
Consolidated Guidance About Materials Licenses

Program-Specific Guidance About
Master Materials Licenses

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Vol.10, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Master Materials Licenses," dated December 2000, is the tenth program-specific guidance developed for the new process and is intended for use by Federal applicants and licensees, and NRC staff. This document updates the guidance for applicants and licensees previously found in Policy and Guidance Directive PG 6-02, Revision 1: "Standard Review Plan (SRP) for License Application for Master Material License," dated September 25, 1997.

CONTENTS

ABSTRACT	iii
FOREWORD	vii
ACKNOWLEDGMENTS	xi
ABBREVIATIONS	xiii
1 INTRODUCTION AND PURPOSE OF REPORT	1-1
1.1 NRC REVIEW PROCESS AND CRITERIA	1-1
1.2 DEFINITION AND DESCRIPTION	1-2
1.3 ISSUANCE CRITERIA FOR A MASTER MATERIALS LICENSE	1-3
1.4 MASTER MATERIALS LICENSEE AUTHORIZATIONS	1-3
1.5 PRELICENSING CONFERENCE AND READINESS REVIEW	1-4
1.6 PROGRAMS NOT WARRANTING A MASTER MATERIALS LICENSE	1-5
2 FILING AN MML APPLICATION	2-1
2.1 LETTER OF UNDERSTANDING	2-1
2.2 LICENSING AND ENFORCEMENT HISTORY	2-2
2.3 FILING NRC FORM 313	2-3
3 CONTENTS OF NRC FORM 313	3-1
3.1 NRC FORM 313, ITEM 1: LICENSE INFORMATION	3-1
3.2 NRC FORM 313, ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS	3-1
3.3 NRC FORM 313, ITEM 3: LOCATION OF USE	3-1
3.4 NRC FORM 313, ITEM 4: PERSON TO BE CONTACTED ABOUT APPLICATION	3-2
3.5 NRC FORM 313, ITEM 5: MATERIAL TO BE POSSESSED	3-3
3.6 NRC FORM 313, ITEM 6: PURPOSE OF USE OF LICENSED MATERIAL	3-4
3.7 NRC FORM 313, ITEM 7: INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM	3-5
3.7.1 SENIOR MANAGEMENT	3-5
3.7.2 MASTER RADIATION SAFETY COMMITTEE	3-7
3.7.3 RADIATION CONTROL PROGRAM DIRECTOR	3-9
3.7.4 OTHER RADIATION CONTROL PROGRAM STAFF	3-10
3.8 NRC FORM 313, ITEM 8: TRAINING AND EXPERIENCE FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS	3-11
3.9 NRC FORM 313, ITEM 9: FACILITIES AND EQUIPMENT	3-11
3.10 NRC FORM 313, ITEM 10, RADIATION SAFETY PROGRAM	3-11
3.10.1 RADIATION CONTROL PROGRAM – AN OVERVIEW	3-12
3.10.2 PREVIOUS LICENSES	3-14
3.10.3 MATERIAL CONTROL AND ACCOUNTABILITY	3-14
3.10.4 REGULATORY CONFORMANCE	3-14
3.10.5 UPDATING OF RADIATION CONTROL PROGRAM DOCUMENTS	3-16
3.10.6 MANAGEMENT SUPPORT AND RADIATION CONTROL PROGRAM STRUCTURE	3-16
3.10.7 RADIATION CONTROL PROCEDURES – ADMINISTRATIVE CONTROL PROCESSES	3-17
3.10.8 MASTER RADIATION SAFETY COMMITTEE	3-19

CONTENTS

3.10.9	THE RADIATION CONTROL PROGRAM DIRECTOR	3-20
3.10.10	PERMITTING AND INSPECTION STAFF	3-21
3.10.11	RADIATION CONTROL PROGRAM INTERNAL PROCEDURES	3-22
3.10.12	MANAGEMENT AND MASTER RADIATION COMMITTEE AUDITS	3-23
3.10.13	PERMITTING PROCEDURES	3-24
3.10.14	PROGRAM TO MINIMIZE CONTAMINATION AT PERMITTEE FACILITIES	3-26
3.10.15	PERMIT TERMINATION AND DECOMMISSIONING OF PERMIT ACTIVITIES .	3-26
3.10.16	FINANCIAL ASSURANCE	3-28
3.10.17	INSPECTION AND ENFORCEMENT PROCEDURES	3-29
3.10.18	INCIDENT/EMERGENCY RESPONSE PROCEDURES	3-31
3.10.19	PROCEDURES FOR HANDLING ALLEGATIONS	3-32
3.11	NRC FORM 313, ITEM 11: WASTE MANAGEMENT	3-33
3.12	NRC FORM 3131, ITEM 12: LICENSE FEES	3-33
4	AMENDMENTS TO A LICENSE	4-1

APPENDICES

Appendix A	United States Nuclear Regulatory Commission Form 313	A-1
Appendix B	Sample Master Material License	B-1
Appendix C	Checklist for License Application	C-1

FOREWORD

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

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance about Self-Shielded Irradiators	Final Report
6	Program-Specific Guidance about 10 CFR Part 36 Irradiators	Final Report
7	Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance about Exempt Distribution Licenses	Final Report
9	Program-Specific Guidance about Medical Use Licenses	Draft
10	Program-Specific Guidance about Master Material Licenses	Final Report
11	Program-Specific Guidance about Licenses of Broad Scope	Final Report
12	Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution	Final Report
13	Program-Specific Guidance about Commercial Radiopharmacy Licenses	Final Report
14	Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Final Report
16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licensees	Final Report

FOREWORD

Vol. No.	Volume Title	Status
17	Program-Specific Guidance About Licenses for Special Nuclear Material of Less Than Critical Mass	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Final Report
19	Guidance For Agreement State Licensees Proposing to Work in NRC Jurisdiction (Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters) and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)	Final Report
20	Guidance About Administrative Licensing Procedures	Final Report

The current document, NUREG-1556, Vol. 10, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Master Material Licenses,” dated December 2000, is the tenth program-specific guidance developed for the new process. It updates the guidance for applicants and licensees previously found in NMSS Policy and Guidance Directive, PG 6-02, Rev. 1, “Standard Review Plan (SRP) for License Applications for Master Material Licenses,” dated September 25, 1997.

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 NRC to issue an MML to a Federal organization, NRC must ensure that the organization is capable of performing certain functions and activities as a regulator, in much the same manner that 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/or special nuclear material at multiple sites; and has an organizational structure capable of providing adequate oversight and inspection of its permittee.

NUREG-1556, Vol. 10, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Master Material Licenses,” dated December 2000, represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following address:

<<http://www.nrc.gov/NRC/NUREGS/SR1556/ V10/index.html>>.

FOREWORD

NUREG-1556, Vol. 10, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Master Material Licenses,” dated December 2000, is not a substitute for NRC regulations, and compliance is not required.

Donald A. Cool, Director
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ABBREVIATIONS

CFR	Code of Federal Regulations
DF	Decommissioning Funding Plan
IMC	Inspection Manual Chapter
LOU	Letter of Understanding
MML	Master Materials License
MRSC	Master Radiation Safety Committee
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
RCP	Radiation Control Program
RCPD	Radiation Control Program Director
RSO	Radiation Safety Officer
SRP	Standard Review Plan

1 INTRODUCTION AND 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 NRC license reviewers and other NRC personnel use in reviewing MML applications and current MMLs. In order for NRC to issue an MML to a Federal organization, NRC must ensure that the organization is capable of performing certain functions and activities in a manner that assures 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 assure 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 equivalent NRC licensees.

As a guidance document, NRC has used the terms “must” and “shall” to designate those programs and commitments it requires an applicant/licensee to meet in its MML in order to comply with either the requirements in 10 CFR 30.33 or the requirements in other NRC regulations. “Should” is used in this document to designate information the Staff believes is necessary to make a licensing decision consistent with the Commission’s regulations. “Should” provisions are one way to comply with the Commission’s regulations. To the extent an applicant chooses to take a different approach, it will need to justify why the requested information is not necessary in light of the information provided. In the absence of justification, it is NRC’s expectation that the applicant/licensee will opt to use the approach in this document in order to maximize the uniformity in the MML licensee’s organizational structure, programs and policies with the NRC regulatory process for its licensees and the MML permittees.

1.1 NRC REVIEW PROCESS AND CRITERIA

After receipt of an MML application, the appropriate NRC Regional Office will process the application and forward it to NRC Headquarters via a technical assistance request for review and coordination. There a team, the “MML Application Review Team,” consisting of Headquarters and Regional staff (including at least one current or former project manager for an existing MML), experienced in licensing and inspection procedures, will review the application. The team leader will typically be from the Region in which the MML is to be based. Because the existing organization’s licenses may be located in multiple Regions, when evaluating a new application, regional inspection and licensing staff should make sure to coordinate and communicate information regarding the application.

NRC will review the applicant’s regulatory philosophy and commitment to follow NRC requirements and criteria as evidenced 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 program, independence of the MML governing body,

INTRODUCTION AND PURPOSE OF REPORT

and commitment to the MML. NRC staff should make one or more pre-licensing visits, and conduct a readiness review prior to issuance of any new MML.

During the readiness review process, NRC will visit the applicant and review the applicant's operational and administrative readiness in light of its ability to assume the responsibilities of an MML licensee. NRC staff performing the readiness review may include Headquarters and Regional staff experienced in reviewing the management and coordination of centrally controlled licensing and inspection efforts, MML project management experience, and familiarity with the MML application.

1.2 DEFINITION AND DESCRIPTION

An MML is a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization, authorizing 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 ties the licensee to a framework for oversight and internal licensee inspection of the MML.

A master materials licensee remains an NRC licensee and MML permittees are required to meet NRC regulatory requirements. In the MML, NRC provides a Federal organization with the authority necessary to undertake a limited number of activities as a regulator; therefore, to be granted an MML, the organization must demonstrate that it has a regulatory program that complies with NRC's regulations, e.g., the requirement in 10 CFR 30.33(a)(3) that the MML licensee must be qualified by training and experience to use materials for the purposes requested. Because this includes the issuance of permits for the possession and use of byproduct, source, and/or special nuclear material at multiple sites, the MML licensee must have an organizational structure capable of providing adequate oversight and inspection of the permittee.

In order for NRC to issue an MML to a Federal organization, NRC must ensure that the organization can demonstrate it is capable of performing certain functions and activities in a manner that meets the same standards that NRC, pursuant to the Atomic Energy Act of 1954, as amended, applies to itself. In addition, to provide consistency with other NRC programs and licensees, NRC must be able to assure itself that the MML licensee's inspectors and permit reviewers are able to meet the same training requirements (Inspection Manual Chapter (IMC)-1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," and that in their regulation of a permittee, the MML will use the same licensing and inspection guidance (IMC-2800, and IMC-2600 ("Materials Inspection Program,") as its NRC counterparts. Further, the licensee must have a system for tracking its permitting and inspection actions. MML licensees are inspected annually by NRC to review the management, inspection, permitting, and enforcement activities performed under the license (IMC 2810, "Master Materials License Inspection Program.")

1.3 ISSUANCE CRITERIA FOR A MASTER MATERIALS LICENSE

A Master Materials License (MML) will be issued only to Federal organizations that successfully meet the criteria in 10 CFR 30.33 (and 10 CFR 40.32 or 10 CFR 70.31, as appropriate), and can demonstrate that it is qualified by training and experience to be granted an MML. This should include at a minimum:

- A centralized control of activities involving the use of byproduct materials under specific licenses of broad and limited scope. Normally, an applicant should have had a centrally-coordinated program for at least 5 years. (While recognizing the applicant does not have a Master Materials Program at the time of application, NRC will evaluate the applicant's past centralized program for elements fundamental to a Master Materials Program.)
- An acceptable regulatory performance record, based on NRC licensing and inspection of activities for the last 5 years. (NRC will compare the applicant's existing licensees' performance record with that of other similar licensees for the same time period.)
- A radioactive materials use program for the last 5 years requiring a variety of licenses and radionuclides and the operational flexibility to cover numerous uses, users, and locations typically in multiple NRC Regions.
- Either proposed or existing centralized Radiation Control Program, centralized 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. (NRC will compare these elements with similar elements for existing MML licensees.)
- Demonstrated readiness to assume the responsibilities of an MML licensee as evidenced by acceptable performance of the licensee's centrally-controlled program based on an operational readiness review conducted by NRC.

1.4 MASTER MATERIALS LICENSEE AUTHORIZATIONS

Master materials licensees may permit any byproduct material authorized in the MML or by regulation to be used by components of their organization. The applicant may also request authorization to issue permits for the possession and use of specifically licensed quantities of source and special nuclear material. The MML licensee, through its master radiation safety committee (MRSC), may issue permits for the possession and use of licensed materials in accordance with NRC regulations and licensee permit review and approval procedures and criteria established by the MML licensee's MRSC. To ensure licensing uniformity for MML equivalent NRC licensees and MML permittees, the MRSC-permitting criteria must be consistent with NRC regulations and licensing policies, procedures, and guides. To ensure inspection uniformity for equivalent NRC licensees and MML permittees, the MML must also establish an

INTRODUCTION AND PURPOSE OF REPORT

inspection program consistent with NRC regulations and inspection and enforcement policies, procedures, and guides.

The Letter of Understanding (LOU) for an MML will, among other things, identify certain exclusionary activities that unless specifically authorized on the license, the MML cannot conduct. Typically, the exclusions stated in an LOU provide that, unless specifically authorized, persons licensed under 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 (manufacture or distribution of items to persons exempt from licensing, items to general licensees, radioactive drugs for medical distribution, and sealed sources and medical devices containing sealed sources for medical distribution), 10 CFR Part 34 (radiography), 10 CFR Part 35 (medical use), 10 CFR Part 36 (irradiators), or 10 CFR Part 39 (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., medical use).

Note: Although an MML applicant can request authorization to use source or special nuclear materials requiring a specific license pursuant to 10 CFR Parts 40 or 70, if the applicant does not request this authorization, a specific condition will be added to the LOU that prohibits the MML from conducting these activities.

1.5 PRELICENSING CONFERENCE AND READINESS REVIEW

After NRC staff reviews an application for an MML and determines it is generally complete and responsive to NRC Form 313 and this standard review plan, NRC will schedule one or more prelicensing visits at the MML applicant's Radiation Control Program central office. The prelicensing visits will include a conference with the applicant's senior management and proposed MRSC members.

A prelicensing visit provides NRC staff an opportunity to:

- Better evaluate the applicant's proposed program and necessity for an MML;
- Meet with the applicant's senior management, proposed MRSC members, and other responsible staff;
- Convey the importance of the applicant's responsibilities;

- Discuss and agree on additional information and commitments;
- Review implementation details.

Prior to issuance of an MML, NRC will perform a readiness review to determine the operational and administrative readiness of the centrally-controlled Radiation Safety Program to assume the responsibilities of an MML licensee. In the readiness review, NRC will examine the operational and administrative performance of the centrally-controlled Radiation Safety Program as they pertain to: (1) management oversight, document management, and radiation control procedures; (2) status of the materials inspection program; (3) technical quality of inspections; (4) technical staffing and training; (5) technical quality of licensing actions; and (6) responses to incidents and allegations.

1.6 PROGRAMS NOT WARRANTING A MASTER MATERIALS LICENSE

If 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 Letter of Understanding (LOU), a description of the applicant's regulatory performance and centralized experience for the last 5 years, and a completed NRC Form 313 (see Appendix A), to the appropriate NRC Regional Office.

Complete all items in the application in enough detail for NRC to determine that the proposed equipment, facilities, training and experience, and Radiation Control Program satisfy regulatory criteria and are adequate to protect health and minimize danger to life, property, and the environment.

License applications are available for review by the general public in the NRC Public Document Rooms or electronically from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room). Therefore, do not submit proprietary information unless absolutely necessary. If submittal of such information is necessary, follow the procedure in 10 CFR 2.790. Failure to follow this procedure may result in disclosure of proprietary information to the public or substantial delays in processing the application. Also, do not submit personal information about individual employees unless necessary. Home addresses and telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by NRC.

The applicant should file the application in duplicate and retain a third copy for its licensing files. A Federal agency may apply for an MML for licensed activities at facilities or sites under its control anywhere in U.S. jurisdiction.

2.1 LETTER OF UNDERSTANDING

Where responsibilities are divided between the MML management and NRC, the division of responsibilities and requirements for coordination will be clearly defined and documented in a LOU between NRC and the applicant. The following are some examples of responsibilities that may be divided:

- Investigations of allegations;
- Enforcement activities;
- Permit termination and decommissioning;
- Use of byproduct material without specific regulations, policies, or guidance published by NRC;
- Waste incineration in accordance with 10 CFR 20.2002.

FILING AN MML APPLICATION

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

- Report to and notify NRC in accordance with regulatory requirements;
- Request authorization for exemptions to the regulations;
- Submit environmental assessment reports pursuant to 10 CFR Part 51;
- Submit decommissioning financial assurance in accordance with 10 CFR 30.35;
- Submit an emergency contingency plan for possession of licensed materials pursuant to 10 CFR 30.32(I)(1);
- 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 Letter of Understanding that defines and describes the division of responsibilities and the requirements for coordination between the applicant and NRC. (The final letter will be negotiated between NRC and the applicant before issuance of the MML.)

2.2 LICENSING 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, review, and coordination of licensing and inspection efforts. Management, review, and coordination experience will also be assessed during the readiness review.

NRC will evaluate the applicant's performance for the last 5 years using, at a minimum, the following indicators:

- Demonstrated proficiency at completing license applications;
- Timely and effective communications within the organization at all levels regarding Radiation Safety Program issues;
- Self-identification and correction of generic safety issues and regulatory compliance;
- Existence of cases brought to NRC's attention in which employee radiation safety concerns were not adequately addressed by the applicant;

- Inspections that resulted in:
 - no cited violations
 - violations cited in a notice of violation
 - violations considered for escalated enforcement;
- NRC findings with significant programmatic implications;
- Escalated enforcement cases that involved management oversight issues;
- Recurrent violations;
- Escalated enforcement cases that involved repeat violations;
- Timely, comprehensive, and effective response to violations.

Response from Applicant: Describe regulatory performance in licensing, inspection and centralized experience in management, review, and coordination of licensing and inspection efforts for the last 5 years.

2.3 FILING NRC FORM 313

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

As with the rest of the application, the applicant must complete all items in NRC Form 313 in enough detail for NRC to determine that the proposed equipment, facilities, training and experience, and Radiation Control Program satisfy regulatory criteria and are adequate to protect health and minimize danger to life, property, and the environment.

3 CONTENTS OF NRC FORM 313

The following comments apply to the indicated items of NRC Form 313:

Note: Throughout this document, descriptive items that will not be incorporated into the license as a requirement are indicated by a single asterisk (*). Applicants should clearly identify in the MML application information that constitutes binding commitments (tie down) as opposed to descriptive information. In some cases, descriptive information is needed only for the issuance of the license. In other cases, where changes may affect license conditions and authorizations, the applicant is instructed to notify NRC of the changes. This is to let NRC determine the licensing significance of the changes and whether an amendment is needed.

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

3.1 NRC FORM 313, ITEM 1: LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. Since MMLs have an indefinite expiration date, they are not renewed, and subitem C should always be blank.

3.2 NRC FORM 313, ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Only Federal agencies can apply for an MML. Corporations and private individuals may not apply for an MML. The address specified here should be the mailing address for official correspondence. This may be either the address of the Chairman of the Master Radiation Safety Committee (MRSC) or the Radiation Control Program Director (RPCD). Since an MML has an indefinite license period, if granted an MML, the applicant should inform NRC of any subsequent changes in its mailing address, either during the application process or if granted an MML.

3.3 NRC FORM 313, ITEM 3: LOCATION OF USE

The Federal Organization's Radiation Control Program and Federally-Controlled Fixed Sites

Specify the proposed location of the MML applicant's Radiation Control Program (RCP) Office by the street address, city, and state or other descriptive address (e.g., 5 miles east on Highway 10, Anytown, State). This should be the location of the docketed permittee files for the master materials licensee or where they can be readily retrieved for review. The licensee should maintain a list of locations by program code identical to the one used by NRC and provide an updated list to NRC.

Temporary Job Sites

If permittees will use radioactive material at temporary job sites, 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 NRC can include this information on the license.

Field Studies

If permittees will use radioactive material in field studies, NRC must specifically identify and authorize these activities on the MML. Appendix I of 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, NRC must approve these activities and specifically identify and authorize them on the MML.

Response from Applicant:

- Provide location of MML applicant's Radiation Control Program (RCP) Office.
- Confirm whether the docketed permittee files for the master materials licensee will be located at the RCP Office. (Identification of the actual location of all MML program documents and files is requested in Section 3.9.)
- Provide up to date list of permittee locations by program code.
- Identify if permittees 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 facility.

3.4 NRC FORM 313, ITEM 4: PERSON TO BE CONTACTED ABOUT APPLICATION

The applicant should specify the individual who will be the RCPD and provide his or her telephone number.

Response from Applicant: Identify the individual who will be the RCPD and provide his or her telephone number.

3.5 NRC FORM 313, ITEM 5: MATERIAL TO BE POSSESSED

While the major authorization in the MML will specify any byproduct 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 in curie, millicurie, etc. NRC must describe the authorized uses of these materials on the license and uses broad descriptive terms to do so. Therefore, the applicant should categorize this information into general areas of use, e.g., research and development activities, routine gauging activities, self-contained irradiators, instrument calibrators, and medical applications. If certain nuclides will be needed in much larger quantities than others, they should be listed separately in Items 5a, 5b, and 5c of NRC Form 313, rather than including these under the broad authorization for that class of licensed material (e.g., any byproduct material). Under Item 5b, describe by manufacturer and model number all large activity sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators) that are not registered in accordance with 10 CFR 32.210.

The maximum quantity for each individual nuclide and total cumulative possession authorized by the MML licensee for individual permittees should be commensurate with each permittee's needs, facilities, procedures, and 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 licensee is used to determine when a decommissioning funding or 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, or requiring consideration of the need for an emergency plan for responding to a release, in accordance with 10 CFR 30.32.

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 in curie, millicurie, etc., and general areas of use (e.g., research and development activities, routine gauging activities, self-contained irradiators, instrument calibrators, and medical applications).
- Separately identify nuclides that will be needed in much larger quantities.
- Identify by manufacturer and model number all large activity sealed sources used in devices (e.g., self-contained irradiators, panoramic irradiators, instrument calibrators) that are not registered in accordance with 10 CFR 32.210.
- Identify facilities or permittees that may possess quantities of materials requiring financial assurance or an emergency plan.

3.6 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 NRC's licensing program codes. 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 tied down in its license and letter of understanding, it would be necessary to 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 Master Radiation Safety Committee (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 NRC.

State if you intend to use 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.

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

Note: 10 CFR 51.22(c)(14)(v) identifies as a "categorical exclusion" (from the requirement to prepare an environmental assessment or impact statement) the issuance, amendment, or renewal of licenses for use of radioactive material for research and development and for educational purposes; however, this "categorical exclusion" 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 and NRC to perform an environmental assessment pursuant to 10 CFR Part 51. Field studies that do not deliberately release radioactive material into the environment, such as tagging of animals and penning them to prevent escape, may be eligible for a "categorical exclusion" pursuant to 10 CFR 51.22.

Response from Applicant:

- Explain why an MML is needed.
- Describe in general terms the purposes for which it will use licensed material.
- State if you intend to use 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 "categorical exclusion" in 10 CFR 51.22(c)(14) (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 NRC to determine whether a categorical exclusion is appropriate.

3.7 NRC FORM 313, ITEM 7: INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM

To assist the applicant in correctly identifying the individuals for the functional positions of senior management, Master Radiation Safety Committee, and Radiation Control Program Director, these sections include descriptive information on some of their duties and responsibilities that will also be discussed in Section 3.10, "Radiation Safety Program." These sections may also request information such as delegations of authorities and establishment of oversight programs under Item 7 of NRC Form 313 and discuss other aspects of program responsibilities under Item 10. The applicant should review the discussions in Items 7 and 10, as well as the checklist Appendix C concurrently, to understand the elements of an MML program.

3.7.1 SENIOR MANAGEMENT

The importance of the senior management's role in the development and functioning of an MML program cannot be overemphasized. NRC issues an MML to accommodate licensees 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; therefore, NRC grants significant authority to MML licensee management to develop and implement an appropriate Radiation Control Program. Consequently, MML licensee management should establish effective administrative controls, oversight, and provisions for organization and management, including management review, necessary to ensure safe operations.

When an MML is issued, the Federal Organization's senior executive management (the highest level of licensee management) is responsible for the regulatory activities authorized in the license. Since both the MML licensee and its permittees are governed by NRC requirements,

senior management and the Radiation Control Program need to assure the licensing, inspection, event response, and allegation resolution regulatory activities of the MML are performed in the same manner for its permittees as NRC does for its licensees. Consequently, MML licensee management should be knowledgeable of NRC requirements and policies.

The applicant should describe senior executive management oversight and processes used by the highest level of management to ensure adequate control over MML-licensed activities (see Section 3.10, "Radiation Safety Program"). To ensure safe operations and compliance with regulatory requirements, NRC expects such oversight to include senior management membership and active participation in regular meetings of the MRSC, as well as oversight of the RCPD and support staff and annual audits of the program.

MML licensees are required to establish an MRSC that represents management when reviewing and approving permit applications; therefore, senior executive management (highest level of licensee 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 license provisions, and permit conditions. (These delegations of authority are also addressed in Sections 3.10.6, "The Master Radiation Safety Committee," and 3.10.7, "The Radiation Control Program Director.") The MML licensee retains the ultimate responsibility for the conduct of licensed activities. It is also essential that the MML licensee devote sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the Radiation Control Program at all levels.

The application should include an organizational chart of the applicant's management structure depicting reporting paths and flow of authority. Include a statement empowering the MRSC by outlining its authority to oversee the licensed program and its responsibility for control and direction of the Radiation Control Program and the RCPD. Also state 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 3.10.

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 assure safe operations.
- 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 license provisions and permit conditions.

- Confirm and describe senior management commitment to devote sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the Radiation Control Program at all levels.
- Describe the senior management oversight and mechanisms used by management to ensure adequate control over MML-licensed 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 assure safe operations and regulatory compliance.

3.7.2 MASTER RADIATION SAFETY COMMITTEE

The MRSC not only has the authority to control and direct the centralized Radiation Safety Program, 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. MRSC provides guidance and information on the Radiation Control Program to the highest level of senior executive management, ensures that adequate resources are provided by licensee management, and provides oversight to the RCPD in developing, implementing, and maintaining the Radiation Control Program. The MRSC should ensure that the highest level of executive management is periodically given all relevant information regarding the Radiation Control Program, particularly when the highest level of management will make decisions that may affect the program.

Membership of the MRSC must include:

- A senior manager from the applicant's executive management organization, to serve as the Chairman and empowered with full authority to commit licensee resources to support the conduct of the MML;
- RCPD, who serves as the Executive Secretary of the MRSC;
- Manager from the applicant's finance organization;
- Managers capable of establishing RCP policies. These managers should be drawn from major division, department, or organizational elements that represent the permittee community.

Other members can include:

- Managers responsible for establishing and implementing major program activities under the MML;
- Managers who represent permitting and inspecting organizations;
- Representatives of occupationally-exposed workers.

CONTENTS OF NRC FORM 313

Note: All members of the MRSC should have the education, training, experience, and knowledge to address Radiation Control Program issues adequately.

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 executive secretary) in the event of his/her required absence;
- Vote.

The following are duties of the Executive Secretary of the MRSC, an assigned duty 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 and policies;
- Provide the committee with quarterly reports on the status of the program.

In addition, the Executive Secretary 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, allegation responses, and enforcement actions.

Response from Applicant:

- Describe the composition, duties, and functions of the MRSC.
- Identify the individual members of the MRSC by position title and job description*.

* The identities of the members of the Radiation Safety Committee are descriptive information. If there are significant changes to actual membership of the MRSC, i.e., functionally significant changes in position titles and job descriptions, you should notify NRC. 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.

CONTENTS OF NRC FORM 313

CONTENTS OF NRC FORM 313

- Describe how the applicant ensures that each MRSC member has the education, training, experience, and knowledge to address Radiation Control Program issues adequately.
- Identify the Chairman* of the MRSC
- Describe the duties of the MRSC Chairman and provide assurances that the chairman has full authority to commit licensee resources to support the conduct of the MML.
- Describe the duties of the Executive Secretary.

* The identity of the individual designated the Chairman of the MRSC is descriptive information and is not tied down in the license; however, if the Chairman of the MRSC changes, you should notify NRC.

3.7.3 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 Radiation Control Program with the assistance and support of the MRSC and senior executive management, serving as the Executive Secretary of the MRSC. The RCPD's position as Executive Secretary of the MRSC helps to ensure clear understanding of mission goals and precise communications between the MRSC and the RCP staff.

Executive management is obligated to select an RCPD who has sufficient training and experience to address all facets of the applicant's Radiation Control Program. 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 a Radiation Safety Program 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, 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*¹ designated as the RCPD.
- Provide documentation*¹ on the education, training, and experience demonstrating the individual designated as the RCPD is qualified to manage the RCP.

3.7.4 OTHER RADIATION CONTROL PROGRAM STAFF

The RCP professional staff should have the following qualifications:

- Sufficient education, training, and experience in the physical and/or life sciences;
- Bachelor’s degree, or equivalent training and experience;
- At least 40 hours 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.

Written job descriptions, readily 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-1246) 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.*²
- Describe procedures and criteria for ensuring that members of the RCP office staff are adequately qualified. (These procedures are part of the Radiation Control Program procedures generically addressed in 3.10.4, Regulatory Conformance.)

*¹ The information identifying the individual designated RCPD and his/her qualifications is descriptive information and is not tied down in the license. If the RCPD changes, you should notify NRC.

*² Listing the RPC staff positions is descriptive information and is not tied down in the license. If the number of RPC staff positions change or significant changes are made in job descriptions, you should notify NRC.

3.8 NRC FORM 313, ITEM 8: TRAINING AND EXPERIENCE FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

To meet the requirements of 10 CFR Part 19, applicants with special facilities such as large irradiators, iodination facilities, high dose rate remote brachytherapy (HDR) facilities, etc., must assure that site access training will be provided prior to assigning individuals to work in or frequent restricted areas.

Response from Applicant:

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

3.9 NRC FORM 313, ITEM 9: FACILITIES AND EQUIPMENT

To meet the requirements of 10 CFR 30.33(a)(2), applicants must describe facilities and equipment used by the RCP staff to facilitate day-to-day operations.

Response from Applicant:

- Provide location and description of all facilities used by the RCP staff to carry out its activities.*
- State in the application where the master or central permittee files and all other docketed and required files and records will be maintained.
- Provide a list and description of the uses of laboratory equipment such as counting systems, portable survey equipment, air monitoring, or other devices necessary for conducting the inspection of permittees.*

* The information on the locations, facilities and laboratory equipment are descriptive information and are not tied down 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 the applicant maintains the same level of coverage described in the application.

3.10 NRC FORM 313, ITEM 10, RADIATION SAFETY PROGRAM

The applicant should refer to Section 3.7 for additional discussion on the role and duties of senior management, the Chairman of the Master Radiation Safety Committee, Radiation Control Program Director, and Master Radiation Safety Committee in the Radiation Safety Program. Information such as delegations of authorities and establishment of oversight programs that are

part of the authorities and management of a Radiation Safety Program, may have been requested under Item 7 of NRC Form 313, while discussion of other aspects of program responsibilities are found under Item 10. The applicant should review the discussions in Items 7 and 10, as well as the checklist in Appendix C concurrently to ensure the information on the MML Radiation Safety Program is complete.

3.10.1 RADIATION CONTROL PROGRAM – AN OVERVIEW

The MML program used to establish central control over all elements of the NRC-regulated Radiation Safety Program and centrally manage the permitting/inspection licensed activities is called the Radiation Control Program (RCP). These licensed activities also include, but are not limited to, enforcement, event response, emergency response, and allegation resolution activities. Because the MML licensee and its permittees are governed by NRC requirements, the Radiation Control Program needs to assure that with respect to NRC-licensed materials, all these activities are performed by the MML licensee in the same manner for its permittees as NRC does for its licensees. Thus, the applicant should commit to implementing licensing and inspection programs in accordance with NRC criteria. As discussed in Section 3.10.4, “Regulatory conformance,” the applicant may adopt alternative program procedures, provided these procedures are described.

In order to meet the requirements in 10 CFR 30.33(a)(3) and ensure safe operations under the license, applicants for MMLs must have established administrative controls and provisions. These should include:

- Organization and management;
- Procedures;
- Recordkeeping;
- Material control and accounting;
- Management review.

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; recordkeeping requirements related to the program are in 10 CFR 20.2102. These requirements apply to an RCP.

In order for NRC to approve the MML application, it must include a complete description of the applicant’s RCP. In this section, that description should take the form of concise commitments and a narrative overview of the detailed program described in greater detail in other sections. Both the narrative overview and the more detailed documents describing the program should, as a minimum, address the following elements: program authorities and responsibilities, communications, quality control surveillance, program audits, procurement, staff selection and qualification, 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 and inspection program. These NRC guidance documents may in some cases be adopted in their entirety. Other NRC guidance documents may need to 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. If NRC guidance is used, the applicant must provide procedures to ensure that the program is updated as NRC guidance is changed, and that staff is trained in current NRC guidance.

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;
 - procedures;
 - recordkeeping;
 - material control and accounting;
 - management review.
- Describe the licensing and inspection program.

Note: While both the description of the written administrative control processes and the licensing and inspection program for the narrative overview of RCP need to be concise, they also need to be sufficient in detail, clarity and specificity to describe how management oversight for 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, etc.;

- Other considerations essential to the successful implementation of the RCP.

3.10.2 PREVIOUS LICENSES

When NRC issues an MML, it terminates all NRC licenses that will become permits issued under the regulatory control of the MML licensee. 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) or some types of licensees. In order for NRC to terminate the correct licenses, NRC must have a list of those licenses that will be incorporated into the MML program.

Response from Applicant: List the radioactive materials licenses the applicant wants to include in the MML.*

* The list of materials licenses to be included in the MML is descriptive information to assist NRC in accurately terminating licenses and is not tied down in the license.

3.10.3 MATERIAL CONTROL AND ACCOUNTABILITY

MML applicants should develop and maintain an effective inventory and accountability system, establishing procedures for properly transferring, controlling, and accounting for material throughout the applicant's organization, including its movement among facilities. The inventory and control system should also ensure that licensed possession limits are not exceeded. A successful program requires the dedication of sufficient staff and equipment. See NUREG-1556, Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope," for additional useful information on control and accountability.

Response from Applicant: Describe the inventory control and accountability system of licensed material.

3.10.4 REGULATORY CONFORMANCE

In order for NRC to approve the license, NRC must have a statement from the applicant's management that the applicant will follow NRC regulations. The applicant may use operational control levels that are more restrictive than NRC regulations; however, at a minimum, the applicant's requirements must be as restrictive as NRC's regulations.

The applicant should commit to following specific NRC guidance documents in implementing its licensing and inspection program. These NRC guidance documents may in some cases be adopted in their entirety. Other NRC guidance documents may need to 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, 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. Therefore, the applicant must provide procedures to ensure that the program is updated as NRC guidance is changed, and that staff is trained in current NRC guidance.

In order for NRC to approve the MML application, it must contain all policies, procedures, directives, and guides the applicant has developed and will use to manage its RCP pursuant to NRC regulations, policies and guides. (See Section 3.7.4, and the remainder of sections in 3.10 for discussions specific to staff qualification, administrative control, organizational, audit, permitting, inspection, enforcement, incident response, emergency response, and allegation policies, procedures, and guides that must be submitted.) The application must specify those NRC policies, procedures, and guides that the applicant will adopt in their entirety in its RCP. NRC will review the policies, procedures, and guides 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 need to be provided in their entirety. New guidance developed by the applicant also needs to be included its 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 guides developed and to be used to manage its RCP pursuant to NRC regulations, policies and guides.*¹
- Specifically identify those NRC policies, procedures, and guides that are adopted in their entirety into the RCP.*²

*¹ NRC will review the policies, procedures, and guides 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 guides are discussed in more detail in other sections, the documents associated with the management of these programs needs to be submitted in this section.

- If NRC guidance is used, provide procedures to ensure that the program is updated as NRC guidance is changed, and that staff is trained in current NRC guidance.

3.10.5 UPDATING OF RADIATION CONTROL PROGRAM DOCUMENTS

The RCP must have established 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 NRC for review and license amendment, if the document is specifically referenced in the license or causes a material change in the MML licensee's policies and procedures.

Response from Applicant: Describe the process for review and approval of changes to RCP procedures and documents.

3.10.6 MANAGEMENT SUPPORT AND RADIATION CONTROL PROGRAM STRUCTURE

An MML licensee authorizes the receipt, possession, distribution, use, transportation, transfer, and disposal of NRC-regulated radioactive material (e.g., byproduct (and source and special nuclear material, if requested)) at permittee locations. As discussed in Section 3.7.1, the applicant's senior executive management (the highest level of licensee management) is responsible for the appropriate Radiation Control Program. This includes Senior management's devoting sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the Radiation Control Program at all levels and delegating 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 license provisions, and permit conditions. The MRSC provides administrative control of all NRC-licensed radioactive material used by the licensee and its permittees.

For NRC to issue an MML, the applicant must demonstrate that it is financially and technically qualified to conduct an MML program effectively. This includes operating funds to support program needs such as the following:

- Staff travel necessary to conduct an effective permitting compliance program (including pre-permitting site visits, routine inspections, follow-up or special inspections, and responses to incidents and other emergencies);
- Instrumentation and other equipment to support the RCP;
- Administrative costs;
- Laboratory costs;
- Laboratory service;

CONTENTS OF NRC FORM 313

- Computer and/or word processing support;
- Preparation of correspondence;
- Office equipment;
- To meet the requirements in 10 CFR 30.38, the MML program must have financial assurance for decommissioning of its sites.

To meet the requirements of 10 CFR 30.33(a)(2), the RCP must be supported with sufficient staffing and technical expertise and should be located in the MML organization parallel with other comparable health and safety programs. The applicant's overall radiation management structure must ensure that the RCPD has access to the highest levels of MML management and some measure of financial and administrative control over permitting and inspection personnel.

The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency. The licensee should place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy. The lines of communication and administrative control between the users and the central office (RCPD) must be clearly drawn to provide authority over the staff and uniformity in inspection policy, procedures, and supervision.

The application must include 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.

Response from Applicant:

- Provide information that indicates the applicant has and will continue to provide sufficient operating funds to support the MML program needs.
- Describe the lines of communication and administrative control between the user and the RCPD.

3.10.7 RADIATION CONTROL PROCEDURES – ADMINISTRATIVE CONTROL PROCESSES

To meet the requirements in 10 CFR 30.33(a)(2), the applicant for MML must ensure safe operations under the license; therefore, applicants for MMLs must have established administrative controls and provisions. These should include:

- Organization and management;
- Procedures;
- Recordkeeping;

- Material control and accounting;
- Management review.

The applicant should develop and implement written administrative control processes. These processes should be clear, specific, and detailed enough to demonstrate that the applicant's management will adequately oversee program activities. They should be related to administrative controls and provisions listed above and as a minimum, they should address the following:

- Program authorities and responsibilities;
- Communications;
- Quality control surveillance;
- Program audits;
- Procurement;
- Staff selection and qualification;
- Information dissemination;
- Document control and retrieval;
- Other program elements essential to the successful implementation of the RCP.

Response from Applicant: Submit written administrative control procedures* related to the administrative controls and provisions listed above in sufficient detail, clarity and specificity to describe how management oversight for program activities will be carried out. As a minimum, they should address the following:

- Program authorities and responsibilities;
- Communications;
- Quality control surveillance;
- Program audits;
- Procurement;
- Staff selection and qualifications;
- Information dissemination;
- Document control and retrieval;
- Other program elements essential to the successful implementation of the RCP.

* The information provided in the written administrative control procedures is descriptive information and is not tied down in the license.

3.10.8 MASTER RADIATION SAFETY COMMITTEE

The authority of the MRSC is contained in the Delegation of Authority for the MRSC signed by the applicant's highest level management. Management's delegation of authority was discussed in Section 3.7.1, "Senior Management." The composition of the MRSC was discussed in Section 3.7.2, "The Master Radiation Safety Committee." The composition and responsibilities of the MRSC are documented in the MRSC's Charter. Both the MRSC delegation of authority and Charter are key documents in the establishment of an effective MML program.

Responsibilities of the MRSC 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 Office and the RCPD, and auditing the implementation of the RCP;
- Advising senior executive management of the results of the MRSC audits and program reviews;
- Ensuring adequate resources are provided to implement the RCP, including implementation of permittee Radiation Safety Programs;
- Ensuring 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 NRC Inspection Manual Chapter 1246 (IMC-1246);
- Maintaining records under the MML;
- Reviewing permit applications and recommending action to be taken by the Chairman or his designated representative;
- Meeting at least quarterly with the required quorum (i.e., Chairman, RCPD, and two-thirds of the remaining membership) to review the activities of the RCPD;
- 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 inspections are conducted to assess permittee compliance with the provisions of the NRC license, NRC regulations, and the specific permits;
- Establishing enforcement policies and procedures;
- Advising senior executive management and 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.

The application should include the organizational and procedural manuals that address each item above; the written delegation of authority for the MRSC; and its charter and quorum requirements (i.e., Chairman, 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 above.
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 the highest level of management empowering the MRSC by outlining its authority to oversee the licensed program and its responsibility for control and direction of the Radiation Control Program and the RCPD.
- Provide the Charter for the MRSC, documenting its composition and responsibilities.
Note: The Delegation of Authority and the MRSC Charter must state the MRSC’s authority to suspend or terminate activities based on poor performance or violation of safety standards and provide assurance of the chairman’s full authority to commit licensee resources to support the conduct of the MML.
- 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.

3.10.9 THE RADIATION CONTROL PROGRAM DIRECTOR

The authority of the RCPD is contained in the Delegation of Authority for the RCPD signed by the applicant’s highest level of management. Responsibilities of the RCPD may also be delegated by the MRSC. In order for NRC to approve the MML application, the application must include a copy of the written delegation of authority from the senior executive manager 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 the measure of administrative and financial control over permitting and inspection personnel.

The responsibilities and authorities of the RCPD include, but are not limited to, the following:

- Managing and controlling the RCP;
- Serving as the Executive Secretary of the MRSC;
- Conducting day-to-day operations of the RCP and issuing permits in accordance with procedures approved by the Chairman of the MRSC;
- Serving as the routine point of contact between the MML licensee and NRC for matters concerning the MML;
- Informing the MRSC and senior executive 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 senior executive manager to the RCPD.
- Provide a description of the RCPD'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.

3.10.10 PERMITTING AND INSPECTION STAFF

The MML licensee's permitting and inspection staff is responsible for the following:

- Providing guidance to licensee organizations in the preparation of requests for permits;
- Providing content of NRC generic communications to appropriate permittees in a timely manner;
- Reviewing permit applications for completeness and compliance with current regulations, policies, and guides;
- Preparing permits and forward to the MRSC (or delegate) for review and approval;

- Performing inspections to assess compliance with current licensee and NRC regulations, policies, guides, and provisions of the MML and specific permits;
- Preparing reports of inspection results and forward reports of non-compliance to the MRSC;
- Conducting technical assistance visits, as necessary;
- Conducting pre-licensing visits;
- Responding to incidents.

If the RCP staff are not co-located, the applicant should describe in detail how the staff will effectively manage the day-to-day operations of the RCP. The applicant should describe how it will accomplish the following:

- Respond to events at permittee facilities;
- Maintain uniformity of program implementation;
- Maintain daily communications;
- Ensure consistency of guidance provided to permittees;
- Provide training to RCP staff;
- Monitor and evaluate RCP staff performance.

Response from Applicant:

- Describe the duties of the permitting and inspection staff.
- If the RCP staff are not co-located, describe in detail how the staff will effectively manage the day-to-day operations of the RCP, and describe how it will accomplish the following:
 - respond to events at permittee facilities;
 - maintain uniformity of program implementation;
 - maintain daily communications;
 - ensure consistency of guidance provided to permittees;
 - provide training to RCP staff;
 - monitor and evaluate RCP staff performance.

3.10.11 RADIATION CONTROL PROGRAM INTERNAL PROCEDURES

In order to meet the requirements in 10 CFR 30.33, the RCP must establish written internal procedures* to ensure the following:

- MML satisfies NRC requirements and criteria;

- * The applicant must confirm it has written internal procedures that as a minimum address the functions addressed above, but it does not need to submit them with the application.
- Staff performs its duties as required;

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 functions required of the program.

In order for NRC to issue the license and monitor oversight of the MML, the RCP staff must 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, and enforcement actions.

Response from Applicant: Confirm that you have written internal procedures that, at a minimum, address the functions addressed above; however, these do not need to be submitted with the application.

3.10.12 MANAGEMENT AND MASTER RADIATION COMMITTEE AUDITS

The MRSC should be fully aware of the operations and activities of the RCP Office through frequent and routine meetings. The MRSC should conduct interactive management audits and evaluations of the RCP office's performance, including the RCPDs. Results of the MRSC's audit and program reviews should be reported to senior executive management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with NRC regulations and license conditions. An MML licensee should 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 adopted in advance of the audits, establishing criteria that will be used to determine acceptable versus unacceptable performance. Management policies and guidelines should be in place for reporting audits to senior executive management. In order to meet the requirements of 10 CFR 30.33(a)(3), inspectors must demonstrate competence in evaluating health and safety problems and in determining compliance with NRC regulations. Inspectors must demonstrate to supervisory personnel an understanding of regulations, inspection guides, and policies prior to conducting inspections independently. The MML should establish a system similar to NRC's qualification journal system found in IMC-1246.

Because NRC must ensure consistency between NRC and MML inspection programs, the RCPD or the inspection staff supervisor must conduct annual field evaluations of each inspector to assess performance and assure use of appropriate and consistent policies and guides.

In order for NRC to approve the MML application, it must contain a description of senior executive management oversight and the mechanisms used by senior executive management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's RCP. This oversight may include independent audits of the program, frequent meetings with the MRSC, and periodic site visits of selected permittees.

In order to meet the requirements in 10 CFR 30.33(a)(3), permit reviewers must demonstrate competence in reviewing applications for permits. In addition, permit reviewers must demonstrate an understanding of regulations, licensing policy and guidance directives, and permitting practices prior to reviewing and issuing permits independently. This should include an audit sampling each permit reviewer's actions to assess performance and assure appropriate and consistent policies and guides.

Response from Applicant:

- Provide the process* that describes senior executive management oversight and the mechanisms used by senior executive management to ensure awareness of NRC regulations, the provisions of the license, and the compliance status of the institution's RCP.
- Provide a copy* of the audit program for the senior executive management and the MRSC to audit the performance of the RCP office, 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 prior to 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 prior to reviewing and issuing permits independently.

* The process described in the first bullet and the copy of the audit programs are descriptive information and are not tied down in the license. You should notify NRC of significant changes to these programs.

3.10.13 PERMITTING PROCEDURES

In order for NRC to approve the MML application, it must include copies of its permitting procedures, policies, and guides. If the applicant commits to using NRC licensing procedures, policies, and guides, it may list those NRC documents used and provide only those licensee

documents that differ. The applicant must commit to updating its permitting guidance as it receives updates to NRC licensing guidance. The applicant should provide in its application specific timeliness goals for issuing permits and updating its licensing guidance as updates are received from NRC.

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

- Descriptions of isotopes and quantities to be used;
- Qualifications of persons who will use material;
- Ensuring that persons using material are either the MML's employees or the MML's contract employees;
- Facilities and equipment;
- Ensuring that facilities and sites are controlled by the MML's Federal agency;
- Operating and emergency procedures;
- Minimization of contamination.

To establish the basis for permitting actions, this information should clearly, completely, and accurately document the isotopes, forms, quantities, authorized uses, and permissive and restrictive conditions, and be readily available for audit during pre-permitting visits. Prior to 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 (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions. Compliance history should be considered when issuing new permits or modifications to existing permits.

Standard permit conditions identical to current NRC standard license conditions should be used to expedite and provide uniformity in the permitting process. Custom conditions may be developed, provided they are not less restrictive than any applicable NRC requirements and criteria.

To ensure consistency with NRC's licensing program, the MML applicant must maintain orderly files to allow efficient, accurate retrieval of information and documentation associated with the permitting program. The applicant should provide a copy of the administrative procedures to accomplish this.

Response from Applicant:

- Provide copies of permitting procedures, policies, and guides.

- If using NRC licensing procedures, policies, and guides, list them.
- Provide licensee documents that differ from NRC licensing procedures, policies, and guides.
- Describe standard permit conditions if they are not identical to current NRC standard license conditions, and indicate when custom conditions will be used.
- Provide specific timeliness goals for issuing permits and updating licensing guidance as updates are received from NRC.
- Describe document management procedures.

3.10.14 PROGRAM TO MINIMIZE CONTAMINATION AT PERMITTEE FACILITIES

In order for NRC to approve an MML application after August 20, 1997, the applicant must 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. All MML applicants for a new license and their permittees need to 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.

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.

3.10.15 PERMIT TERMINATION AND DECOMMISSIONING OF PERMIT ACTIVITIES

Permit termination and decommissioning were identified in Section 2.1, "Letter of Understanding," as an example of shared responsibilities between NRC and the MML. NRC's requirements for termination of byproduct material licenses are described in 10 CFR Parts 30, 40, and 70. The internal procedures that NRC staff follow to terminate a byproduct materials license are in NRC IMC 2605. The applicant may either provide its permit termination procedures or commit that it will terminate its permits in accordance with NRC regulations, policies, and guides as provided for in the LOU.

The NRC decommissioning procedures are contained in NRC IMC 2605 and the Decommissioning Handbook. The applicant must provide its own decommissioning procedures or commit that it will decommission permit facilities as described in NRC IMC 2605 and handbook as provided for in the LOU.

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

NRC retains its authority to review and approve decommissioning plans (DPs) on a case-by-case basis and in accordance with the guidance provided below. MML Permit termination and decommissioning procedures are subject to NRC regulations and should use Inspection Manual Chapter IMC 2605 and Nuclear Material Safety and Safeguards (NMSS) Decommissioning Handbook guidance to determine the appropriate decommissioning types.

For byproduct materials (Part 30 permittees), the MML must comply with the following notification and reporting directions:

Initiation of Decommissioning:

Permittees must notify the MML of changes in operating status in accordance with 10 CFR 30.36 (d) and the MML must notify NRC of all changes in operating status pursuant to the notification requirements in 10 CFR 30.36, unless the permittee's principal activities are limited to either; (1) possession of sealed sources with no history of leakage; or (2) possession of only radioactive isotopes with short half lives (less than 120 days). For all other principal activities, the notification must contain sufficient information for NRC to determine if a DP is needed and whether NRC needs to review and approve the permittee's plan.

Decommissioning:

Permittees must submit a DP in accordance with 10 CFR 30.36 (d), if required by paragraph (g)(1). The MML is required to transmit all DPs to NRC. If NRC determines a DP is required when the MML does not, the MML must either provide the DP or documentation supporting the MML determination. Simple decommissioning will be the responsibility of the MML. Unless notified to the contrary by NRC, the MML may review and approve DPs. NRC will maintain the authority to review and approve DPs on a case-by-case basis. Decommissioning actions that do not qualify for a categorical exclusion in accordance with 10 CFR 51.22 will, in all cases, remain the responsibility of NRC.

Request for extensions:

Permittees requesting to extend time periods established in 10 CFR 30.36 (d), in accordance with 10 CFR 30.36 (f), must submit such requests to the MML. The MML is required to transmit the request to NRC. Although these requests are not considered to be exemptions to the regulation, NRC will maintain the responsibility for reviewing requests and granting approvals.

Completion of Decommissioning and Termination of the Permit:

Upon completion of decommissioning, permittees must submit a request for permit termination in accordance with 10 CFR 30.36 (h). Permittees that elect to request an

alternative schedule for completion of decommissioning must submit the request to the MML in accordance with 10 CFR 30.36 (h). The MML is required to transmit the request to NRC. Upon completion of decommissioning, permittees must submit a completed Form 314 or equivalent, and a final survey report in accordance with 10 CFR 30.36 (j). NRC will maintain the authority to review and approve final survey reports on a case-by-case basis. The MML is required to submit a copy of the final survey report to NRC for those permittees that filed a DP in accordance with 10 CFR 30.36. NRC's decision to review and approve final survey reports will be based on the complexity of the decommissioning activities. In general, unless notified to the contrary by NRC, the MML may review and approve final survey reports.

Decommissioning Records

For the MML to meet the requirements of 10 CFR 30.51, permittees must keep records showing the receipt, transfer, and disposal of byproduct materials in accordance with 10 CFR 30.51. Permittees shall forward these records to the MML for storage until the MML is terminated. NRC will review MML records submitted by permittees on an annual basis to verify that permittee records meet the intent of 10 CFR 30.51.

The MML application must state that the applicant will provide copies of permit termination requests and permit decommissioning plans to NRC. The application must also state that specific permit decommissioning plans will be submitted, when requested by NRC due to interest in a specific site, to NRC for review and approval prior to approval by the MML RCP. NRC will maintain the authority to review and approve decommissioning plans on a case-by-case basis; however, in general, unless requested by NRC, the MML may review and approve decommissioning plans.

Response from Applicant:

- Provide permit termination procedures or commit that permits will be terminated in accordance with NRC regulations, policies, and guides, as provided for in the LOU.
- Provide decommissioning procedures or commit that permit facilities will be decommissioned as described in NRC IMC 2605 and handbook, as provided for in the LOU.
- Confirm that copies of permit termination requests and permit decommissioning plans will be provided to NRC.
- Confirm that specific permit decommissioning plans will be submitted to NRC, when requested, for review and approval prior to final approval by the MML RCP.

3.10.16 FINANCIAL ASSURANCE

In order to meet the requirements in 10 CFR 30.35, the applicant must describe its program for establishing and maintaining adequate funds to decommission all its permitted facilities. In cases involving multiple independent sites under a single license, the financial assurance and, if

required, the decommissioning funding plan would have to delineate procedures and cost estimates for each facility or site. The MML 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. NRC uses NUREG-1336, Rev. 1 and Policy and Guidance Directive FC 90-2.

Response from Applicant:

- Describe how the decommissioning financial assurance requirements described in 10 CFR 30.35 will be met.
- Describe the program that ensures adequate funds to decommission all its permitted facilities are established and maintained.

3.10.17 INSPECTION AND ENFORCEMENT PROCEDURES

In order to meet the requirements in 10 CFR 30.33, the RCP Office (RCPD and/or staff) must maintain an inspection program adequate to assess permittee compliance with NRC regulations, MML requirements, and permit conditions. To ensure consistency between NRC and the MML applicant's inspection and enforcement programs, the RCPD must maintain statistics adequate to permit program management to assess the status and results of the inspection program on a periodic basis. This statistical information must include the number of inspections conducted, the number overdue, the length of time overdue, and priority categories. This information must be readily available for NRC to review. The RCPD must prepare a semiannual inspection plan that includes the number of inspections to be performed, the level of inspection experience required for the individual permits, identification of special needs, and periodic status reports for completion of the inspections within the plan's schedule. NRC will also use this information in monitoring its oversight of the MML program.

The MRSC must either establish an inspection priority system identical to NRC's in Manual Chapter 2800, or the MML management may request authorization from NRC through the MML's licensing Region to alter the inspection frequency to meet the MML's priorities. The specific frequency of inspections should be based upon the potential hazards from permitted operations, e.g., broad scope permits, major processors, and industrial radiographers must be inspected approximately annually, and smaller or less hazardous operations may be inspected less frequently.

The MML must have inspection guides consistent with current NRC guidance and provide technical guidance in the inspection of permitted programs. To ensure this 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, assuring exit interviews with management, and issuing

appropriate notification of violations or health and safety problems. Independent measurements must be sufficient in number and type to ensure the permittee's control of materials and to validate the permittee's measurements, pursuant to 10 CFR 30.33. In addition, the RCP must have access to laboratory support capability to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, and other necessary analyses on a priority established by the RCP.

Procedures should be established for maintaining permittee compliance histories. Briefing of supervisors or the senior inspector should be performed upon return from inspections.

For MML facilities with separate permitting and inspection staffs, procedures should be established for feedback of inspection information to permit reviewers.

Although the documentation format may vary depending on the type of inspection or inspection findings (reference NRC IMC 2800 regarding use of inspection records versus formal inspection reports), findings of inspections must be documented for future use by MML 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 measurements made by the inspector. Inspection documents forwarded to the permittee must describe the scope and results of the inspection, including identification of any items of noncompliance, health and safety issues, and areas of permittee's program that should receive special attention by permittee management. Corrective actions planned or taken by the permittee for items of noncompliance must be documented and retained in the permittee file for future evaluation by MML inspectors.

The applicant should establish an enforcement program to ensure consistent assessment of the regulatory and safety significance of violations. To ensure uniform enforcement policies between MML permittees 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 its methods used for assessing the severity of violations and taking enforcement actions for the more severe violations. It should also include referral of Severity Level I, II and III violations to NRC for 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 this section.
- 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.

3.10.18 INCIDENT/EMERGENCY RESPONSE PROCEDURES

In order for NRC to approve the MML application, the application must provide the RCP Office procedures for responding to spills, fires, release or loss of material, overexposures, and contamination of personnel at permittee facilities. The applicant must describe its provisions for immediate response and handling of such incidents, including off-hours notification of appropriate RCP Office staff, state and local authorities, and, when applicable, NRC. The plan must define the oversight responsibilities of the RCP management and staff, including actions to be taken by permittees. The plan must be specific as to persons responsible for initiating response actions, conducting operations, and performing cleanup. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the permittee, the permittee staff should understand the actions that must be taken to secure the area and respond to immediate hazards, and whom they should contact. 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. The MML applicant must identify these permittees and submit copies of the approved emergency plans required in 10 CFR 30.32(i)(1). If applicants determine that they need an Emergency Plan, they should submit a detailed plan pursuant to 10 CFR 30.32(i). Guidance for this submittal is contained in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities."

The applicant's RCP Office emergency response procedures must require that inquiries be promptly made to evaluate the need for onsite review of events. Onsite review of events must be initiated promptly for incidents that are required to be reported to NRC in fewer than 30 days. For those incidents not requiring reporting to NRC in fewer than 30 days, review of events must be made during the next scheduled inspection. Onsite investigations must be made promptly of non-reportable incidents that could be relevant to other permitted operations (e.g., equipment failure, improper operating procedures) and those incidents that may be of significant public interest and concern.

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., NRC and Department of Health and Human Services, Food and Drug Administration). This includes compliance with 10 CFR Part 21 and other applicable regulations.

Response from Applicant:

- Provide RCP Office incident/emergency response procedures as described above, including, but not limited to, the following for both work-hour and off-hour incidents:
 - 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 people and property at permittee facilities;
 - area and permittee facility access control and security;
 - mechanisms and responsibilities for notifying RCP Office 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;
- Provide appropriate Emergency Plan(s), according to 10 CFR 30.32(i)(1), if applicable.

3.10.19 PROCEDURES FOR HANDLING ALLEGATIONS

Handling allegations will be a shared responsibility included in the LOU. In order to meet the requirements in 10 CFR 30.7, the MML applicant must establish a program for responding to employee radiation safety concerns which provides for timely investigation and response to these concerns and address prevention of reprisals against employees for expressing their radiation safety concerns to management. The program should include a strong statement encouraging employees to bring forward any perceived radiological safety issues. The program must include training that clearly articulates the right of any employee to raise his or her radiation safety concerns directly to NRC, if he or she so desires.

Allegations received by NRC staff from licensed personnel may be investigated by NRC or referred to the MRSC for investigation.

The application must specify whether the applicant will follow NRC's procedures for handling allegations (Management Directive 8.8) or include equivalent procedures for handling allegations that are referred to the MRSC.

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 MRSC.
- Provide procedures for handling and documenting employee concerns, including a description of the training that will be provided to all employees to ensure they understand their right to contact NRC directly about radiation safety or regulatory issues.

3.11 NRC FORM 313, ITEM 11: WASTE MANAGEMENT

To assure the applicant will meet the waste disposal requirements in 10 CFR Part 20, the applicant must describe the methods its permittees will use for disposal of radioactive waste. The following disposal methods will be authorized:

- Transfers to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with 10 CFR 20.2001(a);
- Decay-in-storage;
- Disposal of materials that contain radioactivity from hydrogen-3 and carbon-14 in scintillation counting media and in animal tissue in concentration of 0.05 microcurie or less per gram, subject to certain restrictions stated in 10 CFR 20.2005;
- Release of radioactive materials into air and water in conformance with 10 CFR 20.1302 and 20.2003.

Other disposal methods must be specifically addressed in the application. This may include, but is not limited to, treatment or disposal by incineration, land burial, or consolidation of waste from multiple permittee facilities for subsequent disposal.

The applicant must 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 prior to January 28, 1981, to bury radioactive materials pursuant to 10 CFR 20.304.

Response from Applicant:

- Describe the methods permittees will use for 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 prior to January 28, 1981, to bury radioactive materials pursuant to 10 CFR 20.304.

3.12 NRC FORM 3131, ITEM 12: LICENSE FEES

No application fees, license fees, amendment fees, approval fees, or inspection fees are required for a U. S. Government Agency; however, in accordance with 10 CFR 171.16(d), an annual fee will be assessed. There may be an additional annual fee for each Sealed Source Device Registration the MML has.

4 AMENDMENTS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application that was included in the license tie-down condition is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The licensee requires an amendment to change the scope of the program. In addition, the licensee must notify NRC when changing the Radiation Control Program Director or changing the Chairman of the Master Radiation Safety Committee.

Applications for license amendment must do the following:

- Be sure to use the most recent guidance in preparing an amendment;
- Submit, in duplicate, either an NRC Form 313 or a letter requesting amendment;
- Provide the license number;
- Provide a complete and up-to-date application, if many outdated documents are referenced or there have been significant changes in regulatory requirements, the licensee's organization, or the Radiation Control Program. Alternatively, describe clearly the exact nature of the changes, additions, and deletions.

Appendix A

United States Nuclear Regulatory Commission Form 313

NRC FORM 313 (8-1999) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40	U. S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120	EXPIRES:08/31/2002		
<h2 style="margin: 0;">APPLICATION FOR MATERIAL LICENSE</h2>		Estimated burden per response to comply with this mandatory information collection request 7.4 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 Records Management Branch (T-8 E8), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@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, 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.					
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U. S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001		IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN. SEND APPLICATIONS TO: MATERIALS LICENSING SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351			
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO: LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U. S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415		ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, 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 SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-8064			
ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: SAM NUNN ATLANTA FEDERAL CENTER U. S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORSYTH STREET, S.W., SUITE 23T85 ATLANTA, GEORGIA 30303-8931					
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) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)				
3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED		4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION TELEPHONE NUMBER			
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.					
5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED				
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS				
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.				
11. WASTE MANAGEMENT.	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:70%; border-bottom: 1px solid black;">FEE CATEGORY</td> <td style="width:30%; border-bottom: 1px solid black;">AMOUNT ENCLOSED \$</td> </tr> </table>			FEE CATEGORY	AMOUNT ENCLOSED \$
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, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 82 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.					
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	

Appendix B

Sample Master Material License

Sample Master Material License

The Master Materials License authorizes the use of byproduct material in any form and as needed or limited to some maximum quantity. It authorizes the licensee to possess and use this material for generic categories of use requested in the application and to issue permits to licensee organizational activities for these authorized uses at licensee facilities. The license must specifically authorize the following items or the licensee is excluded from these uses:

- Conducting tracer studies in the environment involving direct release of byproduct material;
- Receive, acquire, own, possess, use, transfer, or import devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials;
- Conduct activities that require a specific license issued by the Commission under Part 32, 43, or 35 of Title 10 of the Code of Federal Regulations;
- Possess and use source material;
- Possess and use special nuclear materials;
- Conduct research on human subjects using source, special nuclear material, or the radiation from an NRC licensed utilization facility;

Because of all the possible variations involved in a Master Materials Program, the license conditions are uniquely developed for each master materials license. The following sample licenses provide common authorizations and license conditions that should be applicable to each master materials license, but does not constitute a complete master materials license.

Research License Conditions

- The Master Radiation Safety Committee shall assure that all uses of byproduct material on human research subjects are authorized and performed in accordance with the requirements in 10 CFR 35.6.
- This license does not authorize the use of source material, special nuclear material, or radiation from an NRC licensed utilization facility on human subjects.

A sample license appears on the following pages.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Department of the Federal Government Federal Radiation Safety Committee 2. Washington, D.C. 23455	In accordance with application dated January 1, 1998 3. License number 99-12345-01 4. Expiration date Indefinite 5. Docket No. 030-11111 Reference No.
--	---

6. Byproduct, source, and/or special nuclear material A. Any byproduct material B. Any source material C. Special nuclear material	7. Chemical and/or physical form A. Any B. Any C. Any	8. Maximum amount that licensee may possess at any one time under this license A. As needed B. As needed C. As needed; however, quantities for any site or permit authorized by the Federal Radiation Safety Committee shall not exceed the critical mass quantities as determined by the procedures specified in 10 CFR, Part 150.11(a)
---	--	---

9. Authorized Use:
 A., B., and C. For uses authorized by the Master Radiation Safety Committee as described in its application dated January 1, 1998, including, but not limited to the following:

- (1) Medical use defined in 10 CFR Part 35.
- (2) Research and development as defined in 10 CFR Part 30.
- (3) Radiography as defined in 10 CFR Part 34.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-12345-01

Docket or Reference Number
030-11111

CONDITIONS

10. Licensed materials may be used at Department of the Federal Government facilities by Department of the Federal Government personnel as authorized by permits issued by the Master Radiation Safety Committee.
11. Licensed materials may only be used by, or under the supervision of, individuals designated by the Master Radiation Safety Committee.
12. This license does not authorize the use of source material, special nuclear material, or radiation from an NRC licensed utilization facility on human subjects.
13. Department of the Federal Government requirements, policies, and directives governing the use of licensed radioactive materials must be consistent with the Nuclear Regulatory Commission's regulations.
14. The Master Radiation Safety Committee shall assure that all uses of byproduct material on human research subjects are authorized and performed in accordance with the requirements in 10 CFR 35.6.
15. The Master Radiation Safety Committee shall submit requests for approval to the Nuclear Regulatory Commission for exemptions from the Commission's regulations.
16.
 - A. The licensee shall require permittees to conduct a physical inventory every six months to account for all sources and/or devices received and possessed under their respective permits.
 - B. The licensee shall require that permittees maintain records of physical inventories for five years from the date of each inventory. Records shall include the quantities and kinds of licensed material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.

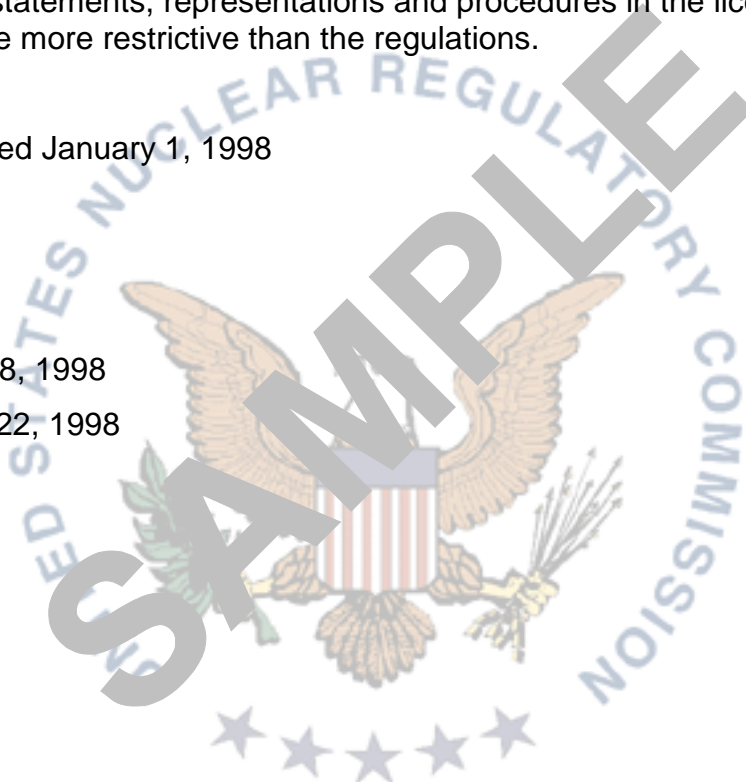
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-12345-01Docket or Reference Number
030-11111

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

A. Application dated January 1, 1998

B. Letters dated:

- (1) January 28, 1998
- (2) February 22, 1998



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

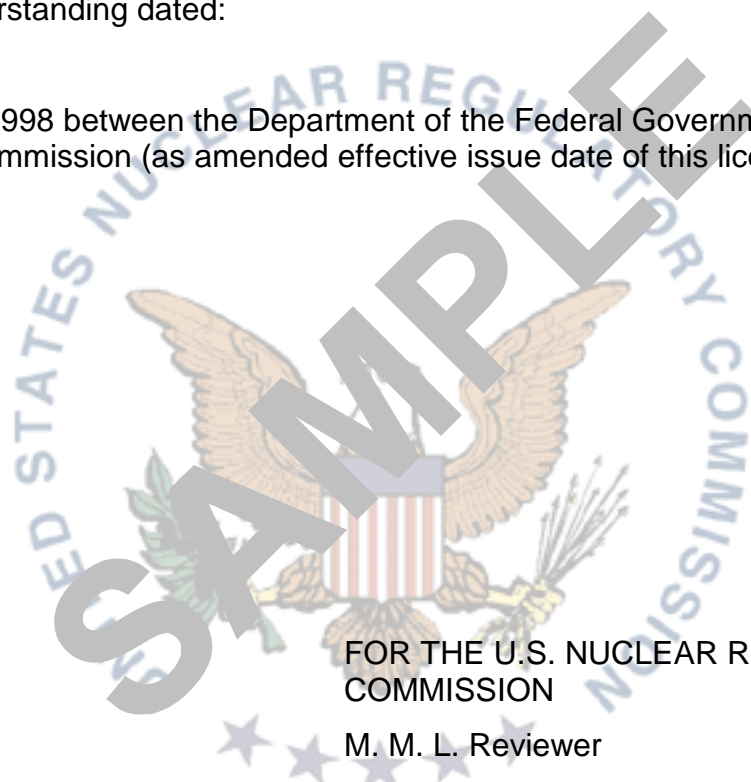
License Number
99-12345-01

Docket or Reference Number
030-11111

16. continued

C. Letter of Understanding dated:

February 22, 1998 between the Department of the Federal Government and the Nuclear Regulatory Commission (as amended effective issue date of this license).



FOR THE U.S. NUCLEAR REGULATORY
COMMISSION

M. M. L. Reviewer

DATE _____

BY _____

Region X, Division of Nuclear Materials Safety
111 Nuclear Way
Atomic City, ST 33333

Appendix C

Checklist for License Application

MASTER MATERIALS LICENSE APPLICATION CHECKLIST

I. Applicant Information

Applicant Name:	Application Date:
-----------------	-------------------

License No.:	Docket No.:	Mail Control No.:
--------------	-------------	-------------------

Mailing Address:

Point of Contact:

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

II. Issuance Criteria for a Master Materials License (1.3)

Item	Criteria	Yes	No
1.	Applicant meets the requirements of 10 CFR 30.33?		
2.	Applicant currently employs a centralized program to control activities involving the use of byproduct materials under specific licenses of broad scope and limited scope? Program in place for ____ years.		
3.	Applicant has an acceptable regulatory performance record, based on NRC licensing and inspection of prior activities for the last 5 years?		
4.	Applicant's use of licensed material for last 5 years has required a variety of licenses and radionuclides, and the operational flexibility to cover numerous uses, users, and locations in multiple locations (typically multiple NRC Regions)?		

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Item	Criteria	Yes	No
5.	Applicant's proposed or existing centralized Radiation Control Program, centralized 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 the applicant proposed to assume responsibility for permitting and inspecting?		
6.	Applicant demonstrated readiness to assume the responsibilities of an MML licensee as evidenced by acceptable performance during the operational readiness review of the licensee's centrally-controlled program?		

NOTE: For each item described above, briefly describe the basis for the decision to check the yes or no column:

Item	Assessment

MML Applicant: _____

Mail Control No.: _____

III. Prelicensing Conference and Readiness Review (1.5)

Prelicensing Scheduled Date(s)			
Conference(s) Conducted			
Readiness Review Scheduled Date			
Readiness Review Completed			
	Acceptable	Unacceptable	Weak
Operational and administrative performance of the centrally-controlled Radiation Safety Program for:			
1. Management oversight, document management, and radiation control procedures;	_____	_____	_____
2. Status of the materials inspection program;	_____	_____	_____
3. Technical quality of inspections;	_____	_____	_____
4. Technical staffing and training;	_____	_____	_____
5. Technical quality of licensing actions; and	_____	_____	_____
6. Responses to incidents and allegations.	_____	_____	_____

NOTE: Attach a copy of the prelicensing visit and readiness review reports.

Comments:

MML Applicant: _____

Mail Control No.: _____

IV. Review of Application (2.0)

A. Letter of Understanding (2.1)

Letter of Understanding Issues	Yes	No
Applicant submitted proposed LOU?		
LOU adequately addresses all required issues?		
– Investigations of allegations	___	___
– Enforcement activities	___	___
– Permit termination and decommissioning	___	___
– Use of byproduct material for which NRC has not published guidance	___	___
– Waste incineration	___	___
– Reporting and notification	___	___
– Exemptions to regulations	___	___
– Environmental assessment reports	___	___
– Decommissioning financial assurance	___	___
– Emergency contingency plans	___	___
Others:		

Comments on the LOU:

MML Applicant: _____

Mail Control No.: _____

Comments on the LOU:

B. Licensing and Enforcement History (2.2)

The reviewer should contact other license reviewers both inside and outside the Region to discuss the applicant’s historical proficiency at completing license applications. The reviewer should also review the inspection history for the applicant’s specific licenses and compare the results of these inspections, by program code, to the total NRC licensee population.

Applicant Performance Indicators (last 5 years)	Yes	No
Proficient completion of license applications?		
Timely and effective communication at all organizational levels on Radiation Safety Program issues?		
Self identification and correction of generic safety issues and regulatory compliance?		
Significant number of employee safety concerns expressed to NRC that were not adequately addressed by applicant?		
Inspection history indicative of good performer based on number of inspections that resulted in no cited violations, notices of violations, or escalated enforcement?		
Frequent NRC findings with significant programmatic implications?		
Number of escalated enforcement cases that involved management oversight issues significant?		
Number and nature of recurrent violations significant?		
Number of escalated enforcement cases that involved repeat violations significant?		
Responses to violations are timely, comprehensive, and effective?		

Comments on applicant licensing and inspection performance:

MML Applicant: _____

Mail Control No.: _____

Item	Yes	No
Applicant specified adequate RCPO address?		
Applicant indicated location of docketed permittee files for the master materials licensee is different from location of RCP Office? (The actual location should be provided in Section 3.9.)		
Applicant specified locations of all its proposed permittees?		
All locations are under the control of the applicant's Federal control? (Check for consistency with response to Section 3.10.2.) (If no, describe in the comments section and coordinate with the Office of the General Counsel before issuing the MML.)		
Applicant identified facilities designed or established for special uses? (If yes, briefly describe facilities in comments section and confirm appropriate training and experience information is provided in Section 3.8.)		
Applicant will authorize permittee use at temporary job sites? (If yes, briefly describe types of use in comments section.)		
Applicant will use radioactive material in field studies? (If yes, briefly describe types of use in comments section and coordinate to see if an environmental assessment is needed prior to issuance of the MML.)		
Applicant identified 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 facility. (If yes, describe in the comments section and coordinate with the Office of the General Counsel before issuing the MML.)		

Comments on Locations of Use:

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

D. NRC Form 313, Item 4: Person to be Contacted About Application (3.4)

Item	Yes	No
Applicant specified point of contact?		
Applicant specified point of contact's telephone number?		

E. NRC Form 313, Item 5: Material to be Possessed (3.5)

Items for Material to be Possessed	Yes	No
Applicant requested possession of byproduct material?		
Applicant requested possession of source material?		
Applicant requested possession of special nuclear material?		
Applicant adequately described each radionuclide class by chemical or physical form, quantity in curie, etc.?		
Applicant requested possession of radionuclides to be listed as specific line items? (If yes, describe in comments section.)		
Applicant's request categorized into general areas of use?		
Applicant described uses by individuals other than the applicant's employees or contract employees? (If yes, describe in the comments section.)		
Applicant described facilities or permittees that may possess quantities of licensed materials requiring financial assurance (10 CFR 30.35)? (If yes, describe in comments section.)		
Applicant described facilities or permittees that may possess quantities of licensed materials requiring an emergency plan (10 CFR 30.32)? (If yes, describe in comments section.)		

Comments on Material to be Possessed

MML Applicant: _____

Mail Control No.: _____

F. NRC Form 313, Item 6: Purpose of Use of Licensed Material (3.6)

Items on Purpose of Use of Licensed Material	Yes	No
Applicant described, in general terms, purposes for which it will use licensed material?		
Applicant explained why it needed an MML?		
The uses specified are consistent with the applicant's prior licensed activities?		
The uses specified are categorized in a classification scheme similar to NRC's licensing program codes?		
Applicant included a list of total possession limits for each category of use requested?		
Applicant requested possession and use of licensed materials which should be subject to a separate license (e.g., authorization to manufacture or commercially distribute license material)? (If yes, describe in comments section.)		
Applicant has permittees that desire to perform field studies? (If yes, describe in comments section and coordinate with the Office of the General Counsel prior to issuance of the MML.)		
Applicant desires to authorize field studies that are not eligible for the categorical exclusion pursuant to 10 CFR 51.22? (If yes, describe in comments section and coordinate with the appropriate NRC Offices to see if an environmental assessment is needed prior to issuance of the MML.)		

Comments on Purpose of Use of Licensed Material

MML Applicant: _____

Mail Control No.: _____

G. NRC Form 313, Item 7: Individuals Responsible for the Radiation Safety Program (3.7)

Senior Management (3.7.1)	Yes	No
Applicant's management controls and oversight are adequate to ensure that permitted activities are properly conducted?		
Applicant's senior management have established administrative controls and provisions relating to organization and management, including management review necessary to assure safe operations?		
Senior management has delegated, in writing, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct MML personnel at all levels regarding NRC regulations, MML license provisions, and permit conditions?		
Applicant's senior management has devoted sufficient financial resources (i.e., funds, equipment, personnel, materials) to support the Radiation Control Program at all levels?		
The applicant described the senior management oversight and mechanisms used by management to ensure adequate control over MML licensed activities?		
Senior management oversight activities include: <ul style="list-style-type: none"> - Membership and active participation in MRSC meetings - Oversight of RCPD and support staff - Annual audits of the program to assure safe operations and regulatory compliance 	___ ___ ___	___ ___ ___
The applicant submitted an organization chart depicting its management structure, reporting paths, and flow of authority?		

Comments on Senior Management

MML Applicant: _____

Mail Control No.: _____

Master Radiation Safety Committee (3.7.2)	Yes	No
<p>The applicant's description of its MRSC indicates that:</p> <ul style="list-style-type: none"> - It functions to provide guidance and information on the RCP to senior executive management - It ensures that adequate resources are provided by management - It provides oversight to the RCPD in the development, implementation, and maintenance of the RCP 	<p>___</p> <p>___</p> <p>___</p>	<p>___</p> <p>___</p> <p>___</p>
<p>MRSC membership includes:</p> <ul style="list-style-type: none"> - A senior manager from the executive management organization to serve as the Chairman - Managers from major divisions or organizational elements that represent the permittee community that are capable of establishing RCP policies - The RCPD who serves as the Executive Secretary - A manager from the applicant's finance organization - Managers responsible for establishing and implementing major program activities - Managers that represent permitting and inspecting organizations - Representatives of occupationally exposed workers 	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>
<p>The applicant identified all MRSC members by position title and job description?</p>		
<p>The applicant's procedures to ensure that each MRSC member has the education, training, experience and knowledge necessary to address Radiation Control Program issues are adequate?</p>		
<p>The applicant identified the Chairman of the MRSC?</p>		
<p>The applicant provided assurances that the chairman has full authority to commit licensee resources to support the conduct of the MML?</p>		
<p>The applicant provided documentation that the individual is qualified to chair the committee?</p>		

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Master Radiation Safety Committee (3.7.2)	Yes	No
<p>The MRSC Chairman is empowered to:</p> <ul style="list-style-type: none"> - 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 executive secretary) when the chairperson is not present - Vote 	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>
<p>Description of the Executive Secretary's duties indicates this individual:</p> <ul style="list-style-type: none"> - Serves as a liaison between the MRSC and the RCP staff - Informs the Chairperson of staff commitments and resources - Assists the Chairperson in preparing the agenda - Advises the committee of current regulations, and proposed changes in NRC regulations and policies - Provides the committee with quarterly reports on the status of the program .. - Prepares an annual audit report including overall conduct, result of the program performance compared to regulatory requirements and commitments, review of permitting actions, inspection reports, and enforcement actions 	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>	<p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p> <p>___</p>

Comments on Master Radiation Safety Committee

MML Applicant: _____

Mail Control No.: _____

Radiation Control Program Director (3.7.3)	Yes	No
RCPD identified?		
RCPD education, training, and experience described?		
RCPD's education, training, and experience adequate?		
RCPD has management experience in large radiation safety program?		

Comments on RCPD:

Other RCP Staff (3.7.4)	Yes	No
Applicant provided a list of the RCP office staff positions?		
– The list included a job title for each position?	___	___
– The list included a job description for each position?	___	___
– The list included the number of individuals for each position?	___	___
Applicant provided procedures and criteria for ensuring that members of the RCP office staff are adequately qualified?		
– Procedures are adequate?	___	___
– Criteria are adequate?	___	___

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Other RCP Staff (3.7.4)	Yes	No
Applicant's requirements for professional staff qualifications include: <ul style="list-style-type: none"> – Sufficient education, training, and experience in the physical and/or life sciences? – Bachelor's degree, or equivalent training and experience? – At least 40 hours training in: <ul style="list-style-type: none"> ▶ the safe handling of radioactive materials? ▶ the characteristics of ionizing radiation? ▶ units of radiation dose and quantities? ▶ radiation detection instrumentation? ▶ 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? 	_____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____
Applicant provided training and experience guidance for staff members whose primary duties include reviewing/issuing permits or conducting inspections?		
<ul style="list-style-type: none"> – It was adequate? 	_____	_____
<ul style="list-style-type: none"> – It required staff to meet training qualifications equivalent to NRC license reviewers and inspectors (NRC Inspection Manual Chapter (IMC-1246))? ... 	_____	_____

Comments on Other RCP Staff

MML Applicant: _____

Mail Control No.: _____

H. NRC Form 313, Item 8: Training and Experience for Individuals Working in or Frequenting Restricted Areas

Training and Experience Items (3.8)	Yes	No
Applicant uses licensed materials at special use facilities?		
Applicant's special use facilities require site access training?		
Applicant described training and experience required of individuals who work at special use facilities?		
Applicant's training and experience requirements adequate?		

Comments on Training and Experience Requirements for Special Use Facilities

I. NRC Form 313, Item 9, Facilities and Equipment

Facilities and Equipment (3.9)	Yes	No
Applicant listed the location of all facilities used by the RCP staff to carry out its activities?		
Applicant described all facilities used by the RCP staff to carry out its activities?		
Applicant stated where the master or central permittee files and all other docketed and required files and records will be maintained?		
Applicant provided a list of laboratory equipment or other devices necessary for conducting the inspection of permittees?		
Applicant described the uses of laboratory equipment or other devices necessary for conducting the inspection of permittees?		

MML Applicant: _____

Mail Control No.: _____

Facilities and Equipment (3.9)	Yes	No
The laboratory equipment or other devices necessary for conducting the inspection of permittees were adequate in:		
– Number	___	___
– Function	___	___
– Availability	___	___
– Other considerations (describe in comments section)	___	___

Comments on Facilities and Equipment

J. NRC Form 313, Item 10, Radiation Safety Program

Radiation Control Program – An Overview (3.10.1)	Yes	No
Applicant provided narrative overview description of the RCP?		
The description of the RCP included a overview description of centralized administrative controls and provisions for:		
– Organization and management	___	___
– Procedures	___	___
– Recordkeeping	___	___
– Material control and accounting	___	___
– Management review	___	___

MML Applicant: _____

Mail Control No.: _____

Radiation Control Program – An Overview (3.10.1)	Yes	No
Each narrative description for the above addressed: <ul style="list-style-type: none"> – Program authorities and responsibilities – Communications – Quality control surveillance – Program audits – Procurement – Staff selection and qualification – Information dissemination, document control and retrieval, etc. – Other considerations essential to the successful implementation of the RCP .. 	_____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____
The overview written administrative control procedures for the RCP are sufficient to describe how management oversight for program activities will be carried out?	_____	_____
The description of the RCP included a narrative overview description of the licensing and inspection program?	_____	_____
The narrative description of the licensing and inspection program addressed: <ul style="list-style-type: none"> – Program authorities and responsibilities – Communications – Quality control surveillance – Program audits – Procurement – Staff selection and qualification – Information dissemination, document control and retrieval, etc. – Other considerations essential to the successful implementation of the RCP .. 	_____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____

Comments on the Radiation Control Program – An Overview

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Previous Licenses (3.10.2)	Yes	No
Applicant provided list of materials licenses to be included under the MML?		
All licensees are part of the Applicant's Federal agency? (If no, explain in the comment section and coordinate with the Office of the General Counsel before issuing the MML.)		
Materials licenses listed are authorized for inclusion in the MML? (If no, describe in the comment section.)		

Comments on Previous Licenses

Material Control and Accountability (3.10.3)	Yes	No
Applicant described its inventory control and accountability system for licensed material?		
It included procedures for properly transferring material throughout the applicant's organization, including its movement among facilities?		
It included procedures for properly controlling material throughout the applicant's organization, including its movement among facilities?		
It included procedures for properly accounting for material throughout the applicant's organization, including its movement among facilities?		
The inventory and control system is adequate to ensure that licensed possession limits are not exceeded?		
The inventory and control system is adequate to account for material throughout the applicant's organization?		

MML Applicant: _____

Mail Control No.: _____

Comments on Material Control And Accountability

Regulatory Conformance (3.10.4)	Yes	No
Applicant committed to implement regulations consistent with and no less restrictive than NRC regulations?		
Applicant confirms that licensing and inspection programs will be implemented in accordance with NRC licensing and inspection criteria (i.e., NRC regulations, policies and guides) or will submit any alternative procedures?		
– If above answer was no, applicant provided alternative procedures.		
Applicant submitted or otherwise described its policies, procedures, directives, and guides related to the implementation and oversight of its RCP?		
Applicant identified those NRC policies, procedures, and guides which will be incorporated into the RCP in their entirety?		
If NRC guidance is used, applicant provided procedures to ensure that the program is updated as NRC guidance is changed, and that staff is trained in current NRC guidance.		

Comments on Regulatory Conformance

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Updating RCP Documents (3.10.5)	Yes	No
Applicant has established procedures for appropriate and timely updating of its regulations, policies, procedures, and guides to ensure conformance with NRC regulations, policies, procedures, and guides?		
Applicant submitted or otherwise described these procedures?		
Applicant's procedures/description adequate?		
Applicant confirmed that changes to its regulations, policies, procedures, and guides which involve a material change from that submitted in its original application or subsequent amendments will be submitted for review as a part of a license amendment request?		

Comments on Updating RCP Documents

Management Support and RCP Structure (3.10.6)	Yes	No
Applicant has sufficient operating funds to support RCP needs (e.g., financial assurance, travel, training, equipment, administrative costs, etc.)?		
RCP supported with sufficient staffing and technical expertise?		
RCP located within the applicant's organization at a level equivalent with other comparable health and safety programs?		
RCPD has access to highest levels of applicant's management?		
Applicant submitted organizational chart and description depicting:		
– Management structure	___	___
– Reporting paths	___	___
– Flow of authority and control of finances	___	___
– Geographical location of all management and RCP staff components	___	___

MML Applicant: _____

Mail Control No.: _____

Comments on Management Support and RCP Structure

Radiation Control Program – Administrative Control Processes (3.10.7)	Yes	No
The applicant provided written administrative control processes?		
The administrative control processes addressed:		
– Program authorities and responsibilities	___	___
– Communications	___	___
– Quality control surveillance	___	___
– Program audits	___	___
– Procurement	___	___
– Staff selection and qualification	___	___
– Information dissemination, document control and retrieval, etc.	___	___
– Other considerations essential to the successful implementation of the RCP ..	___	___
The applicant’s administrative control procedures were related to administrative controls and provisions for:		
– Organization and management	___	___
– Procedures	___	___
– Recordkeeping	___	___
– Material control and accounting	___	___
– Management review	___	___
Written administrative control processes are sufficient in:		
– detail	___	___
– clarity	___	___
– specificity	___	___
to describe how management oversight for program activities will be carried out?		

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Comments on Radiation Control Program Administrative Control Processes

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Master Radiation Safety Committee (3.10.8)	Yes	No
Applicant identified and described any existing boards or entities that it uses to support the MRSC?		

Comments on the Master Radiation Safety Committee

Radiation Control Program Director (3.10.9)	Yes	No
Applicant provided a copy of the written delegation of authority from the senior executive manager to the RCPD?		
Applicant provided a copy of the written a description of the RCPD's responsibilities?		
RCPD responsibilities and authorities include, but are not limited to:		
– Management and control of the RCP	___	___
– Serving as the Executive Secretary of the MRSC	___	___
– 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 licensee and NRC for matters concerning the MML	___	___
– Informing the MRSC and senior executive management regarding the status of the RCP	___	___
– Implementing the MRSC's enforcement sanctions	___	___
– Stopping work activities which may pose undue risk or hazard or which may violate conditions of the license or the NRC regulations	___	___
– Reviewing all radiological incidents and recommending corrective actions to the MRSC	___	___
Applicant provided documentation to show that the RCPD has access to the highest levels of MML management?		
Applicant described the measure of administrative and financial control the RCPD has over permitting and inspection personnel?		

MML Applicant: _____

Mail Control No.: _____

Comments on the Radiation Control Program Director

Permitting and Inspection Staff (3.10.10)	Yes	No
The applicant's description of the permitting and inspection staff indicates that this staff will:		
– Provide guidance to licensee organizations in the preparation of requests for permits	—	—
– Be responsible for providing content of NRC generic communications to appropriate permittees in a timely manner	—	—
– Review permit applications for completeness and compliance with current regulations, policies and guides	—	—
– Prepare permits and forward to the MRSC for review and signature	—	—
– Perform inspections to assess compliance with current licensee and NRC regulations, policies, and guides and provisions of the MML and specific permits	—	—
– Prepare reports of inspection results, and forward reports of non-compliance to the MRSC	—	—
– Conduct technical assistance visits, as necessary	—	—
– Conduct pre-licensing visits	—	—
– Respond to incidents	—	—

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Permitting and Inspection Staff (3.10.10)	Yes	No
If the RCP staff are not co-located, did the applicant describe how it will:		
– Effectively manage the day to day operations of the RCP?	___	___
– Respond to events at permittee facilities?	___	___
– Maintain uniformity of program implementation?	___	___
– Maintain daily communications?	___	___
– Ensure consistency of guidance provided to permittees?	___	___
– Provide training to RCP staff?	___	___
– Monitor and evaluate RCP staff performance?	___	___

Comments on the Permitting and Inspection Staff

Radiation Control Program Internal Procedures (3.10.11)	Yes	No
The applicant has confirmed it has established written internal procedures which:		
– Assure that the MML satisfies NRC requirements and criteria	___	___
– Assure the RCP staff performs its duties as required	___	___
– Provide a high degree of uniformity and continuity in regulatory practices ...	___	___
– Address internal processing of permit applications, inspection policies and procedures, decommissioning, and other functions required of the program ..	___	___
– Require that the MRSC receive quarterly reports from the RCP staff on the status of the program	___	___
– Require that the MRSC receive a report on the annual audit of the program to include overall conduct, result of the program performance compared to regulatory requirements and commitments, review of permitting actions, inspection reports, and enforcement actions	___	___

MML Applicant: _____

Mail Control No.: _____

Comments on the RCP Internal Procedures

Management and Master Radiation Safety Committee Audits (3.10.12)	Yes	No
The applicant described the process used by senior executive management to ensure its awareness of NRC regulations, the provisions of the license, and the compliance status of the RCP?		
The applicant provided a copy of the senior executive management’s audit program to audit the performance of the RCP and staff?		
The applicant provided a copy of the MRSC’s audit program to audit the performance of the RCP office, RPCD, and permit review and inspection staff?		
The applicant’s MRSC will conduct interactive management audits and evaluations of the RCP office’s performance, including the RCPD’s and will provide the results of these audits to senior executive management?		
The applicant has established a system to: <ul style="list-style-type: none"> – Qualify permit inspectors that is similar to NRC’s inspector qualification system – Audit each inspector’s performance, through field accompaniments on an annual basis – Qualify permit reviewers that is similar to NRC’s license reviewer qualification system – Audit each permit reviewer’s actions to assess performance and assure appropriate and consistent policies and guides 	___ ___ ___ ___	___ ___ ___ ___

Comments on Management and MRSC Audits

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Comments on Management and MRSC Audits		

Permitting Procedures (3.10.13)	Yes	No
The applicant:		
<ul style="list-style-type: none"> - Provided copies of its permitting procedures, policies and guides OR - Committed to utilizing NRC licensing procedures, policies, and guides; listed those NRC documents used; and provided copies of its documents that differ from NRC documents 	___	___
Applicant provided standard license conditions?		
<ul style="list-style-type: none"> - The applicant committed to use NRC's standard license conditions for its permit conditions? 	___	___
<ul style="list-style-type: none"> - Applicant committed to not use custom conditions that are less restrictive than any applicable NRC conditions, requirements, or criteria? 	___	___
The applicant specified its timeliness goals applied to the issuance of permits and the updating of its permitting guidance as updates are received from NRC?		
Applicant described its document management procedures?		

Comments on the Permitting Procedures		

MML Applicant: _____

Mail Control No.: _____

Permittee Minimization of Contamination Program (3.10.14)	Yes	No
Applicant described how facility design and procedures for operation will:		
– Minimize, to the extent practicable, contamination of the permittee’s facilities and the environment	___	___
– Facilitate eventual decommissioning	___	___
– Minimize, to the extent practicable, the generation of radioactive waste	___	___
Applicant’s procedures are adequate?		

Comments on Permittee Minimization of Contamination Program

Permit Termination and Decommissioning of Permit Activities (3.10.15)	Yes	No
Applicant provided its permit termination procedures or committed that it will terminate its permits in accordance with NRC regulations, policies, and guides, as provided for in the LOU?		
Applicant provided decommissioning procedures or committed that permit facilities will be decommissioned as described in the NRC IMC 2605 and handbook, as provided for in the LOU?		
Applicant confirmed that copies of permit termination requests and permit decommissioning plans will be provided to NRC?		
Applicant confirmed that specific permit decommissioning plans will be submitted to NRC, when requested, for review and approval prior to final approval by the MML RCP?		
Applicant’s permit termination program was adequate?		
Applicant’s decommissioning program was adequate?		

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Comments on Permit Termination and Decommissioning of Permit Activities

Financial Assurance (3.10.16)	Yes	No
Applicant described how it will meet the decommissioning financial assurance requirements described in 10 CFR 30.35?		
Applicant described its program for ensuring adequate funds to decommission all its permitted facilities are established and maintained?		
Applicant's financial assurance program is adequate?		

Comments on Financial Assurance

APPENDIX C

MML Applicant: _____

Mail Control No.: _____

Comments on the Inspection and Enforcement Procedures

Incident/Emergency Response Procedures (3.10.18)	Yes	No
Applicant submitted its RCP Office' incident/emergency response procedures?	—	—
The RPC Office's incident/emergency response procedures include, but are not limited to, the following for both work-hour and off-hour incidents:		
<ul style="list-style-type: none"> – RCP management oversight responsibilities – Initial response actions and responsibilities, including immediate safety for: <ul style="list-style-type: none"> ▶ RCP management ▶ RCP staff ▶ Permittee – Identifies persons responsible for: <ul style="list-style-type: none"> ▶ Initiating response action (includes notifications) ▶ Conducting operations ▶ Conducting cleanup ▶ Precautions for people and property at permittee facilities ▶ Area and permittee facility access control and security ▶ Mechanisms and responsibilities for notifying RCP Office staff and external authorities ▶ Provisions for medical and offsite agency assistance ▶ A description of emergency response equipment available for use by the RCP Office staff ▶ Need for onsite review of events 	—	—
Applicant provided Emergency Plan(s) in accordance with 10 CFR 30.32(i)?	—	—

MML Applicant: _____

Mail Control No.: _____

Comments on Incident/Emergency Response Procedures

Procedures for Handling Allegations (3.10.19)	Yes	No
Applicant confirmed it will follow NRC's procedures for handling allegations OR Provided equivalent procedures for handling allegations that are referred to the MRSC	___	___
Applicant submitted its procedures for handling and documenting employee concerns?		
Applicant described the training it will provide to all employees to assure they understand their right to contact NRC directly about radiation safety or regulatory issues?		
Applicant's program for responding to employee radiation safety concerns and providing training is adequate?		

Comments on the Procedures for Handling Allegations

MML Applicant: _____

Mail Control No.: _____

K. NRC Form 313, Item 11: Waste Management

Waste Management (3.11)	Yes	No
Applicant described the methods its permittees will use for disposal of radioactive waste?		
Applicant's disposal methods are adequate and in accordance with regulations?		
Applicant's proposed disposal methods include means other than transfers to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with 10 CFR 20.2001(a), decay-in-storage, disposal of materials that contain radioactivity from hydrogen-3 and carbon-14 in scintillation counting media and in animal tissue in concentrations of 0.05 microcurie or less per gram, subject to certain restrictions stated in 10 CFR 20, 2005, and release of radioactive materials into air and water in conformance with 10 CFR 20.1302 and 20.2003?		
Applicant described other disposal methods and these methods were adequate?		
Applicant described the locations, conditions, and current status of former burial sites?		

Comments on Waste Disposal