
INSPECTION MANUAL CHAPTER 2810

MASTER MATERIAL LICENSE OVERSIGHT AND INSPECTION PROGRAM

2810-01 PURPOSE

To establish the oversight and inspection program applicable to a master materials license (MML). An MML is a multi-site, multi-regional, material (byproduct, source, and/or special nuclear material) license issued to a Federal organization with a centralized radiation control program with regulatory oversight responsibilities for a variety of materials programs. The MML licensee's central radiation control program includes internally managed licensing, inspection, enforcement and allegation programs. The U.S. Nuclear Regulatory Commission (NRC) performs independent inspections of the MML permittees, accompaniments of the MML inspectors, and a comprehensive biennial inspection of the MML radiation control program as part of NRC's oversight of the MML program.

2810-02 OBJECTIVES

- 02.01 To define the roles and responsibilities of the Headquarters MML Program Coordinator and Regional MML Project Managers.
- 02.02 To establish the program for NRC's oversight of the licensee's performance.
- 02.03 To provide standard guidance to inspectors conducting the biennial inspection, accompaniment inspections, and independent inspections.
- 02.04 To define the roles of the lead and assisting regional offices during oversight, the biennial inspection, accompaniment inspections, and independent inspections.
- 02.05 To establish a system for reviewing MML inspection results and enforcement actions and appropriately dispositioning NRC inspection violations and associated enforcement actions, based on NRC enforcement policy.

2810-03 DEFINITIONS

- 03.01 Accompaniment Inspection (Accompaniments). NRC's observation of an MML inspector conducting an inspection of a permittee. The purpose is to evaluate the performance of the MML inspector and their implementation of the inspection program to ensure consistency with NRC's program.
- 03.02 Assisting Region. The NRC region that would be asked to assist the lead region by conducting independent and/or accompaniment inspections, or participation on a biennial inspection team .

03.03 Biennial Inspection. A comprehensive team inspection performed to assess the management of the MML's centralized radiation control program and verify that the program is being implemented consistent with NRC programs and policies. This inspection is designated as a Priority 2 under IMC 2800 and shall be performed within the prescribed scheduling window.

03.04 Independent Inspections. NRC's inspection of the MML permittees. This includes routine and/or reactive inspections performed between the biennial inspections.

03.05 Lead Region. The NRC region that is assigned project responsibility for the MML. The lead region will designate a MML Project Manager who is located within that region.

03.06 Letter of Understanding (LOU). A document that identifies the responsibilities and requirements for coordination between the MML and the NRC, as well as those responsibilities which are retained by the NRC. The LOU is signed by management representatives from both agencies as a matter of legal commitment.

03.07 Master Material License. A multi-site, multi-regional material (byproduct, source, and/or special nuclear material) license issued to a Federal organization that authorizes the licensee to undertake a limited number of regulatory activities as specified in a joint LOU with the NRC. The MML authorizes the licensee to issue permits for the possession and use of licensed material listed on the MML license, and ties the licensee to a framework for oversight and internal licensee inspection of the MML permittees.

03.08 MML Radiation Control Program Director. The staff member who has been designated the responsibility of oversight of the MML's radiation control program and serves as the main point of contact with the NRC.

03.09 MML Radiation Safety Committee. The committee delegated the authority by the highest level of the licensee's management to provide oversight for the MML Centralized Radiation Control Program.

03.10 NRC MML Program Coordinator (PC). The NRC staff member assigned responsibility for overall coordination of the MML program and providing policy and procedure guidance to the MMLs. The PC is a part of the staff within the Office of Nuclear Material Safety and Safeguards (NMSS), Division of Materials Safety, Security, State and Tribal Programs (MSST) .

03.11 NRC MML Project Manager (PM). The NRC regional staff member assigned the oversight project responsibility for an MML.

03.12 Permittee. A holder of a permit issued by the MML's Master Radiation Safety Committee to possess and use byproduct, source, and/or special nuclear material for authorized purposes.

2810-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Headquarters. NMSS/MSST shall assign a staff member as the MML PC to oversee the agency's MML program.

Following are the responsibilities of headquarters:

- a. Coordinate MML Program meetings.
- b. Coordinate MML PM Counterpart meetings.
- c. Attend Master Radiation Safety Committee meetings, as necessary.
- d. Perform inspection accompaniments as necessary to fully assess the scope of the MML program, observe new licensing activities, or observe inspectors, and follow-up on any escalated enforcement actions or safety issues.
- e. Coordinate implementation of the agency's policies and procedures to ensure the MML program is consistently implemented across all regions.
- f. Provide updated guidance regarding the agency's policies and procedures to the MML Radiation Control Program Directors so that the MMLs have the information available to implement their programs consistent with the agency's guidance.
- g. Participate in the biennial review, as necessary.
- h. Facilitate NRC responses to technical questions or inquiries which the MML poses to NRC for purposes of executing the MML.
- i. Monitor training process and selection between the Technical Training Center and NMSS to ensure MML requests for NRC training courses are processed appropriately and timely.

04.02 Lead Region The lead region shall designate a staff member as the NRC MML PM to oversee the MML regulatory activities and to implement the MML Biennial Inspection Program. Consideration should be given to designating a back-up MML Project Manager to address the needs of the MML when the MML Project Manager is not available and to learn the duties and responsibilities for seamless transfer when the MML Project Manager position is changed.

The following are the responsibilities of the lead region:

- a. The PM provides an ongoing assessment of the MML to ensure its radiation control program is consistent, with and pursuant to, NRC regulations, policies, and guidance.
- b. Review a representative sample of the types of permits issued by the MML licensee for the NRC MML PM to adequately assess permittee activities and the licensee's permitting activities.

- c. Review all NRC and a representative sample of MML inspection reports for the NRC MML PM to adequately monitor permittee performance and the licensee's inspection activities.
- d. Review incident or event notifications and reports. Work closely with MML Radiation Control Program Director to ensure the MML has developed consistent, risk-informed processes to review event information, identify safety issues and apply corrective actions for applicable permittees.
- e. Review and monitor allegations and significant safety concerns.
- f. Attend Master Radiation Safety Committee meetings.
- g. Coordinate and perform independent inspections of MML regulated activities to determine MML compliance with NRC regulations, policies and guidance, and to follow-up on any escalated enforcement actions or safety issues. See section 06.01.
- h. Coordinate and perform inspection accompaniments to observe MML inspectors and evaluate the effectiveness of MML inspections. See section 06.02.
- i. Coordinate the onsite biennial inspection of the MML radiation control program including selection of inspection team members and coordinating dates. See section 06.03.
- j. Monitor all other activities as necessary.
- k. Develop and implement guidance for the transition of duties to future PMs.
- l. Facilitate NRC responses to technical questions or inquiries which the MML poses to NRC for purposes of executing the MML.

04.03 Assisting region. The following are the responsibilities of the assisting region:

- a. Conduct independent inspections as requested by the lead region. See section 06.01.
- b. Conduct accompaniment inspections as requested by the lead region. See section 06.02.
- c. Provide qualified team members for the biennial review inspection, as requested by the lead region.

04.04 Regional Material Inspectors : Comply with the provisions in the "General Requirements" and "Specific Requirements" sections of this Inspection Manual Chapter (IMC).

2810-05 GENERAL REQUIREMENTS

05.01 The methodology for conducting independent inspections shall be the same as set out in the inspection procedures of IMC 2800, with the addition of the specific requirements listed below. Additionally, the NRC MML PM may request the inspector obtain information necessary for the Biennial Inspection.

05.02 The methodology for conducting the accompaniment inspections shall be performed in accordance with the inspection procedures of IP 87129, with the addition of the specific requirements listed in section 2810-06 below.

05.03 The methodology for conducting the biennial inspection shall be performed in accordance with IP 87129.

05.04 NRC staff shall charge time related to MML inspection, licensing, and oversight activities to the charge codes provided by the MML PM. Time should not be charged to the respective program code. The MML PC will notify the MML PMs of any changes to charging time.

2810-06 SPECIFIC REQUIREMENTS

06.01 MML Independent Inspections

- a. Selection of Permittees. Each MML PM will use a risk-informed methodology to select a representative number of MML permittees. That is, emphasis should be placed on permittees where the licensed activities have a higher potential for health and safety problems. They should select 5-15 percent of the permittees over the biennial review period, based on, but not limited to, the following criteria, in order to review the overall MML radiation control program:
 1. Priority 1, 2, and 3 permittees.
 2. A cross-section of program codes.
 3. At least one permittee that was not inspected during the previous biennial review period or if possible, was not recently inspected by the MML
 4. Any previously inspected permittee for which a repeat inspection is warranted due to escalated enforcement or other safety issues.
- b. Scheduling and Coordination. The NRC MML PM will specifically identify the locations to be inspected and the time frame in which the inspections should be conducted. The NRC MML PM should ensure inspections are spread throughout the review period. The lead region may either request assistance from the region in which the MML permittee is located (i.e. local region) or coordinate with the local region to perform the inspection of the MML permittee. If the lead region performs the inspection, then they should inform the local region PM of the inspection logistics.

The NRC regional inspector performing the independent inspection should notify the NRC MML PM at least 4 weeks before the scheduled inspection date. If the NRC MML PM or MML Program Coordinator expresses an interest in participating in the independent inspection, then the inspector should coordinate with the NRC MML PM in advance in order for travel arrangements to be made.

The NRC MML PM will provide advanced notification to the MML Radiation Control Program Director and determine if a member of its staff plans to observe the NRC inspection. (Alternatively, the NRC MML PM could arrange, in advance, a process and time frame for licensee notification, so that notifying the MML Radiation Control Program Director may not be needed for each inspection.) In addition, coordination may be necessary to gain security access to the facility.

If the MML's Radiation Control Program staff wishes to accompany the NRC inspector, the NRC MML PM will notify the NRC regional inspector and coordinate with the MML's Radiation Control Program staff.

The scheduling of inspections should be determined by regional needs and generally should not be modified. Although the MML's Radiation Control Program will be provided with a list of the proposed inspections, individual permittee inspections should not be announced to the permittee if possible by the NRC or the MML's Radiation Control Program personnel.

The NRC regional inspector will coordinate with the NRC MML PM to obtain an inspection report number prior to the inspection.

- c. Conduct of Inspection. Follow the appropriate Inspection Procedure(s) from IMC 2800. As requested by the NRC MML PM, obtain additional information necessary for the biennial inspection or in support of any other special issues.
- d. Violations. The following criteria should be used in citing violations identified during independent inspections of MML permitted activities:
 1. NRC will consider issuing violations to the MML licensee under the following circumstances:
 - (a) The NRC identification of a violation of NRC requirements specified in Title 10 of the U.S. *Code of Federal Regulations*, except under the circumstances specified in Item 2(a) below.
 - (b) NRC identification of a violation of a condition placed on the MML by the NRC, except under the circumstances specified in Item 2(a) below;
 - (c) NRC identification of willful violations of NRC safety requirements, material false statements, or falsification of records. NRC will maintain and consider the option of reviewing and citing similar MML licensee-identified violations, on a case-by-case basis.
 2. The NRC will not consider issuing violations or pursue escalated enforcement action to the MML under the following circumstances:
 - (a) Severity Level IV or minor violations by permittees that have already been identified by the MML Licensee and adequately corrected, or minor violations that are identified by the NRC;

- (b) Identification of non-conformance with permit conditions when the non-conformance does not constitute an apparent violation of NRC requirements. However, if the non-conformance is safety-related, it should be identified to the permittee during the exit meeting. In this case, the NRC MML PM shall notify the MML's Radiation Control Program Director.
- e. Entrance and Preliminary Exit Briefings. During the entrance interview, advise permittee management (typically, the Commanding Officer or the facility administrator or equivalent for a non-military licensee) that an agreement exists between the MML and the NRC.

Notify the NRC MML PM of any findings, before the preliminary exit briefing, whenever possible. However, the NRC MML PM or lead Regional Management must be notified when there is an apparent Severity Level I, II, or III violation.

If the NRC MML PM does not participate in the preliminary exit briefing meeting, advise the PM of the inspection findings as soon as possible. The NRC MML PM will then advise the MML Radiation Control Program Director of the inspection findings if that individual did not participate in the preliminary exit briefing.

When practical, include a member of the MML's Radiation Control Program in the preliminary exit briefing with the permittee. Typically, this can be accomplished by telephone. Preliminary exit briefings should be held with the highest-ranking individual associated with the permitted activity at the permittee facility.

During the preliminary exit briefing at the permittee facility, discuss any potential or apparent violations identified and address the need for the permittee to take immediate corrective action or commit to correct the potential or apparent violations. If an apparent serious health and safety problem exists, telephone the lead region for implementation of immediate action, such as an order to shut down or cease operations.

- f. Follow-Up. After completion of the inspection:

The inspector will submit a completed Inspection Record; NRC Form 591 (if appropriate); draft Notice of Violation (if appropriate); and enforcement recommendations to the NRC MML PM within 5 business days of the last date of the inspection. NRC Form 591 shall not be left with permittee management.

If escalated enforcement is being considered, the NRC MML PM should be provided with a summary of the issues supporting the apparent violations within 5 calendar days from the last day of the inspection. The NRC inspector from the assisting region should draft an inspection report within 5 business days from the last day of the inspection and provide it to the NRC MML PM.

The inspector will provide any additional information that the NRC MML PM requested (e.g., information concerning issues necessary for the biennial review or for review of special issues).

All inspection related correspondence will be issued by the lead region.

g. Final Exit and Issuance of Report.

The NRC MML PM should process the pending inspection report and any potential or apparent violations in accordance with regional policy. The NRC MML PM will hold a final exit meeting with the MML Radiation Control Program Director, to brief the licensee of the inspection findings. The final inspection report should be issued within 30 days of the final exit meeting in accordance with regional policy.

06.02 MML Accompaniment Inspections

- a. Coordination. MML inspection accompaniments are an important aspect of evaluating the MML's performance as part of the biennial inspection of the MML. While the MML must perform inspector accompaniments in accordance with IMC 2800, the NRC accompanying MML inspector(s) is a part of the focus element to evaluate the MML licensee's inspection performance during the biennial inspection.

Over the biennial inspection period, accompany all newly qualified MML inspectors, if possible, and those inspectors who were not accompanied during the previous review period. Priority should be given to conducting inspection accompaniments at permittees that involve activities of higher health and safety or security significance. The scheduling of accompaniment inspections should be determined by the MML's inspection schedule.

The NRC regional inspector performing the accompaniment inspection should contact the NRC MML PM at least 4 weeks before the scheduled accompaniment inspection date.

The NRC MML PM will notify the MML Radiation Control Program Director of the accompaniment inspection and determine if a member of the MML staff plans to observe. If the MML Radiation Control Program staff wishes to observe the accompaniment, the NRC MML PM will notify the NRC regional inspector and coordinate with the MML Radiation Control Program staff.

- b. Conduct of the Accompaniment Inspection.

The purpose of the accompaniment is to determine whether the MML inspector(s) are inspecting MML permittees in accordance with current NRC inspection procedures. The NRC regional inspector will conduct the accompaniment in accordance with Inspection Procedure 87129, Appendix E, "Focus Element - Technical Quality of Materials Inspections," Attachment B, "Inspector Accompaniment Checklist." As requested by the NRC MML PM, the NRC regional inspector will obtain additional information necessary for the biennial inspection or for review of any special issues.

During the accompaniment, the NRC regional inspector should not become involved with the inspection, unless the NRC regional inspector observes an apparent serious health and safety problem that is not being addressed by the MML inspector. The NRC regional inspector will immediately bring the serious health or safety problem to the MML inspector's attention. If the permittee does not correct the situation, notify the MML Radiation Control Program Director. If the situation is still not corrected, notify the lead region immediately.

The NRC inspector performing the accompaniment should provide feedback to the MML inspector, immediately following the completion of the inspection.

c. Follow-Up:

Within 5 business days of completion of the accompaniment the inspector will:

- Submit completed "Inspector Accompaniment Checklist," from IP 87129.

Appendix E, Focus Element - Technical Quality of Materials Inspections," Attachment B.

- Provide any additional information that the NRC MML PM requested (e.g., information concerning issues necessary for the biennial inspection or any special issues).

The NRC MML PM should review the accompaniment documentation and communicate the MML inspector's performance , with the MML Radiation Control Program Director.

06.03 MML Biennial Inspection:

The biennial inspection includes the inspection of the radiation control program office of the MML and integrates the results of the NRC project manager's routine oversight of the program during the review period, which includes observations of MML Radiation Safety Committee meetings, NRC inspections, and accompaniments of MML inspectors. The biennial inspection focus elements include: MML management's oversight, of the radiation control program staffing, training, permitting, inspection, response to events or incidents and safety concerns or allegations, and overall licensee compliance with NRC requirements, the license, and the LOU.

- a. Planning and Coordination. The MML PM will coordinate and lead the onsite biennial inspection. The biennial inspection team will consist of at least three members; however, the exact size and composition of the team will reflect the size and scope of activities of the MML program. The MML PM will assemble the inspection team with consideration of selecting other MML PMs and also NRC staff members with expertise in certain specialties.

The MML PM will coordinate the dates of the biennial inspection with the inspection team and MML radiation control program director. The MML radiation control program director shall be provided with a request for documentation 60 days before the onsite inspection date (See IP 87129 Appendix A).

The MML PM will develop an inspection plan covering routine oversight, events, and program trends. Inspection team members will be assigned focus elements to be reviewed during the biennial inspection.

- b. Conduct. The biennial inspection will be conducted in accordance with the procedures identified in Inspection Procedure 87129.

- c. The Exit and Issuance of Report. The MML PM will conduct the final exit meeting with the MML's Senior Executive Management, to discuss the inspection findings. The MML PM is responsible for compiling inspection documentation from the team members and issuing the report. The final inspection report should be issued within 45 days of the final exit meeting in accordance with Inspection Manual Chapter 0610 and regional policy.

6.04 Enforcement and Allegations:

- a. Enforcement.

The NRC applies its Enforcement Policy to disposition findings related to the biennial inspection of MMLs, as well as independent NRC inspections of MML permittees. The inspection reports are issued to the MML licensee. Enforcement actions taken by NRC against the MML do not preclude the MML from taking any action it deems necessary against its permittee for those violations. NRC may issue a civil penalty (CP) to the MML, but will normally not take action against an MML permittee.

Potential enforcement action identified by another region should be drafted and provided to the NRC MML PM, who will process the enforcement action in accordance with the Enforcement Policy.

The outcome of any NRC enforcement action against the MML depends, among other things, on appropriate corrective actions implemented at the permittee level; therefore, the MML is expected to ensure that permittees provide corrective actions appropriate to their violations.

Based on the Enforcement Policy, when the MML identifies permittee violations of NRC or license requirements that could result in escalated enforcement (SL III, SL II, or SL I), the facts related to the case are provided to the appropriate NRC MML PM.

The NRC MML PM, following the Enforcement Manual and Policy, coordinates any needed Regional Office follow-up of events or incidents using the appropriate inspection guidance for MML licenses. Once the information has been gathered and reviewed, and potential violations that may result in escalated action are identified, the region should disposition potential escalated violations through the normal enforcement process.

Exercise of discretion to either escalate or mitigate enforcement sanctions is addressed in the Enforcement Policy. The Enforcement Manual states in part that discretion to mitigate an escalated enforcement action regarding an MML may be considered when the violation was not willful, the MML has done a thorough investigation and has reported their findings to the MML PM, or when a source is lost.

- b. Allegations:

Allegations are received by the MML and will be processed by the NRC in accordance with NRC Management Directive 8.8 and the Allegation Manual. As soon as possible, but within three calendar days of receipt, allegations shall be provided to the respective NRC MML PM and the lead Regional Office Allegation Coordinator (ROAC), this will enable NRC staff to process the allegation on time. For a potential overriding safety

issue, immediately contact the ROAC and NRC MML PM. The NRC MML PM, in coordination with the OAC, will take the necessary actions to ensure that the allegation is dispositioned. The Allegation Review Board in the lead region will make the determinations in assignment of follow-up actions for allegation evaluation, including referral to the MML licensee or independent follow-up by the NRC. The Allegation Review Board will also assign actions for allegor feedback, as needed. Potential wrongdoing matters are also processed through the allegation program.

2810-07 REFERENCES

IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports"

IMC 2800, "Materials Inspection Program"

IP 87129, "Master Materials Program"

MD 8.8, "Management of Allegations"

END

Attachment 1: Revision History for IMC 2810

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
N/A		Completed 4 year historical CN search	N/A	
N/A	ML12180A017 10/11/12 CN 12-023	Revised to include recommendations from OIG Audit (OIG-11A-14)	N/A	ML12198A063
N/A	ML21137A346 10/29/21 CN 21-036	This was issued in October 2012. In accordance with IMC 0040, "Preparing, Revising, And Issuing Documents For The NRC Inspection Manual," dated July 23, 2020, staff performed a periodic review of this Chapter, determined that time elapsed since documents were last revised, some policies and procedure has been revised. For example, the IMC 2800 that used by this Chapter has been updated in 2017 and again in 2020. Therefore, staff determined that some revisions beyond editorial changes are needed for this Chapter.	N/A	N/A