MANUAL CHAPTER 2810

MASTER MATERIAL LICENSE INSPECTION PROGRAM

2810-01 PURPOSE

To establish the inspection program applicable to master material license (MML) licensees. These licensees have a central radiation control program with regulatory oversight responsibilities for a variety of materials programs in several regions. The MML licensee's central radiation control program includes internally managed licensing and inspection programs. NRC performs a comprehensive inspection of the MML licensee's program (which includes the performance of the licensee, the central radiation control program and the individual permittees) on a biennial basis.

2810-02 OBJECTIVES

- 02.01 To establish the program for NRC's oversight of the licensee's performance and biennial review of the MML licensee's central radiation control program regulatory performance.
- 02.02 To provide standard guidance to inspectors conducting the biennial review, accompaniment inspections, and independent inspections.
- 02.03 To define the roles of the lead and assisting regional offices during oversight, the biennial review, accompaniment inspections, and independent inspections.
- 02.04 To establish a system for handling MML findings, including enforcement.

2810-03 DEFINITIONS

- 03.01 <u>Accompaniment Inspection (Accompaniments)</u>. 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 his/her implementation of the inspection program.
- 03.02 <u>Biennial Review</u>. A comprehensive review of the MML licensee's management of its centralized radiation control program. It integrates the results of the NRC project manager's routine oversight of the program, the biennial review inspection, NRC independent inspections, and accompaniment inspections. It focuses on licensee and

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- permittee compliance with NRC requirements and specific focus elements associated with the MML licensee's management oversight, staffing, training, licensing, permitting, inspection, response to events or incidents and safety concerns or allegations.
- 03.03 <u>Assisting Region</u>. The NRC region in which a permittee is physically located. At the request of the lead region, the assisting region conducts independent inspections and accompaniment inspections, and participates in the biennial review inspection.
- 03.04 <u>Independent Inspections</u>. NRC's inspection of the MML licensee's permittees. This includes routine and/or reactive inspections performed between the biennial reviews.
- 03.05 <u>Master Material License</u>. 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 activities as a regulator. 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.
- 03.06 <u>Master Radiation Safety Committee (MRSC)</u>. The committee delegated the authority by the highest level of the licensee's management to control and direct the MML Centralized Radiation Control Program.
- 03.07 <u>MML Radiation Control Program Director</u>. 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 also serves as the licensee's main point of contact with the NRC.
- 03.08 <u>Lead Region</u>. The NRC region that is assigned project responsibility for the MML. The NRC MML Project Coordinator is located in the lead region.
- 03.09 <u>Permittee</u>. 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.
- 03.10 NRC MML Project Coordinator. The NRC staff member assigned project responsibility for an MML. The NRC Project Coordinator is located in a regional office.
- 03.11 <u>Radiation Control Program Office</u>. The location of the MML's Radiation Control Program Director.

2810-04 RESPONSIBILITIES

04.01 <u>Lead region</u>. The lead region shall assign a staff member as NRC MML Project Coordinator to oversee the MML licensing activities and to implement the MML Inspection Program.

The following are the responsibilities of the lead region:

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Routine Oversight

- a. Review a sufficient number of and types of permits issued by the MML licensee for the NRC MML Project Coordinator to adequately monitor permittee activities and the licensee's permitting activities.
- b. Review all NRC and a sufficient number of MML inspection reports for the NRC MML Project Coordinator to adequately monitor permittee performance and the licensee's inspection activities.
- c. Review incident or event notifications and reports.
- d. Review and monitor allegations and significant safety concerns.
- e. Attend Master Radiation Safety Committee meetings.
- f. Monitor other activities as needed.

Independent Inspections

- a. Annually request a sufficient number of independent inspections, from the regions in which the licensee's permittee is located, for the NRC MML Project Coordinator to adequately monitor licensee and permittee regulatory performance.
- b. Specifically identify the locations to be inspected and the time frame in which the inspections will be conducted.
- c. Choose a representative sample of the MML permittees to be inspected. Less emphasis should be placed on inspection of permittees where the licensed activities have less potential for health and safety problems.
- d. Independent inspections should be conducted so as to avoid re-inspecting recently inspected permittees, unless a repeat inspection is warranted due to escalated enforcement, or other safety issues.
- e. Request each region performing an independent inspection to submit the inspection documentation to the NRC MML Project Coordinator. Inspection documentation must be submitted in accordance with current NRC inspection guidance.

Accompaniment Inspections

- a. Coordinate the annual accompaniment of the MML inspector(s). The purpose is to determine whether the licensee's inspector(s) is (are) inspecting the permittee in accordance with NRC's inspection policies and procedures. During the accompaniment, the NRC inspector should not become involved with the inspection, unless safety significant issues are not being addressed.
- b. Request each region performing accompaniment inspections to submit a completed "Inspector Accompaniment Checklist (Inspection Procedure 87129,

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Appendix E, "Focus Element - Technical Quality of Materials Inspections," Attachment B)" to the NRC MML Project Coordinator.

Biennial Review Inspection

- a. Coordinate the biennial review inspection of the MML Radiation Control Program.
- b. Notify the licensee of the dates of the biennial review inspection and documentation to have available.
- c. Assemble the inspection team.
- d. Develop the scope of inspection based on information from routine oversight, events, and program trends.
- e. Lead the biennial review inspection.
- f. Conduct the Exit Meeting with licensee's Senior Executive Management.
- g. Compile inspection information from team members and issue the inspection report. The inspection report should be issued within 45 days of the inspection end date.

Enforcement

If enforcement action is contemplated, the lead region will conduct enforcement in accordance with the NRC Enforcement Policy.

- 04.02 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 in a timely manner, so that the lead region is able to review and issue the report within established timeliness goals.
- 04.03 <u>Materials Inspector, Division of Nuclear Materials Safety, Regions I to IV</u>. Comply with the provisions in the "General Requirements" and "Specific Requirements" sections of this Manual Chapter (MC).

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- 05.01 The methodology for conducting independent inspections shall be the same as set out in the inspection procedures of MC 2800, with the addition of the specific requirements listed below. Additionally, the NRC MML Project Coordinator may request the inspector obtain information necessary for the Biennial Inspection Review. The same program codes as in MC 2800 shall be used.
- 05.02 The methodology for conducting the accompaniment inspections shall be performed in accordance with the inspection procedures of Inspection Procedure (IP) 87129, with the addition of the specific requirements listed below. Additionally, the NRC MML Project Coordinator may request the inspector to obtain information necessary for the Biennial Inspection Review.
- 05.03 The methodology for conducting the biennial review inspection shall be performed in accordance with the inspection procedures of IP 87129.

2810-06 SPECIFIC REQUIREMENTS

- 06.01 The following are the specific requirements for MML independent inspections:
 - a. <u>Coordination</u>. The inspector performing the independent inspection should contact the NRC MML Project Coordinator at least 3 weeks before the scheduled inspection date.

The NRC MML Project Coordinator 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 Project Coordinator 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.)

If the MML's Radiation Control Program staff wishes to accompany the NRC inspector, the NRC MML Project Coordinator 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 by the NRC or the MMLs Radiation Control Program personnel.

The inspector will coordinate with the NRC MML Project Coordinator, to obtain an inspection report number, before the inspection.

If the NRC MML Project Coordinator has expressed interest in participating in the inspection, notify the MML Project Coordinator of the proposed dates of inspection no later than 30 days in advance.

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- b. <u>Conduct of Inspection.</u> Follow the appropriate Inspection Procedure(s) from MC 2800. As requested by the NRC MML Project Coordinator, obtain additional information necessary for the biennial review or relating to any special issues.
- c. <u>Violations</u>. The following criteria should be used in citing violations identified during independent inspections of MML permitted activities:
 - NRC will issue 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>U.S. Code of Federal Regulations</u>, 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 issue violations to the MML under the following circumstances:
 - (a) NRC will not take any further enforcement action, to cite or to pursue escalation for: Severity Level IV or minor violations by permittees that have already been identified 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 Project Coordinator shall notify the MML's Radiation Control Program Director.
- d. <u>Entrance and exit meetings</u>. During the entrance interview, advise permittee management (typically, the military activity's Commanding Officer or the facility administrator or equivalent for a non-military licensee) that an agreement exists between the MML and the NRC. When practical, include a member of the MML's Radiation Control Program in the exit meeting by telephone. Exit meetings should be held with the highest-ranking individual associated with the licensed activity.

During the exit meeting, discuss any violations found, and address the need for the permittee to take immediate corrective action or commit to correct the 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.

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Notify the NRC MML Project Coordinator of your findings, before the exit briefing, whenever possible. However, the NRC MML Project Coordinator or lead Regional management (if the Project Coordinator is not available) must be notified when there are apparent Severity Level I, II, or III violations.

If the NRC MML Project Coordinator does not participate in the exit meeting, advise him or her of the inspection findings as soon as possible. The NRC MML Project Coordinator will then advise the MML Radiation Control Program Director of the inspection findings if that individual did not participate in the exit meeting.

- e. <u>Follow-Up</u>. 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 Project Coordinator, within 15 calendar 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 Project Coordinator should be provided with a summary of the issues supporting the apparent violations within 5 calendar days of the last day of the inspection. The NRC MML Project Coordinator will coordinate with the NRC inspector from the assisting region in preparing a draft inspection report, which shall be provided to the NRC MML Project Coordinator within 15 days of the last day of the inspection.

- 2. The inspector will provide any additional information that the NRC MML Project Coordinator requested (i.e., information concerning issues necessary for the biennial review or for review of special issues).
- 3. All inspection related correspondence will be issued by the lead region.

06.02 The following are the specific requirements for MML accompaniment inspections:

a. <u>Coordination</u>. The inspector performing the accompaniment inspection should contact the NRC MML Project Coordinator at least 3 weeks before the scheduled accompaniment inspection date.

The NRC MML Project Coordinator 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 Project Coordinator will notify the NRC inspector and coordinate with the MML Radiation Control Program staff.

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

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- b. <u>Conduct of the Accompaniment Inspection</u>. 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 Project Coordinator, the inspector will obtain additional information necessary for the biennial review 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.
- c. <u>Follow-Up</u>. Within 15 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.
 - 2. Provide any additional information that the NRC MML Project Coordinators request (i.e., information concerning issues necessary for the biennial review or special issues).
- O6.03 Allegations. All allegations received will be brought to the attention of the NRC MML Project Coordinator and Office Allegation Coordinator (OAC) within 5 calendar days of receipt. The OAC 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

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