by the applicant,
- handling of radioactive materials in relation to fusion machine activities (e.g., tritium handling),
- security of radioactive materials, and
- responding to emergencies and incidents.

Experience should include the following areas:

- planning and conducting evaluations, surveys, and measurements similar to those that the licensee's radiation safety program requires,
- use of licensed materials similar in types, forms, and quantities to those proposed for use under the license,
- security and control of licensed materials,
- storage, handling, disposal, and documentation of radioactive waste materials,
- monitoring inventory and accountability of materials possessed under the license, maintaining records of receipts, transfers, and disposal of licensed materials,
- effluent and environmental monitoring, including tritium,
- planning, conducting, and documenting audits and other evaluations of the radiation safety program,
- evaluation and documentation of radiation exposures,
- maintaining required records of the radiation safety program and providing required reports, and
- other applicable duties and responsibilities, as described in Appendix D of this NUREG.

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree as noted above, RSOs at fusion machine facilities should have at least 40 hours of radiation safety training specific to their job duties, as well as a year of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be an RSO. The RSO designee should have obtained the above training in formal course(s) designed for RSOs, presented by an academic institution, commercial radiation safety consulting company, or a professional organization of radiation protection experts. In addition, the proposed RSO's experience should be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and conducting evaluations, surveys, and measurements similar to those required by the licensee's radiation safety program.

Response from Applicant: Provide the following:

- the name of the proposed RSO and
- information demonstrating that the proposed RSO is qualified by training and experience; information should include, as a minimum:
    - formal training or education in radiation safety [topics covered, duration of training, when training was received, identity and location of training provider (note: a course outline may be provided)],

- experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience), and

- experience performing the duties of an RSO (activities, duration of experience, scope of program).

Note: Applicants should provide information about the proposed RSO's training and experience with the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth, and radiation dose information). Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee and society memberships, and personal private information. Submittal of unrelated material may delay the review process.

8.7.2 Individuals Authorized to Handle Licensed Material

Regulations: 10 CFR 20.1101, 10 CFR 30.32(k), 10 CFR 30.33.

Criteria: Authorized users (AU) must have adequate training and experience with the types and quantities of licensed material they propose to use.

Discussion: Applicants must name at least one individual who is qualified to handle the requested materials (i.e., AU). An AU is an individual whose training and experience have been reviewed and approved by the NRC, who is named on the license, and 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 according to 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 consistent with the radiation protection standards in 10 CFR Part 20.

For fusion machines, an example of an AU would include individuals responsible for radiation protection, tritium handling systems, or waste management.

AUs must have adequate and appropriate training and experience to provide reasonable assurance that they will use licensed material safely. To demonstrate adequate training and experience, an AU should have (i) a college degree at the bachelor's level or equivalent training and experience in physical, chemical, biological sciences, or engineering; and (ii) training and experience commensurate with the scope of proposed 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 the types and forms of byproduct material to be used),

- handling and using of radioactive materials relevant to the fusion machine being licensed,
- material control and security, and
- response to emergencies or accidents.

The amount of training and experience needed will depend upon the type, form, quantity, and proposed use of the licensed material requested, but it should cover the subjects stated.

In general, AUs should demonstrate training and experience with the type and quantity of material they propose to handle. For example, an individual trained and experienced only with sealed radioactive sources might not be qualified to use or supervise the use of unsealed licensed material. In addition, someone using only trace quantities of a radioactive material may not understand the risks of working with quantities of radionuclides larger orders of magnitude.

Response from Applicant: Applicants should provide the following:

- The name of each proposed AU with the types and quantities of licensed material to be used; and
- Information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials; information should include, as a minimum:
    - Formal training or education in radiation safety [topics covered; duration of training; when training was received; identity and location of training provider (note: a course outline may be provided)]; and
    - Experience using licensed materials (types; forms; quantities handled; activities performed; duration of experience).

AND

The applicant should provide the following statement: "We will train AUs on facility-specific operating, maintenance, and emergency procedures commensurate with their assigned duties."

Note: Applicants should not submit extraneous information, such as unrelated lists of publications, research grants, committee, and society memberships, etc. Submittal of unrelated material serves only to slow the review process.

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas

Regulations: 10 CFR 19.12, 10 CFR 30.32(k), 10 CFR 30.33.

Criteria: Individuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources) and in the course of their employment are likely to receive in a year an 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, "Instructions to Workers."

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)) in a year must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. Each individual should also receive periodic refresher training at no more than 12-month intervals.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Particular attention should be given to persons performing work with radioactive materials that may require special procedures, such as hot cell work and waste processing.

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.

Training may be in the form of lecture, demonstrations, recorded media, or self-study, and should emphasize practical subjects important to the safe use and possession of licensed material. The guidance in Appendix E of this NUREG may be used to develop a training program. The program should consider both the topics pertinent for each group of workers and the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written/oral test with pass/fail criteria or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or AU on the license and is familiar with the licensee's program).

Response from Applicant: Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

AND

The applicant should provide the following statement: "We will train individuals working in or frequenting restricted areas on operating, maintenance, and emergency procedures commensurate with their assigned duties."

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 2.390, 10 CFR 20.1101(b), 10 CFR 20.1301, 10 CFR 20.1406, 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 30.33(a)(2), 10 CFR 30.32(k), 10 CFR 30.35(g), 10 CFR 30.36.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Under 10 CFR 20.1101(b) and 10 CFR 20.1406, the licensee must keep exposures to workers and the public consistent with the radiation protection standards in 10 CFR Part 20 and the release of residual radioactivity.

Discussion: Applicants must demonstrate that, together with any proposed administrative measures, their facilities and equipment provide sufficient engineered controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials consistent with the radiation protection standards in 10 CFR Part 20, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

8.9.1 General Description of Facility and Site

Discussion: The NRC's safety and environmental review of an application may identify areas where facility or operational changes are needed to comply with NRC requirements. For this reason, applicants may delay completing facilities and acquiring equipment until after the license is issued. In all cases, the applicant may not possess or use licensed material until after the facilities are completed in accordance with the license, equipment is procured, and a pre-licensing assessment has been performed by the NRC, if necessary. Additional information on construction activities and environmental reviews can be found in Appendix C of this NUREG.

Under 10 CFR 30.35(g), licensees must keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Applicants are reminded that records important to decommissioning include:

- 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 or transfer lines that may be subject to contamination, and
- records of spills and unusual occurrences that may result in contamination of the facility or site.

Licensees must provide information showing that facilities meet NRC decommissioning requirements before termination of the license and release of the site under 10 CFR 30.36(k). Therefore, careful facility design is important to prevent contamination, facilitate decontamination, and reduce the costs of decommissioning. For further information, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," of this NUREG.

Applicants should consider seismic impacts in the design of their fusion machine facility. If the fusion machine will not be built in seismic areas (as defined below), it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete with walls, wall penetrations, and entranceways designed to meet the radiation shielding requirements. If built in seismic areas, the applicant must design the concrete radiation shields and foundations for system components to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source, such as American Concrete Institute (ACI) Standard ACI 318-19, "Building Code Requirements for Structural Concrete," or local building codes, if current. For steel components, they should also be designed to the requirements of an appropriate source, such as the American National Standards Institute/American Institute of Steel Construction (ANSI/AISC) Publication 341-10, "Seismic Provisions for Structural Steel Buildings," or local building codes, if current. The licensee must monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

Note: “Seismic area” means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

For additional guidance regarding facilities and equipment, refer to Appendix F of this NUREG, “Facilities and Equipment Considerations.”

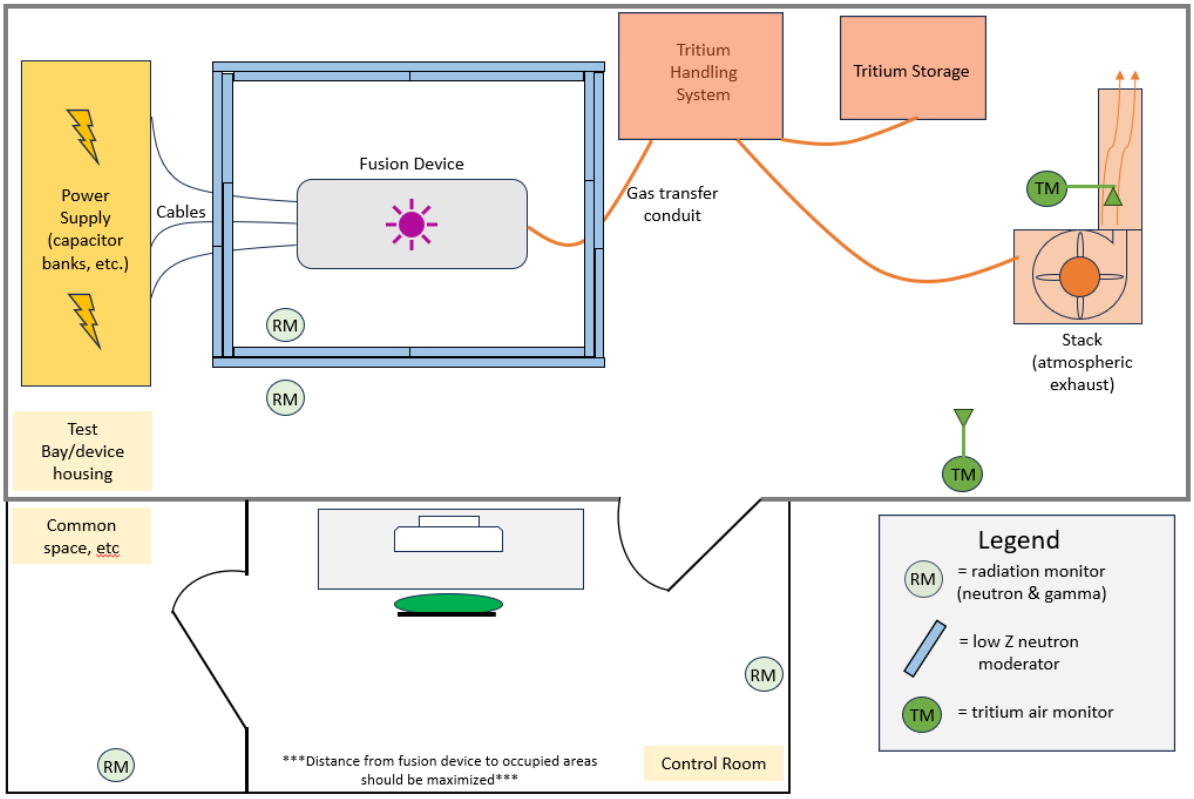
Note: For further information on facility design, see Chapter 4 of NCRP Report No. 127, “Operational Radiation Safety Program.”

Radiation monitors should be deployed for the monitoring of ionizing radiation at the fusion facility. Systems should monitor for tritium, neutron radiation, and radiation from activated shield/building materials. The number of radiation monitors should be sufficient to demonstrate the protection of public health and safety. Placement of these monitors should include locations frequented by radiation workers.

Depending on the fusion fuel and design used, tritium maybe produced as a byproduct from the fusion reaction, either directly or indirectly through the capture of a neutron by lithum-6. A system to handle byproduct tritium will be required for facilities producing tritium from fusion. Tritium handling systems shall be capable of identifying, isolating, and responding to leaks. Tritium facilities shall be equipped with appropriate environmental monitoring approaches to demonstrate compliance with 10 CFR 20, Appendix B limits.

Note: The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. Mark drawings and diagrams that provide the exact location of materials or depict the specific location of safety or security equipment as “Security-Related Information—Withhold Under 10 CFR 2.390.” See generic Figure 8-3.

SECURITY-RELATED INFORMATION—WITHHOLD UNDER 10 CFR 2.390*



*This diagram is for reference only for purposes of this NUREG and does not contain any actual security-related information.

Figure 8-3 Facility Diagram for a Fusion Machine

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, or used (see Appendix F of this NUREG for topics to consider). Also include the following:

- Location(s) of fusion machine and components that will either contain, handle, or produce radioactive materials (a diagram or schematic of facility can be provided);
- Description of the fusion machine, its components, and specifics of its operation. The description should include the movement of radioactive materials through the system and location of radiation fields (e.g., x-ray, gamma, neutron);
- Description of the type of expected activation products based on the materials used to construct the fusion machine design;
- Description and location of shielding sufficient to protect workers and the public from radiation hazards, including high-energy neutrons, as applicable;
- Equipment layout/blueprints of the area which are affected by neutron, X-ray, and gamma radiation and scatter;

- Description of the areas assigned for the production, transfer, storage, preparation, shipping, security, and measurement of radioactive materials;

- Description and diagrams showing the locations of delivery lines, shielded areas, and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety (see Figure 8-3);

- Description of access controls including the specific locations of interlocks and audible and visible alarms to prevent inadvertent entry into the fusion machine area, or the fusion machine area(s) that are high or very high radiation areas. For high radiation areas where an interlock is not appropriate, applicant may propose alternate means of controlling access;

- Description and diagram of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne;

- Verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, and are within the constraints for air emissions under 10 CFR 20.1101(d); and

- For fusion machines in seismic areas, describe the design requirements for maintaining radiation shielding and component integrity important to radiation safety during an earthquake, to include geologic and seismic site considerations (e.g., geotechnical analysis) undertaken prior to construction.

8.9.2 Access Control

Discussion: Access to the area where fusion machine is located shall be restricted during operation. A combination of engineered (e.g., door interlocks) and administrative controls (e.g., visible inspection) should be utilized to prevent entry into high radiation or very high radiation areas. Licensee should have interlocks that have control devices that cause a reduction in radiation levels if an individual inadvertently enters. The interlock should also activate an audible or visible alarm. Inadvertent entry into area of the fusion machine should cease operation of the device. The location of interlocks and audible or visible alarms will depend on the fusion machine design and the location of radioactive materials.

Response from Applicant: Describe procedures for ensuring access control to high radiation or very high radiation areas including the frequency of routine maintenance and testing, as needed.

AND

The applicant should provide the following statement: “We will prepare and maintain access control procedures for routine and emergency operations.”

8.9.3 Shielding

Discussion: The purpose of the design requirements is to limit the radiation exposure to employees, members of the public and to reduce the amount of activation created during fusion operations. In general, materials with a high content of hydrogen isotopes are common neutron shielding materials. The determination of shielding requirements using the methodology in National Council on Radiation Protection and Measurements (NCRP) Report No. 144, "Radiation Protection for Particle Accelerator Facilities" or an equivalent approach that also addresses high-energy neutrons, where needed, is acceptable.

During the construction process, a physical inspection should be conducted by the license applicant of the following items to verify construction meets the shielding design plans:

- Thickness and density of concrete
- High density polyethylene (HDPE) and other shielding materials
- HVAC baffling
- Shielding of conduits (e.g., electrical cabling)
- Penetrations into the fusion machine

The construction design for shielding around the fusion machine should address activation mitigation. To mitigate decommissioning costs, building materials such as ecology blocks, water, and HDPE can be considered in areas likely to be exposed to neutrons. Use of shielding materials that can be easily removed without excavation should be considered.

Response from Applicant: Provide documentation, including calculations and assumptions, demonstrating that the shielding around the fusion machine and other areas of radioactive material use, production, and storage are sufficient to meet the occupational and public dose requirements in 10 CFR 20.1201 and 20.1301.

8.9.4 Fire Protection

Discussion: Fusion machines may contain several energy sources that could initiate a fire. The fusion facility should have adequate fire protection systems to address the specific hazards for the materials or combination of materials that are present. Additionally, systems should be in place to provide detection and timely warning to workers. Fire detection systems may need to be tied to the shutdown of ventilation systems to mitigate the spread of fire. Fire safety procedures should consider best practices for specific industrial and chemical hazards present at the fusion facility. Licensees also need to ensure that fire detection and suppression systems remain operational and shall perform routine testing of the systems.

Response from Applicant: Provide a description of the fire detection and suppression systems including their locations. The applicant should also describe the routine testing of the fire system and actions to be taken if the fire suppression system is not fully operational.

AND

The applicant should provide the following statement: “We will prepare and maintain operating, maintenance, and emergency procedures for the fire protection and suppression systems.”

8.9.5 Radiation Monitors

Discussion: Fusion machine design will dictate the type of radiation monitoring equipment that will be needed at the facility. Fusion machines will have radiation detection equipment that is capable of measuring the type and energy of radiation produced. The number of stationary radiation monitors will depend on facility design and location of radiation hazards at the facility. The licensee will also need radiation detection equipment for monitoring of tritium effluents.

Portable radiation monitoring equipment should be available for use that will include verification of shielding adequacy, contamination incidents, and to survey waste storage areas.

The licensee should perform checks and routine maintenance of the radiation detection systems according to manufacture recommendations.

Response from Applicant: Submit the following statement: “We will have appropriate radiation monitoring for all applicable radiation types that will be maintained and calibrated per manufacturer recommendations.”

8.9.6 Tritium Handling System

Discussion: The tritium handling system should be designed to accomplish its required function (e.g., separate tritium from lithium, store tritium for future use as fuel) while minimizing and controlling the exposure of workers, the public, and the environment to tritium. The size and complexity of the tritium handling system will depend on the fusion machine design. It is anticipated that a significant portion of the onsite tritium will be maintained within the tritium handling system portion of the facility. Tritium ventilation stacks should be isolated from the general building HVAC and other release stacks to reduce the probability of tritium contamination throughout the facility. An applicant may find the information in DOE-STD-1129-2015, “Tritium Handling and Safe Storage,” useful in preparing their response.

Response from Applicant: The applicant needs to provide a description of the tritium handling system with sufficient detail to address the following:

- components and layout of the system,
- radiological and non-radiological safety features to describe the steps taken to monitor and respond to leaks and minimize tritium migration to the environment (e.g., fire suppression, temperature, and vacuum controls),
- how the system is monitored for leaks or other inadvertent release of tritium,

- how tritium will be stored during short and prolonged periods of storage, and
- how the system is monitored during maintenance.

AND

Applicants will also need to provide a description of its procedures for the operation and safe handling of tritium in the system with a focus on radiological safety. A detailed table of contents would aid in the licensing review.

AND

The applicant should provide the following statement: “We will prepare and maintain operating and emergency procedures for the tritium handling system.”

Reference:

- DOE-STD-1129-2015 “Tritium Handling and Safe Storage,” September 16, 2015

8.9.7 Breeding Blankets

Discussion: In a fusion machine, the breeding blanket is used to capture neutrons to produce tritium. The blanket may contain lithium or lead. In addition to producing tritium, the breeding blanket provides shielding and may be used to generate heat for commercial use.

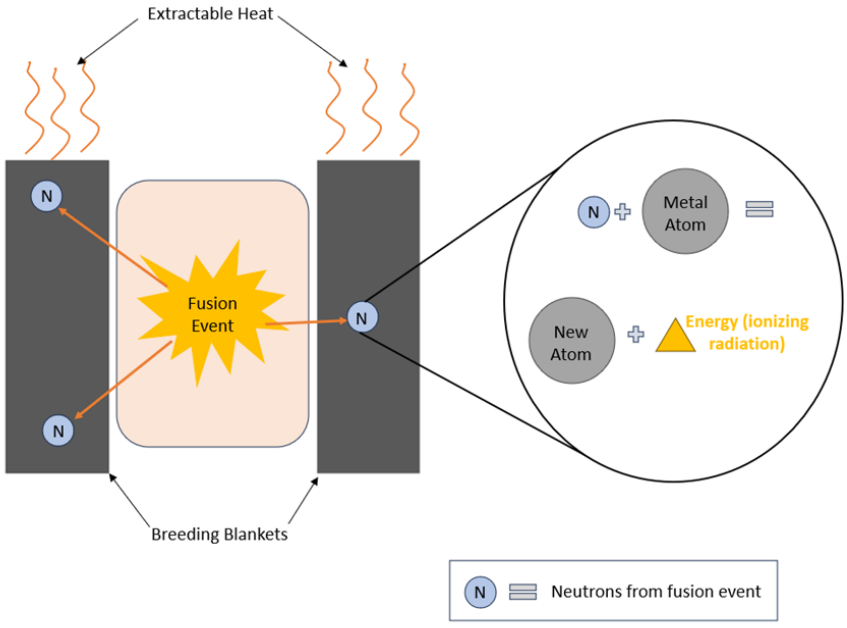


Figure 8-4 Breeding Blankets

Considerations for Repair/Maintenance:

- **Safety:** if possible, breeding blanket mediums will be stored/pumped to another vessel when work must be performed on the breeding blanket vessel itself.

- **Contamination Control:** users will follow radiation safety best practices when dealing with radioactive contaminants from breeding blankets. The risk of release of tritium gas and loose, activated materials is greatest during times of maintenance/repair.

- **Personal Protective Equipment:** personal protective equipment will be provided for maintenance/repair activities on breeding blankets. Personal protective equipment should at least cover: Tyvek suit, respirator, gloves, shoe covers, etc. A radiation work boundary should be established, with areas for proper donning and doffing of contaminated PPE.

- **Respiratory Protection:** respiratory protection should be provided to employees when work is performed on opened breeding blanket vessels. Protection should cover both radiological and chemical hazards.

- **Air Monitoring:** when surfaces of the interior of the breeding blanket are disturbed, stationary and personnel air monitors will be used to monitor airborne radioactivity.

- **Work Oversite:** any work that opens the breeding blanket vessel should be supervised by RSO and applicable Health Physics staff.

Response from Applicant: The applicant needs to provide a description of the breeding blanket with sufficient detail to address the following:

- components and layout of the system,

- radiological and non-radiological safety features (e.g. fire suppression, temperature and vacuum controls),

- how the system is monitored for leaks or other inadvertent release of lithium, tritium, and other materials present in the blanket, and

- how the system is monitored during maintenance.

AND

Applicants will also need to provide a description of its procedures for the operation and maintenance of the breeding blanket system with a focus on radiological safety.

AND

The applicant should provide the following statement: “We will prepare and maintain operating, maintenance, and emergency procedures for the breeding blanket components.”

8.9.8 Heat Exchange Systems

Discussion: Heat exchange systems should be designed to prevent activated materials and tritium from becoming airborne. Parts of the system carrying the highest radiological risk are those in closest proximity to fusion machine. This includes any apparatus that comes into thermal contact with the breeding blanket and lines that carry fluid away from fusion machine. Personnel protection is important during maintenance activities because of the radioactivity associated with activation products.

Regarding system maintenance, any activities that involve opening heat exchange systems to air must account for radiological concerns. For example, maintenance personnel should have adequate respiratory protection or ventilation and contamination controls to protect against tritium and activation products. During the maintenance there should be airborne radiological monitoring for tritium and other contaminants. The RSO or health physics personnel must be present during maintenance activities of any component exposed to the neutron flux from the fusion machine to monitor radiation levels and ensure activities are conducted in a manner consistent with the radiation protection standards in 10 CFR Part 20.

Response from Applicant: The applicant needs to provide a description of the heat exchange system with sufficient detail to address the following:

- components and layout of the system,
- radiological and non-radiological safety features (e.g. fire suppression, temperature and vacuum controls),
- how the system is monitored for leaks or other inadvertent release of radioactive and nonradioactive materials, and
- how the system is monitored during maintenance.

AND

Applicants will also need to provide a description of their procedures for the operation and maintenance of the heat exchange system with a focus on radiological safety. A detailed table of contents would aid in the licensing review.

AND

The applicant should provide the following statement: “We will prepare and maintain operating and emergency procedures for the heat exchange components.”

8.9.9 Power Failures

Discussion: Facilities should have contingency plans in the event of a power failure. During a power failure, it will not be possible to operate the fusion machine, but there are areas at the fusion facility that may require power to onsite systems to maintain safe operations. These systems could include vacuum and ventilation for tritium handling and storage and keeping radiation monitors online and operational. Loss of power could compromise these systems and possibly resulting in an inadvertent release of radioactive material or exposure to workers. To mitigate issues that may arise from power failures, the facility should have backup sources of

power, if needed. Backup sources may include batteries, diesel generators, or uninterruptible power supply to provide power to maintain any systems required for radiological safety. The licensee needs to establish testing and maintenance procedures to ensure that backup power systems will be operational when needed.

During power failures emergency procedures should consider the following:

- Evacuation of building areas where airborne radioactivity concentration will increase with loss of negative pressure (i.e., glovebox areas, tritium storage);
- Respiratory protection requirements in said areas during loss of power;
- Procedures for locking down tritium storage systems, to prevent airborne release. These can be inherent in system (i.e. flow valves closing when unpowered); and
- Procedures for restarting environmental stack/building ventilation. These should include conditions for releasing respiratory protection requirements (air sampling and associated results).

Response from Applicant: If applicable, the applicant should provide a description of the backup power systems including the conditions for automatic initiation of backup power and routine maintenance and testing. The applicant should provide a description of the contingency plans in the event of long-term loss of normal power.

AND

If applicable, applicants should also provide a description of their procedures for operating under alternative power sources and maintenance of the backup power system. Consideration should be given to providing a description of load shedding of non-safety-related equipment and restarting of systems following return of normal power operations.

AND

The applicant should provide the following statement: “We will prepare and maintain procedures for the use and maintenance of systems used in the event of power failures.”

8.10 Item 10: Radiation Safety Program

8.10.1 Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 20.2102, 10 CFR Part 37, Subpart B, 10 CFR Part 37, Subpart C.

Criteria: Licensees must review the content and implementation of their radiation protection programs at least annually to ensure that the program:

- is commensurate with the scope and extent of licensed activities,
- complies with NRC and U.S. Department of Transportation (DOT) regulations and the terms and conditions of the license,

- ensures that occupational doses and doses to members of the public are within Part 20 limits, and

- is documented, and appropriate records are maintained for the duration required by the regulations.

Note: Licensees that are subject to the security requirements in 10 CFR Part 37 are also required to annually review their access authorization program and physical security program.

Discussion: It is in the best interest of licensees to have a strong audit program. Appendix G of this NUREG contains a suggested audit program that is specific to fusion machine licensees and is acceptable to the NRC. Because all areas indicated in Appendix G of this NUREG may not be applicable to every fusion machine licensee and all items may not need to be addressed during each audit, licensees should consider developing a facility-specific audit checklist.

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 performing unannounced audits of byproduct material users to determine whether radiation safety procedures are being followed.

Once problems are identified, comprehensive corrective actions should be taken in a timely manner. The NRC routinely reviews licensees' records to verify whether appropriate corrective actions were implemented in a timely manner to prevent recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them.

Regarding audit records, 10 CFR 20.2102 requires that licensees maintain records of audits and other reviews of program content and implementation for 3 years after the record is made. The NRC has found audit records that contain the following information to be acceptable: (i) date of audit, (ii) name of person(s) who conducted the audit, (iii) persons contacted by the auditor(s), (iv) areas audited, (v) audit findings, (vi) corrective actions, and (vii) follow-up.

For fusion machines, most licensees are not expected to have an aggregated Category 1 or Category 2 quantity of radioactive material unless certain activation products accumulate over time. The regulations in 10 CFR Part 37 may not apply to activated material in walls and components as long as the materials remain an integral component of the fusion machine, as described in NUREG-2155 Rev 2 (See question 3 under 37.11(b)). In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things:

- In accordance with 10 CFR 37.33, review its access authorization programs at least annually to confirm compliance with the requirements of Subpart B of 10 CFR Part 37, and ensure that comprehensive actions are taken to correct any noncompliance that is identified; and

- In accordance with 10 CFR 37.55, review its security program at least annually to confirm compliance with the requirements of Subpart C of 10 CFR Part 37, and ensure that comprehensive actions are taken to correct any noncompliance that is identified.

Response from Applicant: The applicant should not submit its audit program to the NRC for review as part of a license application. The NRC may examine audits during inspections to determine compliance with NRC regulations.

8.10.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1501, 10 CFR 20.2103.

Criteria: Licensees must possess radiation monitoring instruments to evaluate radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured. Each licensee must maintain records showing the results of surveys and calibrations required by and retain these records for 3 years.

Discussion: Licensees must possess calibrated radiation detection and measurement instruments to perform, as necessary:

- dose rate surveys,
- area monitoring,
- personnel and facility contamination measurements,
- air sampling measurements,
- bioassay measurements,
- effluent release measurements,
- environmental measurements, and
- package surveys.

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

- 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,
- stack monitors,

- solid state detectors,
- neutron detectors,
- tritium monitoring devices,
- hand and foot contamination monitors, and
- electronic dosimeters.

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). Applications should include descriptions of the instrumentation available for use and the instrumentation that 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 for contamination. Such instruments should be checked for operational response with an appropriate check source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without performing a calibration with appropriate radioactive sources, as described in Appendix H of this NUREG, "Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program."

The applicant may need to determine the concentration of radioactive air effluents that are released to demonstrate compliance with the 10 CFR 20.1101(d) constraint on air emissions. For real-time monitoring of radioactive air effluents, the applicant should describe the detector and the methodology that will be used to calculate the air effluent release concentrations.

Calibrations requiring the use of radioactive sources should be performed by the instrument manufacturer or persons specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests authorization to calibrate instruments itself. Radiation survey instruments should be calibrated at least annually (every 12 months) unless another frequency is specified by regulation or license condition. Applicants seeking authorization to perform radiation survey instrument calibrations will need to submit procedures for review. Appendix H of this NUREG provides information about instrument specifications and model calibration procedures.

Applicants should be aware that calibrations often require possession and use of a calibration source or device.

Instruments for counting smear wipes to detect contamination and leakage need calibration sources that may be listed on the license. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts a third party to perform calibrations, the licensee must retain calibration records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made, in accordance with 10 CFR 20.2103(a).

Response from Applicant: Provide one of the following:

A description of the instrumentation, including the type of instrument and probe, and the intended purpose of the instrument in performing required surveys.

AND

The statement: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H of NUREG–1556, Vol. 22, “Consolidated Guidance About Material Licenses: Program-Specific Guidance About Possession Licenses for Fusion Machines.”

OR

A description of alternative equipment and procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration of radiation survey equipment will be performed at the required frequency. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer’s license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others. Additionally, provide a description of the instruments that will be used to quantitatively measure the radioactivity in fusion machine processes and effluents. Include the calibration procedures that will be followed to ensure the accuracy of those measurements.

8.10.3 Material Control and Accountability

Regulations: 10 CFR 20.1501(a), 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2102, 10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.32(k), 10 CFR 30.41, 10 CFR 30.51, 10 CFR 30.55.

Criteria: Licensees must do the following:

- develop, implement, and maintain written procedures for safely opening packages,
- develop, implement, and maintain procedures to ensure security and accountability of licensed material,
- maintain records of receipt, transfer, and disposal of licensed material,
- for sources containing Category 1 or Category 2 quantities of radioactive material, update transactions in the National Source Tracking System, including performing annual inventory reconciliation, if applicable,
- conduct physical inventories at intervals not to exceed 6 months (or some other interval justified by the applicant and approved by the NRC) to account for all sealed sources, and
- Develop methodology to account for unsealed material that is received, used, produced, and stored.

Licensees will need to be able to account for all licensed materials. The quantity of unsealed radioactive material used in the fusion machine is important for ensuring compliance with FA consideration, emergency preparedness planning, security in accordance with 10 CFR 20.1802, and maximum authorized possession limits. Each licensee should perform at least annually a comprehensive assessment to account for unsealed radioactive material possessed under the license.

Discussion: To ensure that only trained, experienced, and authorized individuals use or supervise the use of licensed material, the RSO should know who has requested an order of licensed material and the types and quantities of licensed materials requested. Licensed material is considered to become part of the licensee's inventory at the time that it is received by the licensee, be it during normal working hours or after hours when delivered by the carrier, in accordance with procedures established by the licensee. If through some error, the licensee receives material it is unauthorized to possess or receives quantities of material that would result in the total inventory exceeding license possession limits, the licensee should place the package in secure storage and arrange for the return of these materials in a timely manner. If return of the materials is not possible, the licensee should contact the NRC regional office and request issuance of an expedited license amendment. The materials must not be used until the amendment is granted.

Licensees should arrange to receive radioactive packages when they are delivered or to be notified when radioactive packages arrive at the carrier's terminal so that the licensee can pick up the package expeditiously. Licensees are required to develop, implement, and maintain written procedures for safely opening packages, in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages." Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered. Sample procedure for safely opening packages containing licensed materials is included in Appendix I of this NUREG.

When notified that a package of licensed material has arrived, the RSO or their staff should retrieve the package and follow the safe-opening procedures. The RSO or their staff usually receives the incoming package directly from the carrier and performs all verification, surveying, opening, and documentation for inventory. The package is then delivered to the AU, or the AU retrieves the package from the RSO. If the package is transported over public roads by the licensee, it must be repackaged and transported, in accordance with DOT regulations.

If the package of licensed material is delivered to the licensed facility's receiving department, individuals working in that department should be trained to do the following:

- identify the package as radioactive by labeling and shipping papers,
- segregate the package from other incoming items in a secured area until released by the RSO, and
- notify the RSO.

NRC regulations in 10 CFR 20.1906(b) and (c) state the requirements for monitoring packages containing licensed material. These requirements are described in Table 8-2, below.

Table 8-2 Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time
Damaged	Licensed material	Radiation level and radioactive contamination	As soon as practicable but no later than 3 hours after receipt of package

Table 8-2 Package Monitoring Requirements

Package	Contents	Survey Type	Survey Time
Labeled (White 1, Yellow II, Yellow III)	Not gas nor Special Form greater than Type A	Radiation level and radioactive contamination	As soon as practicable but no later than 3 hours after receipt of package
Labeled (White 1, Yellow II, Yellow III)	Gas or Special Form greater than Type A	Radiation level	As soon as practicable but no later than 3 hours after receipt of package
Labeled (White 1, Yellow II, Yellow III)	Not gas nor Special Form less than Type A	Radioactive contamination	As soon as practicable but no later than 3 hours after receipt of package
Labeled (White 1, Yellow II, Yellow III)	Gas or Special Form less than Type A	None	None
Not Labeled	Licensed material	None	None

This table assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has 3 hours after the beginning of the next workday to perform the required surveys.

Regulations in 10 CFR 20.1906(d) require the licensee to notify immediately the final delivery carrier and the NRC Operations Center (310-816-5100), by telephone, when removable radioactive surface contamination exceeds the limits specified in 10 CFR 71.87(i), or when external radiation levels exceed the limits of 10 CFR 71.47, “External radiation standards for all packages.”

Category 1 and Category 2 sources listed in Appendix E to 10 CFR Part 20 (i.e., nationally tracked sources) must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207. The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit an NSTS report to the NRC. The NSTS reports are tracks Category 1 and Category 2 nationally tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.

Licensees are required under 10 CFR 20.1801 and 10 CFR 20.1802 to secure radioactive materials from unauthorized removal or access while in storage in controlled or unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and is not in storage. Applicants should establish policies and procedures for ensuring accountability of licensed material.

Inventory and Accountability of Radioactive Materials

The material inventory and accounting program serves the purpose of confirming the accuracy and reliability of the facility's accounting records, including detecting any unmeasured material losses or diversion or theft of nuclear materials. Statistical methods and tests can be used to evaluate indicated imbalances including measurement uncertainties and accountability anomalies in the quantity of radioactive materials that are received, produced, used, transferred, or otherwise added to or removed from a facility's inventory. All radioactive material in the fusion machine (including activation products), waste, and calibration/reference sources should be included in the licensee's material accountability program.

For fusion designs that use or produce tritium, the quantity of tritium will be a function of the fusion machine's design. Tritium can be found in plasma- facing components in the fuel process system, the vacuum pumps and fuel injectors, neutral beam injectors and other associated components, breeding blanket and associated processing system, waste management, and in storage. The physical properties of tritium make it difficult to measure and quantify inside components of the fusion machines. The tritium accounting will need to provide reasonable assurance that the quantity of tritium possessed, used, and produced does not exceed the maximum possession limits on the license. Licensees will need to propose a methodology to demonstrate the amount of tritium possessed under the license. This methodology could be based on mass balance and calculational methods. Some fusion designs will require that some of the radioactive material (e.g., tritium) will move through the fusion machine as it is produced and consumed and will not be associated with a particular component. In this situation, the licensee can provide the possession limit for the system at a steady state condition to demonstrate compliance with NRC requirements.

For fusion machines that will operate at a high neutron fluence, activation products will accumulate in components of the fusion machine. The type and quantities of radionuclides that will make up the activation products will be dependent on the materials used to construct the fusion machine and its various components. Applicants will need to coordinate closely with their suppliers to understand the material composition of the components of their fusion design and how they will impact the production of activation products. The quantities of activation products will need to be tracked to ensure the buildup of radionuclides with longer half-lives do not exceed license maximum possession limits.

Material accounting of activation products should consider cumulation of the following:

- corrosion products that will be circulating in coolant streams from actively cooled structures like the blanket and divertor,
- "dust" produced by erosion of material from the surfaces facing the plasma, and
- other materials activated by high-energy neutrons, including the potential for activated air.

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every 6 months. Since the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sealed Sources must be leak tested and inventoried as required by license conditions.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Table 8-3. Typically, these records contain the following types of information:

- radionuclide and the activity (in units of Bq or Ci) of byproduct material in each sealed source manufacturer or distributor's name, model number, and serial number (if appropriate) of each device containing byproduct material,
- location of each SSD,
- for inventories, the date of the inventory, and name and signature of the individual conducting the inventory, and
- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer or distributor's name and model number, serial number).

Table 8-3 lists the types and retention times for the records the applicant must maintain of production, use, transfer, and disposal (as waste) of all licensed material (10 CFR 30.51). Other records, such as transfer records, could be linked to radioactive material inventory records.

Table 8-3 Record Maintenance

Type of Record	Record Retention Requirement
Receipt	For as long as the material is possessed and for 3 years following the transfer or disposal of the material
Inventory	For 3 years from the date of the inventory in accordance with license conditions
Transfer	For 3 years after each transfer, unless a specific requirement dictates otherwise
Disposal	Until the NRC terminates the license
Important to Decommissioning	Until the site is related for unrestricted use

Response from Applicant:

- Provide a discussion on the methodology that will be used to perform an annual assessment of unsealed radioactive material possessed under the license.
- Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials and perform an annual assessment of unsealed radioactive material possessed under the license."
- If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."

AND

Provide either of the following:

- A statement that "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory."

OR

- A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.

Notes:

- No response is needed from applicants for package opening procedures. Package opening procedures are reviewed during NRC inspections to ensure compliance with 10 CFR 20.1906.

- Alternative responses will be evaluated using the guidance in this section.

8.10.4 Occupational Dose

8.10.4.1 Dosimetry

Regulations: 10 CFR 19.13, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.2106, 10 CFR Part 20 Appendix B.

Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. Occupational monitoring shall include the radiation dose from both licensed and unlicensed sources of radiation. Applicants must do either of the following:

Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a) and maintain a record of this evaluation for inspection by the NRC.

OR

Provide and require the use of individual monitoring devices (dosimetry) that is exchanged at a recommended frequency. Any personnel dosimeters that require processing to determine the radiation dose must be processed in accordance with the manufacturer's requirements. Some dosimeters may require evaluation by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor.

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

- adults who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):
  - 5 mSv [0.5 rem] deep-dose equivalent,
  - 15 mSv [1.5 rems] lens (of the eye) dose equivalent,
  - 50 mSv [5 rems] shallow-dose equivalent to the skin, or
  - 50 mSv [5 rems] shallow-dose equivalent to any extremity, and
- minors who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately):
  - 1 mSv [0.1 rem] deep-dose equivalent,
  - 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent,
  - 5 mSv [0.5 rem] shallow-dose equivalent to the skin, or
  - 5 mSv [0.5 rem] shallow-dose equivalent to any extremity, and
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent,
- individuals entering a high or very high radiation area as defined in 10 CFR 20.1601 and 10 CFR 20.1602, and
- Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for any of the following:
  - adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation,
  - minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1 mSv [0.1 rem], or
  - declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv [0.1 rem].

Discussion: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure. The licensee should perform a prospective evaluation of the dose that the individual is likely to receive from licensed activities before allowing the individual to receive the dose. In a fusion machine facility, occupational exposure to radiation can result from gamma radiation, neutron fluxes, tritium ingestion or inhalation, and the mobilization of activation products. When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be

considered. Prospective doses may be based on any combination of work location, radiation monitoring, radiation survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received.

For individuals who have received doses at other facilities in the current year, these previous doses need not be considered in the prospective evaluation if monitoring was not required at the other facilities. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. Prospective evaluations need not be made for every individual but may be made for employees with similar job functions or work areas. Further guidance on evaluating the need to provide monitoring is provided in RG 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses and in Appendix J of this NUREG."

If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated and recorded. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. See Appendix J of this NUREG, "Guidance for Demonstrating that Unmonitored Individuals are Not Likely to Exceed 10 Percent of the Allowable Occupational Dose Limits," for additional information.

Radiation workers are often monitored for a year or more to determine a baseline annual dose. The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be reevaluated if there are changes in the licensee's program, such as changes in procedures, frequency of use, quantity of licensed material used, or isotopes used. The licensee should also consider a more frequent exchange of dosimeters when employees start a new job function so that their doses can be more accurately monitored when they are performing unfamiliar tasks.

Most licensees use either thermoluminescent dosimeters (TLDs), optically stimulated luminescence (OSL) dosimeters, or electronic dosimeters. Personnel dosimeters that require processing to determine the radiation dose to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), must be processed in accordance with manufacturer's requirements. Some dosimeters may require NVLAP-accredited processing (10 CFR 20.1501(d)). The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with the dosimeter manufacturer for its recommendations for exchange frequency and proper use of the dosimeter. If monitoring is required, then the licensee must maintain records of the monitoring, regardless of the actual dose received (10 CFR 20.2106). Personnel dosimeters should be stored in an area of low background.

Licensees should use NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," to record 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, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," 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."

Response from Applicant: Provide the following statements:

"We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, and 10 CFR 20.2106, as applicable."

AND

Provide one of the following statements:

"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a)."

OR

"We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated according to the manufacturer's requirements."

OR, IN LIEU OF THESE STATEMENTS,

Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

References:

- NUREG-0938 "Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure"
- NUREG-4884 "Interpretation of Bioassay Measurements"
- RG 8.7 "Instruction for Recording and Reporting Abnormal Occupational Radiation Exposure Data"
- RG 8.9 "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"
- RG 8.25 "Air Sampling in the Workplace"
- RG 8.34 "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"
- RG 8.35 "Planned Special Exposures"
- RG 8.36 "Radiation Dose to the Embryo/Fetus"

8.10.4.2 Bioassay Program

Regulations: 10 CFR 20.1204(a), 10 CFR 20.1201, 10 CFR 20.1502(b).

Criteria: 10 CFR 20.1204(a) states that each licensee must, when required under 10 CFR 20.1502, take suitable and timely measurements of (1) Concentrations of radioactive materials in air in work areas; or (2) Quantities of radionuclides in the body; or (3) Quantities of radionuclides excreted from the body; or (4) Combinations of these measurements.

Discussion: Bioassays determine the kinds, quantities, or concentration, and, in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (in vivo counting) or by analysis and evaluation of material excreted or removed from the human body. Tritium will be found in most fusion machines, and special attention should be given to the internal monitoring of tritium during operations, maintenance, and incidents. Table 8-3 provides a summary specific to the monitoring of tritium.

Frequency of Required Bioassay Measurements

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the annual limit on intake. The 10 percent annual limit on intake criterion is consistent with 10 CFR 20.1502(b), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 percent of the applicable limit (i.e., intakes likely to exceed 0.1 annual limit on intake for adults).

Routine Bioassay Measurements

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

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

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is > 0.02 annual limit on intake [40 derived air concentration (DAC) hours].

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive

material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

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

Special Bioassay 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 sometimes can be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- the presence of unusually high levels of facial or nasal contamination,
- entry into airborne radioactivity areas without appropriate exposure controls,
- operational events with a reasonable likelihood that a worker was exposed to unknown radioactive material,
- quantities of airborne radioactive material (e.g., loss of system or containment integrity),
- known or suspected incidents of a worker ingesting radioactive material,
- incidents that result in contamination of wounds or other skin absorption,
- evidence of damage to or failure of a respiratory protective device, and
- elevated air monitoring results.

Procedures for Collecting Bioassay Samples

The following items should be considered in developing procedures for collecting bioassay samples:

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

Table 8-4 Activity Levels or Concentrations Above Which Tritium Bioassay Programs Should Be Provided			
Types of operation	HTO[5] and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T2)[6] Gas in Sealed Process Vessels[7]	HTO Mixed with More Than 10 kg of Inert H_2O or Other Substances
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci	100 Ci	0.01 Ci/kg
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci	1000 Ci	0.1 Ci/kg
Processes carried out within gloveboxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and box leakage	10 Ci	10,000 Ci	1 Ci/kg

Response from Applicant: Provide a description of the bioassay program for timely evaluation for both routine operations and occurrence of abnormal airborne releases. Or provide an explanation for not having a bioassay program, if not required by 10 CFR 20.1502.

References:

- NUREG-0938 "Information for Establishing Bioassay Measurements and Evaluation of Tritium Exposure"
- NUREG-4884 "Interpretation of Bioassay Measurements"

[5] HTO is a symbol for a water molecule in which a tritium atom (T) is present in place of a normal hydrogen atom (H).

[6] A molecule of hydrogen gas contains two hydrogen atoms. Either one of these atoms may be replaced with T to form HT, or two T atoms may combine to form T2 gas.

[7] This assumes that adequate air monitoring has established that there is no tritium leakage or that no significant amount of tritium gas can be converted to HTO before intake.

- RG 8.7 “Instruction for Recording and Reporting Abnormal Occupational Radiation Exposure Data”
- RG 8.9 “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program”
- RG 8.25 “Air Sampling in the Workplace
- ”RG 8.34 “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses”
- RG 8.35 “Planned Special Exposures”
- RG 8.36 “Radiation Dose to the Embryo/Fetus”

8.10.4.3 Radiation Protection Standards

Regulations:10 CFR Part 20

Criteria: 10 CFR 20.1101 provides the public dose limit and other radiation protection standards.

Applicants for licenses are required by 10 CFR 20.1406, “Minimization of contamination,” to describe how facility design and procedures for operation will keep contamination of the facility and the environment within Part 20 requirements to facilitate eventual decommissioning; and minimize the generation of radioactive waste. applicants should address these concerns for all aspects of their programs.

Discussion: Consideration should be given to the concepts of keeping exposure within the dose limits in 10 CFR Part 20, minimizing contamination, and maintaining control of radioactive materials. Licensee must minimize the possibility of contamination and keep exposures to workers and the public within the dose limits in Part 20.

In the design of facilities, the design objective for controlling personnel exposure from external sources of radiation in areas of continuous occupational occupancy (2000 hours per year).

Effluent Goals

To assist in demonstrating compliance with the requirements of 10 CFR Part 20, the licensee should set goals for effluents at a modest fraction of the values in Appendix B, Table 2, Columns 1 and 2, to §§ 20.1001-20.2401. These goals may be set independently for gaseous and liquid effluents. Goals may need to be adjusted up or down on the basis of the annual review of what may be ALARA for the particular circumstance. If the licensee chooses to demonstrate compliance with 10 CFR 20.1301 through a calculation of the total effective dose equivalent (TEDE) to the in dividual likely to receive the highest dose, the licensee should set the ALARA goal at a modest fraction of the dose limit for members of the public.

Investigation Levels

In addition, the licensee should establish investigation levels at effluent values that are close to normal or anticipated release levels. If exceeded, an investigation should be initiated and corrective actions should be taken, as appropriate.

Radiation Safety Committee

For licensees that have a radiation safety committee as required under 10 CFR Part 33, one responsibility of that committee should be to establish effluent goals. The committee must meet at least annually to review the radiation protection program content.

For licensees with no radiation safety committee, the RSO should be responsible for setting, adjusting, and periodically reviewing the radiation protection program and the ALARA goals.

Annual Reviews

The content and implementation of the radiation protection programs must be reviewed at least annually. This review should include analysis of trends in release concentrations and radionuclide usage as well as other available monitoring data.

Worker Training

Specific training on 10 CFR Part 20 should be provided as a part of the annual employee radiation protection training (see Section 8.8 of this NUREG). For a radiation protection program to be successful, employees must understand the program's goals and principles.

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain an radiation protection program consistent with the requirements in 10 CFR Part 20."

8.10.4.4 Minimization of Contamination

Regulation: 10 CFR 20.1406, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008.

Criteria: Applicants must describe how facility design and procedures for operation are consistent with the requirements in 10 CFR Part 20 that will minimize contamination of the facility and the environment; facilitate eventual decommissioning and the generation of radioactive waste consistent with Part 20 requirements.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to conduct operations and decommissioning efforts to keep radioactive contamination and radioactive waste generation during all phases of the facility life cycle within Part 20 requirements. For fusion machine facilities, it is important to consider the types of materials used for the construction of the facility and for the shielding of the fusion machine. Due to the neutron activation that generally takes place during the operation of the fusion machine, it is important to carefully characterize all of the materials used to minimize the amount of activated products that are produced consistent with Part 20 requirements.

When submitting new applications, applicants should also consider the following:

- implementation of, and adherence to, good health physics practices in operations,
- minimization, to the extent practicable, of distance to areas where licensed materials are used and stored,

- maximization of radiation survey frequency, within reason, to enhance detection or contamination,
- 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 such areas as work surfaces and flooring,
- ventilation stacks and ductwork with minimal lengths and minimal abrupt changes in direction,
- air flows appropriate to the work being conducted,
- use of appropriate plumbing materials with minimal pipe lengths and traps, and
- minimization of the number of disposal sites (sinks) where liquid waste is disposed of if there is a sanitary sewer system.

Response from applicant: The applicant should provide a description of procedures for minimization of contamination consistent with Part 20 requirements.

AND

Provide the following statement:

"We have developed and will implement and maintain written procedures for the minimization of contamination consistent with Part 20 requirements."

8.10.5 Public Dose

Regulations: 10 CFR 20.1301, 10 CFR 20.1302.

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, produced, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) (TEDE) in 1 year from licensed activities;
- Ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour, from licensed operations; and
- Control and maintain constant surveillance over licensed material that is not in storage, and secure stored licensed material from unauthorized access, removal, or use.

Discussion: "Member of the public" is defined in 10 CFR Part 20 as "any individual except when that individual is receiving an occupational dose." "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, sanitary sewerage discharges from licensees, and 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.

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

1. airborne radioactive material,
2. waterborne radioactive material, and
3. external radiation exposure.

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the TEDE from all exposure pathways arising from licensed activities does not exceed 1.0 mSv (100 mrem) to the maximally exposed member of the public. In addition, the licensee must control air emissions, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 0.1 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this, in accordance with 10 CFR 20.2203, and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with 10 CFR 20.1101(d) and 20.1302(b). The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to Section 8.10.10, "Environmental Surveillance" and Section 8.11, "Waste Management," of this NUREG.

The application will be evaluated, and the license reviewer will determine if enough information is present to assure compliance with the limiting exposure to a member of the public. The license reviewer may require the applicant to provide additional information to assure that a member of the public will not receive a total exposure exceeding 0.1 mSv [100 mrem]. During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public [10 CFR 20.1302(b)]. See Appendix K of this NUREG, "Methodology for Determining Public Dose" for examples of methods to demonstrate compliance.

Response from Applicant: No response is required from the applicant, but records and written materials documenting compliance may be examined during NRC inspections.

8.10.6 Safe Operating and Maintenance Procedures

8.10.6.1 Operating Procedures

Regulations: 10 CFR 19.11, 10 CFR 20.1101, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1902, 10 CFR 20.1903, 10 CFR 20.1904, 10 CFR 20.1905, 10 CFR 20.2201, 10 CFR

20.2202, 10 CFR 20.2203, 10 CFR 21.21, 10 CFR 30.32(i), 10 CFR 30.32(k), 10 CFR 30.50, 10 CFR 30.72.

Criteria: Licensees are responsible for the security and safe use of all licensed material from the time it arrives at their facility, during its use and storage, and until it is transferred or disposed. Licensees should develop, implement, and maintain written procedures to ensure safe use of licensed material. The procedures also should include operational and administrative guidelines. 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.

Discussion: Operating procedures must be developed, maintained, and implemented to ensure safe operation of the fusion machine and radiation doses received by occupational workers and members of the public are consistent with the radiation protection standards in 10 CFR Part 20. Copies of operating procedures should be provided or made available. In addition, the applicant must post current copies of operating procedures applicable to licensed activities at each site. If posting of procedures is not practicable, the licensee may post a notice that describes the documents and states where they may be examined.

Improper operation could lead to the damage or malfunction of the fusion machine and possible radiation overexposures. The applicant will provide summaries of the written operating procedures describing their important radiation safety aspects. The level of detail should be sufficient to demonstrate that regulatory requirements have been addressed.

General Safety Procedures

The written procedures should include the following elements:

- contamination controls (see Section 8.10.4.4 of this NUREG),
- exposure control,
- waste disposal practices,
- personnel and area monitoring (including limits),
- use of protective clothing and equipment,
- recordkeeping requirements, and
- reporting requirements.

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

Specific operating and emergency procedures for fusion machines are addressed in specific sections elsewhere in this NUREG-1556 guidance.

Response from Applicant: The applicant should provide a description of their operating procedures with an emphasis on radiation safety of critical fusion components.

AND

Provide the following statements:

"We have developed and will implement and maintain written procedures for operation of the fusion machine."

AND

"Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and (iv) the changes do not degrade the effectiveness of the program."

8.10.6.2 Maintenance

Regulations: 10 CFR 20.1101, 10 CFR 30.32(k).

Criteria: Each fusion facility shall develop and implement a maintenance program. Routine maintenance of fusion machine equipment is necessary to assure its radiation protection purposes, including integrity of process systems, given the extreme operating conditions (e.g., high temperatures, radiation damage, neutron activation). In addition, for certain designs, routine maintenance is necessary to assure that hazards remain within analyzed parameters (e.g., accumulation of "dust" in certain designs.) The program may consider the following:

- listing of items or equipment performing safety-related functions,
- planning, scheduling, testing, and coordinating activities for safety-related items or equipment,
- maintenance history and equipment performance trending,
- types of maintenance (e.g., preventative, or corrective maintenance), and
- protection of workers during maintenance activities.

Maintenance should be planned and carried out as frequently as needed to maintain doses within Part 20 requirements. Individuals performing maintenance should be trained in the procedures they implement.

Discussion: Maintenance of equipment and facilities is necessary to ensure a safe environment for workers and the public. The fusion machine should be designed to ensure that maintenance can be performed routinely consistent with Part 20 requirements. Maintenance staff should be aware of the hazards and the procedures prior to engaging in maintenance activities to keep their exposure to radioactive materials within Part 20 limits. As examples: (i) the staff should survey the system working area before and after maintenance activities and (ii) a maintenance procedure should direct the shutdown and lockout of energized systems before

beginning work in the area. Maintenance procedures should use appropriate engineering and administrative controls to meet Part 20 requirements.

Response from Applicant: The applicant should provide a description of their maintenance procedures for ensuring safe conduct of maintenance activities.

AND

Provide the following statements:

"We have developed and will implement and maintain written procedures for maintenance activities and their frequencies that ensure integrity of fusion machine components and are necessary for radiation protection."

AND

"Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and (iv) the changes do not degrade the effectiveness of the program."

8.10.6.3 Emergency Procedures

Regulations: 10 CFR 19.11; 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2201–2203; 10 CFR 21.21; 10 CFR 30.32(i); 10 CFR 30.32(k); 10 CFR 30.50; 10 CFR 30.72; 10 CFR Part 37 (Subparts B and C).

Criteria: Licensees must do all of the following:

- Keep radiation doses to workers and members of the public within Part 20 requirements;
- Ensure security of licensed material;
- Make the required notifications of events to NRC; and
- Maintain written emergency procedures that contain the following:
    - identification of realistic scenarios and conditions that could result in unplanned radiological exposure or release,
    - identification of roles and responsibilities,
    - maintain appropriate response equipment,
    - ensure prompt notification and reporting,
    - contact information for RSO and other response personnel, and
    - agreements with offsite response organizations (e.g., local fire department and emergency medical technicians).

Discussion: Incidents can happen during any operation with radionuclides, including their transportation, use, production processes, transfer, and disposal. Such incidents can result in contamination or release of material to the environment, as well as unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, sabotage, fires, floods, etc., can adversely affect the safety of personnel and members of the public. Therefore, it is necessary to develop written emergency procedures to minimize, as much as possible, the effect of these incidents on personnel, members of the public, and the environment.

Applicants should establish written emergency procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These emergency procedures should include provisions for immediate response, after hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee's staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact. Typical notification and reporting requirements are described in Appendix L of this NUREG. Applicants should use these guidelines to develop procedures for notification and reporting of incidents and emergencies.

Written emergency procedures should address situations that could lead to an uncontrolled release of radioactive and hazardous materials onsite or into the environment. The licensee's annual audit of their program should include a review of the emergency procedures and any responses that required use of these procedures.

An applicant may consider evaluating the following as potential initiating or contributing events of incidents: energy in the plasma, e.g., plasma disruption due to loss of plasma control,

- magnetic energy, e.g., occurrence of an electric arc could cause local melting and potential loss of integrity of the vacuum vessel or supporting systems,
- thermal energy, e.g., elevated temperatures of fusion machine components could result in a leak from the primary cooling system into the vacuum vessel causing vaporization resulting in a rise in pressure,
- explosive energy, e.g., from hydrogen, dust, or oxidation of dust by water which could result in a loss of vacuum vessel containment,
- cryogenic energy, e.g., a leak of liquid helium or nitrogen can cause sudden vaporization of the cryogen,
- fire caused by electrical shorts or chemical reactions involving large quantities of material present,
- Natural disasters (e.g., floods, tornadoes, hurricanes, wildfires, earthquakes).

Licensees should have a sufficient number of appropriate and calibrated radiation survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be inspected periodically for proper operation and replenished as necessary. Appendix M of this NUREG includes model emergency procedures. Applicants may adopt these procedures or develop their

own, incorporating the safety features included in these model procedures on a technology or site-specific basis.

As fusion technology is novel on the scale licensed under this guidance, the generation of novel radionuclides or changes to the fusion mechanism that may involve new energy mechanisms should be periodically reviewed and safety procedures updated to address new radiological hazards. An applicant must develop emergency procedures to limit exposures and coordinate with responders commensurate with associated hazards. Emergency procedures will also need to be coordinated with an offsite emergency plan if one is required as described in Section 8.10.9 of this NUREG. If the applicant does not need an offsite emergency plan as described in Section 8.10.9 of the NUREG, the evaluations performed for the offsite dose evaluation should be used to as part of the licensee's onsite emergency procedures.

Response from Applicant: Describe realistic emergency scenarios and the procedures for responding to them.

AND

Provide the following statements:

"Procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material."

AND

"Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and (iv) the changes do not degrade the effectiveness of the program."

8.10.7 Surveys and Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 20.2103, 10 CFR 30.53, 10 CFR 32.59.

Criteria: Licensees are required by 10 CFR 20.1501 to make surveys of potential radiological hazards in their workplace. Additionally, licensees are required to perform wipe tests of sealed sources and devices to identity leaking sources. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions for both licensed and unlicensed activities and the licensed facility. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

Radiation surveys are used to detect and evaluate contamination of:

- facilities,
- equipment,
- leakage from sealed sources,
- personnel (during use, transfer, or disposal of licensed material), and
- restricted and unrestricted areas.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

Under 10 CFR 20.1501, surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard, and when necessary for the licensee to comply with the regulations. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

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

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

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.

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 performed in each work area. Appendix N, “Radiation Safety Survey

Topics," of this NUREG contains additional information on survey frequencies and contamination levels.

Any barrier, including equipment, penetrations, seals, etc. relevant to the establishment of an acceptable radiation levels, shall be designed and constructed in such a way as to enable initial and periodic surveys.

All vacuum vessels and attached components that serve as a barrier to the release of radioactive materials should be tested at design pressures before initial operation to demonstrate that radiation levels are acceptable and meet design criteria. Potential hazards of in-service radiation surveys at the operating pressure design may not justify the same frequency of survey performance. In its place, a program of periodic vacuum leak testing and a formal configuration control program to ensure vacuum vessel repairs or modifications do not compromise the design pressure rating should be implemented.

Sealed Source and Plated Foil Leak Test

Sealed sources and devices 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 withdrawn immediately 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.

The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of the radionuclide contained in the source or foil.

Manufacturers, distributors, consultants, and other organizations may be authorized by the NRC or an Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample, according to the sealed source or plated foil manufacturer's (distributor's) and the kit supplier's instructions and return the sample to the leak test service provider 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. The NRC or an Agreement State may, in a license condition, specifically authorize licensees to conduct the entire leak test sequence themselves.

Because the types, forms, and quantities of licensed materials in sealed sources can vary significantly for applicants, leak test requirements are specified in a license condition. Typically, leak tests are not required if:

- sources contain only H-3 (tritium),
- sources contain only byproduct material with a half-life of less than 30 days,
- sources contain only a radioactive gas,
- sources contain 3.7 MBq [100 μCi] or less of beta-emitting or gamma-emitting material or 370 kilobecquerel (kBq) [10 μCi] or less of alpha emitting material, or

- sources are stored and not being used (but must be leak tested before use or transfer, or if stored more than 10 years).

Appendix O, “Model Leak Test Program and Procedures,” of this NUREG provides additional information on this topic.

Response from Applicant:

Surveys and Contamination:

Provide the following statement:

"We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix N to NUREG-1556, Volume 22, “ Program-Specific Guidance About Possession Licenses for Fusion Machines.”

OR

Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage.

Sealed Source and Plated Foils:

Choose one of the following statements:

State: “Leak tests will be performed at the intervals specified by the NRC or applicable Agreement State in the SSD registration certificate.”

AND

If leak tests will be analyzed by an outside entity, state: “Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee, using the instructions from the manufacturer (or distributor) of the sealed source or plated foil and the leak test kit supplier. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services.”

OR

If leak tests will be analyzed by the applicant, state: “We will implement the model leak test program published in Appendix O to NUREG-1556, Volume 22, “ Program-Specific Guidance About Possession Licenses for Fusion Machines.””

OR

Submit a description of alternative equipment or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foil.

8.10.8 Transportation

Regulations: 10 CFR 30.41, 10 CFR 30.51, 10 CFR 71.3, 10 CFR 71.5, 10 CFR 71.14, 10 CFR 71.17, 10 CFR 71.19, 10 CFR 71.47, 10 CFR 71, Subpart G, 10 CFR 71, Subpart H, 49 CFR Part 107, 49 CFR Part 171, 49 CFR Part 172, 49 CFR Part 173, 49 CFR Part 174, 49 CFR Part 175, 49 CFR Part 176, 49 CFR Part 177, 49 CFR Part 178; 49 CFR Part 390, 49 CFR Part 391, 49 CFR Part 392, 49 CFR Part 393, 49 CFR Part 395, 49 CFR Part 396, and 49 CFR Part 397.

Criteria: A 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, will comply with the applicable requirements of DOT regulations in 49 CFR Parts 107, 171 through 178, and 390 through 397, appropriate to the mode of transport. Therefore, applicants who will package, transport, or ship licensed material, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: In accordance with a Memorandum of Understanding between DOT and the NRC, the NRC inspects and enforces DOT's regulations governing the transport of radioactive materials by NRC's licensees. Appendix P of this NUREG provides an overview of the transportation requirements that commonly affect NRC licensees.

Licensees should consider the safety of all individuals who may handle packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces meet the regulatory requirements of 10 CFR 71.47, "External radiation standards for all packages." The DOT regulations require that individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, safety training, and security awareness training. The DOT regulations also specify the frequency of the training and a record retention requirement for training.

Fusion machine licenses may ship and receive types and quantities of radioactive materials that meet the criteria for shipment in a "Type A" or "Type B" packages, as defined by DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For licensees who transport their own packages, the packages must be blocked and braced, and shipping papers must be stored in the driver's compartment, as described in 49 CFR 177.817, "Shipping papers." All domestic shipping paper and label information must be stated in the International System of Units (SI) only or must be in SI units first, with English units in parenthesis. The general license in 10 CFR 71.17, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material, and specifies certain conditions.

Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to the provisions of 10 CFR 71.17 or 10 CFR 71.19, "Previously approved package," as appropriate, is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. For information on certifying a Type B package see NUREG-2216 "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive

Material" and RG 7.9 "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material."

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package before the first use of an approved package and have an NRC-approved quality assurance (QA) plan, as required under the 10 CFR 71.17 general license. For information about QA plans, see Revision 3 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 2015. Licensees should also develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before a licensee makes shipments of licensed materials using a Type B package, the licensee needs to have registered with the NRC as a user of the package and obtained NRC's approval of its QA program.

Note: Transportation activities will be reviewed during NRC inspections, additionally, licensees may be subject to DOT inspections.

Reference:

- NUREG-2216 "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," dated August, 2020
- RG 7.9 "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," dated June 17, 2019
- RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June, 2015

8.10.9 Evaluation to Determine Need for Offsite Emergency Plan

Regulations: 10 CFR 30.32(i).

Criteria: Emergency planning is generally required by the NRC for all licensees as part of its defense-in-depth strategy to protect the health and safety of the public. Therefore, applicants must develop emergency procedures to limit exposures and coordinate with responders, commensurate with associated hazards, as described in Section 8.10.6.3 of this NUREG, and may need to evaluate the need for an offsite emergency plan, as described in this section.

Under 10 CFR 30.32(i), applications to possess radioactive materials in excess of the quantities in 10 CFR 30.72, "Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release" (also referred to as Schedule C), must contain either:

- An evaluation showing the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rem to the thyroid; or

- An emergency plan for responding to a release of radioactive material in accordance with 10 CFR 30.32(i)(3).

Discussion:

Applicants That Will Not Exceed Quantities of Radioactive Materials in Schedule C

Licensees possessing less than Schedule C quantities are not required to produce a dose evaluation or maintain an offsite emergency plan for responding to a release of radioactive material in accordance with 10 CFR 30.32(i)(3). The total quantity of radioactive material requested by the applicant in Sections 8.5.1 and 8.6 of this NUREG cannot exceed Schedule C quantities.

The conservative accident scenarios and dose calculations that formed the technical basis for the Schedule C quantities in 10 CFR Part 30 are described in NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees." The Schedule C lists those quantities that might theoretically deliver an effective dose equivalent of 1 rem in the event of a severe accident. The quantities were calculated by assuming that the most exposed member of the public would inhale a fraction of those materials. External doses from immersion in the cloud and ground shine were then added to the internal dose. The 1-rem effective dose equivalent is a 50-year dose commitment calculated by the methods of International Commission of Radiological Protection Publications 26, 28, and 30 which can be found at 54 FR 14051; April 7, 1989. More recent discussion on offsite consequences specific to fusion machines can be found in UKAEA-RE(21)01 "Technology Report – Safety and Waste Aspects for Fusion Power Plants," dated September 2021.

The NRC has determined that emergencies involving quantities of radioactive materials below Schedule C thresholds could not credibly result in risks to the public that necessitate offsite emergency planning. Therefore, fusion machine applicants possessing radioactive materials less than the amounts in Schedule C only need to include emergency procedures (and/or methodologies) that adequately address events, incidents, and radiation protection on site. Additional guidance for the emergency procedures is captured in Section 8.10.6.3 of this NUREG.

Applicants That Will Exceed Quantities of Radioactive Materials in Schedule C

If an applicant plans to possess radioactive materials in excess of the quantities listed in Schedule C, then they must provide with the application either (i) an evaluation showing that the maximum offsite dose because of a release of radioactive materials would not exceed 0.01 Sv (1 rem) effective dose equivalent or 0.05 Sv (5 rem) to the thyroid, or (ii) an emergency plan for responding to the release in accordance with the criteria listed in 10 CFR 30.32(i)(3). Specifically, the evaluation must show, in sufficient detail, that an accidental release of radionuclides will not result in a public dose greater than (0.01 Sv) 1 rem effective dose equivalent or (0.05 Sv) 5 rem to the thyroid[8].

[8] Applications for fusion machine designs that will not possess radioactive iodine do not need to include a calculation of the thyroid dose in their evaluation but should state in the application that no radioactive iodine is available for release.

The accidental release of radioactive material from a fusion facility will vary based on the specific fusion machine design- and site-specific considerations. The potential sources of energy that could create conditions that could potentially lead to an uncontrolled release of radioactive and hazardous materials onsite or into the environment could include:

- energy in the plasma, e.g., plasma disruption due to loss of plasma control,
- magnetic energy, e.g., occurrence of an electric arc could cause local melting and potential loss of integrity of the vacuum vessel or supporting systems,
- thermal energy, e.g., elevated temperatures of fusion machine components could result in a leak from the primary cooling system into the vacuum vessel causing vaporization resulting in a rise in pressure,
- explosive energy, e.g., from hydrogen, dust, or oxidation of dust by water which could result in a loss of loss of vacuum vessel containment,
- cryogenic energy, e.g., a leak of liquid helium or nitrogen can cause sudden vaporization of the cryogen,
- fire caused by electrical shorts or chemical reactions involving large quantities of hazardous material present, and
- Natural disasters (e.g., floods, tornadoes, hurricanes, wildfires, earthquakes).

The licensee's evaluation for the accidental release of radioactive material should consider realistic accident scenarios and the factors listed below from 10 CFR 30.32(i)(2). If the evaluation does not use these factors, the licensee will need to assume the release fraction listed in 10 CFR 30.72. For a fusion facility that uses tritium, the assumed release fraction is 50% of the total onsite tritium inventory. Factors that should be considered in the licensee's evaluation include:

- Whether the radioactive material is physically separated so that only a portion could be involved in an accident.
- All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged.
- The release fraction in the respirable size range would be lower than the release fraction shown 10 CFR 30.72 due to the chemical or physical form of the material.
- The solubility of the radioactive material would reduce the dose received.
- Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 10 CFR 30.72.
- Operating restrictions or procedures would prevent a release fraction as large as that shown in 10 CFR 30.72.
- Other factors appropriate for the specific facility.

Development of an Emergency Plan for Offsite Releases

Applicants that plan to possess radioactive materials in excess of the Schedule C and that determine it is necessary to develop an emergency plan based on the evaluation in the previous section, can refer to RG 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," Revision 1, issued April 2011, for guidance. Additionally, applicants should consider the information in Section 8.10.6.3 of this NUREG for onsite emergency procedures.

Because of the performance-based nature of 10 CFR Part 30, this section provides general guidance on the content of emergency plans for offsite releases but does not give specific methods for compliance. The methods needed to demonstrate preparedness will vary based on the specific fusion machine design- and site-specific considerations. If the NRC or industry develops design-specific guidance at a future date, applicants may reference those documents within their applications. Applicants can begin interacting with the NRC early in the application development process to ensure that significant issues and content to support the application are identified and resolved early.

The NRC will review each application to determine whether an applicant has described how the performance-based framework in 10 CFR Part 30 will be met. The NRC staff will evaluate applications using a graded approach based on site-specific consequence analyses.

Response from Applicant: If the license application requests possession of quantities of radioactive materials exceeding the thresholds in Schedule C, submit an evaluation demonstrating the maximum offsite dose from a release of radioactive materials. If the evaluation demonstrates that the accidental release of radioactive material would exceed 0.01 Sv (1 rem), the applicant also needs to develop and submit an emergency plan containing the elements in 10 CFR 30.32(i)(3).

Reference:

- UKAEA-RE(21)01 "Technology Report – Safety and Waste Aspects for Fusion Power Plants," dated September 2021

8.10.10 Environmental Surveillance

Regulations: 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302.

Criteria: Regulations in 10 CFR 20.1302 require licensees to "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 10 CFR 20.1301." The licensee can demonstrate compliance with 10 CFR 20.1301 by measurement or calculation.

Discussion: Fusion machines will use or produce tritium during normal operations. A small fraction of the tritium is expected to be released as an airborne effluent as part of normal operations. The fraction of tritium released will be in the form of tritiated water (HTO) and gas (HT). From a radiation dosimetry perspective, the chemical form taken by the tritium released from the facility will have an impact on the dose to members of the public. The ratio of onsite tritium as HT and HTO can change once the tritium is released into the environment. The

licensee will need to determine the public dose based on the tritium ratio of HT and HTO in the environment.

As described in Section 8.5.3 of this NUREG, an applicant for a license will need to submit an environmental report if the fusion machine will be used commercially and not for research and development or for educational purposes[9]. Part of the environmental review requires the applicant to consider the radiological impacts on the environment and the public from the operation of their facility. An applicant will need to consider the location and characteristics of the radioactive material onsite and that is included in effluent release and evaluate the principal radiological exposure pathways for the tritium. This assessment often includes an environmental surveillance program, which may continue after the fusion machine is operating. For additional guidance about accepted methodologies for determining doses to members of the public, see Appendix K of this NUREG.

The effluent release values for tritium in Appendix B of 10 CFR Part 20 are based on the effluent being 100% HTO. The regulations in 10 CFR 20.1302(c) allow the applicant to adjust the effluent concentration values in Appendix B to Part 20 based upon actual chemical and physical characteristics. This adjustment must be approved by the NRC; if approved, the revised release value will be added to the applicant's license as a separate license condition.

Response from applicant: No response is required from the applicant, but records and written materials documenting compliance should be available for examination during NRC inspections.

Note: During NRC inspections, licensees must be able to demonstrate, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. For guidance about accepted methodologies for determining doses to members of the public, see Appendix K of this NUREG.

References:

- NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs"

8.10.11 Security Program

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2201, 10 CFR Part 37.

Criteria: Licensees must ensure the security of licensed material (10 CFR 20.1801 and 10 CFR 20.1802). Licensees must report any lost, stolen, or missing licensed material in an aggregate quantity exceeding specified limits (10 CFR 20.2201).

Discussion: Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. Regulations in 10 CFR 20.1801 and 20.1802 require licensees to secure radioactive materials from unauthorized removal or access while in

[9] Please note that other permits, whether local, State, or another Federal agency may still be required as appropriate with related or required environmental evaluations. Such other permits would be independent of whether a license is to be issued from the NRC or from an Agreement State.

storage in controlled and unrestricted areas and to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and not in storage.

To meet 10 CFR 20.1801, all licensed materials stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so that individuals who are not knowledgeable about the presence of the radioactive materials cannot be inadvertently exposed to or contaminated by the material and cannot take the material. When any licensed material is used or handled in controlled or unrestricted areas, it must be under constant surveillance to prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: (i) storage and use of licensed materials only in restricted areas, (ii) limiting access to an entire facility or building or portion of the building only to radiation workers, (iii) providing storage areas that can be locked to prevent access to the material, and (iv) implementing procedures that require a radiation worker to be within "line of sight" of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may need to be paid to security procedures at facilities that may have unusual needs due to the activities performed.

Physical Security

In accordance with 10 CFR Part 37, licensees that possess aggregated Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain an access authorization program (Subpart B) and a security program (Subpart C) to ensure physical protection of the radioactive material.

Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37, lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 10 CFR Part 37 requirements.

Note: There are radionuclides that are not included in the list of radionuclides in Table 1 of Appendix A to 10 CFR Part 37 because they are not commercially available in quantities that could be used in a significant radiological dispersal device. Applicants should be aware that new fusion technologies may produce these radionuclides (e.g., Po-210)[10] in sufficient quantities to require implementation of enhanced security requirements.

Any licensee that has not previously been made subject to the provisions of 10 CFR Part 37, Subpart C must notify the NRC regional office specified in 10 CFR 30.6 in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold. Pursuant to 10 CFR 37.43(b), as part of the security program, the licensee must develop and maintain written procedures that document how the requirements of Subpart C will be met.

Before giving individuals unescorted access to Category 1 or Category 2 quantities of radioactive material (as defined in 10 CFR 37.5), licensees must conduct background

[10] See Table III in, "The 2010 Radiation Source Protection and Security Task Force Report," (ML102230141) for a list of additional radionuclides that may require enhanced security.

investigations of these individuals to determine that they are trustworthy and reliable, in accordance with 10 CFR 37.25. In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material. Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Cybersecurity

When assessing the potential cybersecurity implications of fusion machines being licensed under 10 CFR Part 30, the licensee should assess as appropriate the cybersecurity posture for Category 1 and Category 2 quantities of radioactive material. As part of this assessment, the licensee should consider the cybersecurity practices documented in IN 2019-04, "Effective Cyber Security Practices to Protect Digital Assets of Byproduct Materials Licensees," which provides information for effectively protecting digital assets.

Response from Applicant: No response is required from an applicant or licensee. If 10 CFR Part 37 applies, compliance with access authorization and security program requirements may be reviewed during NRC inspections.

References:

- NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"
- NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material"
- IN 2019-04, "Effective Cyber Security Practices to Protect Digital Assets of Byproduct Materials Licensees" (ML18044A350)
- IAEA-TECDOC-1344, "Categorization of radioactive sources," July 2023

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1501, 10 CFR 20.1904, 10 CFR 20.1906, 10 CFR 20.2001, 10 CFR 20.2002, 10 CFR 20.2003, 10 CFR 20.2004, 10 CFR 20.2005, 10 CFR 20.2006, 10 CFR 20.2007, 10 CFR 20.2008, 10 CFR 20.2108, 10 CFR Part 20 Appendix G, 10 CFR 30.35, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 61.7, 10 CFR 61.55, 10 CFR 61.56, 10 CFR 61.57.

Criteria: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for waste disposal of licensed material. Licensed materials must be disposed of in accordance with NRC requirements by one of the following methods:

- transfer to an authorized recipient (10 CFR 30.41, 10 CFR 20.2006, 10 CFR 20.2008),
- decay in storage (DIS) (10 CFR 20.2001(a)(2)),
- release in effluents within the limits in 10 CFR 20.1301, or
- as authorized under 10 CFR 20.2002 through 20.2005.

Waste must be disposed of in accordance with regulatory requirements and license conditions. Licensees are responsible for ensuring that waste is transferred only to authorized recipients. 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. Appropriate FA for waste disposal at the time of decommissioning must be provided. Appropriate records of waste disposal must be maintained.

Discussion: This section addresses radioactive waste generated by use of a fusion machine. The applicant should discuss the methods for management and disposal of radioactive waste, including minimization, characterization, handling, secure storage, and disposal.

Appropriate training should be provided to waste handlers. U.S. Environmental Protection Agency guidance for developing a comprehensive program to reduce hazardous waste was transmitted to licensees by the NRC in IN 94-23, “Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program,” dated March 1994. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from nonradioactive, short half-life from long half-life, liquid waste from solid waste).

The applicant should adopt procedures consistent with Part 20 requirements that will minimize the volume of waste being transferred to disposal facilities. The NRC Policy Statement, “Low-Level Radioactive Waste Management and Volume Reduction,” dated May 2012, addresses issues the applicant should consider when developing volume reduction procedures. The NRC recognizes that volume reduction is only one aspect of an effective waste management program. As part of ensuring public health and safety, licensees should consider reductions in occupational exposures and security in determining how best to manage waste. Licensees also may consider operational efficiency and cost as part of their waste management strategies.

Licensees required to provide a DFP by 10 CFR 30.35 should account for the cost of disposing of waste generated by decommissioning or otherwise managed at the time of decommissioning in the DFP. NUREG-1757 Volume 3, Revision 1, “Consolidated Decommissioning Guidance Financial Assurance, Recordkeeping, and Timeliness,” provides guidance on developing a DFP.

Although the NRC continues to favor the disposal of low-level radioactive waste (LLW) over storage, as described further below in the section titled “Extended Interim Storage,” it recognizes that licensees may safely manage waste in a variety of ways, consistent with NRC

regulations and guidance. The following methods of waste handling, both storage and disposal, may be considered and should be addressed in the application, as appropriate:

Transfer to an Authorized Recipient

Licensees may transfer radioactive waste to an authorized recipient for disposal. The licensee is responsible for verifying that the intended recipient is authorized to receive the radioactive waste in accordance with 10 CFR 20.2001(a) before shipment. Each shipment must comply with all applicable NRC and DOT requirements.

A licensee transferring waste to an authorized disposal facility under 10 CFR 20.2006 or 10 CFR 20.2008 should ensure that the waste meets the disposal facility's waste acceptance criteria (WAC). In addition, 10 CFR 20.2008(a) requires that a licensee transferring fusion machine waste to an authorized disposal facility under 10 CFR 20.2008 is responsible for demonstrating that either:

- the waste is manifested and labeled for disposal consistent with the description of the applicable waste class in 10 CFR 61.7, based on the physical, chemical, and radiological characteristics of the waste, or

- the disposal site licensee has completed a site-specific inadvertent intrusion assessment that considers the form of and radionuclides in the fusion machine waste.

The waste classification tables in 10 CFR 61.55 are part of the NRC regulatory framework to protect an individual who could inadvertently intrude into a LLW disposal facility after closure[11]. However, during the development of the waste classification tables, the NRC may not have considered all the potential wasteforms and radionuclides that could be generated by fusion machines. Therefore, to ensure protection of an inadvertent intruder, 10 CFR 20.2008(a) requires that disposal site licensees that accept fusion machine waste without the licensee demonstrating the manifested waste class is consistent with the description of the applicable waste class in 10 CFR 61.7 would need to perform a site-specific inadvertent intrusion assessment. One way for a fusion machine licensee to demonstrate that waste is consistent with the applicable waste class description in 10 CFR 61.7 is to show that the waste has a physical, chemical, and radiological characteristics similar to the waste the NRC considered during the development of 10 CFR Part 61, as described further below.

Wasteforms considered during the development of 10 CFR Part 61 include wasteforms that may be generated by fusion machines, such as activated metal, cement-solidified liquids, polymer-solidified liquids, contaminated soil, contaminated equipment, contaminated building rubble, ion-exchange resins, incinerator ash, and calcined waste. Additional wasteforms considered during the development of 10 CFR Part 61 are described in Section 3.4 of NUREG-

[11] In comparison, the 10 CFR Part 61 requirements for protection of the general population from releases of radioactivity and protection of individuals during operations rely on assessments of the actual forms and radionuclide concentrations of the waste. Therefore, any novel properties of fusion machine wastes that affect radionuclide release from a disposal site or the dose to individuals during disposal site operations must be evaluated by the disposal site operators to determine waste acceptability. Those analyses would be similar to analyses disposal site operators routinely conduct for non-fusion waste to determine waste acceptability.

0782, Volume. 2, “Draft Environmental Impact Statement on 10 CFR Part 61 ‘Licensing Requirements for Land Disposal of Radioactive Waste’.”

Table 8-4, below, shows the radionuclides the NRC considered quantitatively during the development of 10 CFR Part 61. The table includes radionuclide concentrations that the NRC staff calculated to protect individuals from inadvertent intrusion at that time. Table 8-4 provides guidance for determining when a site-specific inadvertent intrusion analysis is needed. For example, a disposal site that accepts fusion machine waste that contains only the radionuclides in Table 8-4 at concentrations below the constraints listed in the table for the applicable disposal waste class would not need to perform a site-specific intrusion analysis.

Table 8-4 provides constraints based on waste class because some regulatory requirements for inadvertent intruder protections depend on the waste class (e.g., solidification, intrusion barrier, depth of burial). However, Table 8-4 includes some values that are not part of the 10 CFR 61.55 waste classification tables. Those values were calculated with the same calculations and data sources the NRC used to develop 10 CFR Part 61 but were not included in the waste classification tables to facilitate implementation of 10 CFR Part 61 when it was originally promulgated. The NRC staff subsequently determined the values provide a consistent level of safety for an inadvertent intruder as the values in 10 CFR Part 61.55. Although Table 8-4 references the waste class, it does not affect waste classification. The waste class is determined based on requirements of 10 CFR 61.55. Furthermore, Table 8-4 does not affect the appropriate timeframe for a disposal site licensee to demonstrate compliance with 10 CFR 61.41, “Protection of the general population from releases of radioactivity.”

To assess whether radionuclides other than those in Table 8-4 are present in fusion machine waste, licensees should use the guidance in NUREG/BR-0204 for providing a radiological description of a waste. That is, a licensee should consider a radionuclide to be present in waste if it meets any of the following criteria:

- the concentration is greater than 0.01 times the concentration limit for that radionuclide in the disposal facility WAC,
- the radionuclide does not appear in 10 CFR 61.55 tables or the disposal facility WAC and the concentration is greater than 0.26 megabecquerel (MBq) per cubic centimeter,
- the activity represents a reportable quantity under DOT regulations (see 49 CFR 172.101, Appendix A, “Office of Hazardous Materials Transportation Color Tolerance Charts and Tables”), or
- the activity is 0.01 or more of the total activity within the disposal container.

The NRC recognizes that in some cases the threshold based on the above criteria may be below a practical detection level. In accordance with 10 CFR 61.55(a)(8), the reported activity of a radionuclide can be derived from the lower limit of detection value or by indirect methods (e.g., scaling factors). The use of indirect methods is acceptable if there is reasonable assurance that the indirect methods can be correlated with measurements.

If a licensee determines there are radionuclides in the waste that were not considered quantitatively during the development of the 10 CFR 61.55 waste classification tables, the fusion machine licensee may propose a different method to demonstrate the waste is consistent with the description of the applicable waste class in 10 CFR 61.7. If the licensee does not make that

determination, to comply with 10 CFR 20.2008(a) the licensee must ensure the disposal site has completed a site-specific intrusion assessment that considers the radionuclides in the fusion machine waste. The site-specific intrusion assessment must demonstrate that individuals who inadvertently intrude into the waste after the period of active instructional controls (e.g., typically 100 years after disposal site closure) will not receive a dose greater than 5 mSv (500 mrem) from the waste. Guidance on performing a site-specific intrusion assessment is available in the NRC Draft NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61."

Table 8-5 Radionuclides Considered Quantitatively During the Development of 10 CFR 61.55 with Constraints Below Which a Site-Specific Intrusion Assessment Is Not Needed

Radionuclide		Constraint if Disposed with Specified Waste Class			Basis
	Unit	Class A	Class B	Class C	
Sum of Radionuclides with less than a 5-year half-life	Ci/m^3	700	No limit	No limit	a, b
H-3	Ci/m^3	40	1.1×10^8	No limit	a, c, d
C-14	Ci/m^3	0.8	0.8	8	a
C-14 in activated metal	Ci/m^3	8	8	80	a
Cl-36	Ci/m^3	110	110	1100	c
Co-60	Ci/m^3	700	67,000	No limit	a, c, d
Ni-59	Ci/m^3	2.2	2.2	22	e
Ni-59 in activated metal	Ci/m^3	22	22	220	a
Ni-63	Ci/m^3	3.5	70	700	e
Ni-63 in activated metal	Ci/m^3	35	700	7000	a
Sr-90	Ci/m^3	0.04	150	7000	a
Nb-94	Ci/m^3	0.02	0.02	0.2	e
Nb-94 in activated metal	Ci/m^3	0.2	0.2	2	a
Tc-99	Ci/m^3	0.3	0.3	3	a

Table 8-5 Radionuclides Considered Quantitatively During the Development of 10 CFR 61.55 with Constraints Below Which a Site-Specific Intrusion Assessment Is Not Needed

Radionuclide	Unit	Constraint if Disposed with Specified Waste Class			Basis
		Class A	Class B	Class C	
I-129	Ci/m^3	0.008	0.008	0.08	a
Cs-135	Ci/m^3	84	84	840	e
Cs-137	Ci/m^3	1	44	460	a
Eu-152	Ci/m^3	0.06	6.2	No limit	c
Eu-154	Ci/m^3	0.02	1.5	5,100,000	c
U-235	Ci/m^3	0.04	0.04	0.4	e
U-238	Ci/m^3	0.05	0.05	0.5	e
Np-237	nCi/g	10	10	100	f
Pu-241	nCi/g	350	350	3,500	a
Pu-238, Pu-239, Pu-240, Pu-242, Am-241, Am-243, Cm-243, Cm-244	nCi/g	10	10	100	g
Cm-242	nCi/g	2,000	2,000	20,000	a

Notes:

a) Values in 10 CFR 61.55.

b) Analyses performed during the development of 10 CFR Part 61 and subsequent NRC staff analyses confirming analysis was bounding for other radionuclides with a half-life less than 5 years.

c) Values calculated with the codes and data used during the development of 10 CFR Part 61. The NRC staff determined these values provide a level of protection provided by that regulation.

d) No Class C limit because calculated value exceeds specific activity of radionuclide.

e) Values calculated during the development of 10 CFR Part 61. The NRC staff determined these values provide a level of protection provided by that regulation.

f) During the development of the waste classification tables, Np-237 was grouped with other alpha emitting transuranic nuclides despite having a lower calculated dose constraint because the NRC staff did not expect it to be present in significant quantities in LLW. Subsequent NRC staff calculations found that changes in dosimetry after the development of the waste classification tables reduced the projected dose such that it is not expected to pose excess risk to an inadvertent intruder if disposed of at the existing waste classification limits for alpha emitting transuranic nuclides with half-life greater than 5 years.

g) Values calculated for individual radionuclides during the development of 10 CFR Part 61 were found sufficiently similar to be combined as "alpha emitting transuranic nuclides with half-life greater than 5 years."

A model procedure for determining whether a site-specific intrusion analysis is required for a disposal facility accepting fusion machine waste is contained in Appendix Q of this NUREG, "Model Waste Management Procedures."

Decay in Storage

The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for DIS. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage.

Licensees should review RIS 2004-17, Revision 1, "Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material," dated September 2005.

Waste that has been decayed in storage (DIS) may be disposed of as ordinary trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Applicants must maintain accurate records of such disposals.

Applicants should ensure that adequate space and facilities are available for the storage of such waste, and care should be taken to ensure that the waste form does not degrade or interact adversely with the waste container. Procedures for management of waste by DIS should include methods of segregation, surveys before disposal, and maintenance of records of disposal.

Licensees can minimize the need for storage space if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radionuclides of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and, thus, may be disposed of in shorter time periods, freeing storage space. The holding time of the waste should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage.

The NRC does not consider storage as a substitute for final disposal of radioactive wastes. Storage other than for DIS should be used for no longer than necessary. Additional guidance is provided in this section under "Extended Interim Storage."

A model procedure for DIS is contained in Appendix Q of this NUREG, "Model Waste Management Procedures."

Release into Air and Water

Release of radioactive material into air and water must conform to the requirements described in 10 CFR 20.1302(b)(2). The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the constraint on air emissions of radioactive material required by 10 CFR 20.1101(d), which effectively reduces the limits specified in 10 CFR 20.1302(b)(2) for release of gaseous effluents. Applicants control the release of radioactive material into air and water within Part 20 requirements.

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 10 CFR 20.2003. Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are readily soluble in water or biological material

that is readily dispersible. In NRC IN 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," criteria are provided for evaluating the solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensees should carefully consider the possibility of reconcentration of radionuclides that are released into the sewage system. The NRC alerted licensees to the potentially significant problem of reconcentration of radionuclides released to sanitary sewage systems in NRC IN 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.303 [now 10 CFR 20.2003]."

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage system meet 10 CFR 20.2003 criteria and do not exceed the monthly and annual limits specified in the regulations, as follows:

- Material is readily soluble in water or is readily dispersible biological material;
- Quantity of licensed material or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer does not exceed the concentration specified in Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20;
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in Table 3 of Appendix B to 10 CFR Part 20 cannot exceed unity; and
- Total quantity of licensed material and other radioactive material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radionuclides combined.

Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage system. A model procedure for disposal of radioactive waste via a sanitary sewer is described in Appendix Q of this NUREG.

The regulations at 10 CFR 20.2003 are not applicable for releases to a private sewerage treatment system, a septic system, or leach fields. Licensees may make releases to these systems as effluents released to unrestricted areas under 10 CFR 20.1301, "Dose limits for individual members of the public." However, if licensed material is released to a private sewerage treatment system, septic system, or leach field, the sludge or other solids from these systems may become contaminated with radioactive material. Such sludges may be required to be disposed of as radioactive waste, using one of the methods described in this section.

Licensees should account for the cost of disposal of such sludges in a DFP, if one is required. As indicated above, NUREG-1757 Volume 3, Revision 1, "Consolidated Decommissioning Guidance Financial Assurance, Recordkeeping, and Timeliness," provides guidance on developing a DFP.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 10 CFR 20.2004. Applicants proposing incineration should be aware that a

notice in the *Federal Register* may be required before disposal of ash as ordinary waste can be approved. However, approval of incineration pursuant to 10 CFR 20.2004 does not require notice in the *Federal Register* if the ash is disposed as radioactive waste or transferred to a specific licensee. Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," dated January 1997, provides guidance on the disposal of ash. A model procedure for waste incineration is described in Appendix Q of this NUREG.

Waste Volume Reduction

Licensees should review the NRC Policy Statement, "Low-Level Radioactive Waste Management and Volume Reduction," dated May 2012. In general, licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized disposal facility. However, the NRC recognizes that volume reduction is only one aspect of an effective waste management program. As part of ensuring public health and safety, licensees should consider reductions in occupational exposures and security in determining how best to manage waste. Licensees also may consider operational efficiency and cost as part of their waste management strategies.

Procedures to minimize waste volumes include segregating, consolidating, compacting, or allowing certain waste to DIS. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity or increased radiation levels) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Other Methods Specifically Approved by NRC Under 10 CFR 20.2002

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste-containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and describe the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained within regulatory limits. If the waste is transferred for disposal, the licensee is responsible for ensuring that the waste recipient meets the requirements of 10 CFR 20.2008, as described under "Transfer to an Authorized Recipient," above.

If implementation of the alternative disposal method could affect additional governmental jurisdictions, the licensee should refer to State and Tribal Communication Letter FSME 12-025, dated March 13, 2012, "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ML12065A038).

Additional Considerations

The application should describe the considerations given to maintaining doses with Part 20 limits before disposal of radioactive materials and discuss the potential for unmonitored or unanticipated release of radioactive materials from likely release points (e.g., hoods and incinerator stacks) to work areas. To comply with Part 20 requirements in 10 CFR 20.1101, "Radiation protection programs," radioactive material waste stream concentrations should be a fraction (generally 10 percent to 20 percent) of the limits specified in 10 CFR Part 20, Appendix B, Table II. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of licensed material possessed, or possessed and in use, a program for

physically measuring releases should be in place whenever releases exceed the specified point at which expected doses might warrant additional review to ensure that they remain within Part 20 limits.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan their disposal. As part of the purchase agreement with the source supplier, applicants may want to consider including provisions for return of the sealed sources to the supplier at the end of the useful life of the sources.

Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), if licensees are authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, the licensees must, in accordance with 10 CFR 30.51(e) transfer the following records to the new licensee:

- records of disposal of licensed material made under:
  - 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," and
- records required by 20.2103(b)(4) of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

Extended Interim Storage

The NRC does not consider interim or long-term storage as a substitute for final disposal of LLW. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon onsite extended interim storage of radioactive waste only as a last resort. The protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. Other than DIS, LLW should be stored only when disposal capacity is unavailable and for no longer than is necessary. NRC IN 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 5, 1990, provides guidance to licensees for requesting an amendment to authorize extended interim storage of LLW. Regulatory Issue Summary (RIS) 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated May 9, 2008, updates information provided in IN 90-09. In addition, the NRC issued RIS 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste," dated August 16, 2011, which refers to other helpful guidance documents.

A fusion facility may need to store inadvertently activated components to allow for the decay of short-lived radionuclides before disposal or recycling. The NRC issued IN 90-09 and RIS 2008-12 at a time when access to LLW disposal facilities may have been disrupted or limited and requested licensees to amend their licenses to ensure that their licenses had adequate authorization such as higher possession limits and financial surety. According to IN 90-09, extended storage will generally be for a period of no greater than 5 years. Applicants for a

fusion machine license that plan to store inadvertently activated components for an extended period to allow for the decay of short-lived radionuclides should review IN 90-09 for guidance to ensure their application includes adequate information. The following sections of this NUREG are examples where the applicant should include information important to extended storage:

- FA and DFP in Section 8.5.2 to include costs necessary for disposal,
- possession limits in Section 8.6 includes any the radionuclides in the waste being stored,
- training of individuals in Section 8.8 who will work or frequent the storage area,
- description of the extended storage area(s) in Section 8.9.1,
- required radiation monitoring and routine surveys in Sections 8.9.5 and 8.10.7,
- maintaining an accurate inventory of radionuclides present in Section 8.10.3,
- operation and emergency procedures in Section 8.10.6,
- including the extended waste storage area in offsite evaluation in Section 8.10.9, and
- security of the waste storage area in 10 CFR Part 20 and if necessary, 10 CFR Part 37 requirements.

Response from Applicant

If waste is to be disposed of by transfer to an authorized recipient, provide a description of the waste and an assessment of whether the waste has novel physical, chemical, or radiological characteristics.

AND

State that: “We will use the model waste procedures published in Appendix Q in NUREG-1556, Volume 22, “Program-Specific Guidance About Possession Licenses for Fusion Machines.”

OR

If the applicant wishes to use only selected model procedures, state that: “We will use the [specify either (i) decay in storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix Q in NUREG-1556, Volume 22, “ Program-Specific Guidance About Possession Licenses for Fusion Machines.”

OR

Describe procedures for waste collection, storage, and disposal by any of the authorized methods described in this section.

References:

- IN 94-23, “Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program,” dated March 1994

- IN 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20,” dated January 1994

- IN 84-94, “Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003),” dated December 1984

- IN 90-09, “Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” dated February 1990

- NUREG-1575 Volume 3, Revision 1, “Consolidated Decommissioning Guidance Financial Assurance, Recordkeeping, and Timeliness,” dated February 2012

- NUREG-0782, Volume. 2, “Draft Environmental Impact Statement on 10 CFR Part 61 ‘Licensing Requirements for Land Disposal of Radioactive Waste’,” dated September 1981

- RIS 2008-12, “Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” dated May 2008

- RIS 2011-09, “Available Resources Associated with Extended Storage of Low-Level Radioactive Waste,” dated August 2011

- Policy and Guidance Directive (PG) 8-10, “Disposal of Incineration Ash as Ordinary Waste,” January 1997 (ML003744979 and ML003752866) and Addendum (ML003744984 and ML003744988)

- Policy Statement, “Low-Level Radioactive Waste Management and Volume Reduction,” *Federal Register* Vol. 77, No. 84 page 25760, dated May 1, 2012 (ML15023A098)

- RIS 2004-17, Revision 1, “Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material,” dated September 2005

- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 “Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR” (ML12065A038)

- Division of Waste Management and Environmental Protection, Environmental and Performance Assessment Directorate, Operating Procedures, EPPAD 3.5 (Draft for Interim Use), “Review, Approval, and Documentation of Low-Activity Waste Disposals in Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a),” dated August 2009

- RIS 2016-11, “Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002,” dated November 13, 2016

8.12 Item 12: License Fees

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

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

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC headquarters in Rockville, MD, 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address for fees questions is Fees.Resource@nrc.gov.

8.13 Item 13: Certification

A representative of the corporation or legal entity filing the application should sign and date NRC Form 313. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in Chapter 3, "Management Responsibility," of this NUREG, signing the application acknowledges management's commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).

- When an application references commitments, those items will be incorporated into the license and therefore, will become binding and conditions to the license.

9 LICENSE AMENDMENTS AND RENEWALS

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee should submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [Title 10 of the *Code of Federal Regulations* (10 CFR) 2.109, "Effect of timely renewal application," and 10 CFR 30.36(a)].

Applicants for license amendment or renewal should:

- Use the most recent guidance in preparing an amendment or renewal request;
- Submit either NRC Form 313 or a letter requesting amendment or renewal;
- Provide the license number and docket number;
- For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix B of this NUREG. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

10 APPLICATIONS FOR EXEMPTIONS

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11.

Criteria: Licensees may request exemptions from NRC regulations. The licensee 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 also use existing specific exemption outlined in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.11, if they meet the established criteria.

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

Exemptions are not intended to revise regulations or apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36(d), (g), (h), and (j), 10 CFR 30.51(d), (e), and (f).

Criteria: The licensee must:

- Notify the NRC, in writing within 60 days of the occurrence of any of the following:
  - the expiration of its license,
  - a decision to permanently cease principal activities[12] at the entire site,
  - for licenses subject to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.36, a decision to permanently cease principal activities 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,
  - no principal activities under the license have been conducted for a period of 24 months, and
  - no principal activities have been conducted for a period of 24 months 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;
- Submit a decommissioning plan, if required by 10 CFR 30.36(g);
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j);
- Submit, to the appropriate NRC regional office, completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources); and
- Before a license is terminated, send records important to decommissioning that are required by 10 CFR 30.35(g) to the appropriate NRC regional office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee, in accordance with 10 CFR 30.35(g).

Discussion: To comply with the above criteria, before a licensee can decide whether it must notify the NRC under 10 CFR 30.36(d), the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release, according to NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

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12 'Principal activities' are activities 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.

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

The current regulatory guidance concerning decommissioning of facilities and termination of licenses is found in NUREG–1757, "Consolidated Decommissioning Guidance." Appendix B of the handbook contains a comprehensive list of the NRC's decommissioning regulations and guidance. Applicants are encouraged to consult NRC staff about updates of decommissioning guidance, due to ongoing revisions. Licensees who have large facilities to decommission should review NUREG–1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," and NUREG–1575 Supplement 1, "Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME)."

Supplemental information on the implementation of the final rule on radiological criteria for license termination was published in the *Federal Register* (63 FR 64132; November 18, 1998). Supplemental information on the implementation of the final rule on radiological criteria for license termination also was published in the *Federal Register* (64 FR 68395; December 7, 1999) which addresses screening values in soils for the most common radionuclides and in the *Federal Register* (65 FR 37186; June 13, 2000) for screening values for building surfaces and soils contaminated with radionuclides not addressed in the prior *Federal Register* notices.

The computer code "DandD" offers an acceptable method for calculating screening values to demonstrate compliance with the unrestricted dose limits. Table H–1 of NUREG–1757 provides acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination, and Appendix N of this NUREG discusses methods for conducting site -specific dose assessments for facilities with contamination levels above those in the table.

For information about requirements that apply to the timeliness of decommissioning, see RIS 2015-19, Revision 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief," dated September 27, 2016, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": https://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. The licensee's obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions as summarized in the "Criteria" above.

Reference:

- NRC Form 314

APPENDIX A

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF NRC FORM 313 FOR A POSSESSION LICENSE

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF NRC FORM 313 FOR A POSSESSION LICENSE

Item No.	Suggested Response	Agree to Use	Response/ Description Attached
5.	**RADIOACTIVE MATERIAL**		
	Unsealed and Sealed Byproduct Material • For unsealed materials: - Provide an element name with mass number, chemical and/or physical form, and a maximum requested possession limit for each radionuclide produced.	N/A	❒
	- Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored and waste materials	N/A	❒
	• For sealed radioactive materials:	N/A	❒
	- Identify each radionuclide that will be used in each source.	N/A	❒
	- Provide the manufacturer or distributor's name and model number for each sealed source, device, or source/device combination requested.	N/A	❒
	- Confirm that each sealed source, device, or source/device combination is registered as an approved sealed source or device by NRC or an Agreement State, and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.		
	- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certification of registration issued by the NRC or by an Agreement State.	N/A	❒
	- Provide all available information identified in 10 CFR 32.210(c) if the sealed source device, or source/device combination is not registered and was manufactured before October 23, 2012. Provide sufficient additional information to demonstrate under 10 CFR 30.32(g)(2)(ii) that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.	N/A	❒
	- Provide the manufacturer, model number, radionuclide, and quantity for calibration and reference sources with less than 1 mCi beta/gamma and 10 µCi alpha. (10 CFR 30.32(g)(3)).	N/A	❒
	- Applicants who request a possession limit in excess of the quantities specified in 10 CFR 30.72, must	N/A	❒

Item No.	Suggested Response	Agree to Use	Response/ Description Attached
	perform an evaluation of potential offsite doses. If the offsite dose from an accidental release of radioactive material exceeds 10 mSv (1 rem), the applicant must submit an emergency plan, as specified in 10 CFR 30.32(i).		
5.	**RADIOACTIVE MATERIAL**		
	Financial Assurance and Recordkeeping for Decommissioning State the following: "Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office or assign the records to the appropriate NRC regional office before the license is terminated." **AND** If FA is required, submit a DFP and evidence of financial assurance following the guidance of NUREG–1757, Volume 3.	❒ N/A	❒ ❒
	Environmental Review For fusion machines not subject to a categorical exclusion, an environmental report is required. All other fusion machine applicants should submit the report following the format in NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs."	N/A	❒
6.	**PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED**		
	• Provide the following statement: "Radioactive materials used in the fusion machine will be possessed, used, produced, and stored in accordance with NRC regulations." • Provide a complete list of radioactive material that will be possessed specific to the fusion process that includes the radionuclide, chemical form, maximum possession limit, and proposed use. For all other material that is not used specific to the fusion process, specify its proposed use (e.g., calibration of instruments). • Specify if the fusion machine will be used for either research and development or educational purposes, for commercial operation, or both.	❒ N/A N/A	❒ ❒ ❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
7.	**INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**		
	Radiation Safety Officer Provide the following: • The name of the proposed RSO and • Information demonstrating that the proposed RSO is qualified by training and experience; information should include, as a minimum: - Formal training or education in radiation safety [topics covered, duration of training, - When training was received, identity and location of training provider (note: a course outline may be provided)], - Experience using licensed materials (types, forms, quantities handled, activities performed, duration of experience), and - Experience performing the duties of an RSO (activities, duration of experience, scope of program).	N/A N/A	❒ ❒
	Individuals Authorized to Handle Licensed Material Applicants should provide the following: • The name of each proposed AU with the types and quantities of licensed material to be used; and • Information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials; information should include, as a minimum: - Formal training or education in radiation safety [topics covered; duration of training; when training was received; identity and location of training provider (note: a course outline may be provided)]; and - Experience using licensed materials (types; forms; quantities handled; activities performed; duration of experience). **AND** The applicant should provide the following statement: "We will train AUs on facility-specific operating, maintenance, and emergency procedures commensurate with their assigned duties."	N/A N/A ❒	❒ ❒ ❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
8.	**TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**		
	Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. **AND** The applicant should provide the following statement: "We will train individuals working in or frequenting restricted areas on operating, maintenance, and emergency procedures commensurate with their assigned duties."	N/A ❒	❒ ❒
9.	**FACILITIES AND EQUIPMENT**		
	General Description of Facility and Site Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, or used (see Appendix F of this NUREG for topics to consider). Also include the following: • Location(s) of fusion machine and components that will either contain, handle, or produce radioactive materials (a diagram or schematic of facility can be provided); • Description of the fusion machine, its components, and specifics of its operation. The description should include the movement of radioactive materials through the system and location of radiation fields (e.g., x-ray, gamma, neutron); • Description of the type of expected activation products based on the materials used to construct the fusion machine design; • Description and location of shielding sufficient to protect workers and the public from radiation hazards, including high-energy neutrons, as applicable; • Equipment layout/blueprints of the area which are affected by neutron, X-ray, and gamma radiation and scatter; • Description of the areas assigned for the production, transfer, storage, preparation, shipping, security, and measurement of radioactive materials; • Description and diagrams showing the locations of delivery lines, shielded areas, and equipment, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety; • Description of access controls including the specific locations of interlocks and audible and visible alarms to prevent inadvertent entry into the fusion machine or high radiation areas.	N/A	❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
9.	**FACILITIES AND EQUIPMENT**		
	General Description of Facility and Site (Cont.) • Description of access controls including the specific locations of interlocks and audible and visible alarms to prevent inadvertent entry into the fusion machine area, high or very high radiation areas or other areas where radioactive materials are stored; • Description and diagram of the ventilation system; confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; • Verification that ventilation systems ensure that effluents are within the dose limits of 10 CFR 20.1301, and are within the Part 20 constraints for air emissions under 10 CFR 20.1101(d); and • Describe the design requirements for maintaining radiation shielding and component integrity important to radiation safety during an earthquake, to include geologic and seismic site considerations (e.g., geotechnical analysis) undertaken prior to construction.		
	Access Control The licensee needs to describe procedures for ensuring access control to areas where radioactive materials are used or stored including the frequency of routine maintenance and testing **AND** The applicant should provide the following statement: "We will prepare and maintain access control procedures for routine and emergency operations."	N/A ❒	❒ ❒
	Shielding Applicant needs to provide documentation, including calculations and assumptions, demonstrating that the shielding around the fusion machine and other areas of radioactive material use, production, and storage are sufficient to meet the occupational and public dose requirements in 10 CFR 20.1201 and 20.1301.	N/A	❒
	Fire Protection Applicant needs to provide a description of the fire detection and suppression systems including their locations. The applicant should also describe the routine testing of the fire detection and suppression systems and actions to be taken if the systems are not fully operational. **AND** The applicant should provide the following statement: "We will prepare and maintain operating,	N/A ❒	❒ ❒

	maintenance, and emergency procedures for the fire protection and suppression systems."		
Item No.	**Suggested Response**	**Agree to Use**	**Response/ Description Attached**
9.	**FACILITIES AND EQUIPMENT**		
	Radiation Monitors Applicant needs to provide the following statement: "We will have appropriate radiation monitoring for all applicable radiation types that will be maintained and calibrated per manufacturer recommendations."	❒	❒
	Tritium Handling System The applicant needs to provide a description of the tritium handling system with sufficient detail to address the following: • Components and layout of the system, • Radiological and non-radiological safety features (e.g., fire suppression, temperature, and vacuum controls), • How the system is monitored for leaks or other inadvertent release of tritium, • How tritium will be stored during short and prolonged periods of storage, and • How the system is monitored during maintenance. **AND** Applicants will also need to provide a description of its procedures for the operation and safe handling of tritium in the system with a focus on radiological safety. A detailed table of contents would aid in the licensing review. **AND** The applicant should provide the following statement: "We will prepare and maintain operating and emergency procedures for the tritium handling system."	N/A N/A ❒	❒ ❒ ❒
	Breeding Blankets The applicant needs to provide a description of the breeding blanket with sufficient detail to address the following: • Components and layout of the system, • Radiological and non-radiological safety features (e.g. fire suppression, temperature and vacuum controls), • How the system is monitored for leaks or other inadvertent release of lithium, tritium, and other materials present in the blanket, and • How the system is monitored during maintenance. **AND** Applicants will also need to provide a description of its procedures for the operation and maintenance of the breeding blanket system with a focus on radiological safety. **AND** The applicant should provide the following statement: "We will prepare and maintain operating, maintenance, and	N/A N/A ❒	❒ ❒ ❒

	emergency procedures for the breeding blanket components."		
Item No.	**Suggested Response**	**Agree to Use**	**Response/ Description Attached**
9.	**FACILITIES AND EQUIPMENT**		
	Heat Exchange Systems The applicant needs to provide a description of the heat exchange system with sufficient detail to address the following: **FACILITIES AND EQUIPMENT** **Heat Exchange Systems** • Components and layout of the system, • Radiological and non-radiological safety features (e.g. fire suppression, temperature and vacuum controls), • How the system is monitored for leaks or other inadvertent release of radioactive and nonradioactive materials, and • How the system is monitored during maintenance. **AND** Applicants will also need to provide a description of their procedures for the operation and maintenance of the heat exchange system with a focus on radiological safety. A detailed table of contents would aid in the licensing review. **AND** The applicant should provide the following statement: "We will prepare and maintain operating and emergency procedures for the heat exchange components."	N/A N/A ❒	❒ ❒ ❒
	Power Failures The applicant needs to provide a description of the backup power systems including the conditions for automatic initiation of backup power and routine maintenance and testing. The applicant should provide a description of the contingency plans in the event of long-term loss of normal power. **AND** Applicants will also need to provide a description of their procedures for operating under alternative power sources and maintenance of the backup power system. This description should include load shedding of non-safety related equipment and restarting of systems following return of normal power operations. **AND** The applicant should provide the following statement: "We will prepare and maintain procedures for the use and maintenance of systems used in the event of power failures."	N/A N/A ❒	❒ ❒ ❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Audit Program The applicant should not submit its audit program to the NRC for review as part of a license application. The NRC may examine audits during inspections to determine compliance with NRC regulations.	N/A	N/A
	Radiation Monitoring Instruments A description of the instrumentation, including the type of instrument and probe, and the intended purpose of the instrument in performing required surveys.	N/A	❒
	AND		
	"We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H of NUREG–1556, Vol. 22, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Possession Licenses for Fusion Machines."	❒	❒
	OR	N/A	❒
	A description of alternative equipment and procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration of radiation survey equipment will be performed at the required frequency. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others. Additionally, provide a description of the instruments that will be used to quantitatively measure the radioactivity in fusion machine processes and effluents. Include the calibration procedures that will be followed to ensure the accuracy of those measurements.	N/A	❒
		N/A	❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Material Control and Accountability • Provide a discussion on the methodology that will be used to perform an annual assessment of unsealed radioactive material possessed under the license • Provide the following statement: "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials and perform an annual assessment of unsealed radioactive material possessed under the license." • If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207." **AND** Provide either of the following: • A statement that "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory." **OR** • A description of the procedures for ensuring that no sealed sources have been lost, stolen, or misplaced.	❒	❒
	Occupational Dose: Dosimetry Provide the following statements: "We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, and 10 CFR 20.2106, as applicable." **AND** Provide one of the following statements: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502(a)."	❒ ❒	❒ ❒

Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Occupational Dose: Dosimetry "We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated according to the manufacturer's requirements." **OR, IN LIEU OF THESE STATEMENTS,** Provide a description of an alternative method for demonstrating compliance with the referenced regulations	N/A	❒
	Occupational Dose: Bioassay Program Provide a description of the bioassay program for timely evaluation for both routine operations and occurrence of abnormal airborne releases. Or provide an explanation for not having a bioassay program, if not required by 10 CFR 20.1502.	N/A	❒
	Occupational Dose Provide the following statement: "We have developed and will implement and maintain within Part 20 requirements."	❒	❒
	Occupational Dose: Minimization of Contamination The applicant should provide a description of procedures for minimization of contamination. **AND** Provide the following statement: "We have developed and will implement and maintain written procedures for the minimization of contamination."	N/A ❒	❒ ❒
	Public Dose No response is required from the applicant, but records and written materials documenting compliance may be examined during NRC inspections.	N/A	N/A
	Safe Operating and Maintenance Procedures: Operating Procedures The applicant should provide a description of their operating procedures with an emphasis on radiation safety of critical fusion components. **AND** Provide the following statements: "We have developed and will implement and maintain written procedures for operation of the fusion machine." **AND** "Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and	N/A ❒ ❒	❒ ❒ ❒

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Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Safe Operating and Maintenance Procedures: Operating Procedures (iv) the changes do not degrade the effectiveness of the program."		
	Safe Operating and Maintenance Procedures: Maintenance The applicant should provide a description of their maintenance procedures for ensuring safe conduct of maintenance activities. **AND** Provide the following statements: "We have developed and will implement and maintain written procedures for maintenance activities that ensure integrity of fusion machine components and are necessary for radiation protection." **AND** "Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and (iv) the changes do not degrade the effectiveness of the program."	N/A ❒ ❒	❒ ❒ ❒
	Safe Operating and Maintenance Procedures: Emergency Procedures Describe realistic emergency scenarios and the procedures for responding to them. **AND** Provide the following statements: "Procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material." **AND** "Procedures will be revised only if (i) the changes are reviewed and approved by the licensee management and the RSO in writing, (ii) the licensee staff is provided training in the revised procedures before implementation, (iii) the changes are in compliance with NRC regulations and the license, and (iv) the changes do not degrade the effectiveness of the program."	N/A ❒ ❒	❒ ❒ ❒
	Surveys and Leak Tests For Surveys and Contamination: Provide the following statement: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination	❒	❒

Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Surveys and Leak Tests (Cont.) levels published in Appendix N to NUREG-1556, Volume 22, " Program-Specific Guidance About Possession Licenses for Fusion Machines." **OR** Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage. For Sealed Source and Plated Foils: Choose one of the following statements: State: "Leak tests will be performed at the intervals specified by the NRC or applicable Agreement State in the SSD registration certificate." **AND** If leak tests will be analyzed by an outside entity, state: "Leak tests will be analyzed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Leak tests may be collected by the licensee, using the instructions from the manufacturer (or distributor) of the sealed source or plated foil and the leak test kit supplier. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services." **OR** If leak tests will be analyzed by the applicant, state: "We will implement the model leak test program published in Appendix O to NUREG-1556, Volume 22, " Program-Specific Guidance About Possession Licenses for fusion machines." **OR** Submit a description of alternative equipment or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foil.	N/A ❒ ❒ N/A	❒ ❒ ❒ ❒
	Transportation No response is needed from applicants during the licensing phase. However, before a licensee makes shipments of licensed materials using a Type B package, the licensee needs to have registered with the NRC as a user of the package and obtained NRC's approval of its QA program. Transportation activities may be reviewed during NRC inspections.	N/A	N/A

Item No.	Suggested Response	Agree to Use	Response/ Description Attached
10.	**RADIATION SAFETY PROGRAM**		
	Evaluation to Determine Need for Offside Emergency Plan If the license application requests possession of quantities of radioactive materials exceeding the thresholds in Schedule C, submit an evaluation demonstrating the maximum offsite dose from a release of radioactive materials. If the evaluation demonstrates that the accidental release of radioactive material would exceed 0.01 Sv (1 rem), the applicant needs to develop and submit an emergency plan containing the elements in 10 CFR 30.32(i)(3).	**N/A**	❒
	Environmental Surveillance No response is required from the applicant, but records and written materials documenting compliance may be examined during NRC inspections.	N/A	N/A
	Security Program No response is required from an applicant or licensee. If 10 CFR Part 37 applies, compliance with access authorization and security program requirements may be reviewed during NRC inspections.	N/A	N/A
11.	**WASTE MANAGEMENT**		
	If waste is to be disposed of by transfer to an authorized recipient, provide a description of the waste and an assessment of whether the waste has novel physical, chemical, or radiological characteristics.	N/A	❒
	AND		
	State that: "We will use the model waste procedures published in Appendix Q in NUREG-1556, Volume 22, " Program-Specific Guidance About Possession Licenses for Fusion Machines."	❒	❒
	OR		
	If the applicant wishes to use only selected model procedures, state that: "We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix Q in NUREG-1556, Volume 22, " Program-Specific Guidance About Possession Licenses for Fusion Machines."	❒	❒
	OR		
	Describe procedures for waste collection, storage, and disposal by any of the authorized methods described in this section.	N/A	❒

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APPENDIX B

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Checklist for Requests to Withhold Proprietary Information from Public Disclosure (Under 10 CFR 2.390)

In order to request that the NRC withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit the following:	
☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	Is signed under oath and affirmation (notarization may suffice).
☐	Clearly identifies (such as by name or title and date) the document to be withheld.
☐	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
☐	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	To the best of the applicant's knowledge, is the information currently available in public sources?
☐	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

APPENDIX C

COMMENCEMENT OF CONSTRUCTION AT EXISTING AND PROPOSED BYPRODUCT MATERIAL FACILITIES

Commencement of Construction at Existing and Proposed Byproduct Material Facilities

Purpose and Scope

The commencement of construction applies to all Part 30 applicants and licensees; however, this appendix focuses on the requirements for fusion machines.

If a licensing action initiated pursuant to Part 30 meets any of the criteria in 10 CFR 51.20 or 51.21, then commencement of construction of a facility before the NRC staff has completed its environmental review process is grounds for denial of the license application, in accordance with 10 CFR 30.33(a)(5). If the NRC has not determined that an environmental assessment or an environmental impact statement is required in accordance with 10 CFR 51.22(b), then commencement of construction before the NRC staff concludes the environmental process should not be the sole basis for denial of the license application.

If the licensing action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, the NRC had already determined that this category of actions does not have a significant impact on the environment. Any construction activities undertaken before the issuance of a license are entirely at the risk of the applicant or licensee.

Background

The NRC amended its regulations in September 2011, by revising certain provisions applicable to the licensing and approval processes for byproduct material, source material, and SNM licenses in the final rule, "Licenses, Certifications, and Approvals for Materials Licensees" (76 FR 56951; September 15, 2011) (Material Licenses Construction Rule). The revisions contained in the Material Licenses Construction Rule revised the definitions of "construction" and "commencement of construction" for materials licensing actions.

The definition of "commencement of construction" in 10 CFR 30.4 is as follows:

> *Commencement of construction* means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this Part that has a reasonable nexus to:
>
> 1. Radiological health and safety; or
>
> 2. Common defense and security.

The definition of "construction" in 10 CFR 30.4 is as follows:

> *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., paved 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 radiological health and safety, or common defense and security.

The Atomic Energy Act of 1954, as amended, expressly limits the NRC's regulatory authority to matters concerning the radiological public health and safety or common defense and security and non-radiological hazards, to the extent such hazards result from the actual processing of byproduct material. The NRC has determined that this authority does not extend to site preparation activities that do not have a nexus to radiological health and safety or common defense and security.

This appendix should be used to evaluate whether the construction of a fusion machine has a nexus to radiological health and safety, and thus falls under the jurisdiction of the NRC for licensing purposes. An activity or action has a reasonable nexus to radiological health and safety if that activity or action has a rational, direct link to ensuring that a materials facility is operating, or will operate, in accordance with the NRC's regulations and in a manner that protects the public health and safety or the common defense and security from radiological hazards. The definitions of construction in 10 CFR 30.4 lists activities that are not considered "construction." This appendix provides examples of activities at fusion machines that fall under each of the excepted activities that do not constitute construction.

Site preparation activities that are not considered "construction," while not under NRC jurisdiction may be subject to the regulatory authority of another federal, state, or local agency which may require National Environmental Policy Act or state environmental review. NRC's responsibilities under the National Historic Preservation Act of 1966, as amended (NHPA), must also be satisfied before a license is issued. Specifically, as noted in the statements by the NRC

published with the final Material Licenses Construction Rule, under certain circumstances the NRC may be required to deny a license application if the NRC determines that the applicant intentionally significantly adversely affected, or allowed to be affected, a historic property with intent to avoid the requirements of Section 106 of the NHPA.

Applying Commencement of Construction to Fusion Machines

This section clarifies the delineation of site preparation activities and construction activities for fusion machines. It is important to recognize that the NRC may have regulatory authority over activities that can occur before construction begins such as procurement of basic components as defined in 10 CFR Part 21.

Licensing of a fusion machine may qualify for a categorical exclusion under 10 CFR 51.22. However, under 10 CFR 51.101, commencement of construction (as defined in 10 CFR 30.4) of a new fusion machine for other than research and development or educational purposes may not occur prior to until the issuance of a record of decision or until a final finding of no significant impact. Prior to the conclusion of the environmental review process, applicants for byproduct material licenses or license amendments should not perform construction activities that have a nexus to radiological health and safety (e.g., the installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity).

However, excavation and other site preparation activities that do not have a reasonable nexus to radiological public health and safety, whether permanent or temporary, are not “construction” activities. For example, piles driven to support the erection of a bridge for a temporary or permanent access road to a new facility would not be considered as construction and may be performed prior to the NRC staff concluding its environmental review of a proposed action.

The installation of a temporary feature within an excavation for a building in which materials license activities will be conducted and that will be removed during construction is a site preparation activity. Such features include retaining walls, dewatering systems, ramps, and other structures that will have no physical presence following construction.

Construction includes installation of the foundation, including soil compaction; the installation of permanent drainage systems and geofabric; the placement of backfill, concrete (e.g., mudmats), or other materials that will not be removed before placement of the foundation of a structure; the placement and compaction of a subbase; the installation of reinforcing bars to be incorporated into the foundation of the structure; the erection of concrete forms for the foundations that will remain in place permanently (even if nonstructural); and the placement of concrete or other material constituting the foundation of any safety-related feature.

The term “permanent” in this context includes anything that will exist in its final, in-place facility location after commencement of operations with licensed material. Construction also includes the “onsite, in-place” fabrication, erection, integration, or testing activities for any in-scope safety-related equipment. The terms “onsite, in-place, fabrication, erection, integration, or testing” describe the process of constructing a facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. The fabrication, assembly, and testing of components and modules in a shop building, warehouse, or laydown area, even if located onsite, is not construction. However, the installation or integration of the safety-related equipment into its final plant location is construction.

Construction also includes driving piles for safety-related equipment. Hence, an applicant must obtain a license before driving piles for safety-related equipment. However, driving piles that do not ensure the structural stability or integrity of a safety-related structure (e.g., piles driven to support the erection of a bridge for a temporary or permanent access road) is not construction; therefore, those piles may be driven prior to the NRC staff concluding its environmental review of a proposed action.

An applicant for a new fusion machine license under Part 30 may perform the non-construction activities identified in revised 10 CFR 30.4 at any time. However, activities that have a reasonable nexus to radiological health and safety for purposes of a fusion machine include, but are not limited to, construction of systems subject to 10 CFR Part 30.32(k) and the following:

- *Access Control:* adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas;
- *Site*: potential need for protection against flooding and earth slides;
- *Base (soil, rock) for the Fusion Components and Shielding Structures:* strength, settlement, liquefaction, ground water, and soil compaction;
- *Footers and Foundations:* strength and reinforcement, alignment with fusion components and shielding structures;
- *Shielding Structure:* strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding materials;
- *Penetrations Through Shielding:* any significant effect on structural strength, shielding, or both;
- *Hard Wiring:* adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair;
- *Uninterruptable Electrical Power Supply:* adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system; and
- *Fire Protection System:* adequacy to detect fire and smoke and to be manually as well as automatically initiated.

Reference:

- NUREG–1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003

APPENDIX D

TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety, security, and compliance with both NRC and DOT regulations and the conditions of the license. Typically, these duties and responsibilities include the following:

- Ensure that licensed material that the licensee possesses is limited to the types and quantities of byproduct material listed on the license.
- Maintain documentation demonstrating that the dose to individual members of the public does not exceed the limit specified in 10 CFR 20.1301.
- Ensure security of radioactive material.
- Post documents as required by 10 CFR Parts 19.11, "Posting of notice to workers," and 10 CFR 21.6, "Posting requirements."
- Ensure that licensed material is transported in accordance with applicable NRC and DOT requirements.
- Ensure that radiation exposures are maintained within Part 20 limits..
- Oversee all activities involving radioactive material, including monitoring and surveys of all areas in which radioactive material is used.
- Act as liaison with the NRC and other regulatory authorities.
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to 10 CFR Parts 19 and 20, and any other applicable regulations.
- Oversee proper delivery, receipt, and conduct of radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution.
- Determine the need for personnel monitoring, distribute and collect personnel radiation monitoring devices, evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching the limits, and recommend appropriate remedial action.
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material before use, at periodic intervals (refresher training), and as required by changes in procedures, equipment, regulations, etc.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping of waste storage and disposal records.
- Oversee the storage of radioactive material not in current use, including waste.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Maintain an inventory of all radionuclides possessed under the license, and limit the quantity to the amounts that the license authorizes.
- Immediately terminate any unsafe condition or activity found to be a threat to public health and safety or property.

- Supervise decontamination and recovery operations.
- Maintain other records not specifically designated above, for example, records of receipts, transfers, and surveys as required by 10 CFR 30.51, "Records," and 10 CFR Part 20, Subpart L, "Records."
- Hold periodic meetings with, and provide reports to, licensee management.
- Ensure that all radioactive materials users are properly trained.
- Perform periodic audits of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license (e.g., leak tests; inventories; use limited to trained, approved users); the content and implementation of the radiation safety program to achieve occupational doses and doses to members of the public that are within Part 20 requirements, in accordance with 10 CFR 20.1101; and required records are maintained.
- Ensure that the results of audits, identification of deficiencies, and recommendations for change, are documented (and maintained for at least 3 years) and provided to management for review; ensure that prompt action is taken to correct deficiencies.
- Ensure that the audit results and corrective actions are communicated to all radiation workers, including ancillary personnel.
- Ensure that all incidents and personnel exposure to radiation in excess of 10 CFR Part 20 limits are investigated and reported to the NRC and other appropriate authorities, if required, within the required time limits.
- Maintain understanding of and keep up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to NRC during the licensing process.
- Develop, implement, maintain, and distribute, as appropriate, up-to-date operating, emergency, and security procedures.

Model Delegation of Authority

Memo To: Radiation Safety Officer (RSO)

From: Chief Executive Officer

Subject: Delegation of Authority

You, , have been appointed RSO and are responsible for ensuring the safe and secure use of radiation. You are responsible for managing the radiation protection program, identifying radiation protection problems, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, stopping unsafe activities, and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations, when justified, to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the NRC at any time. It is estimated that you will spend ____ hours per week conducting radiation protection activities.

_____

Signature of Management Representative Date

I accept the above responsibilities,

_____

Signature of Radiation Safety Officer Date

cc: Affected department heads

APPENDIX E

RADIATION SAFETY TRAINING

Radiation Safety Training

This appendix is intended only as a guide for developing a training program. Individuals working with radionuclides may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty, or which areas to enter or avoid. Conversely, authorized users may require detailed information on certain topics. As a result, instruction for some individuals may be accomplished by providing a simple hand-out, whereas others may require extensive training, including a written exam to assess retention of the topics presented.

The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

Frequency of Training

- before assuming duties with, or in the vicinity of, radioactive materials
- whenever there is a significant change in duties, regulations, or the terms of the license
- annually (refresher training)

General Information

A. Radiation safety

1. radiation vs. contamination
2. internal vs. external exposure
3. biological effects of radiation
4. Part 20 radiation program requirements
5. use of time, distance, and shielding to maintain doses within Part 20 requirements
6. contact dose rates and dose rates at a distance from high-activity sources
7. dose reduction responsibilities

B. Regulatory requirements

1. RSO
2. material control and accountability
3. personnel dosimetry
4. radiation safety program audits
5. transfer and disposal
6. recordkeeping
7. radiation surveys

8. postings
9. labeling of containers
10. handling and reporting of incidents or events
11. licensing and inspection by the NRC
12. need for complete and accurate information
13. employee protection
14. deliberate misconduct

Licensee-Specific Program Elements

A. authorized individuals and supervised individuals
B. worker-specific activities during both routine and maintenance operations
    1. personal protective equipment and use of personnel monitoring devices
    2. limitations and conditions relative to handling unsealed licensed material (e.g., tritium) and what equipment to use when working with such material
        a. use of licensed material that should be confined to radiochemical fume hoods or glove boxes
        b. shielding or remote handling equipment to be used when licensed materials are handled
    3. prohibitions of eating, smoking, and drinking in areas where licensed materials are possessed and used
C. Moving/transferring/shipping radionuclides to different areas or licensees
D. Applicable regulations and license conditions
E. Areas where radioactive material is used or stored
F. Potential hazards associated with radioactive material in each area where the individuals will work (e.g., neutron hazards and activated materials)
G. Appropriate radiation safety procedures
H. Each individual's obligation to report unsafe conditions to the RSO
I. Appropriate response to spills, fires, release of material, accidental contamination of personnel, or other unsafe conditions
J. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable
K. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence)
L. Emergency procedures
    1. RSO name and telephone number
    2. immediate steps to prevent or control spread of contamination
    3. cleanup instructions, decontamination

M. Survey program
    1. radiation survey instrument accessibility
    2. who is responsible
    3. types, contamination, and areas
    4. frequency
    5. levels of contamination
    6. personnel, hands, shoes
    7. records
N. Waste
    1. liquids
    2. solids
    3. air effluents
    4. sanitary sewer
    5. burial (transfer to low-level waste repository)
    6. storage
    7. decay in storage
    8. waste storage surveys
    9. incineration
    10. records
O. Dosimetry
    1. whole body
    2. extremities
    3. lens of the eye
    4. lost or replacement badges and dose assessment
    5. bioassay procedures
    6. records
P. Instrumentation
    1. radiation survey meters – use, calibration frequency, use of check sources
    2. analytical instruments – gas-flow counters, liquid scintillation counters
Q. Procedures for receiving packages containing radioactive materials (if applicable)
    1. normal
    2. off-duty
    3. notification of user and RSO
    4. security

5. exposure levels
6. possession limit
7. receipt of damaged packages

R. Sealed sources
1. leak test requirements
2. inventory requirements
3. exempt quantities
4. records

S. NRC/State/Licensee audit findings

T. Other topics

U. Question and answer period

Safety and Use of Radionuclides

A. Control procedures for obtaining permission to use radioactive materials at the facility; give limitations on quantity to be handled per user, allowed per experiment, etc.

B. Protective clothing and what laboratory apparel to wear and which equipment to use.

C. Limitations and conditions relative to handling unsealed licensed material and which laboratory equipment to use when working with such material. As an example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or gloveboxes. Explain what shielding or remote handling equipment should be used when beta or gamma emitting licensed materials are handled.

D. Routine survey and monitoring procedures to be followed for contamination control include where and how contaminated articles and glassware are to be handled and stored.

E. Emergency procedures concerning spills, fires, release of material, or accidental contamination of personnel.

F. Decontamination procedures to use and whom to contact in case of an emergency.

G. Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.

H. Requirements for storage, labeling of containers, and identification of areas where licensed materials are used.

I. Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.

J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters, and handling animal excreta and carcasses for disposal.

K. Records to be maintained on use and disposal of licensed materials

L. Prohibition of pipetting by mouth.

M. Prohibition of eating, smoking, and drinking in areas where licensed materials are possessed or possessed and used.

APPENDIX F

FACILITIES AND EQUIPMENT CONSIDERATIONS

Facilities and Equipment Considerations

The application should contain detailed descriptions and diagrams of the facility. It should include the construction material used and the shielding properties of each material. The application should include workloads, energy levels and shielding calculations. Scaled drawings and sketches should be submitted showing the relationship between restricted areas (areas where the licensee limits access to protect individuals against undue risks from exposure to radiation and radioactive materials) and unrestricted areas and the location of all pertinent safety-related equipment.

Below is a list of topics that should be considered when developing the facilities and equipment for various fusion machines. Not every topic will be applicable to all licensees.

Handling Unsealed Material and Contamination Controls

- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas of use should be well-lighted to avoid spills and other incidents that could result in contamination buildup.
- Bench-top or open work areas may be used for sealed sources, small quantities of solid materials in a form not likely to become airborne or dispersed, and 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.
- Handling or use of unsealed radioactive material should be performed 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. Ventilation systems for these facilities should be designed so that airborne radioactive material work areas are at negative pressure compared to nonradioactive work areas.
- Tritium handling systems should be connected to appropriate tritium management systems to discourage the spread of airborne radioactivity into work areas. Licensees should have procedures in place for anticipated fault scenarios. Procedures should include respiratory protection for airborne radioactivity if elevated radiation levels are detected that would cause worker dose to exceed allowed values, as well as air sampling to ensure the area is free of contamination before entering.
- 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. If appropriate, supply and exhaust fans can be interlocked such that if exhaust fans shutdown, the shutdown of supply fans is also triggered. This interlock system prevents work areas from becoming positively pressurized with respect to the surrounding parts of the facility.
- 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, unsealed volatile licensed materials, and 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 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) 10 CFR Part 20, Appendix B.

- Glove boxes are sealed boxes with transparent viewing windows, sealable ports or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- For the most efficient operation of hoods and glove boxes, minimize storage of materials and equipment inside the work areas.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow, rather than by hand.

Minimization of Radiation Exposure

- To reduce radiation exposure from gamma-emitting radioactive materials, 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.
- Appropriate neutron shielding must be present for all fusion activities that generate a neutron flux.
- To reduce the exposure from high-energy beta-emitting materials, shielding of low atomic number material, such as high-density plastic, may be used.
- Shielded shipping containers frequently are used for continued storage after receipt of materials. Such containers must be access controlled and in a secure area.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of operations to be conducted.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials. In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- 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. Penetrations for plumbing and ductwork in shielded areas shall be back shielded and evaluated post installation.
- Personnel dosimetry storage should be designated in areas where radiation levels are constantly at background.

Waste and Effluents

- 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 that personnel frequently occupy. Additionally, these containers should be effectively enclosed to prevent airborne contamination from radioactive materials deposited. If radioactive waste materials are volatile, the containers should be stored in ventilated areas.
- If compaction of waste is performed, ensure that facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure that air sampling for internal exposures is available, if needed, per 10 CFR 20.1204.
- Adequate air and water effluent monitoring equipment should be used to demonstrate compliance with the limits found in 10 CFR Part 20, Appendix B, if applicable, and tested for operability at the frequency established by the manufacturer.
- 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.

Table F-1 Construction Monitoring & Acceptance Testing for Fusion Machines

Fusion Machine Type	Fusion Machine Element	Licensee Requirement
All	Shielding	Monitor the construction of the shielding to ensure that its construction meets design specifications and generally accepted building code requirements for shielding type. Document shielding during the construction process to ensure proper installation. Upon fusion machine installation a commissioning report shall be conducted to ensure proper shielding is installed.
	Foundations	Monitor the construction of the foundations to verify that their construction meets design specifications.
	Radiation Monitors	Verify the operation of radiation monitors for all ionizing radiation types of interest. Radiation monitors should data log for a period of time to extrapolate historical information.

Table F-1 Construction Monitoring & Acceptance Testing for Fusion Machines		
Fusion Machine Type	**Fusion Machine Element**	**Licensee Requirement**
All	Radiation Monitors	Test the ability of alarm systems linked to radiation monitors (if applicable).
	Access Control	Test the completed access control system to ensure that it functions as designed and that all alarms, controls, and interlocks work properly.
	Fire Protection	Test the ability of the heat and smoke detectors to detect a fire and to activate alarms. The licensee must test the operability of the fire extinguishing system. It is not necessary that licensees turn on extinguishers (i.e., water or chemicals) during tests of the operability of their fire protection systems
	Computer Systems	Verify that the access control system will operate properly if offsite power is lost, and verify that the computer has security features that prevent an operator from commanding the computer to override the access control system when it is required to be operable.
	Wiring	Verify that the electrical wiring and electrical equipment that were installed meet the design specifications (e.g., radiation-resistant wiring installed in appropriate locations and according to code).
	Tritium Handling	Whether tritium is present as a fuel or byproduct, the licensee must demonstrate a proper system for storage and processing of tritium. Test vacuum pressure on tritium storage system to verify leakage is within allowed tritium exposure limits.
All	Tritium Handling	In case of a tritium leak, procedures should be in place to survey and clean the area. Monitoring of airborne radioactivity levels and plans to clear the area around storage system for re-entry must be present.

Table F-1 Construction Monitoring & Acceptance Testing for Fusion Machines		
Fusion Machine Type	**Fusion Machine Element**	**Licensee Requirement**
		For maintenance activities, licensee must have plans for protecting operators from contamination and tritium inhalation/uptake.
	Breeding Blankets	Ensure breeding blankets are installed per design requirement.
		For emergency conditions, licensee must demonstrate plans to monitor airborne radioactivity levels and plans to clear area for re-entry.
		For maintenance activities, licensee must have plans for protecting operators from contamination and tritium inhalation/uptake. Additionally, licensees must have plan for monitoring gamma radiation exposure from materials activated by neutron flux.
Magnetic Confinement (Tokamak)	Magnets	For emergency conditions, demonstrate that magnets will power down, ceasing fusion activities.
	Fuel Injection System	Demonstrate that fuel injection system is a closed system that does not allow unprotected exposure of operators to fuel during routine operation.
Pulsed Fusion	Power Supply	Demonstrate electrical and fire safety procedures for routine and emergency conditions.
		For maintenance activities, ensure proper lockout/tagout procedures are in place to de-energize equipment prior to work.

1
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APPENDIX G

SAMPLE AUDIT PROGRAM

Sample Audit Program

An audit is conducted, in part, to fulfill the requirements of Title 10 of the Code of Federal Regulations (10 CFR) 10 CFR 20.1101 for an annual review of the content and implementation of the licensee's radiation protection program. Audits should be performance-based and include observations of licensed activities, interviews with personnel, and inspection of facilities and equipment. Audits should also identify program weaknesses and allow licensees to take early corrective actions [before an NRC inspection]. During an audit, the auditor needs to keep in mind not only the requirements of the NRC's regulations but also the licensee's commitments in its applications and other correspondence with the NRC. The auditor also should evaluate whether the licensee is maintaining exposures to workers and the general public within Part 20 requirements, if not, make suggestions for improvement.

The form in this appendix can be used to document the annual audit of the radiation protection program. Guidance on completing each section of the form is listed below. In the "remarks" portions of the form, note any deficiencies identified and the corrective actions taken (or to be taken).

Section 1 – Audit History. Enter the date of the last audit, whether any deficiencies were identified, and whether actions were taken to correct the deficiencies.

Section 2 – Organization and Scope of Program. Give a brief description of the organizational structure, noting any changes in personnel or procedures, and amendments to the license. Describe the scope of licensed activities at the audited location. Check if the RSO is the person identified on the license and fulfills the duties specified in the license.

Section 3 – Training, Retraining, and Instructions to Workers. Ensure that workers have received the training required by 10 CFR 19.12 Be sure that the user has received training and has a copy of the licensee's safe use and emergency procedures before being permitted to use byproduct material. Note whether refresher training is conducted in accordance with licensee commitments. Ensure that each worker has a copy of the licensee's procedures and, by interview or observation of selected workers, that he or she can implement them.

Section 4 – Audits. Verify that audits fulfill the requirements of 10 CFR 20.1101, are conducted in accordance with licensee commitments, and are properly documented.

Section 5 – Facilities. Verify that the licensee's facilities are as described in its license documents.

Section 6 – Materials. Verify that the license authorizes the quantities and types of byproduct material that the licensee possesses.

Section 7 – Leak Tests. Verify that all sealed and plated foil sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Section 8 – Inventories. Verify that inventories are conducted at least once every 6 months to account for all sources; inventory records should be maintained.

Section 9 – Radiation Surveys. Verify that the licensee has appropriate, operable, and calibrated survey instruments available, that the instruments are calibrated (at the required

frequency) in accordance with license conditions and in accordance with 10 CFR 20.2103. Calibration records must be retained for 3 years after the record is made. Verify compliance with 10 CFR 20.1301. Check that radiation levels in areas adjacent to use are within regulatory limits and records are in accordance with 10 CFR 20.2103. Records of surveys must be retained for 3 years after the record is made. Evaluate the licensee determination that effluent releases comply with 10 CFR 20.1101(d). Review the assumptions used to determine doses to members of the public.

Section 10 – Receipt and Transfer of Radioactive Material (Includes Waste Disposal). Verify that packages containing byproduct material, received from others, are received, opened, and surveyed in accordance with 10 CFR 20.1906, "Procedures for receiving and opening packages." Ensure that transfers are performed in accordance with 10 CFR 30.41 and 10 CFR 40.51, as appropriate. Records of surveys, receipt, and transfer must be maintained in accordance with 10 CFR 20.2103, 10 CFR 30.51, and 10 CFR 40.61, as appropriate.

Section 11 – Transportation. Determine compliance with DOT requirements, if applicable.

Section 12 – Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. Alternately, if personnel dosimetry is provided and required, verify that it complies with 10 CFR 20.1501(c) and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; and determine reasons for significant differences in exposures. If any worker declared her pregnancy in writing, evaluate the licensee's compliance with 10 CFR 20.1208. Check whether records are maintained as required by 10 CFR 20.2101, 2102, 2103, 2104, and 2106.

Section 13 – Auditor's Independent Measurements (if made)**.** The auditor should make independent survey measurements and compare the results with those that the licensee made or used.

Section 14 – Notification and Reports. Check on the licensee's compliance with the notification and reporting requirements in 10 CFR Parts 19, 20, 30, 40, and 70. Ensure that the licensee is aware of the telephone number for NRC's Emergency Operations Center (301-816-5100).

Section 15 – Posting and Labeling. Check for compliance with the posting and labeling requirements of 10 CFR 19.11, 20.1902, 20.1904, and 21.6.

Section 16 – Recordkeeping for Decommissioning. Check to determine compliance with 10 CFR 20.1501(b) and 10 CFR 30.35(g), and 10 CFR 40.36(f).

Section 17 – Bulletins and Information Notices. Check to determine if all NRC correspondence (e.g., RISs, bulletins, INs, and NMSS newsletters) issued since the previous audit and applicable to academic, research and development, and other licenses of limited scope have been reviewed. Check whether the licensee took appropriate action (e.g., training, updating procedures, etc.) in response to this NRC correspondence.

Section 18 – Special License Conditions or Issues. Verify compliance with any special conditions on the licensee's license. If the licensee has any unusual aspect of its work, review and evaluate compliance with regulatory requirements.

Section 19 – Continuation of Report Items. This section is self-explanatory.

Section 20 – Problems or Deficiencies Noted; Recommendations. This section is self-explanatory.

Section 21 – Evaluation of Other Factors. Evaluate licensee management's involvement with the radiation safety program, whether the RSO has sufficient time to perform their duties, and whether the licensee has sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.

Sample Checklist

Audit Report No.

License No.

Licensee's name and mailing address:

Audit of activities at (address):

Contact at Audit Location

Telephone No.

Date of this Audit

Summary of Findings and Action:

[ ] No deficiencies

[ ] Deficiencies

[ ] Action on previous deficiencies

Recommendations:

Auditor:

Date:

(Signature)

1. AUDIT HISTORY [ ] N/A (N/A means “Not applicable”–Initial Audit)

A. Last audit of this location conducted

B. Problems or deficiencies identified during last two audits or 2 years, whichever is longer [ ] Y [ ] N

C. Open problems or deficiencies from previous audits:

Status	Requirement	Prob./Def.	Corrective Action Taken (Y/N)	Open/Closed

D. Any previous problem or deficiency not corrected or repeated

[ ] Y [ ] N [ ] N/A

Explain:

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure

1. Structure is as described in license documents [ ] Y [ ] N

2. Multiple authorized locations of use [ ] Y [ ] N

3. Briefly describe scope of activities involving byproduct material, frequency of use, staff size, etc. [ ] Y [ ] N

4. Amendments and program changes [ ] Y [ ] N

B. RSO [ ] Y [ ] N

1. Authorized on license [ ] Y [ ] N

2. Fulfills duties as RSO [ ] Y [ ] N

C. Use only by authorized individuals [ ] Y [ ] N

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per 10 CFR 19.12 [ ] Y [ ] N

B. Training program required [ ] Y [ ] N

C. Training records maintained [ ] Y [ ] N

D. Evaluation of individuals' understanding of procedures and regulations based on interviews, observation of selected workers

[ ] Y [ ] N

1. Each has an up-to-date copy of the licensee's safe use an emergency procedures

2. Adequate understanding of:

Current safe use procedures [ ] Y [ ] N

Emergency procedures [ ] Y [ ] N

E. 10 CFR Part 20 Workers cognizant of requirements for:

1. Radiation Safety Program (10 CFR 20.1101) [ ] Y [ ] N

2. Annual dose limits (10 CFR 20.1301, 20.1302) [ ] Y [ ] N

3. New NRC Forms 4 and 5 [ ] Y [ ] N

4. 10 percent monitoring threshold (10 CFR 20.1502) [ ] Y [ ] N

5. Dose limits to minors (10 CFR 20.1207) [ ] Y [ ] N

6. Dose limits to embryo or fetus and declared pregnant women (10 CFR 20.1208) [ ] Y [ ] N

7. Procedures for opening packages (10 CFR 20.1906) [ ] Y [ ] N

Remarks:

4. INTERNAL AUDITS, REVIEWS, OR INSPECTIONS

A. Audits are conducted [ ] Y [ ] N

1. Audits conducted by

2. Frequency

B. Content and implementation of the radiation protection program reviewed annually [10 CFR 20.1101(c)] [ ] Y [ ] N

A. Records maintained (10 CFR 20.2102) [ ] Y [ ] N

Remarks:

5. FACILITIES

A. Facilities as described in license application

B. Commensurate security procedures implemented (20.1801, 20.1802; Part 37 if applicable) [ ] Y [ ] N

C. Shielding as described in application [ ] Y [ ] N

Remarks:

6. MATERIALS

Isotopes, quantities, and use as authorized on license [ ] Y [ ] N

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with the NRC (consultant, leak test kit, licensee performed) [ ] Y [ ] N

B. Frequency: every 6 months or other interval, as approved by NRC or Agreement State [ ] Y [ ] N

C. Records with appropriate information maintained [ ] Y [ ] N

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals [ ] Y [ ] N

B. Records with appropriate information maintained [ ] Y [ ] N

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment: [ ] Y [ ] N

1. Appropriate operable survey instrumentation possessed or readily available [ ] Y [ ] N

2. Appropriate operable area and effluent monitoring instrumentation possessed [ ] Y [ ] N

3. Calibrated as required (10 CFR 20.1501) [ ] Y [ ] N

4. Calibration records maintained [10 CFR 20.2103(a)]

[ ] Y [ ] N

B. Briefly describe survey requirements [10 CFR 20.1501(a)]

1. Airborne radioactive material – effluents released and/or worker personal area monitoring

2. Waterborne radioactive material – effluents released to unrestricted areas and/or sewer releases

3. External exposure of public and/or workers – contamination and/or ambient radiation and/or bioassay

4. Facilities and equipment – restricted and unrestricted areas

5. Decommissioning – release of equipment for unrestricted use and/or release of facilities for unrestricted use

C. Performed as required [10 CFR 20.1501(a)] [ ] Y [ ] N

1. Radiation levels within regulatory limits [ ] Y [ ] N

2. Corrective action taken and documented [ ] Y [ ] N

D. Records maintained (10 CFR 20.2103) [ ] Y [ ] N

E. Protection of members of the public

1. Evaluate the licensee determination that effluent releases comply with 10 CFR 20, Appendix B and 10 CFR 20.1101(d). Review the assumptions used to determine doses to members of the public.

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 millirem (mrem) in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [10 CFR 20.1301(a)(1), 20.1302(b)] [ ] Y [ ] N

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [10 CFR 20.1301(a)(2)] [ ] Y [ ] N

3. Records maintained (10 CFR 20.2103, 20.2107) [ ] Y [ ] N

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Procedures describe how packages are received and by whom [ ] Y [ ] N

B. Written package opening procedures established and followed [10 CFR 20.1906(e)] [ ] Y [ ] N

C. If package shows evidence of degradation, monitor for contamination and radiation levels [ ] Y [ ] N [ ] N/A

D. Monitoring of degraded packages performed within time specified [10 CFR 20.1906(c)] [ ] Y [ ] N [ ] N/A

E. Transfer(s) between licensees (including "disposal") performed per (10 CFR 20.2001 an Appendix G, 10 CFR 30.41, 40.51) [ ] Y [ ] N [ ] N/A

F. Records of receipt or transfer maintained (10 CFR 20.2103(a), 30.51, 40.61, 70.51) [ ] Y [ ] N

G. Transfers within licensee's AUs or locations performed as required [license condition (L/C)] [ ] Y [ ] N [ ] N/A

H. Package receipt or distribution activities evaluated for compliance with (10 CFR 20.1301, 20.1302) [ ] Y [ ] N [ ] N/A

Remarks:

11. TRANSPORTATION [10 CFR 71.5(a) and 49 CFR 170-180] [ ] N/A

A. Licensee shipments are

1. Delivered to common carriers [ ] Y [ ] N [ ] N/A

2. Transported in licensee's own private vehicle [ ] Y [ ] N [ ] N/A

3. No shipments since last audit [ ] Y [ ] N [ ] N/A

B. Hazardous Material (HAZMAT) Training

1. Applicability and responsibility for training and testing (49 CFR 172.702) [ ] Y [ ] N [ ] N/A

C. Packages [ ] N/A

1. Authorized packages used [49 CFR 173.415, 173.416(b)]

[ ] Y [ ] N [ ] N/A

2. Closed and sealed during transport [49 CFR 173.475(f)]

[ ] Y [ ] N

D. Shipping Papers [ ] N/A

1. Prepared and used [49 CFR 172.200(a)] [ ] Y [ ] N

2. Proper shipping name, hazard class, United Nations (UN) number, quantity, package type, nuclide, reportable quantities, radioactive material, physical and chemical form, activity, category of label, Transportation Index (TI), shipper's name, certification, and signature, Emergency response phone number, "Cargo Aircraft Only" (if applicable) (49 CFR 172.200–204)

[ ] Y [ ] N

3. Readily accessible during transport [49 CFR 177.817(e)]

[ ] Y [ ] N

E. Vehicles [ ] Y [ ] N

1. Cargo blocked and braced [49 CFR 177.842(d)] [ ] Y [ ] N

2. Placarded, if needed (49 CFR 172.504) [ ] Y [ ] N

3. Proper overpacks, if used (shipping name, UN Number, labeled, statement indicating that inner package complies with specification package) (49 CFR 173.25) [ ] Y [ ] N

F. Any incidents reported to DOT (49 CFR 171.15, 171.16) [ ] Y [ ] N

Remarks:

12. PERSONNEL RADIATION PROTECTION

A. Part 20 requirements are incorporated into the radiation protection program [10 CFR 20.1101(b)] [ ] Y [ ] N

B. Prospective evaluation performed showing that unmonitored occupationally exposed individuals are not likely to receive >10 percent of allowable limit [10 CFR 20.1502(a)] [ ] Y [ ] N [ ] N/A

OR

C. External dosimetry provided and required [ ] Y [ ] N [ ] N/A

1. Supplier

Frequency

2. Supplier is National Voluntary Laboratory Accreditation Program-approved [10 CFR 20.1501(c)] [ ] Y [ ] N

3. Dosimeters exchanged at required frequency (L/C) [ ] Y [ ] N

D. Occupational intake monitored and assessed [10 CFR 20.1502(b)] [ ] Y [ ] N [ ] N/A

E. Reports [ ] N/A

1. Reviewed by

Frequency

2. Auditor reviewed personnel monitoring records for period

to

3. Prior dose determined for individuals likely to receive doses (10 CFR 20.2104) [ ] Y [ ] N

4. Maximum exposures TEDE

Other

5. NRC Forms or equivalent [10 CFR 20.2104(d), 20.2106(c)]

a. NRC Form 4 “Cumulative Occupational Exposure History” [ ] Y [ ] N

Complete: [ ] Y [ ] N

b. NRC Form 5, “Occupational Exposure Record for a Monitoring Period” [ ] Y [ ] N

Complete: [ ] Y [ ] N

6. Worker declared her pregnancy in writing during inspection period (review records) [ ] Y [ ] N [ ] N/A

If yes, determine compliance with (10 CFR 20.1208) [ ] Y [ ] N

Check for records per [10 CFR 20.2106(e)] [ ] Y [ ] N

F. Records of exposures, surveys, monitoring, and evaluations maintained (10 CFR 20.2102, 20.2103, 20.2106, L/C) [ ] Y [ ] N

Remarks:

13. AUDITOR’S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument

Serial No.

Last calibration

B. Auditor's measurements compared to licensee's [ ] Y [ ] N

C. Describe the type, location, and results of measurements:

14. NOTIFICATION AND REPORTS [ ] N/A

A. Licensee in compliance with (10 CFR 19.13) (reports to individuals, public and occupational, monitored to show compliance with Part 20) [ ] Y [ ] N [ ] N/A

B. Licensee in compliance with (10 CFR 20.2201) (theft or loss) [ ] Y [ ] N [ ] None

C. Licensee in compliance with (10 CFR 20.2202, 30.50, 40.60, 70.50) (incidents) [ ] Y [ ] N [ ] None

D. Licensee in compliance with (10 CFR 20.2203, 30.50, 40.60, 70.50) (overexposures and high radiation levels) [ ] Y [ ] N [ ] None

E. Licensee aware of telephone number for NRC Emergency Operations Center (301-816-5100) [ ] Y [ ] N

F. Licensee in compliance with 10 CFR 20.2207, if applicable (reports of transactions involving nationally tracked sources) [ ] Y [ ] N [ ] N/A

15. POSTING AND LABELING

A. NRC Form 3 "Notice to Workers" is posted (10 CFR 19.11) [ ] Y [ ] N

B. 10 CFR Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted (10 CFR 19.11, 21.6) [ ] Y [ ] N

C. Other posting and labeling per (10 CFR 20.1902, 1904) and the license is not exempted by (10 CFR 20.1903, 1905) [ ] Y [ ] N

Remarks:

16. RECORDKEEPING FOR DECOMMISSIONING (if needed) [ ] N/A

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [ ] Y [ ] N

B. Records include all information outlined in [10 CFR 30.35(g), [ ] Y [ ] N 40.36(f), 70.25(g) and 70.51(b)(3)]

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. NRC correspondence (e.g., RISs, Bulletins, Information Notices, NMSS newsletters) issued since last audit have been reviewed [ ] Y [ ] N

B. Appropriate actions taken in response to RISs, bulletins, information notices [ ] Y [ ] N

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES [ ] N/A

A. Review special license conditions or other issues, and describe findings:

B. Problems or deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS [ ] N/A

(If more space is needed, use separate sheets and attach to report.)

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS [ ] N/A

Note: Briefly state (i) the requirement and (ii) how and when violated. Provide recommendations for improvement.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program or RSO oversight [ ] Y [ ] N

B. RSO has sufficient time to perform their radiation safety duties and is not too busy with other assignments [ ] Y [ ] N

C. Licensee has sufficient staff [ ] Y [ ] N

Remarks and recommendations:

APPENDIX H

RADIATION MONITORING, INSTRUMENT SPECIFICATIONS, AND MODEL SURVEY INSTRUMENT AND AIR SAMPLER CALIBRATION PROGRAM

Radiation Monitoring, Instrument Specifications, and Model Survey Instrument and Air Sampler Calibration Program

This appendix covers the types of instrumentation that may be used by fusion machine facilities for radiation safety and compliance activities. It also covers the calibration of dose and dose rate measurement instruments, surface contamination measurement instruments, and instruments used to collect samples for indirect dose measurements such as air sampling.

Radiation Monitoring Instrument Specifications

The specifications in Table H–1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility or facilities. Additional information about instruments and their uses also can be found in NUREG–1575, "Multi-Agency Radiation Survey and Sited Investigation Manual (MARSSIM)," Chapter 6 and Appendix H.

Table H–1 Typical Survey Instruments* (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
Rate Meters	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
BF3 Proportional Tube*	Neutron	Thermal neutron	High
Gas Proportional	Neutron	Fast neutron	Moderate
Plastic and Liquid Scintillator	Neutron	Fast Neutron	Moderate

Table H–1. Typical Survey Instruments* (Instruments Used to Measure Radiological Conditions at Licensed Facilities)

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter	Alpha	All energies	High
	Beta	All energies	High
	Gamma	All energies	Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Note: Table adapted from "The Health Physics and Radiological Health Handbook, Revised Edition," edited by Bernard Shleien, 1992 (except for * item).

In addition to selecting an instrument that is appropriate for the radiation(s) of interest, it is important to know if the instrument is sufficiently sensitive so as to make measurements at the required level. This is particularly important for measurements such as for leak test samples, bioassay measurements, and decommissioning of facilities or equipment. The minimum detectable activity (MDA) for the instrument should be a fraction (10 to 50 percent) of the target activity being measured.

When the sample count time and the background count time are the same, a simplified calculation can be used to determine the MDA for a static measurement. This simplified calculation assumes that the Type I error (false positive) and Type II error (false negative) are both selected to be equal in probability and at the 95 percent confidence error.

This simplified equation is:

$$\mathrm{MDA} = \left(2.71 + 4.65\sqrt{(\mathrm{bkg} \times \mathrm{t})}\right) / (\mathrm{t} \times \mathrm{E})$$

where:

MDA = minimum detectable activity in disintegrations per minute (dpm)

bkg = background count rate in counts per minute (cpm)

t = background counting time and sample counting time in minutes (min)

E = detector efficiency in counts per disintegration (c/d)

Note 1: This calculation can be modified for more complex situations as described in NUREG–1575, Chapter 6, "Field Measurements Methods and Instrumentation."

Note 2: This equation applies only to instruments used in scalar mode, accumulating counts of radiation detected over a defined period of time. It is NOT applicable to survey instruments used in rate meter mode.

Example:

A gamma counter is used in scalar mode to perform whole body counting for 1-minute.

background count rate (bkg) = 300 cpm

sample counting time (t) = 1 min

background counting time (t) = 1 min

efficiency (E) = 0.15 c/d

$$\mathrm{MDA} = \left(2.71 + 4.65\sqrt{(\mathrm{bkg} \times \mathrm{t})}\right)/(\mathrm{t} \times \mathrm{E})$$

$$= \left(2.71 + 4.65\sqrt{(300\mathrm{cpm} \times 1\ \mathrm{min})}\right)/\left(1\ \mathrm{min} \times 0.15(\mathrm{c/d})\right) = 555\mathrm{dpm}$$

According to this calculation, the licensee would be confident that 95 percent of the time, the instrument can reliably detect measurements as low as 555 dpm. This is the minimum activity that the instrument can detect; results below this number are not reliable at the 95 percent confidence interval. However, all numerical results should be recorded.

Model Radiation Survey Instrument Calibration Program

Training

Before independently calibrating radiation survey instruments, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
  - principles and practices of radiation protection
  - radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
  - mathematics related to the use and measurement of radioactivity
  - biological effects of radiation
- On-the-job training will consist of the following:
  - observing authorized personnel performing radiation survey instrument calibration

- conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual already authorized to perform calibrations

Frequency of Calibration of Radiation Measurement Instruments and Equipment

- A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in NRC regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement device has changed, by repair or alteration, or whenever system performance is observed to change significantly.

- Routine maintenance should be performed as recommended by the manufacturer.

- Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance. Facilities and Equipment for Calibration of Dose and Dose Rate Measuring Instruments.

- To reduce doses received by individuals not calibrating radiation survey instruments calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

- The calibration source should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

- The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use.

- Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR Part 20.

- Individuals conducting calibrations of radiation survey instruments will wear assigned dosimetry.

- Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Calibration Sources for Dose or Dose Rate Measuring Instruments

Radioactive sealed sources will be used for calibrating dose and dose rate measuring radiation survey instruments; these sources will have the following characteristics:

- Each source should approximate a point source.

- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microgray/hour (µGy)/h (0.1 millirad/h (mrad/h)) and 10 percent for dose rates less than 1.0 µGy/h (0.1 mrad/h).

- The sources should contain a radionuclide that emits radiation of identical or similar type and energy as the environment in which the calibrated device will be used.

- The sources should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour (μC/Kg/h) (30 milliroentgen per hour (mR/h) at 100 centimeters (cm) (e.g., 3.1 GBq (85 mCi) of Cs-137 or 780 MBq (21 mCi) of cobalt-60).

Note: Inverse square and radioactive decay laws should be used to correct changes in exposure rate due to changes in distance or source decay.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose or dose rate radiation survey meters. These are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, the response of the instrument should be checked at approximately 20 percent and 80 percent of full scale. Instrument's readings should be within ±x (noted below) of the conventionally true value for the following ranges:

  - Background to 10 μGy/h (1.0 mrad/h); ±x = ±30%
  - 10 μGy/h (1.0 mrad/h) to 1.0 mGy/h (100 mrad/h); ±x = ±20%
  - 1.0 mGy/h (100 mrad/h) to 10 Gy/h (1,000 rad/h); ±x = ±10

Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for the linear readout instruments.

Digital readout instruments should be calibrated the same as linear display instruments.

Notes:

- For most licensees, readings above 50 μC/Kg/h (200 mR/h) need not be calibrated, unless the licensee expects to make measurements at higher dose rates. Regardless, such scales should be checked for operation and response to radiation.

- Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured.

Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count rate meter and a detector that is appropriate for the types of radiation being measured.

The efficiency of radiation survey meter must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the reading should be adjusted at mid-scale on one of the scales and the responses on the other scales should be observed. The radiation survey instrument efficiency factor (e.g., cpm/dpm) thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of ±x for the following ranges:

- alpha measurement

  0.01 Bq/cm^2 to 2.0 Bq/ cm^2 (60 to 12,000 dpm/100 cm^2); ±x = ±20%

  2.0 Bq/ cm^2 to 200 Bq/ cm^2 (12,000 to 1,200,000 dpm/100 cm^2); ±x = ±10%

- beta measurement

  0.05 Bq/ cm^2 to 2.0 Bq/ cm^2 (300 to 12,000 dpm/100 cm^2); ±x = ±20%

  2.0 Bq/ cm^2 to 200 Bq/ cm^2 (12,000 to 1,200,000 dpm/100 cm^2); ±x = ±10%

Calibration of Analytical Instruments Such as Liquid Scintillation Counters, Gamma Counters, Gas-Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment, according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small and can be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments uses radioactive sealed sources. These should be suitable for the geometry of the samples to be analyzed. The calibration sources should have a known activity and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the sample type, and other environmental conditions.

Calibration Records

Calibration records, for all radiation survey instruments, should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey 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

- the exposure reading indicated with the radiation survey instrument in the "battery check" mode (if available on the instrument)

- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)

- for radiation survey instruments with internal detectors, the angle between radiation flux field and a specified surface of the instrument

- for radiation detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure

- the exposure rate or count rate from a check source, if used

- the name of the person who performed the calibration and the date on which the calibration was performed

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

- for exposure rate meters, the source radionuclide used to calibrate the instrument (with correction factors) for each scale

- for surface contamination measurement instruments, the efficiency of the radiation survey instrument, for each of the radionuclides the instrument will be used to measure (if efficiency is not calculated before each use)

- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated

- the date of calibration and the next calibration due date

- the apparent exposure rate or count rate from the check source, if used

Air Sampler Calibration

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

Licensees can find guidance on total air sample volume calibration methods acceptable to NRC staff in the publication titled "Air Sampling Instruments," which can be found in the 9th Edition, American Conference of Governmental Industrial Hygienists, 2001. This information is supplemented below.

Frequency of Calibration of Air Sampling Equipment

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (See RG 8.25, Rev. 1, "Air Sampling in the Workplace").

- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.

- Routine instrument maintenance should be performed, as recommended by the manufacturer.

- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit for Measurement of Air Sample Volume

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

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

E_c = The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration.)[13]

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

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

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

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

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

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

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

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

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

$$V_s = V_1 (P_1/760) (273/T_1)$$

where:

V_s = volume at standard pressure and temperature (760 mm Hg and 273 °K)

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in °K

P_1 = pressure of V_1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

References:

- NUREG–1400, “Air Sampling in the Workplace,” September 1993
- NUREG–1575, “Multi-Agency Radiation Survey and Sited Investigation Manual (MARSSIM)”
- RG 8.25, “Air Sampling in the Workplace,” Revision 1, June 1992
- Health Physics and Radiological Health, 4th Edition. Edited by Thomas E. Johnson and Brian Kent Birky, 2012

- American National Standards Institute (ANSI) N323AB-2013, “American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments”

- “Air Sampling Instruments,” American Conference of Governmental Industrial Hygienists, 9th Edition, 2001

APPENDIX I

MATERIAL RECEIPT AND TRANSFER

Material Receipt and Transfer

The licensee is authorized to possess only the radionuclides in the types and forms listed on the license, and the total quantity possessed under the license must not exceed the maximum possession limit listed on the license. Therefore, the RSO must know how much material is possessed under the license, in all locations, at any time. The licensed inventory includes all radioactive materials in use, in storage, and in waste. The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 30.51 and 10 CFR 40.61 require the licensee to maintain records of receipt, transfer, and disposal of all licensed materials.

Sample Procedure for Ordering and Receiving Radioactive Material

- The RSO should approve or place all orders for radioactive material and should ensure that the requested material quantities (and for sealed sources and devices, the manufacturer and model of the source or device) are authorized by the license and that the possession limits are not exceeded.

- During normal working hours, carriers should be instructed to deliver radioactive packages directly to the RSO (or designated receiving area).

- During off-duty hours, security or other designated trained personnel should accept delivery of radioactive packages in accordance with the procedure outlined in the sample memorandum below.

Sample Memorandum

Memorandum for Security Personnel

From: RSO, President, Vice President, etc.

Subject: Procedures for Receipt of Packages Containing Radioactive Material

Prior to accepting the package, thoroughly observe the condition of the package, if the package appears to be damaged or leaking, immediately contact the RSO. Ask the carrier to remain at the facility until it can be determined that neither the carrier nor the vehicle is contaminated.

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

Radiation Safety Officer:

Office Phone:

Home Phone:

Sample Instructions to Personnel Involved in Material Receipt

Shipping and Receiving Personnel

During normal working hours, immediately upon receipt of any package of licensed material, each package must be visually inspected for any signs of shipping damage, such as crushed or punctured containers or signs of dampness. Any obvious damage must be reported to the RSO immediately. Do not touch any package suspected of leaking. Request the person delivering the package remain until the RSO responds to monitor the package to determine if additional surveys are required of the vehicle or personnel.

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

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

Name:

Phone:

For additional information on worker training, see Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)," of this NUREG.

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

Individuals at a licensee's facility may receive and use material pursuant to a general license as authorized in 10 CFR Parts 31, 40, or 70. Generally licensed materials are distributed by manufacturers authorized by the NRC to distribute materials directly to the persons who will use them under a general license. Some common items include nickel-63 sources in electron capture detectors in certain gas chromatographs, tritium gas contained in self-luminous exit signs, and calibration sources in liquid scintillation counters. The licensee should develop a policy for how their institution will require responsible use and tracking of this material.

If the licensee possesses generally licensed materials, and wishes to transfer them to a specific license, the licensee should review the regulations in 10 CFR Part 30, 31, 40, or 70, as applicable, to determine how this may be done.

Sample Procedure for Safely Opening Packages Containing Licensed Materials

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

- Wear gloves to prevent hand contamination.
- Visually inspect the package for any sign of damage (e.g., crushed, punctured). If damage is noted, stop and notify the RSO.
- Monitor the external surfaces of a labeled package according to specifications in accordance with procedures established for picking up, receiving, and opening packages (10 CFR 20.1906(e)).
- Check DOT White-I, Yellow-II, or Yellow-III label or packing slip for activity of contents, to ensure that the shipment meets the activity as requested by the order and does not exceed license possession limits.
- Open the outer package (following supplier's directions if provided). Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material, high count rate on smear). If anything is found other than what was expected, stop and notify the RSO.
- Survey the packing material and packages for contamination before discarding. If contamination is found, treat as radioactive waste. If no contamination is found, obliterate the radiation labels before discarding in the regular trash.
- Maintain records of receipt, package survey, and wipe test results.
- Notify the final delivery carrier and the NRC Operations Center at 301-816-5100, by telephone, when removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i) or external radiation levels exceed the limits of 10 CFR 71.47, "External radiation standards for all packages."

Type B Packages

The procedure for receiving, opening, and unloading a Type B package should descriptions include, at a minimum, the following measures:

- any special actions to be taken if the tamper-indicating device is not intact, or if surface contamination or radiation survey levels are too high
- any special-handling equipment needed for unloading and handling the package
- a description of any proposed special controls and precautions for handling and unloading
- adherence to the requirements of 10 CFR 20.1906
- examination of the package for visible external damage

- procedures controlling the radiation level limits on unloading operations
- procedures for the safe removal of fission or other radioactive gases, contaminated coolants, and solid contaminants, if any
- the appropriate method, including any special instructions, to open the package
- the appropriate method to remove the contents
- verification that the contents are completely removed
- any additional requirements listed in the Certificate of Compliance

Sample Transfer Policy Statements

Internal Transfers

Licensed materials that may be transferred from one department or AU's control to another should have prior approval from the RSO. The RSO should develop a written transfer procedure to ensure that transfers are done in accordance with the license conditions. All transfers must be done in a way that minimizes the probability of spillage or breakage. Double containers should be used, including suitable shielding, for such transfers.

External Transfers

Licensed material should not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers or shipments must be packaged and labeled in accordance with DOT, NRC, and U.S. Postal Service regulations, whichever is applicable. Before any transfer from the licensee, the licensee must verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41, 40.51, and 70.42.

APPENDIX J

GUIDANCE FOR DEMONSTRATING THAT UNMONITORED INDIVIDUALS ARE NOT LIKELY TO EXCEED 10 PERCENT OF THE ALLOWABLE OCCUPATIONAL DOSE LIMITS

Guidance for Demonstrating that Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Occupational Dose Limits

Dosimetry is required for individuals likely to receive in a year, from sources external to the body, a dose in excess of 10 percent of the applicable regulatory limits in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1201, "Occupational dose limits for adults." As discussed in Section 8.10.4.1 of this NUREG, personnel dosimeters worn by occupational workers may be film badges, TLDs, OSL dosimeters, or electronic dosimeters. Also, other individuals who enter the room where the fusion machine is located must wear a dosimeter. When groups of visitors enter the radiation room, at least two people must wear dosimeters. In those instances where pocket chambers are used instead of film badges, TLDs or electronic dosimeter, a check of the response of the dosimeters to radiation must be made at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose. To demonstrate that dosimetry is not required for other workers, a licensee needs to have available, for inspection, an evaluation to demonstrate that its workers are not likely to exceed 10 percent of the applicable annual limits.

The most common way that individuals might exceed 10 percent of the applicable limits is by performing work near the fusion machine shields or areas of cable or equipment penetrations. However, even these activities could result in the individual receiving minimal doses. A licensee will need to evaluate the doses that its workers might receive in performing these tasks to assess whether dosimetry is required. The evaluation may be completed by carefully measuring the dose rates when the fusion machine is operating. An evaluation of the actual time workers spend in the area can provide the information needed to estimate the annual dose of the workers.

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year, and 10 percent of that value is 5 mSv [500 millirems] per year.

Example: A careful measurement of the highest dose rate at the face of the shield of the fusion machine is found to be 0.015 mSv/hr (1.5 mrem/hr). An individual is expected to spend no more than 4 hours per week in the area near the shield. Based on the dose rate, assuming the fusion machine is operating continuously while the work is being performed, the annual dose is expected to be less than 3.0 mSv (300 mrem) (i.e., 4 h/week × 1.5 mrem/h × 50 weeks/year). Based on the above specific information, no dosimetry is required if the individual performs work in the area less than 6.6 hours per week.

APPENDIX K

METHODOLOGY FOR DETERMINING PUBLIC DOSE

Methodology for Determining Public Dose

This appendix describes methods for determining radiation doses to members of the public. Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv [100 millirem (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.

- Air emissions of radioactive materials to the environment, excluding radon-222 and its daughters, do not result in a TEDE in excess of 0.1 mSv [10 mrem] per year. As required in 10 CFR 20.1101(d), if the licensee exceeds this 0.1 mSv [10 mrem] per year air emission dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203, and promptly take appropriate corrective action to ensure against recurrence.

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

Doses to Members of the Public	
INCLUDE doses from • Radiation or radioactive material released by a licensee • Sources of radiation under the control of a licensee • Air effluents from sources of licensed radioactive materials • Licensed material in transportation or storage at the licensee's facility	DO NOT INCLUDE doses from • Sanitary sewerage discharges from licensee activities done in accordance with 10 CFR 20.2003, "Disposal by release into sanitary sewerage" • Natural background radiation • Medical administration of radioactive material including patients released under 10 CFR 35.75 • Voluntary participation in medical research

As defined in 10 CFR 20.1003, the term *unrestricted area* means "an area, access to which is neither limited nor controlled by the licensee." For purposes of this definition in 20.1003, an "unrestricted area" is an area where access is neither limited nor controlled by the licensees for purposes of limiting exposures to radiation and radioactive materials. An "unrestricted area" for purposes of 20.1003 may be controlled for other purposes, such as for security purposes (see, e.g., 10 CFR 20.1801 and 20.1802), and still be considered an "unrestricted area" as long as it is not required to be controlled for limiting exposure to radiation and radioactive materials. Typical unrestricted areas may include offices, shops, areas outside buildings, and storage areas for nonradioactive materials, and other facilities and laboratories where licensed materials are not normally used or stored.

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

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose, in an unrestricted area from licensed operations, does not exceed 1 mSv [100 mrem] in a year, or

- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in 10 CFR Part 20, Appendix B, Table 2, "Effluent Concentrations." The licensee must also show that if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year, and

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

Measurements

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

- dose rate surveys for radiation exposures from external radiation sources

- measurements of radionuclides in air and water effluents

- use of environmental dosimeters in unrestricted areas

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

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged during fusion machine operation. Due to the uncertainty of this type of discharge, it may be important to perform effluent monitoring continuously or at least during the operation of the fusion machine. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement, and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air-flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

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

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. The occupancy factor for an area is defined as the average fraction of time the maximally exposed individual is present and exposed to a radiation source. If a source is used intermittently, the occupancy factor is a fraction of the hours in a week that a given person would occupy the area. If the result of the calculation using an occupancy factor of 1 demonstrates that the public dose limit is not exceeded, then there is no need for further evaluation.

If, however, the licensee would rather choose a more realistic assumption of the individual's occupancy at the points of highest internal and external exposures, then the licensee may use the occupancy factors in Table K–1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present. The occupancy factors in Table K-1 are general guidance values and may be used if more detailed information is not available.

Table K–1 Standard Occupancy Factors[14]	
Occupancy Factor	**Description**
1	Full occupancy areas such as administrative and clerical offices, receptionist areas, laboratories, pharmacies and other work areas fully occupied by an individual, attended waiting rooms, and occupied space in nearby buildings
1/2	Rooms where individuals are present for a major part of the day
1/5	Corridors, employee lounges, staff rest rooms and classrooms
1/20	Unattended waiting rooms, public rest rooms, unattended vending rooms, storage areas, janitor's closets, attics, outdoor areas with seating, and recreational areas
1/40	Outdoor areas with only transient pedestrian or vehicular traffic, unattended parking lots, vehicular drop off areas (unattended), stairways, and unattended elevators

Records

In accordance with 10 CFR 20.2107, "Records of dose to individual members of the public," the licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until the Commission terminates the license. In general, radiation survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey, the name of the surveyor, the date of the survey, the location of the survey(s) including a description or drawing of the areas surveyed, survey results, and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, MDA of the system, and the estimated uncertainty of measurements.

[14] Adapted from NCRP Report No. 147, "Structural Shielding Design for Medical X-Ray Imaging Facilities," issued November 19, 2004 and NCRP Report No. 151, "Structural Shielding Design and Evaluation for MegaVoltage X- and Gamma-Ray Radiotherapy Facilities," issued December 31, 2005.

APPENDIX L

TYPICAL NOTIFICATION AND REPORTING REQUIREMENTS

Typical Notification and Reporting Requirements

The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

Notifications must be made to the NRC Operations Center at 301-816-5100. The center is staffed 24 hours a day and accepts collect calls. Immediate notifications must be made no later than four (4) hours after identification. Written reports are to be submitted to the appropriate NRC regional office listed in 10 CFR 20, Appendix D.

Table L–1 Typical NRC Notification and Reporting Requirements for Incidents

Event	Notification of NRC Operations Center	Written Report	Regulatory Requirement
Package received with removable radioactive surface contamination exceeding the limits of 10 CFR 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	Immediate [NRC and final delivery carrier must be notified]	None	20.1906(d)
Theft or loss of licensed material equal to or greater than 1000 times the quantities in Appendix C of Part 20	Immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sv [25 rems]	Immediate	30 days	10 CFR 20.2203(a)(1) 10 CFR 20.2202(a)(2)
Release of radioactive material that results in dose of five ALIs in 24 hours	Immediate	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Extremity dose greater than 2.5 Gray [250 rads]	Immediate	30 days	10 CFR 20.2202(a)(1)(iii) 10 CFR 20.2203(a)(1)

Table L–1 Typical NRC Notification and Reporting Requirements for Incidents			
Event	**Notification of NRC Operations Center**	**Written Report**	**Regulatory Requirement**
Whole body dose greater than 0.05 Sv [5 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i) 10 CFR 20.2203(a)(1)
Release of radioactive material that results in dose of one ALI in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(2) 10 CFR 20.2203(a)(1)
Extremity dose greater than 0.5 Sv [50 rems] in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii) 10 CFR 20.2203(a)(1)
Whole body dose greater than 0.05 Sv [5 rems]	None	30 days	10 CFR 20.2203(a)(2)(i)
Dose to individual member of public greater than 1 mSv (0.1 rem)	None	30 days	10 CFR 20.2203(a)(2)(iv)
Theft or loss of licensed material greater than 10 times and less than 1000 times the quantities in Appendix C of Part 20.	30 days	30 days	10 CFR 20.2201 (a)(1)(ii)
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i) & (ii)
Declaration of an emergency when license has an emergency plan required by 10 CFR 30.32(i)(3)	1 hour	none	10 CFR 30.32(i)(3)(viii)

Table L–1 Typical NRC Notification and Reporting Requirements for Incidents

Event	Notification of NRC Operations Center	Written Report	Regulatory Requirement
Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits	Immediate	30 days	10 CFR 30.50(a) & (c)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4) & (c)(2)
Unplanned contamination event that requires restricted access for more than 24 hours and involves a quantity of material greater than five times the lowest ALI for the material as specified in 10 CFR Part 20, Appendix B and requires the area to be restricted for a reason other than to allow radionuclides with half-lives less than 24 hours to decay	24 hours	30 days	10 CFR 30.50(b)(1) & (c)(2)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2) & (c)(2)

Table L–1 Typical NRC Notification and Reporting Requirements for Incidents			
Event	**Notification of NRC Operations Center**	**Written Report**	**Regulatory Requirement**
Unplanned medical treatment to an individual at a medical facility with spreadable contamination on the individual's clothes or body	24 hours	30 days	10 CFR 30.50(b)(3) & (c)(2)
Any incident where an attempt was made or believed to be made to commit theft or unlawful diversion of more than 10 curies of tritium at any one time or with more than 100 curies in a calendar year	Immediate	15 days	10 CFR 30.55(c)

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APPENDIX M

GENERAL TOPICS FOR SAFE USE OF RADIONUCLIDES AND MODEL EMERGENCY PROCEDURES

General Topics for Safe Use of Radionuclides and Model Emergency Procedures

Workers at the facility shall be protected from routine hazards to a level commensurate with that of comparable industrial facilities by a combination of administrative controls and design features. The level of protection required depends on the level of risk from the hazard present in the specific facility.

Radioactive and hazardous material confinement barriers of sufficient number, strength, leak tightness, and reliability shall be incorporated in the design of fusion machines to prevent releases of radioactive and/or hazardous materials from exceeding NRC requirements during normal operation or during off-normal conditions. Part 20 requirements should be applied when using these guidelines.

General Topics for Safe Use of Radionuclides

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

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are used.
- Wear disposable gloves at all times when handling licensed materials.
- After each procedure or before leaving the area, monitor hands, shoes, and clothing for contamination in a low background area.
- Do not eat, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Do not store food, drink, or personal effects in areas where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are used or stored.
- Dispose of licensed material only in designated, labeled, and properly shielded receptacles.
- Safely handle sealed sources.
- Secure all licensed material when it is not under the constant surveillance and immediate control of the users.

Security of Radioactive Materials

- Licensed materials in use in controlled or unrestricted areas must be under constant surveillance.
- Licensed materials will be secured by one or more of the following methods:

- storing and using licensed materials only in restricted areas.
- limiting access to an entire facility or building or portion of the building to radiation workers.
- providing storage areas that can be locked to prevent access to the licensed material.
- implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use.

Model Procedures for Handling Emergencies

General

Licensees should not neglect, delay, or ignore appropriate first aid and other immediate medical needs of injured individuals because of suspected contamination.

The name and telephone number of the RSO or alternate persons should be posted conspicuously in areas of use and be readily available to workers in case of emergencies. Licensee should have emergency equipment readily available.

In the event of an incident involving the vacuum vessel or any of the components to the fusion machine, prompt action is required to address potential public safety concerns to ensure the confinement and prevent the release of radioactive and/or hazardous materials. Actions should include, but not be limited to, the following:

1. ensuring the continued removal of heat when required,
2. providing rapid controlled termination of the plasma when required,
3. controlling coolant energy (e.g., pressurized water, cryogens),
4. controlling chemical energy sources (e.g., lithium, hydrogen),
5. controlling magnetic energy (e.g., toroidal and poloidal field stored energy), and
6. limiting airborne and liquid releases to the environment.

The specific design of any particular fusion facility must be considered in determining the importance of potential safety concerns in protecting the public and the environment. A risk-based prioritization scheme (graded approach) should be used to determine the impact of these potential safety concerns for each specific fusion facility.

General Safety Procedures to Handle Spills

The name and telephone number of the RSO or alternate persons should be posted conspicuously in areas of use and be readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill kits should include:

- disposable gloves,
- housekeeping gloves,
- disposable lab coats,
- disposable head coverings,
- disposable shoe covers,
- roll of absorbent paper with plastic backing,
- masking tape,
- plastic trash bags with twist ties,
- “radioactive material” labeling tape,
- marking pen,
- pre-strung “radioactive material” labeling tags,
- box of wipes,
- instructions for emergency procedures,
- clipboard with copy of the radioactive spill report form for the facility pencil,
- appropriate radiation survey instruments, including batteries (for survey meters).

Minor Spills of Liquids or Solids

- Instructions to Workers
    - Notify persons in the area that a spill has occurred.
    - Prevent the spread of contamination by covering the spill with absorbent paper. (Paper should be dampened if solids are spilled.)
    - Clean up the spill, wearing disposable gloves and using absorbent paper.
    - Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.

- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination.
- Check hands, clothing, and shoes for contamination.
- Promptly report the incident to the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).
- Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or in providing requested documentation).

- Reminders to RSO
  - Follow up on the decontamination activities and document the results.
  - As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin. Determine whether any immediate or 24-hour NRC notifications are required by Subpart M, "Reports," of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for protection against radiation," or by 10 CFR 30.50, "Reporting requirements." See Appendix L of this NUREG, "Typical Notification and Reporting Requirements.

Major Spills of Liquids or Solids

- Instructions to Workers
  - Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room.
  - Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened, if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
  - Shield the source only if it can be done without further contamination or significant increase in radiation exposure.
  - Close the room and lock or otherwise secure the area to prevent entry. Post a sign on the entrance to the room to warn anyone trying to enter that a spill of radioactive material has occurred.
  - Notify the RSO immediately.

- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap.

- Allow no one to return to work in the area unless approved by the RSO.

- Cooperate with the RSO and the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).

- Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or requested documentation).

- Reminders to RSO

  - Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by perspiration.

  - Supervise decontamination activities and document the results. Documentation should include the location of radiation surveys and decontamination results.

  - Determine cause and needed corrective actions; consider need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin.

  - Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR Part 20 or by 10 CFR 30.50. See Appendix I of this NUREG.

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

- Instructions to Workers

  - Notify all personnel to vacate the room immediately.

  - Shut down ventilation system, if possible, unless it is determined that the room ventilation system needs to be used to clear the air for access purposes.

  - Vacate the room. Seal the area, if possible.

  - Notify the RSO immediately.

  - Ensure that all access doors to the area are closed and posted with radiation warning signs, or post trained guards at all access doors to prevent accidental opening of the doors or entry to the area.

  - Survey all persons who could possibly have been contaminated. Decontaminate as directed by the RSO.

- Promptly report suspected inhalations and ingestions of licensed material to the RSO.
- Decontaminate the area only when advised or supervised by the RSO.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and the RSO's staff (e.g., in the investigation of root cause(s) and provision of requested bioassay samples).
- Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or requested documentation).

- Reminders to RSO
  - Supervise decontamination activities.
  - Perform air sample surveys in the area before permitting resumption of work with licensed materials.
  - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc.
  - Consider the need for medical exams and whole body counts before permitting involved individuals to return to work with licensed material.
  - Determine the cause(s) of the incident and corrective actions needed; consider the need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document the incident.
  - Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR Part 20 or by 10 CFR 30.50. See Appendix L of this NUREG.

Minor Fires

- Instructions to Workers
  - Immediately attempt to put out the fire by approved methods (e.g., using a fire extinguisher) if other fire hazards or radiation hazards are not present.
  - Notify all persons present to vacate the area and have one individual immediately call the RSO. Call the fire department if instructed to do so by RSO.
  - When the fire is out, isolate the area to prevent the possible spread of contamination.
  - Survey all persons involved in combating the fire for possible contamination.
  - Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap.

- In consultation with the RSO, determine a plan of decontamination and the types of protective devices and radiation survey equipment necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the RSO.
- Cooperate with the RSO and the RSO's staff (e.g., in the investigation of root cause and provision of requested bioassay samples).
- Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or requested documentation).

- Reminders to RSO
  - Supervise decontamination activities.
  - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash affected area again to remove any contamination that was released by the perspiration.
  - Consult with fire safety officials to ensure that there is no possibility of another fire starting.
  - Determine the cause(s) of the incident and needed corrective actions; consider the need for bioassays if licensed material is suspected to have been ingested, inhaled, or absorbed through or injected under the skin. Document the incident.
  - Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR Part 20 or by 10 CFR 30.50. See Appendix L of this NUREG.

Larger Fires, Explosions, or Major Emergencies

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

- Follow the instructions of the RSO and the RSO's staff (e.g., in performing decontamination techniques, radiation surveys, and bioassay sampling and handling, or requested documentation).

- Reminders to RSO

  - Coordinate activities with the facility's industrial hygienist or environmental health and safety office and with the local fire department.

  - Consult with the firefighting personnel and set up a controlled area where the firefighters can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished.

  - Once the fire is extinguished, advise firefighters not to enter potentially contaminated areas where radioactive sources may be present or radiation areas until a thorough evaluation and radiation survey are performed to determine the extent of the damage to the licensed material's use and storage areas.

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

  - Supervise decontamination activities.

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

  - Determine whether any immediate or 24-hour NRC notifications are required by Subpart M of 10 CFR Part 20 or by 10 CFR 30.50. See Appendix L of this NUREG.
  - Copies of emergency procedures should be provided to all users. Post a current copy in each area where radioactive material is used.

Procedures for Collecting Bioassay Samples

If an individual becomes contaminated or exposed to radioactive material through skin absorption, ingestion or inhalation, the RSO or a member of the RSO's staff should estimate the amount of material taken into the body (Section 8.10.4.2 of this NUREG) The following items should be considered in developing procedures for collecting bioassay samples:

- the type of bioassay that must be performed (direct or indirect),

- the number of samples or data points to be collected,

- the frequency of sampling (e.g., hourly, daily, weekly, once),

- the size of the sample to be collected (e.g., 24-hour urine collection),

- the ease or difficulty of sample collection,

- the need for written instructions to be provided to the sample collector, who may also be the contaminated individual.

APPENDIX N

RADIATION SAFETY SURVEY TOPICS

Radiation Safety Survey Topics

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

Training

Before independently performing radiation surveys, an individual should complete both classroom and on-the-job training as follows:

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
    - principles and practices of radiation protection,
    - radioactivity measurements, monitoring techniques, and using instruments,
    - usage and basic mathematics and calculations for measuring radioactivity, and
    - biological effects of radiation.
- Appropriate on-the-job-training consists of the following:
    - Observing authorized personnel using survey equipment, collecting samples, and analyzing samples; and
    - Using survey equipment, collecting samples, and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples will be analyzed in a low background area.
- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma emitters (e.g., iodine-125, cesium-137, cobalt-60).
- A liquid scintillation counting (LSC) system can be used to count samples containing most beta-emitters and gamma emitters (if efficiency is great enough to achieve the required sensitivity for measurements). The LSC is the most common instrument used for measurement of tritium contamination.
- Licensees may use a gas-flow proportional counting system to count samples containing alpha emitters, beta-emitters, and gamma emitters (if efficiency is great enough to achieve the required sensitivity for measurements).
- Real-time tritium monitors to determine tritium concentrations.

Ambient Radiation Level Surveys

- Dose rate surveys, at a minimum, should be performed in locations where workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits or where an individual is working in a dose rate of 0.025 mSv/h (2.5 mrem/h) or more (50 mSv/year divided by 2,000 h/year).

- 10 CFR 20.1301 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year and the dose in any unrestricted area from external sources does not exceed 0.02 mSv (2 mrem) in any 1 hour.

The frequency of ambient surveys depends on the quantity and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker and members of the public from external exposure to radiation. While the regulations do not specify a specific survey frequency, the licensee must conduct such surveys as will ensure that the dose rate limits in Title 10 of the Code of Federal Regulations (10 CFR) Part 20 Subparts C and D are not exceeded.

Contamination Surveys

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

Contamination surveys will be performed:

- to evaluate radioactive contamination that could be present on surfaces of floors, walls, and equipment

- after any spill or contamination event

- when procedures or processes have changed

- to evaluate contamination of users and the immediate work area, at the end of the day or before leaving the area of use, when licensed material is used

- in unrestricted areas at frequencies consistent with the types and quantities of materials in use but generally not less frequently than quarterly

- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material. These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use. If the activity used is greater than or

equal to the smallest ALI (for either inhalation or ingestion) as identified in 10 CFR Part 20, Appendix B, then documented surveys should be performed at least daily and retain records accordance with 10 CFR 20.2103.

Table N–1 contains suggested contamination survey frequencies based on ALIs. The suggested frequency of surveys is based upon the amount of licensed material "in use" at any one time at any particular location. If licensed material has not been used for a period of time greater than the required survey frequency, then it is considered to be "not in use."

Table N–1 Suggested Contamination Survey Frequency

	< 0.1 ALI	≥ 0.1 ALI <1.0	≥ 1.0 ALI
In Use	Monthly	Weekly	Daily
Not in Use	Every 6 Months		

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee must ensure that the amounts do not exceed the contamination levels listed in Table N–2, taken from the "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material" (August 1987) (ADAMS Accession No. ML030590504). Note that, for the purposes of release of facilities for unrestricted use or termination of the license, these values have been superseded by 10 CFR 20, Subpart E, "Radiological Criteria for License Termination," and cannot be used for that purpose.

In particular, the acceptable contamination levels listed below for most alpha emitters exceed the levels which will meet the 10 CFR 20, Subpart E criteria. Table N–2 levels can continue to be used for release of equipment and material from licensed material facilities during operational activities prior to license termination. (63 FR 64132; November 18, 1998)

Table N–2 provides the maximum acceptable residual levels for potentially contaminated equipment that is to be released for unrestricted use. Additional guidance for release of equipment can be found in NUREG–1575, Supplement 1, "Multi-Agency Radiation Survey and

Assessment of Materials and Equipment Manual (MARSAME)." Table N–2 values also may be acceptable criteria for contamination in facilities during facilities in operation.

Table N–2 Acceptable Surface Contamination Levels

Nuclide	Average	Maximum	Removable
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-123, 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)
Other alpha emitters	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)

Notes:

- 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.
- As used in this table, disintegrations per minute (dpm) means the rate of emission by radioactive material as determined by correcting the cpm observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- 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.
- The maximum contamination level applies to an area of not more than 100 square centimeters (cm^2).
- The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped.
- The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/h at 1 cm and 1.0 mrad/ h at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Decommissioning Surveys for Release for Unrestricted Use

When a facility will be closed and released for unrestricted use, the values in Table N–3 provide acceptable residual contamination levels, known as "screening values" for building surfaces. To

the extent practicable facilities should be decontaminated to below these levels. Surveys should be conducted for both removable contamination (not to exceed 10 percent of the values in Table N–3) and for total residual contamination before the facilities or equipment are released from restricted to unrestricted use, to ensure that they meet the applicable limits.

Table N–3 Screening Values for Building Surface Contamination

Radionuclide	Symbol	Screening Level for unrestricted release (dpm/100 cm^2)
Hydrogen-3 (Tritium)	H-3	1.2×10^8
Carbon-14	C-14	3.7×10^6
Sodium-22	Na-22	9.5×10^3
Sulfur-35	S-35	1.3×10^7
Chlorine-36	Cl-36	5.0×10^5
Maganese-54	Mn-54	3.2×10^4
Iron-55	Fe-55	4.5×10^6
Cobalt-57	Co-57	2.1×10^5
Cobalt-60	Co-60	7.1×10^3
Nickel-63	Ni-63	1.8×10^6
Zinc-65	Zn-65	4.8×10^4
Strontium-90	Sr-90	8.7×10^3
Technetium-99	Tc-99	1.3×10^6
Iodine-129	I-129	3.5×10^4
Cesium-137	Cs-137	2.8×10^4
Europium-152	Eu-152	1.3×10^4
Tungsten-181	W-181	1.1×10^6
Iridium-192	Ir-192	7.4×10^4

Note: Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100 percent of surface contamination is removable; and therefore, the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10 percent to 100 percent range) may calculate site-specific screening levels using the DandD, Version 1 computer code. Other computer codes may be used to calculate appropriate release levels for other radionuclides not addressed in Table N-3, to comply with decommissioning requirements.

Units are disintegrations per minute per 100 cm^2 (dpm/100 cm^2). One dpm is equivalent to 0.0167 Bq. The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv [25 mrem] in a year unrestricted release dose limit in 10 CFR 20.1402, "Radiological criteria for unrestricted use." For radionuclides in a mixture, the "sum of fractions" rule applies; see 10 CFR Part 20, Appendix B, Note 4 for an example of the "sum of fractions" calculation. Refer to NUREG–1757, "Consolidated Decommissioning Guidance," for further information on application of the values in this table.

Table N–3 was derived using the DandD screening code, Version 1, (DandD, v1.0) and its default input parameters. Table N–3 provides criteria that permit licensees to demonstrate compliance with the unrestricted release dose criterion in the License Termination Rule in Subpart E of 10 CFR Part 20. Sites with building surface contamination levels below those listed in Table N–3 would be deemed acceptable for release for unrestricted use in accordance with the dose criteria in 10 CFR 20.1402, provided that residual radioactivity has been reduced to Part 20 levels.

The table is intended for use as criteria to facilitate license termination for many simple routine decommissioning cases without a site-specific dose assessment. For facilities with contamination levels above those in Table N–3, additional site-specific dose assessments may be necessary, and licensees should refer to NUREG–1757 regarding acceptable methods for conducting the appropriate dose assessment, such as using the current version of DandD to develop site-specific screening criteria. The most recent version of the DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the Web site: https://www.marssim.com/Dose_Modeling.htm. Links to other useful software and guidance documents are also found at that Web site.

Table N–3 does not include screening values for radionuclides that emit alpha particles, or for soil contamination. Screening values for radionuclides not listed in the table may be found in "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination" (63 FR 64132; November 18, 1998) for building surfaces; "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination" (64 FR 68395; December 7, 1999) for soils; and "Use of Screening Values to Demonstrate Compliance with the Final Rule on Radiological Criteria for License Termination" (65 FR 37186; June 13, 2000), which references Tables 5.19 (surface contamination) and 6.91 (surface soil) from NUREG/CR–5512, Vol. 3, "Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment, October 1999." Tables 5.19 (surface contamination) and 6.91 (surface soil) are for use in determining acceptable screening values are for radionuclides not listed in the first two *Federal Register* notices.

The type of surveys to be performed for decommissioning of facilities, and the number and locations of survey points or samples to be collected, should be determined using guidance found in NUREG–1757. Licensees may be able to use the "Simple Approaches for Conducting Final Radiological Surveys" found in Appendix B of NUREG–1757, Volume 2. If the decommissioning of a facility is too complex to allow use one of the "simple approaches," then a licensee may have to develop a more formal decommissioning plan.

Survey Record Requirements

Each survey record will include the following:

- a diagram of the area surveyed
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe test was taken
- ambient radiation levels with appropriate units
- contamination levels with appropriate units

- make and model number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date

Licensees should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature. In addition, 10 CFR 30.35(g), 40.36(f) and 70.25(g) state, in part, that records of information important to the decommissioning of a facility, including records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site, must be maintained.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- determine whether the confinement of radioactive materials is effective
- measure airborne radioactive material concentrations in the workplace
- estimate worker intakes of radioactive material
- determine posting requirements
- determine what protective equipment and measures are appropriate
- warn of significantly elevated levels of airborne radioactive materials

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays. Refer to RG 8.25, "Air Sampling in the Workplace," dated June 1992 and NUREG–1400, "Air Sampling in the Workplace," dated September 1993.

Airborne Effluent Release Monitoring

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

Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated April 2012, provides guidance on methods (calculation or COMPLY code) acceptable to the NRC for compliance with the constraint on air emissions to the environment.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur any time

unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and Part 20 requirements. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or 10 percent of the permissible air effluent concentrations found in Column 1 of Table 2 in 10 CFR Part 20, Appendix B, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (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."

Liquid Effluent Release Monitoring

The licensee must evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. These releases must meet the limits in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public," and 20.2003, "Disposal by release into sanitary sewerage," respectively.

The topic of sanitary sewer releases is more fully discussed in Appendix Q of this NUREG.

Bioassay Monitoring

Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends on the exposure potential and the physical and chemical characteristics of the radioactive material, as well as the route of entry to the body. The licensee should consider the following elements when determining the frequency of routine bioassay measurements:

- potential exposure of the individual
- retention and excretion characteristics of the radionuclides
- sensitivity of the measurement technique
- acceptable uncertainty in the estimate of intake and committed dose equivalent

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

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

Routine Bioassay Measurements

Routine bioassay measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting or urinalysis) and the samples collected will vary according to the radionuclides and the compounds to which they are attached. Sample collection procedures should be developed to ensure that appropriate types, sizes, and numbers of samples are collected that will provide appropriate physiological information for the dose assessment. An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

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

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

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

Collection of Emergency Bioassay Samples

In the event of an emergency in which an individual becomes contaminated and radioactive material was taken into the body through skin absorption or other means, or an individual is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body may be required. Frequently, this estimate is made by performing a bioassay of the individual. Bioassays may be performed through direct methods, such as whole body counting or thyroid counting, using appropriate instruments, or indirect methods, such as sampling urine or other excreta from the body. This would allow the licensee to calculate the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed.

Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay screening program, and the licensee's radiation safety program should include procedures and equipment for appropriate sample collection in an emergency. The following items should be considered in developing these procedures:

- type of bioassay that must be performed (direct or indirect)
- number of samples or data points to be collected
- frequency of sampling (hourly, daily, weekly, or one-time)
- size of the sample to be collected (e.g., 24-hour urine collection)
- ease or difficulty of sample collection
- need to provide written instructions to the sample collector, who may be the contaminated individual

Special Bioassay Monitoring

Because of uncertainty about the time of intakes or the absence of other data, such as exposure duration or the physical and chemical form of the material, correlating positive results to actual intakes for routine bioassay measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, the licensee should consider the following circumstances:

- the presence of unusually high levels of facial or nasal contamination
- entry into airborne radioactivity areas without appropriate exposure controls
- operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity)
- known or suspected incidents of a worker ingesting radioactive material
- incidents that result in contamination of wounds or other skin absorption
- evidence of damage to or failure of a respiratory protective device
- elevated air monitoring results

References:

- NUREG–1400, “Air Sampling in the Workplace
- ”NUREG–1549, Draft Report for Comment, “Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination” July 1998 (ML993250291)
- NUREG–1575, “Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)” Revision 1, August 2000
- NUREG–1575, Supplement 1, “Multi-Agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME),” January 2009

- NUREG–1757, "Consolidated Decommissioning Guidance" Volume 1, Decommissioning Process for Materials Licensees (Revision 2), September 2006 Volume 2, Characterization, Survey, and Determination of Radiological Criteria (Revision 1), September 2006

- NUREG/CR-0041, Revision 1, "Manual of Respiratory Protection Against Airborne Radioactive Material"

- NUREG/CR-4884, "Interpretation of Bioassay Measurements"

- NUREG/CR-5512, Volume 2, "Residual Radioactive Contamination from Decommissioning: User's Manual DandD Version 2.1," April 2001 (ML010940257)

- NUREG/CR–5512, Volume 3, "Residual Radioactive Contamination from Decommissioning, Parameter Analysis, Draft Report for Comment," October 1999 [containing Tables 5.19 (surface contamination) and 6.91 (surface soil)] (ML082460902)

- RG 4.20, Revision 1, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors"

- RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"

- RG 8.20, Revision 2, "Applications of Bioassay for Radioiodine"

- RGRG 8.25, Revision 1, "Air Sampling in the Workplace"

- RG 8.32, "Criteria for Establishing a Tritium Bioassay Program"

- *Federal Register:* "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," 63 FR 67132-34, November 18, 1998

- *Federal Register: "Supplementa*l Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," 64 FR 68395-96, December 7, 1999

- *Federal Register:* "Use of Screening Values to Demonstrate Compliance With the Final Rule on Radiological Criteria for License Termination," 65 FR 37186, June 13, 2000

- ANSI N13.1-2011, "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities"

- ANSI N13.30-2011, "Performance Criteria for Radiobioassay"

- ANSI N42.18-2004, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 2004

- NCRP Commentary No. 3, "Screening Techniques for Determining Compliance with Environmental Standards–Releases of Radionuclides to the Atmosphere," published in January 1989, and the addendum published in October 1989

- U.S. Department of Energy, DOE G 441.1-1C, “Radiation Protection Programs Guide for Use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection,” certified November 18, 2010

APPENDIX O

MODEL LEAK TEST PROGRAM AND PROCEDURES

Model Leak Test Program and Procedures

This appendix provides applicants and licensees with model leak test procedures and sample calculations for determining activity on a wipe test sample.

All Safety-Class Structures, Systems, and Components that provide a containment barrier should be leak checked before initial operations and periodically thereafter and should meet the requirements specified in the safety analysis.

All vacuum vessels and attached components that provide a confinement barrier should be leak checked at design pressures before initial operation to demonstrate that leakage requirements specified in the safety analysis are met by the as-built design. Potential hazards of in-service leak testing at the design vessel pressure after deuterium-tritium operations have commenced may not justify such periodic leak testing. In its place, a program of periodic vacuum leak testing and a formal configuration control program to ensure vacuum vessel repairs or modifications do not compromise the design pressure rating should be implemented.

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently.

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

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

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

- observing authorized personnel collecting and analyzing leak test samples
- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak testing and sample analysis

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, analyze leak tests in a low background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.

- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured [e.g., NaI (Tl) well-counter system for gamma emitters; liquid scintillation for beta-emitters; gas-flow proportional counters for alpha emitters].

- If the sensitivity of the counting system is unknown, the MDA should be determined. The MDA may be determined using the following formula:

$$\mathrm{MDA} = \left(2.71 + 4.65\sqrt{(\mathrm{bkg} \times \mathrm{t})}\right)/(\mathrm{t} \times \mathrm{E})$$

where:

MDA = minimum detectable activity in disintegrations per minute (dpm)

bkg = background count rate in cpm

t = background counting time and sample counting time in minutes (min)

E = detector efficiency in counts per disintegration (c/d)

Example:

bkg = 200 cpm

E = 0.1 counts per disintegration (10 percent efficient)

t = 2 minutes

$$\mathrm{MDA} = \left(2.71 + 4.65\sqrt{200\mathrm{cpm} \times 2\mathrm{min}}\right)/(2\,\mathrm{min} \quad \times 0.1) = \left(2.71 + 4.65\sqrt{400}\right)/(0.2)$$

$$\mathrm{MDA} = (2.71 + 93)/(0.2) = 478.55\ \mathrm{dpm}$$

1 Bq = 1 disintegration/second

$$MDA = 478.55\ dpm \times 1\ \mathrm{min}/60\ s = 7.976\ Bq$$

Note: The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for nonequal counting times, as well as derivations of equations and discussions of limitations, can be found in "Decommissioning Health Physics—A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective SSD registration certificate. If a sealed source is not registered, leak tests should be conducted at 6-month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis

- For each sealed source to be tested, list identifying information such as sealed source serial number, manufacturer, model number, radionuclides, and activity of the sealed source.
- Use a radiation survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).
- Select instrumentation that is sensitive enough to detect 185 Bq (0.005 μCi) of the radionuclide contained in the sealed source.
- Using the selected instrument, count and record background count rate.
- Check the counting efficiency of the instrument using a standard source of the same radionuclide as that of the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within plus or minus 5 percent of the stated value and traceable to primary radiation standards such as those maintained by the National Institute of Standards and Technology.
- Calculate the counting efficiency of the detector.

$$\text{Efficiency in cpm/Bq} = ([(\text{cpm from std}) - (\text{cpm from bkg})])/(\text{activity of std in Bq})$$

where:

cpm = counts per minute

std = standard

bkg = background

Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in Bq (or μCi). The activity of the sample in Bq may be calculated using the following formula:

$$\text{Activity of sample [Bq]} = ([(\text{cpm from wipe sample}) - (\text{cpm from bkg})])/(\text{efficiency in cpm/Bq})$$

- Sign and date the list of sources, data, and calculations. Retain records for 3 years [under Title 10 of the Code of Federal Regulations (10 CFR) 20.2103(a)].

- If the wipe test activity is 185 Bq [0.005 µCi] or greater, notify the RSO so that the source can be withdrawn from use and disposed of properly. Also, notify the NRC.

APPENDIX P

APPLICABLE U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS

Applicable U.S. Department of Transportation Regulations

Note: The following list of DOT regulations is provided to inform licensees about typical requirements that apply to the transportation of licensed material including the preparation of shipments of licensed material. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, transportation requirements change; therefore, licensees should consult the regulations for definitive information about current requirements. Additional information on transportation requirements may be found at the DOT Web site: https://www.dot.gov/.

Title 10 of the *Code of Federal Regulations* (10 CFR) 71.5 requires compliance with DOT regulations in 49 CFR Parts 107, 171 through 180 and 390 through 397, appropriate to the mode of transport. The following are the major areas in DOT regulations most relevant for transporting radioactive materials as Type A or Type B quantities:

- 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans"

  (1) Table of Hazardous Materials and Special Provisions (Subpart B)

  — Purpose and use of hazardous materials table (49 CFR 172.101)

  — List of Hazardous Substances and Reportable Quantities for radionuclides (49 CFR 172.101, Table 2 to Appendix A), Radionuclides

  (2) Shipping Papers (Subpart C)

  — Preparation and retention of shipping papers (49 CFR 172.201)

  — Description of hazardous material on shipping papers (49 CFR 172.202)

  — Additional description requirements (49 CFR 172.203)

  — Shipper's certification (49 CFR 172.204)

  (3) Marking (Subpart D)

  — Applicability (49 CFR 172.300)

  — General marking requirements for non-bulk packagings (49 CFR 172.301)

  — Prohibited marking (49 CFR 172.303)

  — Marking requirements (49 CFR 172.304)

  — Class 7 (radioactive) materials (49 CFR 172.310)

  — Hazardous substances in non-bulk packagings (49 CFR 172.324)

(4) Labeling (Subpart E)

— General labeling requirements (49 CFR 172.400)

— Exceptions from labeling (49 CFR 172.400a)

— Prohibited labeling (49 CFR 172.401)

— Class 7 (radioactive) material (49 CFR 172.403)

— Placement of labels (49 CFR 172.406)

— Label specifications (49 CFR 172.407)

— RADIOACTIVE WHITE-I label (49 CFR 172.436)

— RADIOACTIVE YELLOW-II label (49 CFR 172.438)

— RADIOACTIVE YELLOW-III label (49 CFR 172.440)

(5) Emergency Response Information (Subpart G)

— Applicability and general requirements (49 CFR 172.600)

— Emergency response information (49 CFR 172.602)

— Emergency response telephone number (49 CFR 172.604)

(6) Training (Subpart H)

— Applicability and responsibility for training and testing (49 CFR 172.702)

— Training requirements (49 CFR 172.704)

- 49 CFR Part 173, “Shippers – General Requirements for Shipments and Packagings,”

— Authorized packagings and overpacks (49 CFR 173.25)

— Definitions (49 CFR 173.403)

— General design requirements (49 CFR 173.410)

— Industrial packages (49 CFR 173.411)

— Additional design requirements for Type A packages (49 CFR 173.412)

— Authorized Type A packages (49 CFR 173.415)

— Requirements for determining basic radionuclide values, and for the listing of radionuclides on shipping papers and labels (49 CFR 173.433)

— Table of A_1 and A_2 values for radionuclides (49 CFR 173.435)

- — Radiation level limitations and exclusive use provisions (49 CFR 173.441)
- — Requirements for NRC approved packages (49 CFR 173.471)
- — Quality control requirements prior to each shipment of Class 7 (radioactive) materials (49 CFR 173.475)
- — Approval of special form Class 7 (radioactive) materials (49 CFR 173.476)

• 49 CFR Part 177, “Carriage by Public Highway”

- — General Information and Regulations (Subpart A)
- — Driver training (49 CFR 177.816)
- — Shipping papers (49 CFR 177.817)

(1) Loading and Unloading (Subpart B)

- — General requirements (49 CFR 177.834)
- — Packages secured in a motor vehicle (49 CFR 177.834(a))
- — Class 7 (radioactive) material (49 CFR 177.842)

1. Minimum Required Packaging for Class 7 (Radioactive) Material:[1] (49 CFR Part 173 and 10 CFR Part 71)[2]

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Minimum Packaging Required For Radioactive Materials Other Than Low Specific Activity (LSA) Material And Surface Contaminated Objects (SCO) Based On Activity Of Package Contents

Radioactive Material Quantity[3]		Limited Quantities and Articles	Type A[4] [9]	Type B
Activity Restrictions		≤ the limits specified in Table 4 of 49 CFR 173.425	≤ A_1 for special form ≤ A_2 for normal form	> A_1 for special form > A_2 for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF[10] package	Type B(U)F or Type B(M)F package

Minimum Packaging Required for LSA Material and SCO[5,6]

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport[7,8]	Unpackaged[8] **IP-1:** solids or liquids/exclusive use **IP-2:** liquids/nonexclusive use **Specification tank cars or cargo tank motor vehicles:** liquids/exclusive use	- - **IP-2:** exclusive use[9] **IP-3:** liquids or gases/nonexclusive use[9]	- - **IP-2:** exclusive use **IP-3:** nonexclusive use	Unpackaged[8] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport[8]	**Packaging shall meet the requirements of 49 CFR 173.24, 24a, and 173.410.** **Transportation shall be an exclusive use shipment.** **Activity per shipment must be less than an A_2 quantity (see 49 CFR 173.427(b)(4)).**				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.

[2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397 (see 10 CFR 71.5).

[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in 49 CFR 173.436 or the values derived according to the instructions in 49 CFR 173.433, must be regulated in transport as Class 7 (radioactive) material.

[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) material greater than A_1 or A_2 (see 49 CFR 173.431(a)). See A_1 and A_2 definitions in 49 CFR 173.403.

[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 meters from the unshielded material or objects (see 49 CFR 173.427(a)(1) and (d)).

[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages, and not classified as LSA material or SCO. For alternate domestic transport provisions, see 49 CFR 173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.

[7] For the quantity of LSA material and SCO transported in a single conveyance, see the limits specified in 49 CFR 173.427(a)(2).

[8] LSA material or SCO shall be appropriately packaged in accordance with 49 CFR 173.427(b) or (d). Certain LSA-I material and SCO-I may be transported unpackaged under the conditions in 49 CFR 173.427(c).

[9] See 49 CFR 173.411(c) and 173.415(a) for requirements related to package record retention (2 years) and associated documentation of physical tests.

[10] See 10 CFR 71.22(a), 71.23(a) and 49 CFR 173.417(a) for regulations regarding the use of non-AF packages for fissile materials.

2. Radiation Level, TI and Criticality Safety Index (CSI) Limits for Transportation by Mode:[1] (49 CFR Parts 173 - 177, and 10 CFR Part 71)[10]

Type of Transport	Nonexclusive Use	Exclusive Use		
Mode of Transport	**Road, Rail, Vessel and Air[9]**	**Road and Rail**	**Vessel**	**Air (Cargo Only)**
Radiation Level Limits[2]				
Package Surface	**2 mSv/h (200 mrem/h)**	**2 mSv/h (200 mrem/h):** other than closed vehicles **10 mSv/h (1000 mrem/h):** closed vehicles	**2 mSv/h[11] (200 mrem/h)**	**2 mSv/h (200 mrem/h)[3]**
Conveyance[4]	**N/A**	**2 mSv/h (200 mrem/h):** outer surfaces (sides, top and underside) of vehicle[5]	**N/A**	**N/A**
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle[5]	**N/A**	**N/A**
Occupied Position	**N/A**	**0.02 mSv/h (2 mrem/h):** in any normally occupied area[6]	**Requirements of 49 CFR 176.708 apply**	**N/A**
TI Limits[2]				
Package[7]	**3:** passenger aircraft **10:** road, rail, vessels and cargo aircraft	**No limit**		**10**
Conveyance[4]	**50:** road, rail and passenger aircraft **50 to No limit:** vessels[8] **200:** cargo aircraft	**No limit**		**200**
Overpack	**N/A:** for road, rail **50 to 200:** vessel[8] **3:** passenger aircraft; **10:** cargo aircraft	**N/A**	**No limit[8]**	**N/A**
CSI Limit for Fissile Material[2]				
Package[7]	**50**	**100**	**100**	**100**
Conveyance[4]	**50:** road, rail and air **50:** for holds, compartments or defined deck areas of vessels[8] **200 to No limit:** for a total vessel[8]	**100**	**200 to No limit:** for a total vessel[8]	**100**
Overpack	**50:** road, rail, vessels[8] and air	**N/A**		

[1] Radiation level, TI, and CSI are defined in 49 CFR 173.403.
[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks; to occupied positions; and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, the sum of the CSIs. [see applicable 49 CFR references for: Rail - 49 CFR 174.700; Air – 49 CFR 175.700 through 175.703; Vessel - 49 CFR 176.700 through 176.708; and Highway - 49 CFR 177.842].
[3] Higher package surface radiation levels may be allowed through an approved special arrangement.
[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft. See definitions in 49 CFR 173.403.
[5] The outer surfaces (sides, top and underside) of vehicles are specified for road and rail vehicles in 49 CFR 173.441.
[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a state or federally regulated radiation protection program when personnel wear radiation dosimetry devices.
[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages (see 49 CFR 173.459).
[8] For details on TI and CSI limits for transport by vessel, see 49 CFR 176.708.
[9] Only excepted packages and packages intended for use in research, medical diagnosis, and treatment are permitted on passenger aircraft (see 49 CFR 173.448(f) and 175.700).

[10] The limits in this table do not apply to excepted packages. See the following references for the radiation level limits for: limited quantities, 49 CFR 173.421; instruments and articles, 49 CFR 173.424; articles containing natural uranium or thorium, 49 CFR 173.426; or empty packaging, 49 CFR 173.428.

[11] 2 mSv/h (200 mrem/h) other than intermodal transport of closed transport vehicles or exclusive use vessel.

3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials: (49 CFR 173.443 and 173.475, and 10 CFR Part 71)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on the external surface of each package, conveyance, freight container, and overpack offered for transport must be kept consistent with the radiation protection standards in 10 CFR Part 20, and shall not exceed the values shown in the following table:

Contaminant	Maximum Permissible Limits (49 CFR 173.443(a), Table 9)		
	Bq/cm^2	µCi/cm^2	dpm/cm^2
Beta and gamma emitters and low toxicity alpha emitters	4	10^{-4}	240
All other alpha emitting radionuclides	0.4	10^{-5}	24

The non-fixed contamination shall be determined by:

(a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;

(b) ensuring each wipe area is 300 cm^2 in size;

(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

A conveyance used for nonexclusive use shipments is not required to be surveyed unless there is reason to suspect that it exhibits contamination (see 49 CFR 173.443(a)(2)).

Provisions for Control of Contamination on Radioactive Material Packages Offered for Transport and at the Time of Receipt

- When offered for transport, the non-fixed contamination on each package of radioactive material must be kept consistent with the radiation protection standards in 10 CFR Part 20 and may not exceed the limits set forth in 49 CFR 173.443(a), Table 9 (as shown above).
- During transport, non-fixed contamination levels on packages transported as exclusive use by rail or highway may not exceed 10 times the limits in 49 CFR 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in 49 CFR 173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in 49 CFR 173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in 49 CFR 173.443(a), Table 9 (as shown above) [see 49 CFR 173.443(b)].
- Each conveyance, overpack, freight container, or tank used for transporting Class 7 (radioactive) material as an exclusive use shipment that utilizes the provisions of 49 CFR 173.443(b) must be surveyed with appropriate radiation detection instruments after each exclusive use transport. If contamination values exceed acceptable levels, the transport vehicle may not be returned to exclusive use transport service, and then only for subsequent exclusive use shipment, unless the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination as specified in 49 CFR 173.443(a), Table 9 (as shown above) [see 49 CFR 173.443(c)].

Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material (49 CFR 173.443(d))

- The contamination levels must not exceed 10 times the levels prescribed in 49 CFR 173.443(a), Table 9 (as shown above).
- Each vehicle is marked with the words "*For Radioactive Materials Use Only*" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- The vehicle must meet the placard requirements of Subpart F of Part 172.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (49 CFR 173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  (a) the packaging is proper for the contents to be shipped;
  (b) the packaging is in unimpaired physical condition, except for superficial marks;
  (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;

(f) each closure, valve, or other opening of the containment system is properly closed and sealed;
(g) each packaging containing liquid in excess of an A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
(h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
(i) the external radiation and contamination levels are within the allowable limits specified in 49 CFR 173.441 and 173.443.

5. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR Part 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information. [1]

Shipping Paper Entries

Always Required	Sometimes Required	Optional Entries
Basic description (in sequence): • **UN Identification number** • **Proper Shipping Name** • **Hazard Class (7)** • **Maximum activity contained in each package in SI units** (e.g., Bq, TBq), or in both SI and customary units (e.g., Ci, mCi) with customary units in parentheses following the SI units • **Number and type of packages** Additional description: • **Name of each radionuclide**[2] • **Description of physical and chemical form** (unless special form) • **"Special form" when not in the proper shipping name** • **Category of label** used • **TI** of each package bearing a Yellow-II or Yellow-III label Additional entry requirements: • 24-hour **emergency telephone number** • **Shipper's Certification** shall be provided by each person offering radioactive material for transportation[3] • Proper page numbering (e.g., Page 1 of 4)	Materials-based requirements: • The CSI or "Fissile Excepted" for fissile material • "Highway route-controlled quantity" or "HRCQ" for highway route-controlled quantities • The letters "RQ" entered either before or after the basic description for each hazardous substance [see 49 CFR 171.8] • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste Package-based Requirements: • The applicable U.S. Department of Energy or NRC package approval identification marking for each Type B(U), Type B(M), or fissile material package • The IAEA Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package Shipment- and Administrative-based Requirements: • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT–SP" followed by the special permit number for a special permit shipment	• The weight in grams or kilograms may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate).
- Emergency response information consistent with 49 CFR 172.600 – 172.606 shall be readily available on the transport vehicle.
- Shipments of excepted radioactive material in excepted packages, under UN2908, UN2909, UN2910, and UN2911, are excepted from shipping paper requirements if (a) the material is not a hazardous substance or hazardous waste and (b) the package does not contain fissile material or contain fissile material that is excepted by 49 CFR 173.453.
- For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat [see 49 CFR 177.817(e)].

[1] International Atomic Energy Agency (IAEA); International Air Transportation Association (IATA); International Civil Aviation Organization (ICAO); International Maritime Organization (IMO).

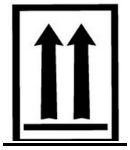
[2] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with 49 CFR 173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

6. 5. Hazard Communication for Class 7 (Radioactive) Materials:

Marking of Packages (49 CFR Part 172, Subpart D; and 49 CFR 173.471, 178.3 and 178.350)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages

Markings Always Required Unless Excepted[1]	Additional Markings Sometimes Required	Optional Markings
For Non-bulk Packages: • Proper shipping name • Identification number (preceded by "UN" or "NA," as appropriate) • Name and address of consignor or consignee, unless the package is: ▪ highway only and no motor carrier transfers; or ▪ part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee **For Bulk Packages:** • Identification number on orange panel or white square-on-point display [see 49 CFR 172.332 or 172.336]: ▪ on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more[2], or ▪ on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons)[2]	**Package-based marking requirements:** • Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 pounds) • Package type as appropriate, i.e., "TYPE IP–1," "TYPE IP–2," "TYPE IP–3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"[1] • Marked with international vehicle registration code of country of origin for IP–1, IP–2, IP–3 or Type A package design (e.g., "USA") • Radiation (trefoil) symbol[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design  • Each NRC-approved package (e.g., Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F) must be marked with the identification marking indicated in the package approval • For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A," and the name and address or symbol of the manufacturer satisfying 49 CFR 178.3 and 178.350 **Materials-based requirements:** • For a non-bulk IP–1 package containing a liquid, use underlined double arrow symbol indicating upright orientation[4], where the symbol is placed on two opposite sides of the packaging [see 49 CFR 172.312]  • For a non-bulk package containing a hazardous substance, mark the outside of each package with the letters "RQ" in association with the proper shipping name **Administrative-based requirements:** • For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in the U.S. Competent Authority Certificate • Mark "DOT–SP" followed by the special permit number assigned for each package authorized by special permit • Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required	• Both the name and address of consignor and consignee is recommended. • Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling. For marking exceptions for LSA material and SCO, [see 49 CFR 173.427(a)(6)(vi)] (e.g., RADIOACTIVE-LSA, RADIOACTIVE-SCO, or RQ, as appropriate). For an overpack, the marking "OVERPACK" in lettering 12 mm (0.5 inches) high. This marking is not required if the package type contained in the overpack is visible from the outside [see 49 CFR 173.25].

Special Considerations for Marking Requirements

- All markings are to be (a) on the outside of each package, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.
- When an overpack is used, see 49 CFR 173.25 and 173.448(g) for marking requirements.

[1] Some marking exceptions exist for excepted packages, as specified in 49 CFR 173.421, 173.422, 173.424, 173.426 and 173.428.

[2] If the identification number marking on a bulk package is not visible, the transport vehicle or freight container must be marked on each side and each end [see 49 CFR 172.331].

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water and conform to the size requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

6. Hazard Communications for Class 7 (Radioactive) Materials: Labeling of Packages (49 CFR 172.400-450)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Requirements for Labels[1]

- Label each package, except for (a) excepted packages of radioactive material; and (b) LSA material and SCO, packaged or unpackaged, when transported under exclusive use controls domestically and when the material or object contains less than an A_2 quantity.
- Labels are required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) not obscured by markings or other attachments, (f) representative of the hazardous material content, and (g) in conformance with the label specifications of 49 CFR 172.407.
- The appropriate radioactive label must be affixed to opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material.

Category of Radioactive Labels [3]

White-I

Yellow-II

Yellow-III

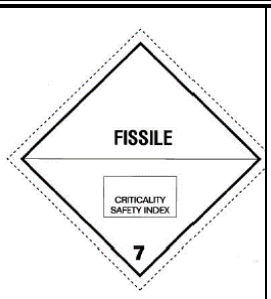
Maximum Radiation Surface Level (RSL)

mSv/h	**RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2[5]
mrem/h	**RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200[5]

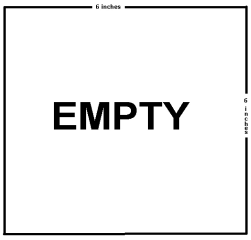
TI:[4]

TI = 0	0 < **TI** ≤ 1	1 < **TI** ≤ 10[5]

Other Radioactive Labels[2]



Fissile



Empty

Fissile labels required for each package containing fissile material, other than fissile excepted material; and labels must be affixed adjacent to radioactive category labels.

Empty labels required for empty Class 7 (radioactive) packages satisfying 49 CFR 173.428; and any previously-used labels must not be visible.

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in 49 CFR 173.433(g); and, for LSA-I material, the term "LSA-I"; (b) maximum activity in appropriate SI units (e.g., Bq, TBq), or appropriate customary units (e.g., Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the TI. Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units [see 49 CFR 173.403 for fissile material definition].
- Each fissile label must contain the relevant CSI [see 49 CFR 172.403(e)].

[1] Additional labels may be required if the contents of a package contains material that also meets the definition of one or more other hazard class. See 49 CFR 172.402 and 406(c) for details on additional labeling requirements. [See 49 CFR 172.400a, 173.421 through 173.427 for details when labels are not required, and see 49 CFR 172.407 for details on label durability, design, size, color, form identification, exceptions, and the trefoil symbol size].

[2] A "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only [see 49 CFR 172.402(c)].

[3] The category of the label must be the higher of the two values specified for RSL and TI [see 49 CFR 172.403(b)].
[4] The TI is determined from the radiation level 1 meter from the package surface [see TI definition in 49 CFR 173.403]. If the measured TI is not greater than 0.05, the value may be considered to be zero. When an overpack is used, it must be labeled in accordance with 49 CFR 172.403(h).
[5] Packages with a TI > 10 or an RSL > 2 mSv/h (200 mrem/h) must be transported under exclusive use provisions [see 49 CFR 173.441(b)]. Any package containing an HRCQ must be labeled as RADIOACTIVE YELLOW-III.

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR Part 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Conditions when Display of Placards is Required [49 CFR 172.504, 172.507(a), 172.508, and 172.512]

- Each bulk package, freight container, unit load device[1], transport vehicle, or rail car containing any quantity of hazardous material must be placarded on each side and each end with the placards specified in 49 CFR 172.504(e).
- Radioactive placards are required for: shipments that contain a package labeled as Radioactive Yellow-III; unpackaged LSA-I or SCO-I when transported under exclusive use provisions; shipments required by 49 CFR 173.427, 173.441, and 173.457 to be operated under exclusive use; and closed vehicles marked “For Radioactive Materials Use Only” transported under 49 CFR 173.443(d).
- The Radioactive placard is placed on a square background on any motor vehicle used to transport a package containing an HRCQ Class 7 (radioactive) material[2].

Visibility and Display of Radioactive Placards [49 CFR 172.516]

- Placards are required to:
  - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled[3]
  - be securely attached or affixed thereto or placed in a holder thereon
  - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins
  - be located, so far as practical, so dirt or water is not directed to it from the transport vehicle wheels
  - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness
  - have “RADIOACTIVE” printed on it displayed horizontally, reading from left to right
  - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter
  - be affixed to a background of contrasting color, or have a dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)	PLACARD FOR HRCQ
	
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see 49 CFR 172.556 and Appendix B of Part 172]	Square background must consist of a white square surrounded by one-inch black border. The placard inside the square is identical to that for other than HRCQ. [see 49 CFR 172.527]

General Specifications for Placards and Subsidiary Hazard Placarding

- Placards must conform to the specifications in 49 CFR 172.519.
- A CORROSIVE placard is also required for each transport vehicle that contains 454 kg (1001 pounds) or more gross weight of non-fissile, fissile excepted, or fissile uranium hexafluoride [see 49 CFR 172.505(b)].

- Placards are also required for subsidiary hazards of POISON INHALATION HAZARD, POISON GAS, or DANGEROUS WHEN WET [see 49 CFR 172.505].

[1] See 49 CFR 172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.
[2] See 49 CFR 173.403 for the definition of HRCQ. A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels [see 49 CFR 172.403(c) and 172.507(a)].
[3] Required placarding of the front of a motor vehicle may be on the front of a truck tractor instead of or in addition to the placarding on the front of the cargo body to which a truck tractor is attached 49 CFR 172.516(b).

7. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR Part 107, Subpart G; 49 CFR 171.15; 49 CFR Part 172, Subparts F and G)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR Part 107, Subpart G)

- Any person, other than those excepted by 49 CFR 107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
  - an HRCQ of radioactive material;
  - a shipment in a bulk packaging with a capacity ≥ 13,248 L (3,500 gallons) for liquids or gases, or > 13.24 cubic meters (468 cubic feet) for solids; or
  - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with 49 CFR 107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by the U.S. Pipeline and Hazardous Materials Safety Administration (PHMSA) and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this Subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at 49 CFR 107.612 and 107.616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR Part 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required [see Part 172, Subpart C], emergency response information shall
  - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
  - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
  - be immediately available for use at all times the hazardous material is present; and
  - include and make available the emergency response telephone number [see 49 CFR 172.604] to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in 49 CFR 172.602 and 172.604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of 49 CFR 172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

- If there is evidence of a leaking package or conveyance, access to the package or conveyance must be restricted, the area impacted and the extent of the contamination must be determined, and appropriate measures must be taken to minimize impact to persons and the environment [see 49 CFR 173.443(e)].
- Except for a road vehicle used solely for transporting Class 7 (radioactive) material [see 49 CFR 173.443(d)], each aircraft used routinely, and each motor vehicle used for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in 49 CFR 173.443(a), Table 9; and 173.443(c) for exclusive use vehicle provisions [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use [see 49 CFR 174.750(a), 175.705(e), and 177.843(b)].

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (49 CFR 171.15 and 171.16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see 49 CFR 171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center by telephone at 800–424–8802 (toll-free) or 202–267–2675 (toll call) or online at https://www.nrc.uscg.mil.
- Each notice must include the information specified in 49 CFR 171.15(a)(1) – (a)(7).
- A detailed incident report must also be submitted as required by 49 CFR 171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each proper shipping name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current edition of the Emergency Response Guidebook is available at https://phmsa.dot.gov/hazmat/outreach-training/erg.

9. Requirements for Training and Safety and Security Plans for Class 7 (Radioactive) Materials: (49 CFR Part 172, Subparts H and I, 49 CFR Part 173, and 10 CFR Part 37)

These are basic reference charts; refer to current U.S. DOT and NRC regulations for complete requirements.

Training (49 CFR Part 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects hazardous materials transportation safety, a systematic program shall be established to ensure that the person:
  - has familiarity with the general provisions of Part 172, Subpart H;
  - is able to recognize and identify radioactive materials;
  - has knowledge of specific requirements of Part 172 that are applicable to functions performed by the employee;
  - has knowledge of emergency response information, self-protection measures and accident prevention methods and procedures; and
  - does not perform any function related to the requirements of Part 172 unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of 49 CFR 172.704(a) and (b), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
  (a) general awareness training providing familiarity with applicable regulatory requirements;
  (b) function-specific training applicable to functions the employee performs;
  (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
  (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
  (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of 49 CFR 172.704(c).
- Records of training shall be created and retained in compliance with the requirements of 49 CFR 172.704(d).

Security (49 CFR Part 172, Subpart I, 49 CFR Part 173, and 10 CFR Part 37)

- A security plan for hazardous materials that conforms to the requirements of Part 172, Subpart I must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
  (a) IAEA Code of Conduct Category 1 and 2 materials (see 49 CFR 172.800(b)(15) and 10 CFR Part 37);
  (b) an HRCQ of radioactive material as defined in 49 CFR 173.403 [see 49 CFR 172.800(b)(15)];
  (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM–QC) by the NRC [see 49 CFR 172.800(b)(15) and 10 CFR Part 37]; or
  (d) a quantity of uranium hexafluoride requiring placarding under 49 CFR 172.505(b) [see 49 CFR 172.800(b)(14)].
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and enroute security.
- The security plan must be
  (a) in writing;
  (b) retained for as long as it remains in effect;
  (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
  (d) revised and updated as necessary to reflect changing circumstances; and
  (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.

- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in Part 172, provided such security plans address the requirements specified in Part 172, Subpart I.
- Additional security planning requirements may apply for rail transport of an HRCQ of radioactive material [see 49 CFR 172.820 and 173.403].

1

APPENDIX Q

MODEL WASTE MANAGEMENT PROCEDURES

Model Waste Management Procedures

General Guidelines

- Periodically review all procedures to ensure that radioactive waste is not created unnecessarily. For example, procedures should be consistent with Part 20 requirements minimize contamination of equipment to avoid waste generation. In addition, procedures should indicate that nonradioactive waste should not be mixed with radioactive waste. Review new procedures to ensure consistency with established waste management procedures.

- Consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.

- Provide waste handling procedures for users within their assigned areas, and for waste handlers who may collect waste from areas of use to bring to a storage area for eventual disposal. Those procedures should be part of the waste management program.

- Provide housekeeping staff with adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or radiation.

- Ensure records are kept for transfer and disposal of byproduct material in accordance with 10 CFR 30.51(a), "Records."

- Before transferring any licensed byproduct material, verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41 (e.g., obtain a copy of the transferee's NRC license or Agreement State license that authorizes the byproduct material). For transfers to an LLW disposal facility under 10 CFR 20.2008, review the additional guidance under "Model Procedure for Transfer of Licensed Material to Authorized Recipient for Near-Surface Disposal," below.

Model Procedure for Decay in Storage

Only waste with a physical half-life of less than or equal to 120 days may be disposed of by decay-in-storage (DIS). Applicants should ensure that adequate space and facilities are available for the storage of waste. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure consistent with the radiation protection standards in 10 CFR Part 20. Storage areas must be in a secure location.

- Waste should be stored in suitable well-marked containers, the containers should provide adequate shielding, and the waste's physical form should be compatible with the waste container.

- Liquid and solid wastes should be stored separately.

- Filled containers should be sealed. Sealed containers should be labeled in accordance with 10 CFR 20.1904 and 10 CFR 20.1905. The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container, total

activity, and the initials of the individual who sealed the container. The container may then be transferred to the DIS area.

- The contents of the container should be allowed to decay for a time after which it is expected that the radiation levels would not be distinguishable from background. The time depends on both the half-life of the radionuclide(s) and the original amount present.

- Prior to disposal as ordinary trash, each container should be monitored as follows:

  - Check the radiation detection survey meter for proper operation with a radiation source,

  - Survey the contents of each container in a low background area,

  - Remove any shielding from around the container,

  - Monitor all surfaces of the container, and

  - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background readings). All radiation labels should be defaced or removed from containers and packages prior to disposal as ordinary trash.

  - If the surveys indicate residual radioactivity, return the container to the DIS area and contact the RSO for further instructions.

- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used, and the initials of the individual performing surveys and disposing of the waste.

Note*:* When large quantities are held for DIS, measurable activities may be present even after many half-lives. Persons performing surveys should be aware of the potential for measurable radiation.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.

- Confirm that the liquid waste being discharged is readily soluble (or is easily dispersible biological material) in water.

- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.

- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste.

- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3.

- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 should not exceed unity.

- Make sure the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 GBq (1 Ci) of all other radionuclide combined.

- Liquid waste should be discharged only via designated sinks or toilets.

- Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to ensure that the material moves out of the sink into the sewer system.

- Survey discharge areas and surrounding work surfaces to confirm that no residual material or contamination remains. Prior to leaving an area, decontaminate all areas or surfaces found to be contaminated.

- For all releases to the sanitary sewer from the licensed facility, maintain records of each radionuclide and the quantity and concentration that is released into the sewer system to demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial waste disposal (e.g., incineration of a licensee's own waste) under 10 CFR 20.2004. Specific NRC approval is not necessary to incinerate certain categories of radioactive waste. For example, 10 CFR 20.2005 provides that tritium and carbon 14 in low-level concentrations, in liquid scintillation media and animal tissue, may be disposed of without regard to radioactivity. Licensees must maintain records for waste disposals under 10 CFR 20.2004 and 10 CFR 20.2005 as required by 10 CFR 20.2108.

After reviewing the disposal program and confirming the existence of waste that requires specific NRC approval for incineration, provide the following information in the license application:

- Describe the training and experience of the person who will be responsible for the onsite and day-to-day supervision of incinerator operations.

- Describe the waste that is proposed to be incinerated, including:

  - a description of the chemical and physical form of the waste containing licensed material;

  - a description of how the waste is segregated, packaged, and labeled for transfer from the generation site to the incinerator;

- names and concentrations of each radionuclide to be incinerated averaged over the weight of the material to be incinerated (µCi/g of waste medium); and

- the total radioactivity of each radionuclide per burn and the total number of burns per year, including a description of procedures for ensuring that these frequencies and activities will not be exceeded.

- Describe the procedures for the packaging, handling, securing, and monitoring of waste to prevent contamination and unnecessary exposure to personnel or property during the waste life cycle.

- Describe the methods for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling, and disposal of the ash residue.

- Describe the recordkeeping procedures for the waste incineration program. Records should be adequate to document all receipts, incineration, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records should be maintained in the same units as applicable regulations.

- Describe the characteristics of the incinerator and site location including:

  - height of the stack;

  - rated air flow (cubic feet per hour or similar units);

  - proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital);

  - distance to the nearest air intake ducts of adjacent buildings; and

  - a description of any scrubbers, filters, or air cleaning equipment that is present.

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

- Provide a copy of the written safety analysis that demonstrates that the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in 10 CFR Part 20.

- Provide a written commitment that the applicant has coordinated with appropriate state and local authorities and that such permits and other authorizations as may be necessary have been obtained.

- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations, and for monitoring all effluent generated by the incineration process. The procedures should ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe disposal procedures for any ash generated exceeding regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees who propose to compact waste:

- Describe the compactor to demonstrate that it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs);
- Describe the type, quantities, and concentrations of waste to be compacted;
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities;
- State the location of the compactor(s) within the waste processing area(s);
- Describe the ventilation and filtering systems used in conjunction with the compactors, including a description of the procedures for monitoring filter blockage and exchange;
- Describe the methods used to monitor worker breathing zones and exhaust systems;
- Describe the types and frequencies of surveys that will be performed for contamination control in the compactor area;
- Describe the instruction provided to compactor operators, including:
    - instructions for protective clothing;
    - checks for proper functioning of equipment;
    - methods of handling uncompacted waste; and
    - examination of containers for defects.
- Deface or remove all radioactivity labels that are visible in the compacted mass.

Model Procedure for Transfer of Licensed Material to Authorized Recipient for Near-Surface Disposal

Licensed material should not be transferred or shipped from one institution to another without the approval of the RSO. Such transfers must be packaged and labeled in accordance with DOT, NRC, or U.S. Postal Service regulations, whichever is applicable. Licensees must maintain records for waste disposals under 10 CFR 20.2002 and 10 CFR Part 61 as required by 10 CFR 20.2108. That recordkeeping requirement includes waste disposed of under 10 CFR Part 61 per the provisions of 10 CFR 20.2008.

Prior to any transfer from the license, the licensee must verify that the recipient is authorized to receive the licensed material, as required by 10 CFR 30.41.

- For transfers of waste to an LLW disposal facility under 10 CFR 20.2008, document whether the waste is manifested and labeled for disposal consistent with the description of the applicable waste class in 10 CFR 61.7, based on the physical, chemical, and radiological characteristics of the waste:

- State whether the waste is activated metal, cement-solidified liquids, polymer-solidified liquids, contaminated soil, contaminated equipment, contaminated building rubble, ion-exchange resin, incinerator ash, calcined waste, or another waste form described in Section 3.4 of NUREG-0782, Volume. 2, "Draft Environmental Impact Statement on 10 CFR Part 61 'Licensing Requirements for Land Disposal of Radioactive Waste'."

- If the waste is not one of the listed wasteforms, indicate that the disposal site licensee has performed a site-specific inadvertent intrusion assessment as required by 10 CFR 20.2008(a) to demonstrate that the waste is acceptable for disposal. Guidance on performing a site-specific intrusion assessment is available in the NRC Draft NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61."

- Compare the radionuclides in the waste to the radionuclides in Table 8-4 in Section 8.11. A licensee should consider a radionuclide to be present in waste if it meets any of the following criteria, either by direct measurement or an indirect method (e.g., use of scaling factors):

    - the concentration is greater than 0.01 times the concentration limit for that radionuclide in the disposal facility WAC;

    - the radionuclide does not appear in 10 CFR 61.55 tables or the disposal facility WAC and the concentration is greater than 0.26 megabecquerel (MBq) per cubic centimeter;

    - the activity represents a reportable quantity under DOT regulations (see 49 CFR 172.101, Appendix A, "Office of Hazardous Materials Transportation Color Tolerance Charts and Tables,"); or

    - the activity or is 0.01 or more of the total activity within the disposal container.

- If the waste contains radionuclides that are not in Table 8-4 of Section 8.11 of this NUREG or contains radionuclides in greater concentrations than the values in that table for the applicable disposal waste class, the licensee should either develop another method to demonstrate that the waste is consistent with the description of the applicable waste class in 10 CFR 61.7 or indicate that the disposal site has performed a site-specific inadvertent intrusion assessment as required by 10 CFR 20.2008(a).

- For any waste offered for transportation for disposal at a licensed LLW land disposal facility, prepare a Uniform Waste Manifest as required by 10 CFR Part 20, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests." Licensees should consult NUREG/BR-0204 Rev.3, "Instructions for Completing the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest," to complete forms required by 10 CFR Part 20 Appendix G.

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This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for fusion machine possession licenses. In particular, the report describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, “Application for Materials License.” This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

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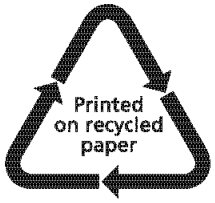

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