United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1556
Volume 10, Rev. 1

Consolidated Guidance about Materials Licenses

Program-Specific Guidance about Master Materials Licenses

Draft Report for Comment

Office of Federal and State Materials and
Environmental Management Programs

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Volume 15, Rev. 1

Consolidated Guidance about Materials Licenses

Program-Specific Guidance about Master Materials Licenses

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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 10, Revision 1, 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.

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Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID **NRC-2014-0068**. Address questions about NRC dockets to Carol Gallagher at 301-287-3422 or by e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: 3WFN-06-A44MP, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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Please be aware that any comments that you submit to the NRC will be considered a public record and entered into the Agencywide Documents Access and Management System (ADAMS). Do not provide information you would not want to be publicly available.

ABSTRACT

This technical report contains information intended to provide program-specific guidance for existing Master Materials Licenses and assist Federal agencies in preparing applications for a Master Materials License. In particular, it 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 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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FOREWORD

The U.S. Nuclear Regulatory Commission's (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, 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
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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
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

Volume No.	*Volume Title*
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	Program-Specific Guidance about Administrative Licensing Procedures
21	Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator
22	Reserved

The current document, NUREG-1556, Volume 10, Revision 1, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Master Materials Licenses," is intended for use by applicants, licensees, and NRC staff. This revision provides a general update to the previous information contained in NUREG-1556, Volume 10, issued December 2000.

This document provides guidance to Federal organizations preparing a Master Materials License (MML) application and Federal organizations that have MMLs. In addition, it provides the criteria NRC license reviewers and other NRC personnel use in reviewing MML applications and current MMLs. In order for the NRC to issue an MML to a Federal organization, the NRC must ensure that the organization is capable of performing certain functions and activities as a regulator, in much the same manner that the NRC, pursuant to the Atomic Energy Act of 1954, performs these functions and activities. To be granted an MML, a Federal organization must therefore demonstrate that it has a regulatory program that, among other things, can safely issue permits for the possession and use of byproduct, source, and special nuclear material at multiple sites, and has an organizational structure capable of providing adequate oversight and inspection of its permittees.

This report takes a risk-informed, performance-based approach to licensing the use of radioactive materials under an MML. A team composed of staff from NRC headquarters and NRC regional offices prepared this document, drawing on members' collective experience in radiation safety in general and as specifically applied to MMLs.

NUREG-1556, Volume 10, Revision 1, is not a substitute for NRC 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 continue a license.

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
CATX	categorical exclusion
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	*Code of Federal Regulations*
DFP	Decommissioning Funding Plan
DP	Decommissioning Plan
EA	Environmental Assessment
EIS	Environmental Impact Statement
ER	Environmental Review
FSME	Federal and State Materials and Environmental Management Programs
FSS	Final Status Survey
FSSR	final status survey report
IMC	Inspection Manual Chapter
ISG	interim staff guidance
LOU	Letter of Understanding
MML	Master Materials License or Master Materials Licensee
NEPA	National Environmental Protection Act
MRSC	Master Radiation Safety Committee
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
PII	personally identifiable information
PM	project manager
RAMQC	Radioactive Materials Quantities of Concern
RCP	Radiation Control Program
RCPD	Radiation Control Program Director
RIS	regulatory issue summary
RSO	Radiation Safety Officer
SOP	Standard Operating Procedures

1. PURPOSE OF REPORT

This report provides guidance to Federal organizations preparing a Master Materials License (MML) application and Federal organizations that have MMLs. In addition, it provides the criteria the U.S. Nuclear Regulatory Commission (NRC) license reviewers and other NRC personnel use in reviewing MML applications and current MMLs. For the NRC to issue an MML to a Federal organization, the NRC must ensure that the organization is capable of performing certain functions and activities in a manner that ensures compliance with the Atomic Energy Act of 1954, as amended, and other applicable regulations consistent with the public health and safety and the environment.

Thus, this document focuses on the information the Federal organization must provide to ensure the NRC that the applicant has adequate staff, facilities, programs, and procedures necessary to assume the regulatory tasks authorized in the license, and that, with respect to NRC-regulated materials, the MML permittees are subject to the same licensing and inspection requirements and policies as other NRC licensees.

To the extent an applicant chooses to take a different approach, it should justify why the requested information is not necessary in light of the information provided. In the absence of justification, the applicant should opt to use the approach in this document in formatting its application.

1.1 NRC Review Process and Criteria

After receipt of an MML application, the NRC regional office where the MML will be based, should designate an NRC MML project manager (PM). An MML application review team, consisting of headquarters and regional staff (including the MML PM) will be established to review the application. Since the existing organization's licenses may be located in multiple regions, communications across the regions and headquarters is necessary.

The NRC will review the applicant's regulatory commitment to follow NRC requirements and criteria, as evidenced by: by the license application; inspection history of the organization's individual licenses; financial status and stability; clerical and professional staffing of the proposed inspection and permitting programs; independence of MML management structure; and commitment to the MML.

The NRC staff should conduct a readiness review, as described in Section 1.5, before issuing any new MML. During the readiness review process, the NRC staff will visit the applicant and review the applicant's operational and administrative readiness to assume the responsibilities of an MML.

1.2 Definition and Description

An MML is a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization, authorizing the use of material at multiple sites. The MML authorizes the licensee to issue permits for the possession and use of licensed material under the license, and provides a framework for oversight and internal licensee inspection of its permittees.

In order for the NRC to issue an MML to a Federal organization, the NRC must ensure that the organization is capable of performing certain functions and activities as a regulator, in much the same manner that the NRC, pursuant to the Atomic Energy Act of 1954, performs these functions and activities. To be granted an MML, a Federal organization must therefore demonstrate that it has a regulatory program that, among other things, can safely issue permits for the possession and use of byproduct, source, and special nuclear material at multiple sites, and has an organizational structure capable of providing adequate oversight and inspection of its permittees.

A master materials licensee is an NRC licensee that is required to meet NRC regulatory requirements. The MML will have expiration dates consistent with all other specific licenses be renewed every 10 years. The MML grants the licensee the authority to undertake a limited number of activities as a regulator. As a result, the organization must demonstrate that it has a regulatory program that is consistent with the NRC's regulations. For example, Title 10 of the *Code of Federal Regulations* (10 CFR) 30.33(a)(3) requires that licensees be qualified by training and experience to use materials for the purposes requested. Since this includes the issuance of permits by the MML for the possession and use of byproduct, source, and special nuclear material at multiple sites, the MML must have a centrally controlled program capable of providing independent oversight and inspection of its permittees.

For the NRC to issue an MML to a Federal organization, the NRC must ensure that the applicant can demonstrate it is capable of performing certain functions and activities in a manner that meets the same standards that the NRC, pursuant to the Atomic Energy Act of 1954, as amended, applies to itself. The NRC should provide current NRC policies and procedures to the licensee, so that the licensee can develop and implement a program consistent with the NRC's program.

In order to provide consistency with NRC's training program, the licensee's inspectors and permit reviewers should meet the training requirements in Inspection Manual Chapter (IMC) 1248 "Formal Qualifications Program for Federal and State Material and Environmental Management Programs" or the requirements of an equivalent training and qualification program. In addition, the MML should use the NRC's licensing and inspection guidance and should have a system for tracking its permitting and inspection actions.

Under IMC 2810, "Master Material License Oversight and Inspection Program," MML are inspected at least biennially by the NRC to evaluate the licensee's implementation of its program.

1.3 Issuance Criteria for a Master Materials License

An MML will be issued only to a Federal organizations that successfully meets the criteria in 10 CFR 30.33, "General requirements for issuance of specific licenses" 10 CFR 40.32, "General requirements for issuance of specific licenses," or 10 CFR 70.31, "Issuance of licenses," as applicable, and can demonstrate that it is qualified to be granted an MML.

Before filing an MML application, the Federal organization should have a centrally controlled program in place for 5 years. The applicant should describe in general terms the purposes for which it will use licensed material and explain why an MML is needed. The MML applicant should demonstrate its readiness for an MML by effectively performing the following through the centrally controlled program:

- Managing the use of byproduct materials under NRC-specific licenses of broad and limited scope. The organization will do this by receiving, reviewing and resolving licensing actions of its proposed permittees before submittal to the NRC.

- Conducting inspections of its prospective permittees and accompanying NRC staff during NRC inspections of the same. The NRC will compare the applicant's existing licensees' performance record with that of other similar licensees for the same time period.

- Developing programs, policies, and procedures for in the following areas: staffing and training, enforcement, incidents, allegations, and decommissioning.

- Establishing the following elements: centralized and independent administrative structure and organization, staff, facilities, equipment, and procedures adequate to protect the health and safety of workers and the public against radiation hazards from the materials and uses over which the licensee proposes to assume responsibility for permitting and inspecting.

The applicant should demonstrate its readiness to assume the responsibilities of an MML as evidenced by acceptable performance of the licensee's centrally controlled program based on an operational readiness review described in Section 1.5, "Prelicensing Visit and Readiness Review" and conducted by the NRC.

1.4 Master Materials Licensee Authorizations

An MML, through its Master Radiation Safety Committee (MRSC), may permit any radioactive material authorized in the MML to be possessed and used by its permittees. The MML applicant may also request authorization to issue permits for the possession and use of specifically licensed quantities of source and special nuclear material. To ensure licensing and inspecting uniformity for MML permittees, the MRSC permitting criteria and inspection program should be consistent with NRC licensing, inspection and enforcement policies, procedures, and guides, and must be consistent with NRC regulations.

The Letter of Understanding (LOU) (discussed in Section 2.4, "Letter of Understanding (LOU)") will, among other things, identify certain exclusionary activities that the MML cannot conduct, unless specifically authorized on the license. Typically, the exclusions stated in an LOU provide that MMLs shall not:

- Grant exemptions to NRC regulations.

- Conduct tracer studies in the environment involving the direct release of radioactive material (field uses).

- Conduct activities authorized under: 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations";10 CFR Part 36, "Licenses and Radiation Safety

Requirements for Irradiators"; or 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging."

- Add or cause the addition of byproduct material to any food or other product designated for ingestion or inhalation by, or application to, a human being, unless specifically authorized, e.g., for medical use.

1.5 Prelicensing Visit and Readiness Review

After the NRC staff reviews an application for an MML and determines it is generally complete and substantially responsive to NRC Form 313 and this guidance, the NRC will schedule at least one pre-licensing visit at the MML applicant's radiation control program (RCP) central office. At a minimum, the pre-licensing visit will include a meeting with the applicant's RCP staff and may, as necessary, include a meeting with the applicant's senior management and proposed MRSC members.

A pre-licensing visit provides NRC staff an opportunity to:

- Better evaluate the applicant's proposed program and necessity for an MML.
- Meet with the applicant's RCP staff, senior management, and proposed MRSC members.
- Communicate the importance of the applicant's responsibilities.
- Discuss deficiencies in the application and agree on additional information and commitments that will be required.

Before issuing an MML, NRC staff will perform a readiness review to determine the operational and administrative readiness of the centrally controlled RCP to assume the responsibilities of an MML. The purpose of the readiness review is to determine if the applicant has a centralized control program, and if it has met the criteria described in Section 1.3 of this guidance for issuance of an MML. In the readiness review, NRC staff will examine the operational and administrative performance of the centrally controlled RCP with regard to: (1) management oversight, document management, and radiation control procedures, (2) status of the inspection program, (3) technical quality of inspections, (4) technical staffing and training, (5) technical quality of permitting actions, (6) of the permitting program, (7) incident and allegation handling programs, (8) enforcement program, and (9) decommissioning program, as applicable.

In addition, to further evaluate the applicant's level of centralized control of the program, NRC staff may conduct independent site visits at a select number of permittees that will be under the MML to review the methods, frequency, and effectiveness of communications between the applicant's RCP office and its permittees.

1.6 Programs Not Warranting a Master Materials License

If the NRC determines that the issuance of an MML is not warranted, the applicant may continue with its existing licensed activities and may submit an application for an MML at a later date without prejudice.

2. FILING AN MML APPLICATION

An applicant for an MML should submit its application, including a draft LOU (See Appendix C), a description of the applicant's regulatory performance and centralized experience for the last 5 years, and a completed U.S. Nuclear Regulatory Commission (NRC) Form 313 (see Appendix A), to the appropriate NRC regional office.

2.1 Paper Application

Applicants for an MML should do the following:

- Use the most recent guidance in preparing an application.
- Complete NRC Form 313 (Appendix A) 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 D.
- Provide sufficient detail for the NRC to determine that equipment, facilities, training, experience, and the radiation control program (RCP) are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet other than NRC Form 313 and Appendix D submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Submit all documents, typed, on 8½- by 11-inch paper.
- Avoid submitting proprietary information and personally identifiable information.
- If submitted, proprietary information and other sensitive information (e.g., personal privacy and security-related) should be clearly identified per Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding" (see Section 2.3, "Identifying and Protecting Sensitive Information").
- Submit an original, signed application.
- Retain one copy of the license application for future reference.

Applications must be signed by the applicant, licensee, or a person duly authorized as required by 10 CFR 30.32(c) (Item 13 of NRC Form 313).

2.2 Where to File

An applicant seeking to become an MML should submit its application to the Division of Materials Safety and State Agreements (MSSA) at NRC headquarters. FSME will then assign a Region to review the application.

2.3 Transfer to Electronic Format

Paper applications received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants should do the following:

- Submit printed or typewritten—not handwritten—text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura (the text of this document is in the Arial font).
- Use 12-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is a high contrast between the ink and paper (black ink on white paper is best).

The NRC will provide additional instructions as the agency implements new mechanisms for electronic license application filing.

2.4 Identifying and Protecting Sensitive Information

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

The licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. Licensing applications that contain sensitive information should be marked as indicated below in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," 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.
- 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, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. As a result, certain types of information are no longer routinely released 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, "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 22, 2005, which can be found on the NRC's Generic Communications Web page under "Regulatory Issue Summaries": http://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additional information on procedures and any updates is available at http://www.nrc.gov/reading-rm/sensitive-info.html.

2.5 Letter of Understanding (LOU)

The LOU is a document that identifies the responsibilities and requirements for coordination between the MML and the NRC, as well as those responsibilities which are retained by the NRC. The LOU is signed by representatives from both agencies

The following are some examples of responsibilities that may be divided:

- Administrative
- Environmental
- Permitting
- Inspection
- Allegations
- Enforcement
- Investigations
- Decommissioning
- Developing Procedures

In the following examples of responsibilities that will not be shared, the licensee would continue to:

- Report to and notify the NRC in accordance with regulatory requirements.
- Request authorization for exemptions to the regulations.
- Submit environmental assessment reports pursuant to 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."
- Submit alternate disposal requests in accordance with 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures."
- Submit decommissioning financial assurance in accordance with 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning."
- Submit an emergency plan for possession of licensed materials pursuant to 10 CFR 30.32, "Application for specific licenses."
- Request authorization for issuance of a permit to individuals or other entities that are not a part of the licensee's organization.
- Request authorization for issuance of a permit to individuals or other licensee entities to work at a new permanent location of use that is not at the MML's federally controlled facility.

Response from Applicant:

- Submit a draft LOU that defines and describes the division of responsibilities and the requirements for coordination between the applicant and the NRC utilizing Appendix C as an example. The LOU will be finalized and signed by the applicant and the NRC prior to issuance of a new or renewed license.

2.6 Permitting and Enforcement History

An MML will be issued only to organizations with a good regulatory performance record, based on NRC licensing and inspection of prior activities; and with experience in centralized management oversight, and coordination of permitting, inspection, enforcement efforts, and decommissioning activities, as applicable. Management oversight and coordination experience will also be assessed during the readiness review.

The NRC will evaluate the applicant's performance using, at a minimum, the following indicators:

- demonstrated proficiency at completing permittee applications
- timely and effective communications within the organization at all levels regarding radiation safety and security program issues

- self-identification and correction of safety or security issues, evaluation of the 'extent of conditions'(i.e. applicability to other permittees) as part of the corrective actions, and regulatory compliance

- handling of employee radiation safety concerns

- inspections that resulted in:

  - noncited violations
  - violations cited in a notice of violation
  - violations considered for escalated enforcement

- RCP handling of NRC findings with significant programmatic implications

- number and type of NRC escalated enforcement cases

- number and type of NRC recurrent violations/events

- prompt actions taken by the RCP to restore safety, security, and compliance; comprehensive corrective actions to fully address the violation and any 'extent of conditions', and lasting corrective actions to prevent recurrence

- identify if there were any missed opportunities to identify or prevent violations or events, across all MML activities

Response from Applicant:

- Describe regulatory performance in licensing, inspection, enforcement, and centralized experience in management oversight and coordination of licensing and inspection efforts for the previous five years. In addition, describe the applicant's corrective action program.

3. APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 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 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 also are 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."

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 the NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

4. 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). Refer to Table 4.1 for the traits of a positive safety culture from NRC's safety culture policy statement.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, the NRC's safety culture policy statement and traits are not incorporated into the regulations. Safety culture traits may be inherent to an organization's existing radiation safety practices and programs. An MML program should develop a corrective action program. An MML that develops and implements a corrective action program will be more adept at identifying and fixing safety problems as well as evaluating effectiveness of the corrective action, both immediately and in the long term. Developing a corrective action program is an action that may correspond with the safety culture training specified in Table 4.1 as "Problem Identification and Resolution" (issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance). However, licensees should be aware that this is just an example, and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix B for the NRC's safety culture policy statement. More information on NRC activities relating to safety culture can be found at: http://www.nrc.gov/about-nrc/safety-culture.html.

Table 4.1 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 potentially impacting 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.
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**
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.

5. CONTENTS OF AN APPLICATION

The following information applies to the indicated items on NRC Form 313 (Appendix A). All items in the application should be completed in enough detail for the NRC to determine that if the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration must be given, when developing the application, to the concepts of keeping exposure as low as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of radioactive materials.

10 CFR 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste. As with ALARA considerations, applicants should address these concerns for all aspects of their programs.

10 CFR 20.1801, "Security of stored material," states that licensees shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

10 CFR 20.1802, "Control of material not in storage," states that licensees shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Refer to Appendix E of this report 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. The majority of materials licensing actions will meet the criteria in 10 CFR 51.22(c) for a categorical exclusion. This means that the licensing action will not require an environmental assessment or environmental impact statement in accordance with 10 CFR 51.22(b), since the NRC has already determined that this type of licensing action does not have a significant impact on the environment. It is the applicant's responsibility to review the guidance in Appendix E to determine whether the categorical exclusion applies to the licensing action.

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. Throughout this document, descriptive items that will not be incorporated into the license as a requirement are indicated by a single asterisk (*). These descriptive items are for information only and will assist the NRC in gaining a complete understanding of the MML program as a whole. It is the intent of the NRC that these items will not be incorporated in the license. Applicants should clearly identify in the

MML application information that constitutes descriptive information. Any changes in descriptive information that occurs while the throughout the life of the license is in effect should be communicated to the NRC so as to allow the NRC to determine the licensing significance of the changes and whether an amendment is needed.

The NRC will return any application not signed by the certifying official (Item 13 of NRC Form 313).

5.1 NRC Form 313, 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.

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 “Amendments and Renewals to a License” in Chapter 6 of this report.

5.2 NRC Form 313, Item 2: Applicant’s Name and Mailing Address

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; these changes do not require a fee.

Also, the applicant should specify the proposed location of the MML applicant’s radiation control program (RCP) Office by providing the street address, city, and State or other descriptive address (e.g., Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State). The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable. In addition, applicants are encouraged to provide global positioning system coordinates, as appropriate. This should be the location of the docketed permittee files for the MML or where they can be readily retrieved for review.

Response from Applicant:

- Provide location of MML applicant's RCP Office.

- Confirm whether the docketed permittee files for the MML will be located at the RCP Office. (Identification of the actual location of all MML program documents and files is requested in Section 5.9, "NRC Form 313, Item 9: Facilities and Equipment.")

5.3 NRC Form 313, Item 3: Location of Use

Federally-Controlled Fixed Sites
The licensee should maintain and have available at all times a current list of locations where permitted material will be used (i.e., permittee's locations of use) by address, including program code used by the NRC.

Temporary Job Sites
If permittees will use radioactive material at temporary job sites, the NRC must specifically authorize this activity on the MML. Applicants should indicate if they will authorize permittees to use radioactive material at temporary job sites, so the NRC can include this information on the license.

Field Studies
If permittees will use radioactive material in field studies, the NRC must specifically identify and authorize these activities on the MML. NUREG-1556, Vol. 11, "Program-Specific Guidance about Licenses of Broad Scope," contains information required for field use of licensed material.

Other Sites
If permittees intend to use radioactive material at facilities and sites (other than temporary job sites) that are not located at the MML's federally controlled facility, the NRC must approve these activities and specifically identify and authorize them on the MML.

Response from Applicant:

- Provide a current list of permittees, locations, and program code.

- Identify permittees that will be authorized to use radioactive material at temporary job sites.

- Identify permittees that intend to use radioactive material in field studies.

- Identify permittees that intend to use radioactive material at facilities and sites, other than temporary job sites, that are not located at the MML's federally controlled facilities.

5.4 NRC Form 313, Item 4: Person to Be Contacted About Application

The applicant should specify the individual who will be the Radiation Control Program Director (RCPD) and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses.

Response from Applicant:

- Identify the individual who will be the RCPD and provide the individual's contact information.

5.5 NRC Form 313, Item 5: Material to Be Possessed

While the major authorization in the MML will specify any radioactive material in any form and as needed or limited to some maximum quantity, there may be specific additional line items for some radionuclides; therefore, the applicant should describe, in general, the licensed material the applicant wishes to possess by isotope class (e.g., byproduct, source, or special nuclear material), chemical or physical form, and quantity (e.g., in curies or, millicuries)., etc. The NRC will describe the authorized uses of these materials on the license and use broad descriptive terms to do so. For example, the applicant should categorize this information into general areas of use, e.g., research and development activities, industrial activities, self-contained irradiators, instrument calibrators, and medical applications. The applicant should provide a list of the manufacturer and model number of all Category 1 and 2 sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators, and radiography cameras). The applicant should specify whether the device(s) is/are registered or not registered in accordance with 10 CFR 32.210, "Registration of product information."

The maximum quantity for each individual nuclide and total cumulative possession authorized by the MML for individual permittees should be commensurate with each permittee's needs, facilities, procedures, personnel, and demonstrated experience/capability. The independent amounts of material at each permittee's facility or site and not the aggregate of all materials possessed by the MML is used to determine whether decommissioning financial assurance or an emergency plan is necessary. The applicant should describe facilities or permittees that may possess quantities of materials requiring financial assurance, in accordance with the requirements of 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning"; 10 CFR 40.36, "Financial assurance and recordkeeping for decommissioning"; and 10 CFR 70.25, "Financial assurance and recordkeeping for decommissioning," or requiring consideration of the need for an emergency plan for responding to a release, in accordance with 10 CFR 30.32, "Application for specific licenses."

Response from Applicant:

- Identify the licensed material to be possessed by: isotope class (e.g., byproduct, source, or special nuclear material); chemical or physical form; quantity (e.g., in curie or, millicurie), etc.; and general areas of use (e.g., research and development activities, industrial activities, self-contained irradiators, instrument calibrators, radiography, or medical applications).

- Identify by manufacturer and model number all Category 1 and 2 sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators, and radiography cameras). The applicant should specify whether the device(s) is registered or not registered in accordance with 10 CFR 32.210.

- Identify permittees that may possess quantities of materials requiring financial assurance or an emergency plan.

5.6 NRC Form 313, Item 6: Purpose of Use of Licensed Material

The applicant should describe in general terms the purposes for which it will use licensed material and explain why an MML is needed. The uses should be consistent with the applicant's prior licensed activities and categorized in a classification scheme according to the NRC's licensing program codes. The NRC staff understands that the information provided regarding "purpose of use" in this section is a self-imposed limitation contained within the application. If an MML applicant wants to initiate an intended use other than that described in its application and incorporated in its license and LOU, it should submit an amendment request to the license to modify/expand the "purpose of use." Applicants should include a list of total possession limits for each category of use requested.

Note: If the newly added purpose of use includes material use in a unique or specialized activity (e.g., sealed source fabrication), the applicant may be required to submit the criteria used by the MRSC in evaluating in-house requests for such use. In this specific example, NUREG-1556, Vol. 3, "Applications for Sealed Source and Device Evaluation and Registration," provides guidance for the evaluation and registration of sealed sources and devices with the NRC.

The applicant should state if it intends to use or approve sealed sources other than those that have been registered with the NRC's Sealed Source and Device Registry and describe the training and experience of individuals responsible for reviewing applications for use.

If the applicant has a permittee that wants to perform field studies that involves deliberately releasing licensed material to the environment, then the applicant should include the information outlined in NUREG-1556, Vol. 11, "Program-Specific Guidance about Licenses of Broad Scope," in the application, so that the NRC can approve and specifically authorize the field studies on the MML.

Note: Regulations in 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," include the issuance, amendment, or renewal of licenses for use of radioactive material for research and development and for educational purposes as a categorical exclusions (CATX), from the requirement to prepare an environmental assessment (EA) or environmental impact statement (EIS); however, this CATX does not encompass field studies in which licensed material is deliberately released directly into the environment for purposes of the study (e.g., tagging animals or insects that remain in the wild). Field studies may require applicants to file an environmental report (ER) and the NRC to perform an EA pursuant to 10 CFR Part 51. Field studies that do not deliberately release radioactive material into the

environment, such as tagging of animals and penning them to prevent escape, may be eligible for a CATX under 10 CFR 51.22.

Any questions should be referred to the appropriate regional office.

Response from Applicant:

Explain why an MML is needed.

- Describe in general terms the purposes for which licensed materials will be used.

- State if you intend to use or approve sealed sources other than those that have been registered with the NRC's Sealed Source and Device Registry, and describe the training and experience of individuals responsible for reviewing applications for use of these materials.

- Identify any uses that are not identified as a CATX in 10 CFR 51.22 (including field studies deliberately releasing licensed material to the environment), and provide information needed for specific authorization.

- Provide sufficient information about field studies where there is no planned deliberate release of radioactive material to the environment for the NRC to determine if a categorical exclusion is appropriate.

5.7 NRC Form 313, Item 7: Individuals Responsible for the Radiation Safety Program

The following sections are provided to assist the applicant in correctly identifying the individuals for the functional positions of senior management, MRSC, and RCPD. These sections provide descriptive information on some of the duties and responsibilities of these positions, which are also discussed in Section 5.10, "Radiation Safety Program." In addition, as part of the information that should be submitted under Item 7 of NRC Form 313, the applicant should specify any delegations of authority for these positions, as well as the management tools used for the oversight of the program. Other aspects of program responsibilities should be submitted.

5.7.1 Senior Management

The importance of senior management's role in the development and functioning of an MML program cannot be overemphasized. The NRC issues an MML to accommodate licensees who are involved in extensive radioactive materials programs where the demand is great for a variety of radionuclides, uses, and locations of use across NRC regional boundaries. The NRC grants significant authority to MML management to develop and implement an appropriate RCP. An adequate RCP should ensure the implementation of consistent health, safety, and security programs by all of the proposed MML facilities. Consequently, the MML management should establish effective administrative controls, oversight, and provisions for organization and management, including management review and self-assessments that are essential to ensure safe operations under the license.

When an MML is issued, the organization's senior management (the highest level of the licensee's management) is responsible for the regulatory activities authorized under the license. Since the MML is governed by NRC requirements, senior management and the MRSC needs to ensure that the training, licensing, inspection, enforcement, event response, allegation resolution, decommissioning, and other regulatory activities are implemented so as to be consistently with the NRC's policies and procedures. It is the responsibility of the NRC to provide the MML with current NRC policies and procedures; however, it is the responsibility of the MML management to incorporate NRC requirements and policies into the MML processes and programs.

The applicant should describe senior management oversight and processes used by the highest level of management to ensure that there is consistent and adequate control over MML activities (see Section 5.10, "Radiation Safety Program"). To ensure safe operations and compliance with regulatory requirements, such oversight should include senior management membership and active participation in regular meetings of the MRSC. The MRSC should have oversight of the RCPD and support staff and perform annual audits of the program.

MML are required to establish an MRSC that represents management when reviewing and approving permit applications; therefore, senior management should delegate to the MRSC and the RCPD, in writing, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions, and permit conditions. These delegations of authority are also addressed in Sections 5.10.8, "The Master Radiation Safety Committee Responsibilities," and 5.10.9, "Radiation Control Program Director Responsibilities." The licensee retains the ultimate responsibility for the conduct of licensed activities. It is also essential that the licensee devote sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the RCP at all levels.

The application should include an organizational chart of the applicant's management structure depicting reporting paths, flow of authority, and the control of finances necessary to implement the MML. The applicant should include a statement empowering the MRSC by outlining its authority to oversee the licensed program and its responsibility for control and direction of the RCP and the RCPD. In addition, the applicant should describe provide the MRSC's authority to suspend or terminate activities based on poor performance or violation of safety standards. These issues are addressed further in Section 5.10, ""Radiation Safety Program."

Senior management should designate a point-of-contact to act as the liaison, typically the RCPD, between the MML and the NRC regional MML PM during the application process, as well as during operation under of the MML. The roles and responsibilities of the MML liaison should be described in the MML policies and procedures. The MML policies and procedures should describe the expected types of interactions and exchanges of information between the MML and the NRC, including both formal and informal communication mechanisms.

Response from Applicant:

- Provide an organizational chart depicting the licensee's management structure, reporting paths, flow of authority, control of finances, and geographical location of all management and staff components of the RCP.

- Describe established management controls and oversight used to ensure that permitted activities are properly conducted. This should include senior management's established administrative controls and provisions relating to organization and management, including management review necessary to ensure adequate protection of public health, safety and security, and to protect the environment.

- Provide senior management's written delegations to the MRSC and RCPD providing for sufficient authority, organizational freedom, and management prerogative to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions, and permit conditions.

- Provide the point of contact as the liaison to the NRC MML PM and describe the expected types of interactions and exchanges of information, including both formal and informal communication mechanisms.

- Confirm and describe senior management commitment to devote sufficient financial resources (e.g., funds, equipment, personnel, materials) to support the RCP at all levels.

- Describe the senior management oversight and mechanisms used by management to ensure adequate control over MML activities. The senior management oversight activities should include:

  - membership and active participation in MRSC meetings

  - oversight of RCPD and support staff

  - annual audits of the program to ensure safe operations, regulatory compliance, and consistency with NRC' s policies and procedures

5.7.2 Master Radiation Safety Committee

The MRSC not only has the authority to control and direct the centralized RCP, but it also serves as a means by which the highest level of the licensee's senior management gains an overview of the entire MML program, i.e., permittee activities and the respective roles of the RCPD, MRSC, and permittees. The MRSC provides guidance and information on the RCP to the highest level of senior management, ensures that adequate resources are provided by licensee management, and provides oversight to the RCPD in developing, implementing, and maintaining the RCP. The MRSC should ensure that the highest level of executive management is periodically given all relevant information regarding the RCP, particularly when the highest level of management will make decisions that may affect the program.

Membership of the MRSC should include:

- A senior manager from the applicant's executive management organization to serve as the Chairperson and empowered with full authority to commit licensee resources to support the conduct of the MML.

- The RCPD.

- A manager from the applicant's finance organization.
- Managers capable of establishing RCP policies. These managers should be drawn from major divisions, departments, or organizational elements that represent the permittee community.

Other members may include:

- Manager(s) responsible for establishing and implementing major program activities under the MML.
- Manager(s) who represent permitting and inspecting organizations.
- Representative(s) from legal counsel.
- Representative(s) of occupationally exposed workers.

The Chairperson of the Committee should be empowered, at a minimum, to do the following:

- Set the agenda.
- Direct committee meetings.
- Determine the existence of a quorum.
- Verify the minutes.
- Summarize the committee’s position regarding decisions.
- Sign all official documents of the committee.
- Appoint a temporary replacement Chairperson (not the RCPD) in the event of his/her required absence.
- Vote.

The following are duties of the RCPD:

- Serve as a liaison between the MRSC and the RCP staff.
- Inform the Chairperson of staff commitments and resources.
- Assist the Chairperson in preparing the agenda.
- Advise the committee of current regulations and proposed changes in NRC regulations, policies and procedures.
- Provide the committee with quarterly reports on the status of the program.

- Advise the committee of any radiation safety or security trends that may need to be assessed or evaluated.

In addition, the RCPD should prepare an annual audit report that summarizes overall program activities, the results of program performance compared to regulatory requirements and license commitments (as determined through licensee and NRC inspections and evaluations), and their permitting actions, inspection reports, incident/event, allegation responses, enforcement actions, and decommissioning, as applicable.

Response from Applicant:

- Describe the composition, duties, and functions of the MRSC.

- Identify the Chairperson and individual members of the MRSC by position title and job description.

- Describe the duties of the MRSC Chairperson and provide commitment that the Chairperson has full authority to commit licensee resources to support the conduct of the MML.

- Describe the duties of the RCPD.

Note: The identities of the members of the MRSC are descriptive information and are not incorporated into the license. If there are significant changes to actual membership of the MRSC, i.e., functionally significant changes in position titles and job descriptions, the NRC should be notified. Notification is not needed for reorganizations that change the position titles without changing the basic radiation safety responsibilities of the position or for the reassignments of new individuals into designated positions.

Note: The Chairperson of the MRSC will be listed on the MML.

5.7.3 Radiation Control Program Director

The RCPD should ensure that radiation safety activities are being performed according to approved policies and procedures and that the daily operation of the licensed program is in compliance with all regulatory requirements. The RCPD implements the RCP with the assistance and support of the MRSC and senior management. The RCPD helps to ensure a clear understanding of mission goals and precise communications between the MRSC and the RCP staff.

Senior management should select an RCPD who has sufficient training and experience to address all facets of the applicant's RCP. The RCPD's qualifications should include:

- An academic degree in a physical or biological science or engineering.

- Specific training in radiation health sciences.

- Considerable professional experience (generally a minimum of 5 years) with a broad spectrum of radioactive materials.

Generally, an RCPD at an MML should have:

- Experience managing an RCP where a broad spectrum of isotopes were used and licensed activities were conducted.

- Management abilities such as developing and administering a budget, supervising a staff, and familiarity with human resource matters.

- Good writing and oral communication skills.

It is essential for the RCPD to have a thorough knowledge of NRC regulatory requirements.

Response from Applicant:

- Provide the minimum generic qualifications of the RCPD.

- Identify the individual* designated as the RCPD.

- Provide documentation* on the education, training, and experience demonstrating the individual designated as the RCPD is qualified to manage the RCP.

- Describe communications between the MML staff and the NRC MML PM.

5.7.4 Other Radiation Control Program Staff

The RCP professional staff should have the following qualifications:

- Sufficient education, training, and experience in the physical or life sciences.

- Bachelor's degree, or equivalent training and experience.

- Specific training in the safe handling of radioactive materials and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct to be used.

- Additional training commensurate with the types of hazards and technology to be permitted.

- Senior staff should have additional training and experience beyond their original areas of specialization to reflect the broader area of responsibility in their organization,

- Commitment to continued training.

Written job descriptions, identifying professional qualifications needed to fill vacancies, should be prepared. Staff members whose primary duties include reviewing/issuing permits or conducting inspections must meet training qualifications equivalent to NRC license reviewers and inspectors. See NRC Inspection Manual Chapter (IMC) 1248 for guidance on such qualifications.

Response from Applicant:

- Provide a list of the RCP office staff positions by job title, description, and number of individuals for each position.

- Describe procedures and criteria for ensuring that members of the RCP office staff are adequately qualified. (These procedures are part of the RCP procedures generically addressed in 5.10.4, "Regulatory Conformance.")

- Management commitment to training and continued training of program staff in accordance with IMC 1248 or equivalent program for training and qualification of staff.

5.8 NRC Form 313, Item 8: Training and Experience for Individuals Working In or Frequenting Restricted Areas

The applicant must ensure that individuals receive training commensurate with their assigned duties to meet the requirements of 10 CFR Part 19. If applicable, to meet the requirements of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," applicants must ensure that the facility meets the appropriate requirements and the assigned individuals are properly trained before permitting the facility. The established procedures should describe the licensee's responsibility to maintain control of licensed material and secure it from unauthorized removal or access.

Response from Applicant:

- Describe the training and experience required of individuals who will be required to work in, inspect, or frequent any restricted areas included under the MML.

5.9 NRC Form 313, Item 9: Facilities and Equipment

In accordance with 10 CFR 30.33, applicants must describe facilities and equipment used by the licensee to facilitate day-to-day operations.

Response from Applicant:

- Identify all facilities requiring security controls pursuant to 10 CFR Part 37.

- Commit that the facility will meet the appropriate requirements under 10 CFR Part 37, before permitting the respective facility.

- Provide location and description of all facilities used by the MML to carry out its activities.*

- State in the application where all docketed and required files and records will be maintained.

- Provide a list and description of the laboratory equipment such as counting systems, portable survey equipment, air monitoring, or other devices necessary for conducting the inspection of permittees.*

5.10 NRC Form 313, Item 10, Radiation Safety Program

The applicant should refer to Section 5.7 for additional discussion on the role and duties of senior management, the Chairperson of the MRSC, RCPD, and MRSC in the RCP. Information such as delegations of authority and establishment of oversight programs that are part of the authorities and management of an RCP may have been requested under Item 7 of NRC Form 313, while discussion of other aspects of program responsibilities appears under Item 10 of NRC Form 313.

5.10.1 Radiation Control Program–An Overview

The RCP is implemented by the MRSC. This includes the central control over all elements of the NRC regulated radiation safety program and the management of the permitting and inspection activities. These activities also include, but are not limited to, enforcement, event response, emergency response, allegation resolution activities, and decommissioning, as applicable. The applicant should commit to implementing licensing and inspection programs in accordance with NRC criteria. As discussed in Section 5.10.4, "Regulatory Conformance," the applicant may adopt alternative program procedures, provided these procedures are described as part of the license application.

In accordance with 10 CFR 30.33, applicants for MMLs must have established administrative controls that should include, at a minimum:

- central organization and management structure
- procedures
- recordkeeping
- material control and accounting
- management review
- training qualification plan

The requirement to develop, document, and implement a radiation protection program commensurate with the scope of the license request is contained in 10 CFR 20.1101, "Radiation protection programs." The recordkeeping requirements related to the program are contained in 10 CFR 20.2102, "Records of radiation protection programs."

The applicant should include a complete description of its RCP. In this section, that description should include concise commitments and a narrative overview of the detailed program, described in other sections. Both the narrative overview and the more detailed documents describing the program should, at a minimum, address the following elements: program authorities and responsibilities, communications, quality control surveillance, program audits, procurement, staff selection and qualification criteria, training plan, information dissemination, document control and retrieval, and other considerations essential to the successful implementation of the RCP.

Note: The applicant should commit to following specific NRC guidance documents in implementing its licensing, inspection, enforcement, and decommissioning programs. These NRC guidance documents may be adopted in their entirety. Other NRC guidance documents may be modified to reflect the unique characteristics of the applicant's program. Documents adopted in their entirety can be included in the description by reference. When NRC guidance is used, the applicant should commit to maintaining its procedures to ensure consistency with the NRC procedures.

Both the concise narrative overview description of written administrative control procedures for the RCP in this section and the procedures themselves need to be sufficient in detail, clarity, and specificity to describe how management oversight for program activities will be carried out.

Response from Applicant:

- Provide a concise, narrative overview description of the RCP.

- Describe the centralized administrative controls and provisions for:

  - organization and management structure
  - procedures
  - recordkeeping
  - material control and accounting
  - management review

- Describe the licensing, inspection, enforcement, and decommissioning programs.

- Describe the incident response and allegation handling programs.

- Describe the staff training and qualification programs.

- Commit to updating procedures to maintain consistency with NRC policies, procedures, and guidance.

Note: While both the description of the written administrative control processes and the program elements, such as licensing, inspection, enforcement, incidents, allegations, training, and decommissioning should be concise, the descriptions should also contain sufficient detail, clarity, and specificity in order to describe how management oversight for the program activities will be carried out and how the program functions. All elements in the narrative overview description of the RCP should concisely address the following (a narrative overview description is not needed when NRC guidance documents are included by reference in the RCP because they were adopted in their entirety):

- Program authorities and responsibilities
- Communications
- Quality control surveillance
- Program audits
- Procurement
- Staff selection and qualification

- Information dissemination, document control and retrieval.
- Other considerations essential to the successful implementation of the RCP

5.10.2 Previous Licenses

Simultaneously, with the issuance of permits by the MML, the NRC will terminate the superseded individual NRC licenses. Because the applicant may elect to have regulatory authority over only some types of materials (e.g., byproduct but not source or special nuclear materials), in order for the NRC to terminate the correct licenses, the NRC must have a list of those licenses that will be incorporated into the MML program.

The regions and the Office of Federal and State Materials and Environmental Management Programs (FSME) are responsible for transferring NRC license docket files to the primary regional office in which the MML will be based. The MML PM should be kept informed of these activities and oversee the coordination and disposition of the NRC license docket files. The NRC license docket files may be maintained in the NRC regional office, transferred to the MML, or archived.

Response from Applicant:

- List the radioactive materials licenses the applicant wants to include in the MML.*

5.10.3 Material Control and Accountability

In accordance with 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," licensees must develop, implement and maintain written procedures for ensuring control and accountability of licensed material. See NUREG-1556, Vol. 11, for additional useful information on control and accountability.

The licensee must update transactions in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207, "Reports of transactions involving nationally tracked sources."

Licensees should maintain records of receipt, transfer, and disposal of licensed material.

Licensed materials should be tracked from the time that they are manufactured or imported through the time of their disposal, export, or decay below quantities requiring inclusion in the NSTS to ensure accountability at all times.

MML applicants should develop and maintain an effective inventory and accountability method, establishing procedures for properly transferring, controlling, and accounting for material throughout the applicant's organization, including its movement among facilities. The inventory and control method should also ensure that the permittees' authorized possession limits are not exceeded.

Licensees should develop procedures to identify when licensed material is lost, stolen, or misplaced (also may have to be reported pursuant to 10 CFR 30.50, "Reporting requirements").

Response from Applicant:

- Describe the administrative controls and provisions relating to materials control and accountability.

- Describe the inventory control and accountability method of licensed material.

- Provide a statement declaring that, "We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207, 'Reports of transactions involving nationally tracked sources'."

- Provide a statement that "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."

5.10.4 Regulatory Conformance

The applicant must commit to follow NRC regulations, but may use operational control levels that are more stringent than those of the NRC. However, at a minimum, the applicant's requirements must be as restrictive as the NRC's regulations.

The applicant should commit to following specific NRC guidance documents in implementing its licensing and inspection programs. These NRC guidance documents may be adopted in their entirety. Other NRC guidance documents may be modified to reflect the unique characteristics of the applicant's program. Documents adopted in their entirety can be included in the RCP description by reference and do not have to be inserted in their entirety.

When the applicant commits to use NRC guidance, the NRC must have assurances that the applicant's program is updated as NRC guidance is changed and that the applicant's staff has training in the updated guidance.

In order for the NRC to approve the MML application, it must contain all policies, procedures, directives, and guidance the applicant has developed and will use to manage its RCP pursuant to NRC regulations, policies and guides. (See Section 5.7.4, "Other Radiation Control Program Staff," and the remainder of sections in 5.10, "Radiation Safety Program," for discussions specific to staff qualification, administrative control, organizational, audit, permitting, inspection, enforcement, incident response, emergency response, decommissioning, and allegation policies, procedures, and guidance documents that must be submitted.) The applicant must specify those NRC policies, procedures, and guidance that it will adopt in their entirety. The NRC will review the policies, procedures, and guidance documents submitted in the application; however, only those policies and directives describing how the MML will manage its RCP will be incorporated into the MML in a license condition.

Note: When submitting documents, the applicant may use the following guidelines for procedures, directives, and guides. If NRC guidance documents are adopted in their entirety, they only need to be referenced. Other NRC guidance documents that need to be modified to reflect the unique characteristics of the applicant's program should be provided in their entirety. New procedures or guidance developed by the applicant also should be included in their entirety.

Response from Applicant:

- Provide management's written commitment to follow NRC regulations.
- Confirm that licensing and inspection programs will be implemented in accordance with NRC licensing and inspection criteria (i.e., NRC regulations, policies and guides), or submit any alternative procedures.
- Submit all policies, procedures, directives, and guidance developed that will be used to manage the RCP pursuant to NRC regulations, policies, and guidance.[1]
- Specifically identify those NRC policies, procedures, and guidance documents that will be adopted in their entirety into the RCP.[2]

5.10.5 Updating of Radiation Control Program Documents

The RCP should establish procedures for appropriate and timely updating of MML internal guidelines and requirements to ensure conformance with revisions to NRC regulations, policies, and guidance.

The applicant should describe the process for review and approval of changes to procedures and documents. The process should include provisions for submitting updated documents to the NRC for review and license amendment if the document is specifically referenced in the MML or causes a material change in the MML policies and procedures.

Response from Applicant:

- Describe the process for review and approval of changes to RCP procedures and documents.

5.10.6 Management Support and Radiation Control Program Structure

An MML authorizes the receipt, possession, distribution, use, transportation, transfer, and disposal of NRC-regulated radioactive material (e.g., byproduct, source, and special nuclear material) at permittee locations. As discussed in Section 5.7.1, "Senior Management," the applicant's senior management is responsible for the RCP. Therefore, senior management must commit to and provide for sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the RCP at all levels. In addition, senior management should delegate in writing to the MRSC and the RCPD, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions, and permit conditions. The MRSC provides administrative control of all NRC licensed radioactive material used by the licensee and its permittees.

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[1] The NRC will review the policies, procedures, and guidance submitted in the application; however, only those policies and directives describing how the MML will manage its RCP will be incorporated into the MML in a license condition.

[2] Although audit, permitting, inspection, enforcement, incident response, emergency response, and allegation policies, procedures, and guidance are discussed in more detail in other sections, the documents associated with the management of these programs should be submitted in this section.

The applicant should demonstrate that it is financially qualified to conduct an MML program effectively. The applicant should ensure that the RCPD has access to the highest levels of MML management with a sufficient level of financial control for the implementation of the program. This includes the availability of sufficient funds to support program implementation for, such areas as the following:

- Travel-related costs necessary to conduct an effective permit compliance program, including, but not limited to, pre-permitting site visits, routine inspections, security inspections, follow-up or special inspections, and responses to incidents and other emergencies
- Training and qualification programs
- Instrumentation and other equipment to support the RCP
- Administrative costs
- Laboratory costs
- Laboratory services
- Computer, software, and word processing support
- Telecommunications, including internet, telephone, or video
- Vehicles
- Office equipment
- Financial assurance for decommissioning sites
- Any indirect costs (e.g. resources used for non-MML activities)

In accordance with 10 CFR 30.33, the RCP must be supported with sufficient staffing and technical expertise. The applicant's overall radiation management structure should ensure that the RCPD has administrative control over the program staff and elements, and has access to the highest levels of MML management for program support. There should be effective communication between the permittees and the RCPD.

The application should include an organizational chart depicting the licensee’s management structure, reporting paths, flow of authority, control of finances, and location of all RCP management and staff.

Response from Applicant:

- Provide information that indicates that the applicant has provided and will continue to provide sufficient operating funds to support the MML program elements.

- Describe the lines of communication and administrative control between the permittees, RCP, and MML management.

- Delegate in writing to the MRSC and the RCPD, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions, and permit conditions.

5.10.7 Radiation Control Policies–Administrative Controls and Provisions

In accordance with 10 CFR 30.33, the applicant must ensure safe operations under the license. The applicant should develop and implement written administrative policies. These policies should be clear, specific, and detailed enough to demonstrate that the applicant has sufficient processes in place, with senior management support, to implement the RCP. At a minimum, the policies should address the following:

- Organization and management, including program authorities and responsibilities
- Communications between the MML and the NRC
- Communications between permittees, RCP staff, and MML senior management
- Implementation of program elements
- Document control, retrieval, and recordkeeping
- Information dissemination
- Material control, procurement, and accounting
- Management review, quality controls, and audit program
- Corrective action program
- Training and qualification program for staff, including staff selection
- Other program elements essential to the successful implementation of the RCP

Response from Applicant:

- Submit policies related to the administrative controls and provisions listed above to demonstrate that the applicant has sufficient processes in place, with adequate senior management support, to implement the RCP. At a minimum, they should address the following:

    - organization and management, including program authorities and responsibilities
    - communications between the MML and the NRC
    - communications between permittees, RCP staff, and MML senior management
    - policy for implementation of program elements
    - document control, retrieval, and recordkeeping
    - information dissemination
    - material control, procurement, and accounting
    - management review, quality controls and audit program
    - corrective action program
    - training and qualification program for staff, including staff selection

- other program elements essential to the successful implementation of the RCP

5.10.8 Master Radiation Safety Committee Responsibilities

The authority of the MRSC is contained in the delegation of authority for the MRSC signed by the applicant's highest level of management. The delegation of authority was discussed in Section 5.7.1, "Senior Management." The composition and the responsibilities of the MRSC were discussed in Section 5.7.2, "The Master Radiation Safety Committee."

Responsibilities of the MRSC should include, but are not limited to, the following:

- Establishing procedures for the control, use, acquisition, and accountability of byproduct, source, and special nuclear material.
- Managing and overseeing the MML.
- Monitoring the performance of the RCP and the RCPD, and auditing the implementation of the RCP.
- Advising senior management of the results of the MRSC audits and program reviews.
- Ensuring that adequate resources are provided to implement the RCP, including implementation of permittee radiation safety programs.
- Ensuring that adequate resources are provided for the training of MRSC, RCP, and permittee staff
- Ensuring that permitting and inspection staff are appropriately qualified, as described in IMC 1248, or an equivalent training and qualification program
- Maintaining records under the MML
- Reviewing permit applications and recommending action to be taken by the Chairperson or his/her designee
- Meeting quarterly with an established quorum (i.e., Chairperson or his/her designee, RCPD, and two-thirds of the remaining membership) to review the activities of the RCP
- Maintaining a current list of quantities, uses, and locations where radioactive material is received, possessed, used, or stored
- Establishing procedures to control the procurement and acquisition of radioactive material to ensure compliance with the MML
- Ensuring that inspections are conducted to assess permittee compliance with the provisions of the license, NRC regulations, and the specific permits
- Establishing enforcement policies and procedures

- Advising senior management and the NRC of all non-compliance items potentially categorized at severity levels I, II, or III, as identified in the NRC enforcement policy

- Providing copies of permits and inspection reports to the appropriate NRC regional office

- Requesting assistance from appropriate individuals and licensee organizations when necessary to assist the MRSC in the execution of its responsibilities

- establishing technical committees to extend staff capabilities for unique or technically complex problems

- Establishing decommissioning policies and procedures

- Conducting at least annually a review of the program, pursuant to 10 CFR 20.1101.

The application should include the organizational and procedural manuals that address each item above; the written delegation of authority for the MRSC; the established quorum requirements (i.e., Chairperson, RCPD, and two-thirds of the remaining membership). The applicant should also describe the conditions under which it will obtain assistance from technical boards and other entities and identify and describe any existing boards or entities that it uses to support the MRSC.

Response from Applicant:

- Provide organizational and procedural manuals that address each item in 5.10.8, "Master Radiation Safety Committee Responsibilities."

  Note: If you describe how you will meet one of the above responsibilities in an organizational or procedural manual that is more appropriately provided in response to another section of this NUREG, you may simply identify the other section of your application where the information is found.

- Provide the delegation of authority from of the highest level of management given to the MRSC, delineating its authority to oversee the licensed program and its responsibility for control and direction of the RCP and the RCPD;

  Note: The delegation of authority should state the MRSC's authority to suspend or terminate activities based on poor performance or violation of safety standards and provide assurance of the Chairperson's full authority to commit licensee resources to support the conduct of the MML.

- Provide the MRSC's composition and responsibilities.

- Describe the conditions under which the MRSC will obtain assistance from technical boards and other entities.

- Identify and describe any existing boards or entities used to support the MRSC.

5.10.9 Radiation Control Program Director Responsibilities

The application should include a copy of the written delegation of authority from senior management to the RCPD and a description of his/her responsibilities. Documentation should also show that the RCPD has access to the highest levels of MML management and should include a description of the RCPD's level of administrative and financial control over the RCP.

The responsibilities and authorities of the RCPD include, at a minimum, the following:

- Managing and controlling the RCP.
- Conducting day-to-day operations of the RCP and issuing permits in accordance with procedures approved by the MRSC.
- Serving as the routine point of contact between the MML and NRC for matters concerning the MML.
- Informing the MRSC and highest level of management regarding the status of the RCP.
- Implementing the MRSC's enforcement sanctions.
- Stopping work activities that may pose undue risk or hazard, or may violate conditions of the license or the NRC regulations.
- Reviewing all radiological incidents and recommending corrective actions to the MRSC.

Response from Applicant:

- Provide a copy of the written delegation of authority from the highest level of management to the RCPD.
- Provide a description of the RPCD's responsibilities.
- Provide documentation to show that the RCPD has access to the highest levels of MML management
- Describe the measure of administrative and financial control over permitting and inspection personnel.

5.10.10 Permitting and Inspection Staff

The MML permitting and inspection staff is responsible for, but not limited to, the following:

- Providing guidance to MML prospective permittees in the preparation of requests for permits.
- Providing content of NRC generic communications to permittees in a timely manner.

- Reviewing permit applications for completeness and compliance with current NRC regulations, policies, and guidance.

- Preparing permits and forwarding to the MRSC (or delegate) for review and approval.

- Performing inspections to assess compliance with NRC regulations and provisions of the MML and specific permits.

- Preparing reports of inspection results and forwarding reports of non-compliance to the MRSC.

- Conducting pre-permitting site visits.

- Responding to incidents.

- Providing decommissioning oversight.

The applicant should describe how the staff will manage the day-to-day operations of the RCP. The description should include, but not be limited to the following:

- Responding to events at permittee facilities
- Maintaining uniformity of program implementation
- Maintaining internal communications
- Ensuring consistency of guidance provided to permittees
- Providing training to RCP staff
- Monitoring and evaluating RCP staff performance

Response from Applicant:

- Describe the duties of the permitting and inspection staff.

- Describe how the staff will manage the day-to-day operations of the RCP, and include the following:

    - responding to events at permittee facilities
    - maintaining uniformity of program implementation
    - maintaining internal communications
    - ensuring consistency of guidance provided to permittees
    - providing training to RCP staff
    - monitoring and evaluating RCP staff performance

5.10.11 Radiation Control Program Internal Procedures

In order to meet the requirements in 10 CFR 30.33, the RCP must establish written internal procedures. These internal procedures should also ensure a high degree of uniformity and continuity in the applicant's regulatory practices. In addition, these procedures should address internal processing of permit applications, inspection policies and procedures, decommissioning, and other function required of the program.

The internal procedures must ensure the following:

- The MML satisfies NRC requirements and criteria.
- The MML complies with its NRC license and the commitments and procedures that are incorporated in the license.
- The MML staff performs its duties as required.

The RCP staff should provide quarterly reports to the MRSC on the status of the program, as well as an annual report on the audit of the program that includes the following:

- overall conduct of the program
- result of the program performance compared to regulatory requirements and commitments
- review of permitting actions, inspection reports, response to events or incidents, enforcement actions, and decommissioning

Response from Applicant:

- Confirm that written internal procedures have been developed that, at a minimum, address the functions in 5.10.11, "Radiation Control Program Internal Procedures."

5.10.12 Management and Master Radiation Safety Committee Audits

The MRSC should be fully aware of the operations and activities of the RCP. The MRSC should conduct management audits and evaluations of the RCP's performance, including the RCPD. Results of the MRSC's audit and program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions. An MML may also consider establishing MRSC subcommittees to evaluate and audit those areas of the program within their areas of expertise.

Audits of the inspectors and permit reviewers should be conducted on an annual basis. Guidelines should be established for evaluating inspector and reviewer performance. Management policies and guidelines should be in place for reporting audit results to senior management. In accordance with 10 CFR 30.33, inspectors should demonstrate competence in evaluating health and safety problems and in determining compliance with NRC regulations. Inspectors should demonstrate an understanding of regulations, inspection guides, and policies before conducting inspections independently. The MML should establish a system similar to NRC's qualification journal system found in IMC 1248.

The RCPD or the inspection staff supervisor should conduct annual field evaluations of each inspector to assess performance and assure use of appropriate and consistent policies and guides.

The MML application should contain a description of senior management oversight and the mechanisms used by senior management to ensure that they are aware of NRC regulations, the

provisions of the license, and the compliance status of the RCP. This oversight may include independent audits of the program, frequent meetings with the MRSC, or periodic site visits of selected permittees.

Permit reviewers should demonstrate an understanding of regulations, licensing policy and guidance directives, and permitting practices before reviewing and issuing permits independently. A sampling of each permit reviewer's actions should be reviewed to assess performance and assure appropriate and consistent use of policies and guides.

Response from Applicant:

- Describe senior management oversight and the mechanisms used to ensure awareness of NRC regulations, the provisions of the license, and the compliance status of the applicant's RCP.

- Provide a copy* of the audit program used by senior management and the MRSC to audit the performance of the RCP, the RCPD, and the inspection and permitting staff.

- Describe how inspectors demonstrate competence in evaluating health and safety problems and in determining compliance with NRC regulations.

- Describe how inspectors demonstrate an understanding of regulations, inspection guides, and policy practices before conducting inspections independently.

- Describe how permit reviewers demonstrate competence in reviewing applications for permits.

Describe how reviewers demonstrate an understanding of regulations, licensing policy and guidance directives, and permitting practices before reviewing and issuing permits independently.

5.10.13 Permitting Procedures

The applicant should include copies of its permitting procedures, policies, and guidance. If the applicant commits to using NRC licensing procedures, policies, and guidance, it may list those NRC documents used and provide only those licensee documents that differ from NRC licensing procedures, policies, and guidance. The applicant should commit to updating its permitting guidance as it receives updates to the NRC licensing guidance. The applicant should provide specific timeliness goals for issuing permits and updating its licensing guidance as updates are received from the NRC.

In addition, the application should contain a description of the RCP's procedures to assess the essential elements of permittee applications that meet current regulatory guidance for the following:

- Descriptions of isotopes and quantities to be used

- Qualifications of persons who will use material

- Assurance that persons using material are either the MML's employees or contract employees
- Facilities and equipment
- Assurance that facilities and sites are controlled by the MML's Federal agency
- Operations and emergency procedures
- Minimization of contamination

To establish the basis for permitting actions, submitted information should document the isotopes, forms, quantities, authorized uses, and permissive and restrictive conditions, and be readily available for audit during pre-permitting visits. Before permit renewal, the RCP should ensure that supporting information in the file reflects the current scope of the permitted program.

Internal permitting guides should include checklists and policy memoranda consistent with current NRC licensing guidance. Permit applicants should be furnished copies of applicable regulatory guidance. Compliance history should be considered when issuing modifications to existing permits or permit renewals.

Standard permit conditions consistent with NRC standard license conditions should be used to expedite and provide uniformity in the permitting process. Custom conditions may be developed. However, any custom conditions that are less restrictive than applicable NRC requirements and criteria must be submitted to the regional office for further review and approval.

The MML applicant should maintain files to allow efficient, accurate retrieval of information and documentation associated with the permitting program.

Response from Applicant:

- Commit to developing and implementing permitting procedures, policies, and guidance:
  - List the NRC licensing procedures, policies, and guidance that will be used.
  - Provide for NRC review any documents that differ from the NRC's licensing procedures, policies, and guidance.
- Provide standard permit condition(s) that are not consistent with NRC standard license conditions.
- Submit custom conditions that are less restrictive than applicable NRC requirements for further review and approval.
- Provide specific timeliness goals for issuing permits and updating licensing guidance as updates are received from the NRC.
- Describe document management procedures.

5.10.14 Program to Minimize Contamination at Permittee Facilities

In accordance with 10 CFR 20.1406, "Minimization of contamination," the applicant must describe how facility designs and procedures for operation will minimize, to the extent practicable, contamination of the permittees' facilities and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Existing MMLs and their permittees and applicants for an MML should consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at a site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Licensees are also required by 10 CFR 20.1501, "General," to make or cause to make such surveys as are necessary to comply with the regulations in Part 20 and are reasonable under the circumstances to evaluate the extent of residual radioactivity. This includes subsurface radioactivity.

Applicants are also required to describe how they will conduct operations to minimize the generation of waste to facilitate future facility decommissioning in accordance with 10 CFR 20.1406. Relevant guidance is available in Regulatory Guide 4.22, Decommissioning Planning During Operations. Applicants should include a description of the introduction of residual radioactivity into the site, including the subsurface, such as by slow, long-term leaks.

Response from Applicant:

- Describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the permittees facilities and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

5.10.15 Decommissioning of Permit Activities and Permit Termination

This section focuses on the termination of the permit held by the permittee and decommissioning of the permittee's site. This section does not address the termination of the MML that is addressed in Chapter 8, "Termination of the MML."

The applicant should describe its approach to permit termination and decommissioning conducted under the NRC decommissioning process.

The NRC's requirements for the decommissioning and termination of licenses for radioactive material are described in 10 CFR Part 30, 10 CFR Part 40, "Domestic Licensing of Source Material", and 10 CFR Part 70,"Rules of General Applicability to Domestic Licensing of Byproduct Material", and Subpart E of 10 CFR Part 20, "Standards for Protection against Radiation," Subpart E. Guidance for both licensees and the NRC, including guidance for implementing the requirement for preparing a decommissioning plan (DP), is found in NUREG-1757, Vols. 1, 2, and 3, "Consolidated Decommissioning Guidance." The applicant may either provide its permit decommissioning and termination procedures or commit that it will decommission its permitted facilities and terminate its permits in accordance with NRC regulations, policies, and guidance as provided in the LOU. Guidance for inspections of decommissioning activities is given in IMC 2602, "Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees."

The NRC and the MML have shared responsibility for decommissioning and permit termination. Nothing in the following guidance describing the shared responsibility between the NRC and the MML precludes the MML from reviewing notifications, decommissioning plans, or other documents for their approval before transmitting them to the NRC.

The NRC retains its authority to review and approve DPs on a case-by-case basis and in accordance with the guidance provided below. MML permit decommissioning and termination are subject to NRC regulations and should be conducted in accordance with NRC guidance in NUREG-1757. The MML must comply with the following notification and reporting directions:

Initiation and Timeliness of Decommissioning

The licensee must notify the NRC of changes in the operating status of its permittees in accordance with 10 CFR 30.36, 10 CFR 40.42, or 10 CFR 70.38, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas," when no principal activities have been conducted under the permit for a period of 24 months. The notification must contain sufficient information for the NRC to determine if a DP is needed and whether the NRC needs to review and approve the licensee's plan.

Decommissioning

The approval of simple decommissioning (i.e., decommissioning groups 1 and 2 as defined in NUREG-1757, Volume 1, Revision 2 Chapter 7, pages 7-1 to 7-5) will be the responsibility of the MML. The approval of complex decommissioning (i.e. decommissioning groups 3 to 7 as defined in NUREG 1757, Volume 1, Revision 2 Chapter 7, and pages 7-1 to 7-5) will remain with the NRC. For complex decommissioning, before submitting DPs to the NRC, the MML should review DPs required by 10 CFR 30.36, 10 CFR 40.42, or 10 CFR 70.38.

Request for Extensions

In accordance with 10 CFR 30.36, 10 CFR 40.42, or 10 CFR 70.38, the licensee may request and receive an approval for an alternative schedule to the specified time periods. Although these requests are not considered to be for exemptions to the regulation, the NRC will maintain the responsibility for reviewing the requests and granting approvals. Guidance on requesting an alternative schedule is provided in NUREG-1757, Volume 3, Sections 2.2 and 2.6.

Completion of Decommissioning and Termination of the Permit

The licensee is required by 30.36(j)(2), 40.42(j)(2), and 70.38(j)(2) to conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of the survey. This report is also known as the final status survey (FSS) report to NRC for work completed under an NRC-approved DP. The NRC maintains the authority to review and approve FSS reports for complex decommissioning activities. The licensee should review the FSS before submitting to the NRC. Guidance for developing an FSS report is provided in NUREG-1757, Volume 2, Section 4.5.

Environmental Reviews

The applicant should document that it recognizes that environmental reviews (i.e., National Environmental Protection Act (NEPA) reviews) for decommissioning would be conducted by the NRC using input provided by the licensee. The licensee does not have the authority to conduct the NEPA review, e.g., CATX/EA/EIS, for any site under the MML. The NRC retains the responsibility for implementing this NEPA requirement.

The licensee must develop the DP in accordance with 10 CFR 30.36(g)(1), 40.42(g)(1), and 70.38(g)(1) and the associated ER (10 CFR 51.45, "Environmental report" and 10 CFR 51.60, "Environmental report—materials licenses"), as necessary, and propose the type of decommissioning for the NRC's consideration. This is the input the NRC would need to conduct the appropriate environmental review.

> The licensee should follow the guidance described in NUREG-1757, Volume 1, in preparing the ER. The ER should provide sufficient detail commensurate with the extent of decommissioning needed and the final disposition of the site. NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," provides further guidance on the development of ERs.

Decommissioning Records

In accordance with 10 CFR 30.51, "Records," 10 CFR 40.61, "Records," or 10 CFR 70.51, "Records requirements," the MML must keep records showing the receipt, transfer, and disposal of byproduct materials. The NRC will review licensee records on a biennial basis to verify that the licensee's records meet the intent of the regulations.

Response from Applicant:

- Provide decommissioning and permit termination procedures or commit that permit facilities will be decommissioned and permits will be terminated as described in NRC regulations, policies, and the guidance in NUREG-1757.

- Confirm that DPs for complex decommissioning sites described above, will be submitted to the NRC for review and approval before commencing decommissioning activities.

5.10.16 Financial Assurance

In accordance with 10 CFR 30.35, the applicant must describe its program for establishing and maintaining adequate funds to decommission its permitted facilities. In cases involving multiple independent sites under a single license, the financial assurance and, if required, the decommissioning funding plan (DFP) would have to delineate procedures and cost estimates for each facility or site. The licensee may treat each permittee's facility independently and sum the amounts needed for each individual permittee to determine the total amount of financial assurance required to meet the regulations. Co-located permittees must be identified and the applicant's plan for financial assurance provided for each location. Guidance is provided in NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance."

Response from Applicant:

- Describe how the decommissioning financial assurance requirements described in 10 CFR 30.35, 10 CFR 40.36, 10 CFR 70.25 will be met.

- Provide documentation that adequate funds to decommission all permitted facilities are established and maintained.

5.10.17 Inspection and Enforcement Procedures

The licensee should maintain an inspection program adequate to assess permittee compliance with NRC regulations, licensee requirements, and permit conditions. To ensure consistency between the NRC and the applicant's inspection and enforcement programs, the licensee should maintain statistics to enable program management to assess the status and results of the inspection program on a periodic basis. This statistical information should include the number of inspections conducted, the number overdue, the length of time overdue, and inspection priority categories. The applicant should prepare an inspection plan that ensures that inspections are performed in accordance with IMC 2800, "Materials Inspection Program."

The applicant should establish an inspection priority system that, at a minimum, is equivalent to that described in IMC 2800. The applicant's inspection guidance should be consistent with current NRC inspection guidance and provide technical guidance in the inspection of permitted programs. To ensure consistency, written inspection policies should establish a policy for: conducting unannounced inspections; obtaining corrective action; following up and closing out previous violations; conducting interviews with workers and observing operations; conducting exit interviews with management; and issuing appropriate notices of violations, and communicating health and safety problems. Independent survey measurements should be sufficient in number and type to ensure the permittee's control of materials and to validate the permittee's measurements. In addition, the licensee should have access to laboratory support capability to: conduct bioassays; analyze environmental samples; analyze samples collected by inspectors; or other necessary analyses on a priority established by the licensee.

Findings of inspections should be documented for future use by licensee inspection staff and permittees. At a minimum, this documentation should include a description of: (1) the scope of inspection, (2) facts and data to substantiate all items of noncompliance, and health and safety issues, (3) the scope of permittee's programs, (4) the substance of discussions with permittee management and the permittee's response, (5) the status of previous items of noncompliance, and (6) the results of any independent survey measurements made by the inspector. Inspection documents forwarded to the permittee should describe the scope and results of the inspection, including identification of any items of noncompliance, health and safety issues, and areas of the permittee's program that should receive special attention by permittee management. Corrective actions planned or taken by the permittee for items of noncompliance should be documented and retained in the permittee file for future evaluation by MML inspectors.

The licensee should establish an enforcement program to ensure consistent assessment of the regulatory and safety significance of violations. To ensure uniform enforcement policies between MML and equivalent NRC licensees, the program should commit to following NRC's enforcement policies, consistent with the legal authority of the MML. The program should include a description of the sanctions to be used and methods used for assessing the severity of violations and taking enforcement actions for the more severe violations. It should also include

a process for notifying the NRC of any potential Severity Level I, II and III violations to NRC for possible NRC action. MML action against its permittees does not preclude NRC from taking action against the MML, its permittees, or its employees.

Response from Applicant:

- Provide permit inspection procedures addressing the elements discussed in section 5.10.17, “Inspection and Enforcement Procedures.”

- Provide enforcement program procedures for assessing the severity of violations and taking enforcement actions for the more severe violations.

- Provide procedures for documenting inspection findings and enforcement actions.

5.10.18 Corrective Action Program

Applicants should develop a corrective action program that will assist the licensee in identifying concerns, in order to help prevent violations and events that may impact public health and safety, common defense and security and protection of the environment, and to prevent recurrence of violations with similar root causes across all MML activities.

The corrective action program should, at a minimum, include a description of how the applicant will accomplish the following:

(1) Identify performance indicators to assist in identifying trends in the program.

(2) Evaluate and resolve any identified trends that may impact the program

(3) Perform self-assessments of the program to identify performance improvements.

(4) Communicate lessons learned, internally, that were identified through the corrective action program.

The corrective action program should also describe the applicant's procedures for responding to events, including its criteria for initiating an investigation, procedures for identification of the causes that contributed to the event, and evaluation of the extent of conditions and potential impacts to other areas of the program. In addition, the corrective action program should address the applicant’s procedures for evaluation of any comprehensive actions to prevent recurrence.

Response from Applicant:

- Provide procedures for a corrective action program that, at a minimum, addresses the elements described in Section 5.10.18, “Corrective Action Program.”

5.10.19 Incident/Emergency Response Procedures

The applicant should develop procedures for responding to emergencies, events, or incidents, including, but not limited to a security threat or event involving permitted material, medical events, spills, fires, release or loss of radioactive material, potential or actual overexposures, and contamination of personnel at permittee facilities. The applicant should describe its provisions for immediate response and handling of such incidents, including off-hours notification to appropriate licensee staff, state and local authorities, and when applicable, the NRC. The procedures should define the oversight responsibilities of the RCP management and staff, including actions to be taken by permittees. The procedures should identify the persons responsible for initiating response actions, conducting operations, and performing cleanup. Only qualified and experienced individuals should conduct decontamination and recovery operations.

Additionally, when permittees request possession of radioactive materials in both unsealed and certain sealed forms in excess of specifically listed quantities, they must prepare an emergency plan. If the applicant determines that there is a need for an emergency plan by certain permittees pursuant to 10 CFR 30.32, the applicant must identify those permittees and submit copies of the approved emergency plans, to the appropriate regional office. Guidance for this submittal is contained in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities."

In accordance with 10 CFR Part 21, "Reporting of Defects and Noncompliance," information on incidents involving failure of equipment must be provided to the agency responsible for evaluation of the device, for assessment of possible generic design deficiency, e.g., the NRC and the U.S. Department of Health and Human Services, Food and Drug Administration.

Response from Applicant:

- Provide incident/emergency response procedures, that address at a minimum, the following:
  - RCP management oversight responsibilities
  - initial response actions and responsibilities, including safety for RCP management and staff, and permittees
  - list of persons responsible for initiating response actions, conducting operations, and performing cleanup
  - precautions for persons and property at permittee facilities
  - permittee facility and site access control and security

- mechanisms and responsibilities for notifying RCP staff and external authorities
- provisions for medical and offsite agency assistance
- description of emergency response equipment available for use by the RCP office staff
- need for onsite review of events
- communications between the permittee facility and RCP
- communications between the RCP office and the NRC.

- Provide appropriate emergency plan(s), according to 10 CFR 30.32, if applicable.

5.10.20 Security Program for Category 1 and Category 2 Materials

Licensees must ensure the security and control of licensed material.

Note: The requirements in 10 CFR 20.2207 are only applicable to those licensees that manufacture, transfer, receive, disassemble, or dispose of Category 1 and Category 2 sources., as specified in Appendix E to 10 CFR Part 20 . The regulations in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," apply to licensees that possess an aggregate amount of category 1 or category 2 quantity of radioactive material., as specified in Appendix A to 10 CFR Part 37.

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. The NSTS is a major security initiative of the NRC. The NSTS is a secure, accessible and easy-to-use computer system that tracks high-risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

In accordance with 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material," licensees authorized to possess Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain an access authorization program and a security program to ensure physical protection of the radioactive material. For additional guidance implementing10 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."

Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37 lists Category 1 and 2 threshold quantities of radioactive material. The applicant should refer to this table to determine if its program exceeds the Category 2 authorization thresholds.

If licensees possess, ship, or receive quantities of material exceeding Category 1, then they must also comply with requirements specific to Category 1 quantities. Refer to 10 CFR Part 37 for these additional requirements.

Per 10 CFR Part 37, Subpart B, licensees must establish an access authorization program to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material and reviewing officials are trustworthy and reliable.

Per 10 CFR Part 37, Subpart C, licensees must establish a physical protection program 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 in use or storage.

Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantity of radioactive materials in transit. These requirements apply to a person delivering material to a carrier for transport, as well as cases in which the person transports material.

Note: Refer to 10 CFR Part 37 and associated guidance in NUREG-2155 for additional details on security guidance.

Response from Applicant:

No response is required from an applicant or licensee that would become newly subject to 10 CFR Part 37.

5.10.21 Procedures for Handling Allegations

Handling allegations is a shared responsibility between the licensee and the NRC, and is addressed in the LOU. In accordance with 10 CFR 30.7, “Employee protection,” the applicant must establish a program for responding to employee radiation safety concerns that provides for timely investigation and response to these concerns. The program must also address the prevention of reprisals against employees for expressing their radiation safety concerns to management. The program should include a policy that encourages employees to bring forward any perceived radiological safety issues. The program should include procedures for training that clearly articulate the right of any employee to raise his/her radiation safety concerns directly to the NRC, if he/she so desires.

Allegations received by the NRC may be investigated by the NRC or referred to the licensee.

The applicant should specify whether it will follow the NRC’s procedures for handling allegations (NRC Management Directive 8.8) or include equivalent procedures for handling allegations that are referred to the licensee.

The applicant should describe the closure process for the allegation, including addressing timeliness and the issuance of the response closure letter to the concerned individual (alleger).

Response from Applicant:

- Confirm that NRC's procedures for handling allegations will be used, or provide equivalent procedures for handling allegations that are referred to the licensee.

- Provide procedures for handling, documenting, investigating, and closing an allegation raised by a concerned individual.

- Provide a description of the training that will be provided to all employees to ensure that they understand their right to contact the NRC directly about radiation safety or regulatory issues.

5.11 NRC Form 313, Item 11: Waste Management

In accordance with the waste disposal requirements in 10 CFR Part 20, the applicant must describe the criteria for approving disposal of radioactive waste.

The applicant should describe the locations, conditions, and current status of former burial sites, whether controlled or uncontrolled, any active monitoring of the site, and the current condition of the burial site, for permittees who were NRC licensees authorized before January 28, 1981, to bury radioactive material when prior section 20.304 authorized such burial.

Response from Applicant:

- Describe the criteria for approving disposal of radioactive waste.

- Describe the locations, conditions, and current status of former burial sites, whether controlled or uncontrolled, any active monitoring of the site, and the current condition of the burial site, for permittees who were NRC licensees authorized before January 28, 1981, to bury radioactive material.

5.12 NRC Form 313, Item 12: License Fees

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," and the amount of the fee enclosed with the application.

There may be an additional annual fees for each Sealed Source Device Registration issued to the MML

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.

6. AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. 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 (10 CFR) 2.109(a), 10 CFR 30.36(a), 10 CFR 40.42(a), 10 CFR 70.33, 10 CFR 70.38(a)).

Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.
- Submit either an 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 if many outdated documents are referenced or there have been significant changes in regulatory requirements, the NRC's guidance, the licensee's organization, or the licensee's radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

7. APPLICATIONS FOR EXEMPTIONS

Licensees may request exemptions from 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.

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"; 10 CFR 40.14, and 10 CFR 70.17, "Specific exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

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

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

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

8. TERMINATION OF THE MML

This section focuses on the termination of the license held by the MML as a licensed entity, and the transfer to the NRC of permits that have not been terminated. This section does not address the termination of individual permitted sites or activities under the MML that are addressed in Section 5.10.15, "Decommissioning of Permit Activities and Permit Termination."

The licensee must do the following:

- When proposing termination of the MML, the licensee must:
  - Notify the U.S. Nuclear Regulatory Commission (NRC), in writing within 90 days of the MML proposed termination of its licensed operations and include the reason for terminating the MML.
  - Notify the NRC of the termination status of all of the MML permits by either:
    - documenting that all the MML permits have already been terminated, or
    - documenting those permits that have been terminated, or
    - transferring the remaining active permits to NRC.
  - Document the justification for not terminating permits that are proposed to be transferred to the NRC (e.g., need for continued permit activities).
  - If active permits are not being transferred at this time, document proposed plans and schedule for permit transfers to NRC.
  - Propose termination of the MML LOU.
- Before completing termination of the MML, the licensee must do the following:
  - Obtain NRC approval of the plans, schedule, and termination of the MML.
  - Transfer all records to the appropriate regional office that has the oversight for the MML for retention, including records for specific permits that have not been terminated.
  - During the period of time between the request for termination and the termination of the license, coordinate activities with the NRC so that there is continued protection of the public health and safety.

Before completing termination of the MML, the NRC will do the following:

- Communicate with the permittees to explain the reassertion of NRC authority and the present fee structure.

- Issue letters to the U.S. Department of Labor and other Federal agencies advising the various agencies of the effective date of the termination of the license.

- Obtain from the MML a computer printout listing of all permittees. The NRC should prepare and issue a letter notifying each permittee of the termination, reassertion of the NRC's authority, and appropriate information for obtaining an NRC license. Please note, all permits must be transferred and licensed by the NRC, before the MML will be terminated.

- Coordinate with the MML to ensure that all the files are transferred to the NRC in an expeditious manner.

- As a final step and after all termination or transfer activities are completed and confirmed by the NRC, the MML financial instrument will be cancelled and returned by the NRC. If the NRC approves the planned transfer of some permitted MML sites to a new licensee under a specific NRC license, NRC-approved financial assurance for each site must be completed by the new licensee before transfer. After the site(s) is transferred, the MML financial instrument will be cancelled and returned to the MML.

Renewed Future Interest in Obtaining a MML

- A Federal agency that has had an MML terminated by the NRC may, at a later date, express interest in obtaining a new MML. The applicant should be treated as any other applicant interested in obtaining an MML, and the guidance in this document should be followed.

Should MML termination be planned by the licensee, the process is likely to be complex and to require substantial discussion and coordination between the licensee and the NRC. Such coordination should occur both before notification as well as during the termination process so that an acceptable plan may be developed that will address the unique circumstances of the MML and its subsequent termination.

Response from Applicant:

- The applicant is not required to submit a response to the NRC during the initial application. However, in its application, the licensee must acknowledge the termination process outlined above; and acknowledge that its obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. The licensee's obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 ("Certificate of Disposition of Materials") or equivalent information, and to perform any other actions summarized above.

NRC Form 314 is available at http://www.nrc.gov/reading-rm/doc-collections/forms.

APPENDIX A

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

APPENDIX A U.S. NUCLEAR REGULATORY COMMISSION FORM 313

Please use the most current version of this form, which may be found at:
http://www.nrc.gov/reading-rm/doc-collections/forms/

NRC FORM 313 (03-2014) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2015**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

☐ A. NEW LICENSE

☐ B. AMENDMENT TO LICENSE NUMBER _____

☐ C. RENEWAL OF LICENSE NUMBER _____

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

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

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

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

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

NRC FORM 313 (03-2014)

APPENDIX B

SAFETY CULTURE STATEMENT OF POLICY

APPENDIX B SAFETY CULTURE STATEMENT OF POLICY

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission's (NRC's) Agencywide Documents Access and Management System (ADAMS) under Accession No. ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations 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 includes 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. The Commission encourages the Agreement States, Agreement State licensees and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined 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 safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

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.

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, schedule, and the cost of the effort versus safety. It should be noted that although the term ''security'' is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

(1) *Leadership Safety Values and Actions*—Leaders demonstrate a commitment to safety in their decisions and behaviors.

(2) *Problem Identification and Resolution*—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.

(3) *Personal Accountability*—All individuals take personal responsibility for safety.

(4) *Work Processes*—The process of planning and controlling work activities is implemented so that safety is maintained.

(5) *Continuous Learning*—Opportunities to learn about ways to ensure safety are sought out and implemented.

(6) *Environment for Raising Concerns*—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.

(7) *Effective Safety Communication*—Communications maintain a focus on safety.

(8) *Respectful Work Environment*—Trust and respect permeate the organization.

(9) *Questioning Attitude*—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes.

It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy.

APPENDIX C

SAMPLE LETTER OF UNDERSTANDING BETWEEN THE MML AND THE U.S. NRC

APPENDIX C SAMPLE LETTER OF UNDERSTANDING BETWEEN THE MML AND THE U.S. NRC

LETTER OF UNDERSTANDING BETWEEN THE (INSERT NAME OF MML) AND THE UNITED STATES NUCLEAR REGULATORY COMMISSION

This document defines the shared responsibilities of the U.S. Nuclear Regulatory Commission (NRC) and the (insert name of MML), regarding the (insert name of centralized organization) implementation of and compliance with the terms and conditions of the (insert name of MML), NRC License Number (insert license number), as amended.

ADMINISTRATIVE

(1) The (insert name of centralized organization) will implement and comply with all NRC regulations. When the NRC has promulgated a rule revising its regulations, the (insert name of centralized organization) and (insert name of MML) permittees will implement and comply with the revised regulations by the effective date of the final rule. The (insert name of centralized organization) will incorporate changes to its policies and procedures within 90 days after the effective date of the final rule to reflect the revisions to the regulations. The (insert name of centralized organization) may elect to be more stringent in its controls.

(2) The MML does not relieve the (insert name of centralized organization) from complying with any other applicable Federal or State law or regulation.

(3) The (insert name of centralized organization) shall seek legal and technical advice from the NRC regarding any questions concerning the interpretation of NRC regulations, policy, procedures and guidance, including but not limited to, advice concerning new or unusual applications of licensed materials not clearly authorized by the MML. The NRC shall provide the requested legal and technical advice to the Radioisotope Committee (RIC) as soon as practicable.

(4) The (insert name of centralized organization) shall not grant exemptions to NRC regulations without specific NRC authorization.

(5) The (insert name of centralized organization) shall ensure that the transportation of licensed material is in accordance with NRC and the U.S. Department of Transportation (DOT) regulations regarding the shipment of radioactive materials. The (insert name of centralized organization) MML is exempt from Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," requirements when using the DOT exemptions issued to the U.S. Department of Defense for purposes of national security or national defense.

(6) The (insert name of centralized organization) shall promptly notify the NRC of, or report to the NRC as appropriate, any events as required by applicable NRC regulations. The (insert name of centralized organization) shall ensure that (insert MML) permittees will make any required notifications or reports directly to the (insert name of centralized organization) as required by (insert MML procedure including procedure number), to allow the (insert name of centralized organization) to make the subsequent notification or report to the NRC as required by the applicable regulation.

(7) The NRC shall provide guidance in areas pertinent to the administration of the MML, including technical assistance in those matters where the NRC has special capabilities and ability, or where the NRC determines that such assistance is in the best interest of its regulatory program or responsibility.

(8) The NRC shall provide new and revised licensing, inspection, security and enforcement guidelines, policies and procedures to the (insert name of centralized organization) as soon as practicable so that the (insert name of centralized organization) can implement the MML consistent with the NRC program. The NRC shall provide training to (insert name of centralized organization) staff, as available, in all NRC training programs concerned with licensing, inspection, health physics, materials security and other regulatory issues related to byproduct, source, and special nuclear material.

(9) The (insert name of centralized organization) shall maintain an adequate level of professional and clerical staffing to carry out its responsibilities under the MML.

(10) When practical, the (insert name of centralized organization) and the NRC shall use electronic means to conduct official business.

ENVIRONMENTAL

(11) For those actions that require NRC approval under the MML, the (insert name of centralized organization) shall provide any relevant environmental information or analysis to support the NRC action. As provided in NRC regulations, certain license amendment requests are required to be accompanied by an applicant-prepared environmental report (ER) that will aid the NRC staff performing its responsibilities under the National Environmental Protection Act of 1969, as amended (NEPA) as implemented by 10 CFR Part 51. The (insert name of centralized organization) shall submit an ER if the criteria of 10 CFR 51.60, "Environmental report—materials licenses," applies. The NRC regulations in 10 CFR 51.45, "Environmental report," set forth the requirements for preparing an ER. Guidance on preparing an ER is set forth in the NRC's NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," Chapter 6. The NRC may also require that environmental information be submitted in accordance with 10 CFR 51.41. In responding to NRC requests under 10 CFR 50.41, or the requirements of 10 CFR 51.45, the applicant may use documents prepared, or information obtained, through its environmental impact analysis work conducted pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, to the extent that such documentation or information is timely, pertinent, and responsive to the NRC's request or requirements.

PERMITTING

(12) The (insert name of centralized organization) shall incorporate into its permitting program the most current version of the NRC's guidance (NUREG-1556 series, "Consolidated Guidance about Materials Licenses"), and the guidance provided in the

applicable Licensing Guidance Toolkits, which are located on the NRC Web site (http://www.nrc.gov), in order to ensure compatibility with NRC's licensing program.

The (insert name of centralized organization) shall not issue a permit to any entity that is not a component or constituent part of the (insert name of licensed entity).

(13) The (insert name of centralized organization) may approve the use of licensed materials in a permit by individuals who are not (insert name of licensed entity) personnel if the (insert name of centralized organization) determines that such individuals are qualified to use such licensed materials under the permit in accordance with applicable NRC requirements, applicable procedures established by the (insert name of centralized organization), the (insert name of centralized organization) issued permit, and any (insert name of licensed entity) facility procedures. The work space of individuals covered by this paragraph must be under the control of the (insert name of licensed entity) (i.e., the work space must be owned by or leased to the United States, under the administrative control of the [insert name of licensed entity]). The individuals covered by this paragraph include, but are not limited to, (insert name of licensed entity) contractors, students in training, and visiting professionals.

The (insert name of centralized organization) must receive NRC authorization before performing any proposed disposal procedures, radioactive waste incineration, establishing any new radioactive waste burial site, low-level radioactive contamination training area, or outdoor depleted uranium munitions testing range, or conducting any field study, which may involve the deliberate release of licensed material directly into the environment. The (insert name of centralized organization) must submit a written description of the proposed activity to the NRC region (XX) office for approval.

INSPECTION

(14) The (insert name of centralized organization) shall incorporate the current NRC Manual Chapter 2800, "Materials Inspection Program," and applicable NRC inspection procedures in its inspection program to ensure compatibility with NRC's inspection program. The (insert name of centralized organization) may telephonically inspect permits with sole commodities (e.g., chemical agent detectors and chemical agent monitors) under program code 03124, according to NRC Manual Chapter 2800.

(15) The (insert name of centralized organization) shall request authorization through the NRC region (XX) office to alter the inspection frequency to meet the MML's priorities.

(16) The NRC retains the authority to conduct unannounced inspections of the (insert name of licensed entity), including permittee programs under the MML, at times and places that is has determined are appropriate, without prior notification to the (insert name of centralized organization). However, the NRC will routinely provide, through the responsible regional office, a 30-day notice to the (insert name of centralized organization) of scheduled NRC inspections for the purpose of coordinating security access to (insert name of licensed entity) installations, scheduling (insert name of licensed entity) inspectors to accompany NRC inspectors, or for other reasons. The (insert name of centralized organization) will inform the NRC region (XX) Office as to whether additional security requirements are required at the respective (insert name of licensed entity) installation. If there are additional security requirements, then the NRC

will process the necessary security clearance in accordance with the installation's procedures. The (insert name of centralized organization) will not notify permittees about any proposed unannounced NRC inspection.

(17) The NRC will perform a biennial inspection of the (insert name of licensed entity) MML program as specified in Manual Chapter 2810, "Master Materials License Inspection Program." This inspection will be coordinated between the NRC region (XX) office and the (insert name of centralized organization) and will be considered an announced inspection.

ALLEGATIONS

(18) The (insert name of centralized organization) will inform the NRC region (XX) office within 5 calendar days of each allegation received.

(19) Allegations received by NRC staff regarding MML activities may either be processed by NRC or referred to the (insert name of centralized organization). Allegations of suspected wrongdoing will be processed by the NRC region (XX) office for entrance into the NRC allegation program. Allegations related to improper action by (insert name of centralized organization) staff, should not be processed under the (insert name of centralized organization) program, but should be referred to the NRC region (XX) office for processing.

(20) The (insert name of centralized organization) should establish a safety conscious work environment in which employees and contractors are free to raise potential or actual issues within NRC jurisdiction that may involve operations, radiological releases, radiation protection or other matters relating to NRC-regulated activities, to their management and to the NRC without fear of retaliation.

ENFORCEMENT

(21) The NRC will coordinate with the (insert name of licensed entity) installation regarding any enforcement action involving generally licensed devices or other regulatory matters that do not involve specifically licensed material under the MML.

(22) The (insert name of centralized organization) shall implement an enforcement program based on the current NRC Enforcement Policy (Policy) to ensure that (insert name of centralized organization) enforcement actions are consistent with the Policy and applicable NRC regulations, and are uniformly applied amongst (insert name of centralized organization) permittees.

(23) The (insert name of centralized organization) shall immediately notify by telephone the NRC Region (XX) project manager when the (insert name of centralized organization) identifies permittee violations of NRC regulations or MML or (insert name of centralized organization) permit requirements that could result in escalated enforcement (i.e., Severity Levels I, II, and III). This will be followed with a written report to be submitted to the NRC within 30 calendar days of the telephonic notification. The facts related to the case shall subsequently be provided to the NRC region (XX) office as specified in the NRC Enforcement Manual.

(24) The (insert name of centralized organization) may take enforcement action against any (insert name of centralized organization) permittee for violations of NRC regulations, MML conditions, or (insert name of centralized organization) permit conditions. However, the (insert name of centralized organization) may not issue a civil penalty to its permittee. The NRC region (XX) office will disposition (insert name of centralized organization) identified apparent escalated violations and NRC identified violations through the normal NRC enforcement process. The NRC reserves the right to impose civil penalties on the MML in accordance with the Enforcement Policy.

INVESTIGATIONS

(25) The (insert name of centralized organization) shall report all suspected wrongdoing or violations of NRC requirements to the NRC region (XX) office. The (insert name of centralized organization) shall address immediate and ongoing safety/security issues promptly and subsequently discuss the safety/security issues with the NRC region (XX) office by telephone, followed by a written report to the NRC region (XX) office within 30 days of the telephonic notice. "Wrongdoing" is defined in 10 CFR 30.10, "Deliberate misconduct."

(26) The (insert name of centralized organization) shall notify the NRC of any suspected deliberate violations. The (insert name of centralized organization) shall not initiate any criminal investigation into suspected deliberate violations without first receiving approval from NRC's Office of Investigations (OI).The NRC's OI may evaluate whether to conduct its investigation in coordination with the (insert name of licensed entity) investigative agency. In accordance with the Memorandum of Understanding between the NRC and the Department of Justice (DOJ), the NRC shall refer substantiated wrongdoing violations to DOJ for prosecutorial consideration.

DECOMMISSIONING

(27) The (insert name of centralized organization) permit termination and decommissioning procedures will comply with applicable NRC regulations, procedures and guidance.

a. The (insert name of centralized organization) will complete permit termination and decommissioning for permittees categorized as Groups 1 and 2 facilities in accordance with the screening criteria in NUREG-1757, Volume 1, Revision 2, "Consolidated Decommissioning Guidance*", and any subsequent revisions.*

b. The (insert name of centralized organization) will submit all actions involving decommissioning for permittees categorized as Group 3 and above to the NRC region (XX) office for approval. In addition, the (insert name of centralized organization) will submit the final status survey report (FSSR) to the NRC region (XX) office for approval. The NRC will approve the decommissioning plan (DP) and FSSR by letter to the (insert name of centralized organization). The NRC shall be responsible for complying with 10 CFR Part 51 for Group 3 and above decommissioning actions.

c. The (insert name of centralized organization) will authorize the NRC approved DP and FSSR by permit condition.

d. To ensure compliance with 10 CFR 30.36, the (insert name of centralized organization) shall ensure that its permittees:

- Notify the (insert name of centralized organization) of changes in operating status in accordance with 10 CFR 30.36(d).

- Submit a DP to the (insert name of centralized organization) in accordance with 10 CFR 30.36(g)(1) for final approval by the NRC before beginning decommissioning.

- Submit any requests to extend time periods established in 10 CFR 30.36(d), in accordance with 10 CFR 30.36(f), to the (insert name of centralized organization).

- Submit any requests for an alternative schedule for completion of decommissioning in accordance with 10 CFR 30.36(i) to the (insert name of centralized organization).

- Submit permit termination requests upon completion of decommissioning, in accordance with 10 CFR 30.36(j), to the (insert name of centralized organization).

- Preserve records showing the receipt, transfer and disposal of byproduct material in accordance with 10 CFR 30.51.

- Forward, upon completion of permit termination and decommissioning, the records of receipt, transfer, and disposal of byproduct material to the (insert name of centralized organization) for storage until the MML is terminated.

e. To ensure compliance with 10 CFR 30.36, the (insert name of centralized organization) shall:

- Notify the NRC region (XX) office of all changes in operating status of permittees pursuant to the notification requirements in 10 CFR 30.36(d).

- Transmit all DPs to the NRC region (XX) office for approval.

- Transmit requests to extend time periods established in 10 CFR 30.36(d), in accordance with 10 CFR 30.36(f), to the NRC region (XX) office for approval.

- Transmit requests for alternative schedules for completion of decommissioning to the NRC region (XX) office for approval.

- Transmit requests for permit termination in accordance with 10 CFR 30.36(j) upon completion of decommissioning activities to NRC region (XX) office for approval, with the exception of Broad Scope permittees who retain the facility or land until such time as they release the facility or land from their ownership, as

described in NUREG-1757, Volume 1, Revision 2, “Consolidated Decommissioning Guidance.”

- Retain permittee records showing the receipt, transfer, and disposal of byproduct material as well as records regarding permittee decommissioning activities until the MML is terminated.

PROCEDURES

(28) The (insert names of licensed entity and centralized organization) will reference its programmatic procedures for the implementation of the MML program:
- (insert the procedure acronym(s), title, and number(s))

(29) The (insert name of centralized organization) is authorized to make program changes and changes to procedures specifically identified above, which were previously approved by the Commission and incorporated into the MML, without prior Commission approval, as long as:

a. The proposed revision is documented, reviewed, and approved by the (insert name of the centralized organization) in accordance with established procedures before implementation.

b. The revised program is in accordance with applicable NRC regulatory requirements and will not change any license conditions of the MML, and the (insert name of centralized organization) has determined that the change will not decrease the effectiveness of the (insert name of centralized organization) radiation safety program.

c. The staff of the (insert name of centralized organization) and the permittee are trained in the revised procedures before implementation.

d. The audit program of the (insert name of centralized organization) and the permittee evaluates the effectiveness of the change and its implementation.

(30) The (insert name of centralized organization) routine implementing procedures are identified as standard operating procedures (SOP) for the MML program and are not incorporated into the MML. Therefore, they may be revised without NRC approval.

(31) The NRC and the MML will review this LOU periodically. If changes are warranted, then the MML and NRC will seek to finalize such changes within 180 days of the review.

SIGNATORIES

The Signatories represent that they have the authority from their respective agencies to enter into this agreement on their agencies behalf and that each agency agrees to uphold their responsibilities as identified above. The responsibilities identified above become effective on the last date show below and shall remain in effect from that date forward unless modified by written agreement of the parties.

_____	_____
(insert name of NRC Certifying Official, title) (insert name of Branch) (insert name of Division) Region (XX)	(MML Certifying Official)
Dated:_____	Dated:_____

APPENDIX D

SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN NRC FORM 313

APPENDIX D SUGGESTED FORMAT FOR PROVIDING INFORMATION REQUESTED IN NRC FORM 313

Instructions:

If there is a box available in the column labeled "Yes," then you may check that box if you are agreeing to the commitment described in the "Suggested Response."

If you check a box in the column marked "Description Attached," then you must provide that information on separate sheets.

I. Applicant Information

Applicant Name:	Application Date:

Mailing Address:

Point of Contact:

- Identify the individual who will be the RCPD and provide the individual's contact information.

Name	Phone (Voice)	Phone (Fax)	E-mail

RCP Office Address:

- Provide location of MML applicant's RCP Office.
- Confirm whether the docketed permittee files for the MML will be located at the RCP Office.

II. Contents of Application (2.0)

A. Letter of Understanding (2.4)

Item No.	Suggested Response	Yes	Description Attached
	Submit a proposed letter of understanding (LOU) (Appendix C). Items in the LOU should include, at a minimum: Administrative; Environmental; Permitting; Inspection; Allegations; Enforcement; Investigations; Decommissioning; and Procedures	[ ]	[ ]

B. Permitting and Enforcement History (2.5)

Item No.	Suggested Response	Yes	Description Attached
	Describe regulatory performance in licensing, inspection, enforcement, and centralized experience in management oversight and coordination of licensing and inspection efforts for the previous five years.		[ ]
	Describe the corrective action program.		[ ]

NRC Form 313, Item 3: Location of Use

- Provide a current list of permittees, locations, and program code.
- Identify permittees that will be authorized to use radioactive material at temporary job sites.
- Identify permittees that intend to use radioactive material in field studies.
- Identify permittees that intend to use radioactive material at facilities and sites, other than temporary jobsites, that are not located at the MML's federally controlled facilities.

C. Contents of Items 5 through 11 of NRC Form 313

Item No.	Suggested Response	Yes	Description Attached
5.	**MATERIAL TO BE POSSESED (5.5)**		
	• Identify the licensed material to be possessed by: isotope class (e.g., byproduct, source, or special nuclear material), chemical or physical form, quantity (e.g., in curie, millicurie), and general areas of use (e.g., research and development activities, industrial activities, self-contained irradiators, instrument calibrators, radiography, or medical applications).		[ ]
	• Identify by manufacturer and model number all Category 1 and 2 sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators, and radiography cameras). Specify whether the device(s) is registered or not registered in accordance with 10 CFR 32.210.		[ ]
	• Identify permittees that may possess quantities of materials requiring financial assurance or an emergency plan.		[ ]
6.	**PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED (5.6)**		
	• Explain why an MML is needed.		[ ]
	• Describe in general terms the purposes for which licensed material will be used.		[ ]
	• State if you intend to use or approve sealed sources other than those that have been registered with NRC's Sealed Source and Device Registry, and describe the training and experience of individuals responsible for reviewing applications for use of these materials.		[ ]
	• Identify any uses that are not identified as a CATX in 10 CFR 51.22 (including field studies deliberately releasing licensed material to the environment), and provide information needed for specific authorization.		[ ]
	• Provide sufficient information about field studies where there is no planned deliberate release of radioactive material to the environment, in order for the NRC to determine if a categorical exclusion is appropriate.		[ ]

Item No.	Suggested Response	Yes	Description Attached
7.	**INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM (5.7)**		
	Senior Management 5.7.1		
	• Provide an organizational chart depicting the licensee's management structure, reporting paths, flow of authority, control of finances, and geographical location of all management and staff components of the RCP.		[ ]
	• Describe established management controls and oversight used to ensure that permitted activities are properly conducted. This should include senior management's established administrative controls and provisions relating to organization and management, including management review necessary to ensure adequate protection of public health, safety and security, and protect the environment.		[ ]
	• Provide senior management's written delegations to the MRSC and RCPD providing for sufficient authority, organizational freedom, and management prerogative to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions and permit conditions.		[ ]
	• Provide the point of contact as the liaison to the NRC MML PM and describe the expected types of interactions and exchanges of information, including both formal and informal communication mechanisms.		[ ]
	• Confirm and describe senior management commitment to devote sufficient financial resources (e.g., funds, equipment, personnel, materials) to support the RCP at all levels.	[ ]	
	• Describe the senior management oversight and mechanisms used by management to ensure adequate control over MML activities. The senior management oversight activities should include:		[ ]
	— membership and active participation in MRSC meetings;		[ ]
	— oversight of RCPD and support staff;		[ ]
	— annual audits of the program to ensure safe operations, regulatory compliance and consistency with the NRC' s policies and procedures.		

Item No.	Suggested Response	Yes	Description Attached
	Master Radiation Safety Committee (5.7.2) • Describe the composition, duties, and functions of the MRSC. • Identify the Chairperson and individual members of the MRSC by position title and job description. The Chairperson will be listed on the MML. • Describe the duties of the MRSC Chairperson and provide commitment that the Chairperson has full authority to commit licensee resources to support the conduct of the MML. • Describe the duties of the RCPD. Note: The identities of the members of the Radiation Safety Committee are descriptive information and are not incorporated in the license. If there are significant changes to actual membership of the MRSC; i.e., functionally significant changes in position titles and job descriptions, the NRC should be notified. Notification is not needed for reorganizations that change the position titles without changing the basic radiation safety responsibilities of the position or for the reassignments of new individuals into designated positions. Note: The identity of the individual designated the Chairperson of the MRSC will be listed on the MML.		[ ] [ ] [ ] [ ]
	Radiation Control Program Director (5.7.3) • Provide the minimum generic qualifications of the RCPD. • Identify the individual designated as the RCPD. • Provide documentation on the education, training, and experience demonstrating that the individual designated as the RCPD is qualified to manage the RCP. • Describe communications between the MML staff and the NRC MML PM. Note: The information identifying the individual designated RCPD and his/her qualifications is descriptive information and is not incorporated in the license. If the RCPD changes, then the NRC should be notified.		[ ] [ ] [ ] [ ]

Item No.	Suggested Response	Yes	Description Attached
	Other Radiation Control Program Staff (5.7.4) • Provide a list of the RCP office staff positions by job title, description, and number of individuals for each position. • Describe procedures and criteria for ensuring that members of the RCP office staff are adequately qualified. (These procedures are part of the RCP procedures generically addressed in 5.10.4, Regulatory Conformance.) • Provide management commitment to training and continued training of program staff in accordance with NRC IMC 1248 or equivalent program for training and qualification of staff. Note: Listing the RCP staff positions is descriptive information and is not incorporated into the license. If the number of RCP staff positions changes, or significant changes are made in job descriptions, the NRC should be notified.		[ ] [ ] [ ]
8.	**TRAINING AND EXPERIENCE FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICETD AREAS (5.8)** **Training and Experience Items** • Describe the training and experience required of individuals who will be required to work in, inspect, or frequent any restricted areas included under the MML.		[ ]
9.	**FACILITIES AND EQUIPMENT (5.9)** • Identify all facilities requiring security controls pursuant to 10 CFR Part 37. • Commit that the facility will meet the appropriate requirements under 10 CFR Part 37, before permitting the respective facility. • Provide the location and description of all facilities used by the MML to carry out its activities.* • State in the application where all docketed and required files and records will be maintained. • Provide a list and description of the laboratory equipment such as counting systems, portable survey equipment, air monitoring, or other devices necessary for conducting the inspection of permittees. Note: The information on the locations, facilities and laboratory equipment is descriptive information and is not incorporated in the license. If the location and facilities used by the RCP staff change, you should notify NRC. Notification is not needed for changes to upgrade equipment, provided that the applicant maintains the same level of coverage described in the application.	[ ]	[ ] [ ] [ ] [ ]

Item No.	Suggested Response	Yes	Description Attached
10.	**RADIATION CONTROL PROGRAM–AN OVERVIEW (5.10.1)**		
	• Provide a concise narrative overview description of the RCP.		[ ]
	• Describe the centralized administrative controls and provisions for: — organization and management structure — procedures — recordkeeping — material control and accounting — management review		[ ]
	• Describe the licensing, inspection, enforcement, and decommissioning programs.		[ ]
	• Describe the incident response and allegations programs.		[ ]
	• Describe the staff training and qualification program.		[ ]
	• Commit to updating procedures to maintain consistency with NRC policies, procedures, and guidance.	[ ]	
	Note: While both the description of the written administrative control processes and the program elements, such as licensing, inspection, enforcement, incidents, allegations and training should be concise, the descriptions should also be in sufficient detail, and be sufficiently clear and specific so as to ensure understanding of how management oversight for the program activities will be carried out and how the program functions. The narrative overview description of the RCP should concisely address the following (a narrative overview description is not needed when NRC guidance documents are included by reference in the RCP because these documents were adopted in their entirety):		
	• program authorities and responsibilities • communications • quality control surveillance • program audits • procurement • staff selection and qualification • information dissemination, document control and retrieval, • other considerations essential to the successful implementation of the RCP		

Item No.	Suggested Response	Yes	Description Attached
	Previous Licenses (5.10.2)		
	• List the radioactive materials licenses the applicant wants to include in the MML.		[ ]
	Note: The list of materials licenses to be included in the MML is descriptive information to assist NRC in accurately terminating licenses and is not incorporated in the license. The regions and FSME are responsible for transferring NRC license docket files to the primary regional office in which the MML will be based. The MML PM should be kept informed of these activities and oversee the coordination and disposition of the NRC license docket files. The NRC license docket files may be maintained in the NRC regional office, transferred to the MML, or archived.		[ ] [ ] [ ]
	Material Control and Accountability (5.10.3)		
	• Describe the administrative controls and provisions relating to materials control and accountability.	[ ]	
	• Describe the inventory control and accountability method of licensed material.		[ ]
	• Provide a statement declaring that, "We will comply with the NSTS reporting requirements as described in 10 CFR 22.2207, 'Reports of transactions involving nationally tracked sources'."		[ ]
	• Provide a statement that "We will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times."		
	Regulatory Conformance (5.10.4)		
	• Provide management's written commitment to follow NRC regulations.		
	• Confirm that licensing and inspection programs will be implemented in accordance with NRC licensing and inspection criteria (i.e., NRC regulations, policies, and guidance) or submit any alternative procedures.		
	• Submit all policies, procedures, directives, and guidance developed that will be used to manage the RCP pursuant to NRC regulations, policies, and guidance.		
	• Specifically identify those NRC policies, procedures, and guidance documents that will be adopted in their entirety into the RCP.		

Item No.	Suggested Response	Yes	Description Attached
	Updating of Radiation Control Program Documents (5.10.5)		
	• Describe the process for review and approval of changes to RCP procedures and documents.		[ ]
	Management Support and RCP Structure (5.10.6)		
	• Provide information that indicates that the applicant has provided and will continue to provide sufficient operating funds to support the MML program elements.		[ ]
	• Describe the lines of communication and administrative control between the permittees, RCP, and MML management.		[ ]
	• Delegate in writing to the MRSC and the RCPD, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct MML personnel at all levels regarding NRC regulations, MML provisions, and permit conditions.		[ ]
	Radiation Control Policies–Administrative Controls and Provisions (5.10.7)		
	• Submit policies related to the administrative controls and provisions listed above to demonstrate that sufficient processes are in place, with adequate senior management support, to implement the RCP. At a minimum, these policies should address the following: -organization and management, including program authorities and responsibilities -communications between the MML and the NRC -communications between permittees, RCP staff and MML senior management -policy for implementation of program elements -document control, retrieval, and recordkeeping -information dissemination -material control, procurement, and accounting -management review, quality controls and audit program -corrective action program -training and qualification program for staff, including staff selection -other program elements essential to the successful implementation of the RCP		[ ]

Item No.	Suggested Response	Yes	Description Attached
	Master Radiation Safety Committee Responsibilities (5.10.8)		
	• Provide organizational and procedural manuals that address each item in 5.10.8. Note: If you describe how you will meet one of the above responsibilities in an organizational or procedural manual that is more appropriately provided in response to another section of this NUREG, you may simply identify the other section of your application where the information is found.		[ ]
	• Provide the delegation of authority given from the highest level of management to the MRSC delineating its authority to oversee the licensed program and its responsibility for control and direction of the RCP and the RCPD. Note: The delegation of authority should state the MRSC's authority to suspend or terminate activities based on poor performance or violation of safety standards and provide assurance of the Chairperson's full authority to commit licensee resources to support the conduct of the MML.		[ ]
	• Provide the MRSC's composition and responsibilities.		[ ]
	• Describe the conditions under which the MRSC will obtain assistance from technical boards and other entities.		[ ]
	• Identify and describe any existing boards or entities used to support the MRSC.		[ ]

Item No.	Suggested Response	Yes	Description Attached
	Radiation Control Program Director Responsibilities (5.10.9)		
	• Provide a copy of the written delegation of authority from the highest level of management to the RCPD.		[ ]
	• Provide a description of the RPCD's responsibilities.		[ ]
	• Provide documentation to show that the RCPD has access to the highest levels of MML management.		[ ]
	• Describe the measure of administrative and financial control over permitting and inspection personnel.		[ ]
	Permitting and Inspection Staff (5.10.10)		
	• Describe the duties of the permitting and inspection staff.		[ ]
	• Describe how the staff will manage the day-to-day operations of the RCP, and include the following: — responding to events at permittee facilities — maintaining uniformity of program implementation — maintaining internal communications — ensuring consistency of guidance provided to permittees — providing training to RCP staff — monitoring and evaluating RCP staff performance		[ ]
	Radiation Control Program Internal Procedures (5.10.11)		
	• Confirm that written internal procedures have been developed that, at a minimum, address the functions addressed in Section 5.10.11, "Radiation Control Program Internal Procedures." Note: The applicant should confirm that it has written internal procedures that at a minimum address the functions addressed in 5.10.11, "Radiation Control Program Internal Procedures," but it does not need to submit them with the application.	[ ]	

Item No.	Suggested Response	Yes	Description Attached
	Management and Master Radiation Safety Committee Audits (5.10.12)		
	• Describe senior management oversight and the mechanisms used to ensure the awareness of NRC regulations, the provisions of the license, and the compliance status of the applicant's RCP.		[ ]
	• Provide a copy of the audit program used by senior management and the MRSC to audit the performance of the RCP, the RCPD, and the inspection and permitting staff.		[ ]
	• Describe how inspectors demonstrate competence in evaluating health and safety problems and in determining compliance with NRC regulations.		[ ]
	• Describe how inspectors demonstrate an understanding of regulations, inspection guides, and policy practices before conducting inspections independently.		[ ]
	• Describe how permit reviewers demonstrate competence in reviewing applications for permits.		[ ]
	• Describe how reviewers demonstrate an understanding of regulations, licensing policy and guidance directives, and permitting practices before reviewing and issuing permits independently.		[ ]
	Note: The process described in the first bullet and the copy of the audit programs are descriptive information and are not incorporated in the license. Applicant should notify the NRC of significant changes to these programs.		

Item No.	Suggested Response	Yes	Description Attached
	Permitting Procedures (5.10.13)		
	• Commit to developing and implementing permitting procedures, policies, and guidance: — List the NRC licensing procedures, policies, and guidance that will be used. — Provide for NRC review any documents that differ from NRC licensing procedures, policies, and guidance.		[ ]
	• Provide standard permit condition(s) that are not consistent with NRC standard license conditions.		[ ]
	• Submit custom conditions that are less restrictive than applicable NRC requirements for further review and approval.		[ ]
	• Provide specific timeliness goals for issuing permits and updating licensing guidance as updates are received from the NRC.		[ ]
	• Describe document management procedures.		[ ]
	Program to Minimize Contamination at Permittee Facilities (5.10.14)		
	• Describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the permittees facilities and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.		[ ]

Item No.	Suggested Response	Yes	Description Attached
	Decommissioning of Permit Activities and Permit Termination (5.10.15)		
	• Provide decommissioning and permit termination procedures or commit that permit facilities will be decommissioned and terminated as described in NRC regulations, policies, and the guidance in NUREG-1757.	[ ]	[ ]
	• Confirm that DPs for complex decommissioning sites described in section 5.10.15, will be submitted to NRC for review and approval before commencing decommissioning activities.	[ ]	
	Financial Assurance (5.10.16)		
	• Describe how the decommissioning financial assurance requirements described in 10 CFR 30.35, 10 CFR 40.36, and 10 CFR 70.25 will be met.		[ ]
	• Provide documentation that adequate funds to decommission all permitted facilities are established and maintained.		[ ]
	Inspection and Enforcement Procedures (5.10.17)		
	• Provide permit inspection procedures addressing the elements discussed in Section 5.10.17.		[ ]
	• Provide enforcement program procedures for assessing the severity of violations and taking enforcement actions for the more severe violations.		[ ]
	• Provide procedures for documenting inspection findings and enforcement actions.		[ ]

Item No.	Suggested Response	Yes	Description Attached
	Corrective Action Program (5.10.18)		
	• Provide procedures for a corrective action program that, at a minimum, address the functions in Section 5.10.18.		[ ]
	Incident/Emergency Response Procedures (5.10.19)		
	• Provide incident/emergency response procedures that address, at a minimum, the following: — RCP management oversight responsibilities; — initial response actions and responsibilities, including immediate safety for RCP management and staff, and permittees; — list of persons responsible for initiating response actions, conducting operations, and performing cleanup; — precautions for persons and property at permittee facilities; — permittee facility and site access control and security; — mechanisms and responsibilities for notifying RCP staff and external authorities; — provisions for medical and offsite agency assistance; — description of emergency response equipment available for use by the RCP staff; — need for onsite review of events; __ communications between the permittee facility and the RCP; __ communications between the RCP and the NRC.		[ ]
	• Provide Emergency Plan(s), according to 10 CFR 30.32, if applicable.		[ ]
	Security Program for Category 1 and Category 2 Materials (5.10.20)		
	• In accordance with 10 CFR Part 37, licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material must establish, implement, and maintain an access authorization program and a security program to ensure physical protection of the radioactive material.	[ ]	

Item No.	Suggested Response	Yes	Description Attached
	Procedures for Handling Allegations (5.10.21)		
	• Confirm that the NRC's procedures for handling allegations will be used, or provide equivalent procedures for handling allegations that are referred to the licensee.	[ ]	
	• Provide procedures for handling, documenting, investigating, and closing an allegation raised by a concerned individual.		[ ]
	• Provide a description of the training that will be provided to all employees to ensure that they understand their right to contact the NRC directly about radiation safety or regulatory issues.		[ ]
11	**Waste Management (5.11)**		
	• Describe the criteria for approving disposal of radioactive waste.		[ ]
	Describe the locations, conditions, and current status of former burial sites, whether controlled or uncontrolled, any active monitoring of the site, and the current condition of the burial site, for permittees who were NRC licensees authorized before January 28, 1981, to bury radioactive material when prior section 20.304 authorized such burial.		[ ]

APPENDIX E

INTERIM STAFF GUIDANCE ON CONSTRUCTION

APPENDIX E INTERIM STAFF GUIDANCE ON CONSTRUCTION

INTERIM STAFF GUIDANCE TO NUREG-1556 AND NUREG-1520: COMMENCEMENT OF CONSTRUCTION AT EXISTING AND PROPOSED SOURCE, BYPRODUCT, AND SPECIAL NUCLEAR MATERIAL FACILITIES AND IRRADIATORS WITH SIGNIFICANT ENVIRONMENTAL IMPACTS

PURPOSE AND SCOPE

This Interim Staff Guidance (ISG) provides guidance to U.S. Nuclear Regulatory Commission (NRC) staff on the new definition of construction and the consideration of activities that can be performed by materials license applicants and potential applicants (hereinafter collectively referred to as "applicants"), and licensees before the NRC staff has concluded its environmental review of the proposed licensing action.

This ISG applies to the review of licensing actions related to the receipt and possession of licensable source, byproduct, and special nuclear material (SNM) for the conduct of any activity which the NRC determines will significantly affect the quality of the environment. This ISG is intended to provide guidance to NRC staff but may also be instructive to all holders of operating licenses for source, byproduct, and SNM facilities and irradiators, and all persons that have submitted applications to construct source, byproduct, and SNM facilities or irradiators, or have submitted letters of intent to submit such applications under Title 10 of the *Code of Federal Regulatio*ns (10 CFR) Parts 30, 36, 40, and 70.

This ISG applies to all Part 30, 36, 40 and 70 materials facilities other than uranium recovery facilities. Site preparation activities at uranium recovery facilities are addressed in Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.

If a licensing action initiated pursuant to 10 CFR Parts 30, 40, or 70 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), 40.32(e), and 70.23(a)(7). However, if the licensing action meets the criteria in 10 CFR 51.22(c) for a categorical exclusion, and 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, as the NRC has already determined that this category of actions does not have a significant impact on the environment. In accordance with 10 CFR 36.15, commencement of construction of an irradiator will only be grounds for denial if the licensee or applicant has not submitted both an application and the requisite licensing fee.

BACKGROUND

The NRC amended its regulations in September 2011, by revising certain provisions applicable to the licensing and approval processes for byproduct, source and SNMs licenses, and irradiators 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" with respect to materials licensing actions conducted under the NRC's regulations. The NRC adopted these changes to further improve the

effectiveness and efficiency of the licensing and approval processes for future materials license applications, as well as to eliminate certain inconsistencies that existed within the NRC's regulations with respect to the use and definition of the terms “construction” or “commencement of construction” for certain materials licensees for purposes of its environmental reviews.

The new definitions of “commencement of construction” in 10 CFR 30.4, 36.2, 40.4, and 70.4 are identical.

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.

In 10 CFR 150.31, *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 radiological health and safety. The regulations in 10 CFR 150.31 address the requirement for Agreement State regulation of byproduct material. Although Agreement State licensees may find this ISG informative, they should also communicate with the pertinent Agreement State agency for that agency’s applicable requirements and guidance.

The new definitions of “construction” in 10 CFR 30.4, 36.2, and 70.4 are also identical.

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:
    (i) Radiological health and safety, or
    (ii) Common defense and security.

“Construction,” as defined in 10 CFR 40.4, also includes the installation of wells associated with radiological operations (e.g., production, injection, or monitoring well networks associated with in-situ recovery or other facilities).

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 by-product 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 guidance provides criteria for NRC staff to use in evaluating whether a particular construction activity 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 or the common defense and security 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 revised definition of construction in 10 CFR 30.4, 36.2, 40.4, 70.4, and 150.31 list activities that are not considered “construction.” This guidance provides examples of activities that fall under each of the excepted activities that do not constitute construction. This guidance addresses some important considerations for materials licensees and applicants that were emphasized in the response to comments on the proposed Material Licenses Construction Rule. For example, 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 SOC to 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 §106 of the NHPA.

DISCUSSION OF EXAMPLES

In addition to the background discussion provided above, the following examples clarify the delineation of site preparation activities and construction activities. 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, the process of dedicating commercial grade items or basic components, or procurement of items relied on for safety (IROFS) as defined in 10 CFR Part 70. It should also be noted that, while site preparation activities may not require prior NRC approval, various local, State, or other Federal permits may be required.

BYPRODUCT MATERIAL (10 CFR PART 30)

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 or the common defense and security. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed 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.

Installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 30 that are related to radiological health and safety or common defense and security should not be performed prior to the conclusion of the environmental review of a license application or amendment. Byproduct material license applicants subject to 10 CFR Part 30 may perform those site preparation activities identified in revised 10 CFR 30.4 before the NRC has completed its environmental review of the license application.

Excavation and other site preparation activities that do not have a reasonable nexus to radiological public health and safety or common defense and security, 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.

IRRADIATORS (10 CFR PART 36)

An applicant for a new irradiator license under 10 CFR Part 36 may perform the non-construction activities identified in revised 10 CFR 36.2 at any time. However, installation of foundations or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to 10 CFR Part 36 that have a reasonable nexus to radiological safety or security should not be performed prior to the submission of an application for a license and the fee required by 10 CFR 170.31. An activity or action has a reasonable nexus to radiological health and safety or the common defense and security if that activity or action has a rational, direct link to ensuring that a licensed 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. Activities that have a reasonable nexus to radiological health and safety or common defense and security include, but are not limited to, construction of systems subject to 10 CFR Part 36, Subpart C, and the following:

- Earthwork
- Pool excavation
- Footings and foundation for pool
- Irradiator foundations and walls
- Backfill pool
- Install pool liner
- Mechanical rough-in
- Electrical rough-in
- Shoring for roof
- Form and place roof
- Slab on grade

Subpart C of 10 CFR Part 36 currently lists the systems that have a nexus to radiological health and safety and defines the related engineering and safety concerns associated with each system:

- Access Control: Adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23. For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before operational testing.
- Site: Potential need for protection against flooding and earth slides.
- Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement, liquefaction, ground water, soil compaction.
- Footers and Foundations for the Pool and Shielding Structures: Strength and reinforcement, alignment with pool and shielding structures.
- Pool and Shielding Structures: Strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding.
- Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.
- Pool Plumbing: Makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems.
- Penetrations Through Shielding: Any significant effect on structural strength, shielding, or both.

- Source Rack Protection: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.
- Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming.
- Source-Rack Movement and Position-Sensing System: Structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system.
- Source-Rack Electrical Control System: Adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms.
- Source-Leak Detection: Adequacy of systems for detecting and isolating leaking sources.
- Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage 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.
- Fire Protection System: Adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool.
- Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered.
- Ozone Ventilation System: Capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components.
- System for Transferring Sources from and to Transport Vehicles: Adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the roof-shield plug and its supports for its removal and replacement; structural and mechanical adequacy of systems for moving shipping containers into and out of the pool area.

URANIUM CONVERSION FACILITIES, ENRICHMENT FACILITIES, FUEL FABRICATION FACILITIES, AND URANIUM HEXAFLUORIDE (UF_6) DECONVERSION FACILITIES (10 CFR PART 40 and 10 CFR PART 70)

If any of the following actions are performed before the NRC staff has completed its environmental review process, then the NRC has grounds for denial of a license application, in accordance with 10 CFR 40.32(e), and 70.23(a)(7):

1. Procurement or construction of engineered items that are items relied on for safety (IROFS) required to meet the performance requirements of 10 CFR 70.61.
2. Construction of guard stations, fences, vehicle barriers, or other features that are, or will become, components of physical security systems required by regulations or orders.

3. Construction or installation of equipment whose purpose is the detection of radioactive material accidents or mitigation of the consequences of radioactive material accidents.
4. Installation of storage tanks that contain chemicals that could affect the safety of licensed material.
5. Construction of facilities or warehouses that will be used for operations involving licensed material.
6. Driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for IROFS and on-site emergency facilities.
7. Erection of buildings, offices, construction trailers and warehouses that will become part of a Standard Practice Procedures Plan for Protection of Classified Information.

Construction includes the onsite, in-place fabrication, erection, integration, or testing activities for any safety related item. The terms “onsite, in place, fabrication, erection, integration, or testing” describe the process of constructing a fuel cycle facility in its final, onsite plant location, where components or modules are integrated into the final, in-plant location. Under the definition of “construction” applicants and existing licensees may be able to fabricate, assemble, and test components and modules in a shop building, warehouse, or laydown area, even if these facilities are located onsite. However, the installation or integration of that safety related equipment into its final plant location is a construction activity and should not be performed until after the NRC staff concludes its environmental review of the license application.

Excavation includes the removal of any soil, rock, gravel, or other material below the final ground elevation to the final parent material, and may be conducted prior to the conclusion of the NRC staff’s environmental review. However, placing permanent, nonstructural dewatering materials, mudmats, or engineered backfill in advance of placing the foundation and associated permanent retaining walls for buildings or structures that will contain licensed materials are construction activities and should not be performed prior to the conclusion of the NRC staff’s environmental review.

Construction includes driving piles for buildings or structures that will contain licensed materials. Hence the driving of piles for such buildings or structures should not be performed before the NRC staff concludes its environmental review. Driving piles that do not ensure the structural stability or integrity of buildings or structures within the scope of the definition of “construction” (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 conclusion of the NRC staff’s environmental review.

In addition to 10 CFR 40.4, 51.4, and 70.4 criteria that are used to determine the scope of activities that fall within the definition of construction, construction includes the necessary excavation for safety related items. A necessary excavation is the portion of an excavation that provides sufficient construction access to the structures that are within the definition of construction. Applicants should ensure, and NRC staff will confirm, that these construction activities are separate from, and do not result in, adverse interactions with construction-related safety related item including influence on the stability (static and dynamic) analyses.

Construction includes any change made to the parent material in which the excavation occurs (e.g., soil compaction, rock grouting); the driving of piles; the installation of foundations; 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; and the installation of reinforcing

bars to be incorporated into the foundation of any safety related items that fall within the definition of construction. The foregoing items fall within the definition of construction because they have a rational, direct link to ensuring that a licensed 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 from radiological hazards.

ACTIVITIES WHICH HAVE NO REASONABLE NEXUS TO RADIOLOGICAL SAFETY OR SECURITY

The NRC has determined that, in general, the following activities at source, byproduct, and SNM facilities and irradiators listed in 10 CFR 30.4, 36.2, 40.4, and 70.4, do not have a reasonable nexus to radiological health and safety and the common defense and security may be performed by a licensee or applicant at any time. Note that in some circumstances, based on the specific licensing proposal, any of these activities could be determined to have a reasonable nexus to radiological health and safety or common defense and security and, based on that determination, these activities would be construction:

(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 10 CFR Parts 30, 36, 40, or 70;
(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:
    (i) Radiological health and safety, or
    (ii) Common defense and security.

While the above site preparation activities may not require prior NRC approval, other Federal, State, or Local permits may be required.

FINAL RESOLUTION

This interim staff guidance will be incorporated into the next revisions of NUREG-1556, and NUREG-1520.

APPLICABILITY

This ISG is applicable to all 10 CFR Parts 30, 36, 40, and 70 license applicants and existing licensees considering site preparation activities or construction activities at a facility that is subject to, or will be subject to, the licensing requirements of these parts.

REFERENCES

1) NUREG-1556, Volume 6, "Consolidated Guidance About Material Facilities: Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses," January 1999.
2) NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Possession Licenses for Manufacturing and Distribution," December 2000.
(3) NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010.
4) Regulatory Issue Summary 2009-12, Uranium Recovery Policy Regarding Site Preparation Activities at Proposed, Unlicensed Uranium Recovery Facilities, September 23, 2009, ML092090353.
5) NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with Materials Facilities," August 2003.
6) DC/COL-ISG-4, "Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations," February 9, 2009, ML082970729.
7) Inspection Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic Wet-Source-Storage Gamma Irradiators," March 27, 2001, ML010990225.
8) Docket No. 030-36974, Final Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC, Underwater Irradiator in Honolulu, Hawaii; August 10, 2007; ML071150121.
9) Docket No. 70-7015, Environmental Assessment for an Exemption to 10 CFR Parts 30, 40, and 70, Commencement of Construction Requirements, Areva Enrichment Services, Eagle Rock Enrichment Facility, Bonneville County, Idaho, February 28, 2010, ML093220528.
10) NUREG-1811, "Environmental Impact Statement for an Early Site Permit at the North Anna ESP Site," December 2006.
11) NUREG-1947, "Final Supplemental Environmental Impact Statement for Combined License (COLs) for Vogtle Electric Generating Plant Unit 3 and 4," March 2011.

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U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

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This technical report contains information intended to provide program specific guidance for existing Master Materials Licenses and assist Federal agencies in preparing applications for a Master Materials License. In particular, it 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 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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