

# **Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Master Materials Licenses (NUREG SR1556, Vol. 10)**

## **Publication Information**

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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.

## **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.

<b>Vol. No.</b>	<b>Volume Title</b>	<b>Status</b>
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

<b>Vol. No.</b>	<b>Volume Title</b>	<b>Status</b>
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
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 a 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 a 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](http://www.nrc.gov/NRC/NUREGS/SR1556/V10/index.html)>.

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.

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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

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
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 a 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 a 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, 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 a 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**

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

The Letter of Understanding (LOU) for a 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 a 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 a 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 a 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 a 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 a 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 a MML is not warranted, the applicant may continue with its existing licensed activities and may submit an application for a MML at a later date without prejudice.

## 2 Filing a MML Application

An applicant for a 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 a 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;

- Investigations of allegations;
- Waste incineration in accordance with 10 CFR 20.2002.

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

A 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 a MML. Corporations and private individuals may not apply for a 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 a MML has an indefinite license period, if granted a MML, the applicant should inform NRC of any subsequent changes in its mailing address, either during the application process or if granted a 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 a 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 a 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 a 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 a MML program.

### **3.7.1 Senior Management**

The importance of the senior management's role in the development and functioning of a MML program cannot be overemphasized. NRC issues a 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 a 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.

**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.

- 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 a 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\*<sup>1</sup> designated as the RCPD.
- Provide documentation\*<sup>1</sup> 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.\*<sup>2</sup>
- 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.)

\*<sup>1</sup> 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.

\*<sup>2</sup> 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;

- Program authorities and responsibilities;
- 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 a 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.\*<sup>1</sup>
- Specifically identify those NRC policies, procedures, and guides that are adopted in their entirety into the RCP.\*<sup>2</sup>

\*<sup>1</sup> 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.

\*<sup>2</sup> 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

A 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 a MML, the applicant must demonstrate that it is financially and technically qualified to conduct a 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;
- 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;

- Program authorities and responsibilities;
- 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;

- Establishing procedures for the control, use, acquisition, and accountability of byproduct, source, and special nuclear material;
- 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**