

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. 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 (HQs) MML Program Coordinator and Regional MML Project Managers.

02.02 To establish the program for NRC's oversight of the licensee's performance and **biennial inspection** of the MML licensee's central radiation control program regulatory 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 handling MML **inspection** findings, including enforcement.

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.

03.03 Biennial Inspection. A comprehensive assessment of the management of the MML's centralized radiation control program and verification that the program is being implemented consistently with the NRC's programs and policies. 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 Letter of Understanding (LOU).

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 representatives from both agencies as a matter of legal commitment.

03.07 Master Material License (MML). 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 MML licensee staff member who implements the licensee's Centralized Radiation Control Program with the assistance and support of the Master Radiation Safety Committee and Senior Executive Management. This individual has responsibility for oversight of licensees and permittees and serves as the licensee's main point of contact with the NRC.

03.09 MML Radiation Safety Committee (MRSC). 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 Federal, State, Materials and Environmental Management Programs (FSME), Division of Materials Safety and State

Agreements (MSSA) Licensing Branch .

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

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.

03.13 Radiation Control Program Office. The primary or designated office location of the MML's Radiation Control Program Director.

2810-04 RESPONSIBILITIES

0401 Headquarters (HQ). The Office of FSME/MSSA shall assign a staff member as the MML PC to oversee the agency's MML program.

Following are the responsibilities of the HQ's office:

Routine Oversight of the MML Program

- a. Coordinate MML Program meetings.
- b. Coordinate MML PM Counterpart meetings.
- c. Attend Master Radiation Safety Committee meetings.
- 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 between the Technical Training Center (TTC) and Office of Federal and State Materials and Environmental Programs (FSME) 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.

Following are the responsibilities of the lead region:

Routine Oversight

- 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 and 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 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. Perform inspection accompaniments to observe MML inspectors and evaluate the effectiveness of MML inspections.
- h. 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.
- i. Monitor all other activities as necessary.
- j. Develop and implement guidance for transition of duties for new PM.
- k. Facilitate NRC responses to technical questions or inquiries which the MML poses to NRC for purposes of executing the MML.

Independent Inspections

- a. Select a representative number of permittees to be inspected during the biennial review period as described in section 06.01. More emphasis should be placed on permittees where the licensed activities have a higher potential for health and safety problems. The independent inspections are one of the elements used by the NRC MML PM to assess licensee regulatory performance.
- b. Specifically identify the locations to be inspected and the time frame in which the

inspections should be conducted. The time frame should be spread throughout the year. The NRC MML PM will provide advanced notice to the MML Radiation Control Director of NRC scheduled inspections at permittees of the MML to coordinate accompaniments and security access, or for other reasons.

- c. In general, independent inspections should be conducted so as to avoid inspecting permittees which will be or have been inspected by the MML within a 12 month period unless such inspection is warranted due to past escalated enforcement or other safety issues.
- d. The lead region may either request assistance from the region in which the MML permittee is located or coordinate with the local region to perform the inspection of the MML permittee. If the local region performs the inspection, then they should inform the region in which the MML permittee is located, of the inspection logistics.
- e. If an assist inspection is requested, the region performing the assist inspection submits the inspection documentation to the NRC MML PM in accordance with the current NRC inspection guidance.

Accompaniment Inspections

- a. Coordinate the accompaniment of MML inspector(s) over the biennial inspection period. The purpose is to determine whether the licensee's inspector(s) is (are) inspecting permittees in accordance with current NRC inspection procedures.
- b. The NRC MML PM should accompany all newly qualified MML inspectors and those inspectors who had not been accompanied during the previous review period.
- c. Priority should be given to conducting inspection accompaniments at facilities that involve activities of higher health and safety or security significance.
- d. During the accompaniment, the NRC inspector should not become involved with the inspection, unless safety significant issues are not being addressed.
- e. Request each region performing accompaniment inspections to submit a completed "Inspector Accompaniment Checklist (Inspection Procedure 87129, Appendix E, "Focus Element - Technical Quality of Materials Inspections," Attachment B)" to the NRC MML PM.
- f. The NRC inspector performing the accompaniment should provide immediate feedback to the MML inspector, once the inspection has been completed.
- g. The NRC MML PM should review the accompaniment documentation and communicate the observation for the conduct of the inspection with the MML Radiation Control Program Director.
- h. Performing the inspector accompaniments should take into consideration the number of inspectors the MML utilizes. While the MML must perform inspector accompaniments in accordance with IMC 2800, the element for NRC accompanying MML inspector(s) is used

by the NRC MML PM to monitor MML licensee's inspection performance as part of the biennial inspection.

Biennial Inspection

- a. Coordinate the onsite biennial inspection of the MML Radiation Control Program.
- b. Coordinate the dates of the biennial inspection with the Inspection Team and MML Radiation Control Program Director. Coordinate with the MML Radiation Control Program Director regarding the documentation and staff to have available during the onsite portion of the inspection.
- c. Assemble the inspection team in accordance with IP 87129, with consideration being given to providing MML PMs as team members for the biennial review inspection, as practical. In addition, consideration may also be given to other NRC staff members with expertise in certain focus areas (e.g., allegations and enforcement).
- d. The biennial inspection team will consist of at least three members. The exact size and composition of the review team will reflect the size and activities of the program.
- e. Develop the scope of inspection based on information from routine oversight, events, and program trends.
- f. Lead the biennial review inspection.
- g. Conduct the exit meeting with licensee's Senior Executive Management.
- h. Compile inspection information from team members and issue the inspection report. The final inspection report should be issued within 45 days of the final exit meeting in accordance with regional policy.

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 a 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.

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

- a. Conduct independent inspections as requested by the lead region.
- b. Conduct accompaniment inspections as requested by the lead region. During the accompaniment, the NRC inspector should not become involved with the inspection, unless safety significant issues are not being addressed.
- c. If requested by the lead region, provide qualified team members for the biennial review inspection.
- d. Provide the lead Region with NRC Independent and Accompaniment Inspection draft reports **within 5 calendar days from the last day of the inspection**, so that the lead region is able to review and issue the report within established timeliness goals.
- e. Provide the lead Region with NRC draft enforcement violation(s) and severity level(s) **within 5 calendar days from the last day of the inspection, including the supporting documentation in order for the lead Region to process the enforcement action.**

04.04 Materials Inspector, Division of Nuclear Materials Safety, Regions I, III, and IV: 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 Activity ID Codes from the HRMS time system should be used for all inspection-related, licensing and coordination activities for each respective MML. The inspection Activity

ID Code for the respective MML should be used instead of the respective Program Code for the specific activity (e.g., JI2230) normally used for other material licenses. In addition, there is an overall programmatic and coordination code that should be used by the HQs MML Program Coordinator, as well as the Regional MML PM for any coordination activities which are not directly supporting the MML, such as annual counterpart meetings and scheduled coordinator telephone calls or briefings.

JM0000: U.S. Air Force MML Licensing
JM0001: U.S. Air Force MML Inspection
JM0002: U.S. Naval MML Licensing
JM0003: U.S. Naval MML Inspection
JM0004: U.S. Veterans Administration MML Licensing
JM0005: U.S. Veterans Administration MML Inspection
A10145: Perform Oversight of Multi-Site Licenses (USN, USAF, DVA)

05.03 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. Additionally, the NRC MML PM may request the inspector to obtain information necessary for the Biennial Inspection.

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

2810-06 SPECIFIC REQUIREMENTS

06.01 The following are the specific requirements for MML independent inspections:

- a. Selection of permittees. The NRC MML PM will use a “risk-informed methodology” (including the criteria listed in Section 06.01.a) to select MML permittees. They should select 5-15 percent 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. Select Priority 1, 2, and 3 permittees;
 2. Select a cross-section of program codes;
 3. Select a permittee that was not inspected during the previous biennial review period or was not recently inspected by the MML;
 4. Select a previously inspected permittee if a repeat inspection is warranted due to escalated enforcement or other safety issues.
- b. Coordination. The 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 Project Manager at least six weeks in advance in order for travel arrangements to be

made.

The NRC MML PM will notify 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 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 by the NRC or the MMLs Radiation Control Program personnel.

The 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 conditions placed on permits by the MML Master Radiation Safety Committee, 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 Exit Briefings. During the entrance interview, advise permittee management (typically, the military's 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 your 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 him or her 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 five 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 The following are the specific requirements for MML accompaniment inspections:

- a. Coordination. The 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 inspector and coordinate with the MML Radiation Control Program staff.

The scheduling of accompaniment inspections should be determined by the MML's inspection schedule.

- b. Conduct of the Accompaniment Inspection. Performing the inspector accompaniments should take into consideration the number of inspectors the MML utilizes. While the MML must perform inspector accompaniments in accordance with IMC 2800, the element for NRC accompanying MML inspector(s) is used by the NRC MML PM to monitor MML licensee's inspection performance as part of the biennial inspection.

The NRC inspector will follow 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 inspector will obtain additional information necessary for the biennial inspection or for review of any special issues.

If during the accompaniment inspection, the NRC inspector observes an apparent serious health and safety problem that is not being addressed by the MML inspector, it should be brought 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 immediate feedback to the MML inspector, once the inspection has been completed.

- 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 observation for the conduct of the inspection by the MML inspector, with the MML Radiation Control Program Director.

Performing the inspector accompaniments should take into consideration the number of inspectors the MML utilizes. While the MML must perform inspector accompaniments in accordance with IMC 2800, the element for NRC accompanying MML inspector(s) is used by the NRC MML PM to monitor MML licensee's inspection performance as part of the biennial inspection.

06.03 Allegations. All allegations received **should** be brought to the attention of the NRC MML **PM** and **Regional** Office Allegation Coordinator (**ROAC**) within **5** calendar days of receipt. The **ROAC** will then take the necessary action to ensure that the allegation is handled in accordance with NRC Management Directive 8.8. The Allegation Review Board in the lead region will make the determinations concerning follow-up actions, including: (1) referral to the MML licensee; or (2) independent follow-up by the NRC. Cases involving harassment and intimidation (H&I) should be reported to the lead region within **3** working days of receipt. As a general rule, H&I cases will be handled by the NRC, and referrals to the MML Radiation Control Program Director will be minimized.

END

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 and Feedback Resolution Accession Number
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