



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20565-0001

NRC INSPECTION MANUAL

IIPB

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TRAINING: No special training requirements have been identified for any documents issued with this change notice.

REMARKS: IMC 2810 (Master Material License Inspection Program) has been revised to clarify responsibilities, guidance, and nomenclature. It also incorporates minor changes due to additions, deletions, and revisions in the Enforcement Policy and organizational units within NRC due to reorganizations.

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END

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UNITED STATES
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NRC IN SPECTION MANUAL

NMSS

MANUAL CHAPTER 2810

MASTER MATERIAL LICENSE INSPECTION PROGRAM

2810-01 PURPOSE

To establish the inspection program for licensees with a master material license (MML). These licensees conduct a variety of materials programs in several regions and have their own internal inspection programs. Note that the frequency and quality of internal inspections conducted by licensees might influence the type and frequency of U.S. Nuclear Regulatory Commission (NRC) inspections, but decisions about when and where to conduct NRC inspections remain with the NRC.

2810-02 OBJECTIVES

- 02.01 To establish the program for NRC inspections of MMLs.
- 02.02 To provide standard guidance on inspecting MML's to NRC inspectors.
- 02.03 To define the role of the assisting regional offices that provide support to the lead regional office, and the role of the lead regional office that has primary responsibility for inspecting a particular licensee.
- 02.04 To provide the policy and procedures for implementing the oversight of MMLs.
- 02.05 To establish a system for handling MML findings, including enforcement.

2810-03 DEFINITIONS

03.01 Master Material License. A multisite, multiregional material (byproduct, source, and/or special nuclear material) license, issued under Program Code 03613, in the Licensing Tracking System. 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.

03.02 Permittee. A holder of a permit, from the MML's radiation safety committee (RSC), or Radioisotope Committee, to use byproduct, source, and/or special nuclear material. The MML may refer to the permittee by some other name, but "permittee" will be used for the purposes of this manual chapter (MC).

03.03 Primary facility. The licensee's main facility or headquarters.

03.04 NRC Project Coordinator. The NRC staff member assigned project responsibility for an MML. Typically, one NRC Project Coordinator will be assigned for each MML, and the NRC Project Coordinator is usually located in a regional office.

03.05 MML's Licensee Coordinator. A licensee staff member who is assigned responsibility for the MML. This person serves as the licensee contact with the NRC Project Coordinator.

03.06 Radiation safety committee (RSC). The committee authorized to oversee the use of licensed material under the MML. The licensee may refer to that committee by another name, such as "Radioisotope Committee," which will be taken to refer to the same group, for the purposes of this MC.

03.07 Lead region. The NRC region that is assigned project responsibility for the MML. The NRC Project Coordinator is assigned to the lead region.

03.08 Assisting region. The NRC region in which a permittee is physically located. The assisting region conducts inspections at the request of the lead region.

2810-04 RESPONSIBILITIES

04.01 Lead region. The lead region shall assign a staff member as Project Coordinator to coordinate the inspections.

The following are the responsibilities of the lead region:

- a. Request one or more assist inspections, annually, in each of the remaining regions where the licensee has permittees. The lead region may ask the assisting region to make several inspections of permittees, depending on the number of user categories, extent of licensee or permittee operations, and becquerel (curie) quantities involved in facilities at the permittees' sites in the assisting region.
- b. Specifically identify the locations to be inspected.
- c. Choose, to be inspected, the locations with the highest safety risks.
- d. Request assist inspections, each following year, of permittees different from those inspected previously, except that assist inspections of those permittees inspected previously should be followed up, when significant violations have been found, to determine if corrective actions have been appropriate.
- e. Place less emphasis on inspection of permittees where the licensed activities have less potential for health and safety problems.
- f. Accompany the licensee's own internal inspector(s) at least once, annually, to a permittee other than the primary facility, to determine whether the licensee's inspector(s) is (are) inspecting the facility in accord with NRC's regulatory requirements and the licensee's requirements. The lead region should review reports of the licensee's internal inspections and its follow-up actions.

- g. Request each region performing assist inspections to collect and summarize inspection findings, in the form of draft reports, and to forward them to the lead region, for follow-up.
- h. Annually inspect the licensee's primary facility, including performing an inspection of management oversight, and conduct an exit interview. The content of the review shall include the findings of assist inspections. The lead region shall review any violations found, as well as the licensee's corrective actions for all NRC inspections conducted previously during the year.
- i. Obtain an up-to-date list of all permittees, from the licensee, annually.
- j. Evaluate written reports from the RSC at the licensee's primary facility, and from licensee permittee RSCs located in other regions (if there is more than one RSC committee or subcommittee).
- k. If, after an inspection, escalated enforcement action is contemplated, the lead region shall invite the licensee to an enforcement conference. There should be no undue delay in sending the licensee the report of an inspection and Notice of Violation, if needed. These should be done promptly by the lead region, after an inspection by the assisting region.
- l. Write an annual inspection report, to include findings of all the involved regions. Include the corrective actions that the licensee has taken, or plans to take, regarding negative NRC inspection findings, as a result of Notices of Violation (if any).

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

- a. Conduct inspections according to the request from the lead region. If the assisting region believes it is necessary to conduct more inspections than requested, the assisting region should request permission from the lead region.
- b. At a permittee, observe the licensee inspector(s) doing an inspection, if the lead region requests it. One or 2 days of observation may be enough to learn if the inspector(s) is (are) inspecting against the license and NRC regulations. During such observations, the NRC inspector should not become involved with the inspection, but, rather, should report any apparent irregularities to the lead region.

04.03 Materials Inspector, Division of Nuclear Materials Safety, Regions I to IV. Comply with the provisions in the "General Requirements" and "Specific Requirements" sections of this MC.

2810-05 GENERAL REQUIREMENTS

The methodology for conducting inspections shall be the same as set out in the inspection procedures of MC 2800, with the exception of the specific requirements given here. The same program codes as in MC 2800 shall be used.

The following are the specific requirements for MML inspections:

06.01 Coordination. Contact, 2 to 3 weeks before the scheduled inspection date, the MML's Licensee Coordinator, listed in Policy and Guidance Directive (P&GD) FC 85-13, before performing an assist inspection of an MML permittee. The MML's Licensee Coordinator, in turn, will notify the MML's RSC and determine if it plans to accompany the NRC on the inspection. [Alternatively, the NRC Project Coordinator could arrange, in advance, a process and timeframe for licensee notification, so that notifying the MML's Licensee Coordinator may not be needed for each inspection.] If the MML's RSC does wish to accompany the NRC inspector, the MML's Licensee Coordinator will notify the assisting region's inspector and assist in coordinating with the MML's RSC. The scheduling of inspections should be determined by regional needs and should not be modified for the convenience of the MML's RSC, MML's Licensee Coordinator, nor NRC inspectors. Although the MML's RSC will be provided with a list of the proposed inspections, individual permittee inspections should not be announced by the NRC or the MML's RSC personnel.

Coordinate with the MML's Licensee Coordinator, to obtain an inspection number, either before or after the inspection.

If the inspection is one that the MML's Licensee Coordinator has asked to accompany, coordinate the inspection date with MML's Licensee Coordinator, at least 30 days in advance of the planned inspection.

06.02 Entrance and exit meetings. During the entrance interview with permittee management (typically, the activity's Commanding Officer, if a military licensee, or the facility administrator or equivalent if non-military), advise permittee management that an agreement exists, between the MML and the NRC, to include a member of the MML's RSC in the exit meeting by telephone, when practicable. When the inspection is completed, ask permittee management to contact the MML's Licensee Coordinator listed in P&GD FC 85-13. Exit meetings should be held with the highest-ranking individual associated with the licensed activity.

Discuss any violations found, during the exit meeting, and attempt to have the permittee commit to correct the violations; otherwise, there may be a significant delay before the MML's RSC is informed. 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.

Notify the MML's Licensee Coordinator, before the exit briefing, whenever possible. This is particularly important when the inspection documents Severity Level I, II, or III violations, or where multiple Severity Level IV violations indicate possible management breakdown. When possible, this will also allow the MML's Licensee Coordinator to participate, by phone, in the exit meeting and to assist the inspector in coordinating RSC participation.

If the MML's Licensee Coordinator does not participate in the exit meeting, advise him or her of the inspection findings as soon as possible. The MML's Licensee Coordinator will then advise licensee management, at the RSC level, of the inspection findings, if it is not possible to contact these individuals at the exit meeting.

If the inspection notes apparent Severity Level I, II, or III violations, or multiple Severity Level IV violations indicate significant management inattention, contact the MML's Licensee Coordinator without delay.

06.03 Follow-Up. After completion of the inspection, submit completed Inspection Record; NRC Form 591 (if appropriate); draft Notice of Violation (if appropriate); and enforcement recommendations to the MML's Licensee Coordinator, within 15 calendar days of the last date of the inspection. NRC Form 591 should not be left with permittee management. After processing by the MML's Licensee Coordinator, Form 591 will be forwarded to the MML's RSC. If escalated enforcement is being considered, the MML's Licensee Coordinator should be notified within 5 calendar days of the last day of the inspection. The NRC Project Coordinator will coordinate with the NRC inspector from the assisting region in preparing a draft inspection report, which shall be provided to the MML's Licensee Coordinator within 15 days of the last day of the inspection. For non-escalated enforcement actions, inspection reports and Notices of Violation will be issued by the NRC Project Coordinator.

06.04 Allegations. All allegations received will be brought to the attention of the lead region NRC 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. Determinations concerning follow-up actions, including: (1) referral to the licensee; or (2) independent follow-up by the NRC, will be made by the Allegation Review Board. 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's RSC will be minimized.

06.05 Violations. The following criteria should be used in citing violations identified during inspections of MML permitted activities:

- a. NRC will issue violations to the MML and its permittees, under the following circumstances:
 1. 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 b.1. below.
 2. NRC identification of a violation of a condition placed on the MML by the NRC, except under the circumstances specified in Item b.1.
 3. NRC identification of any violation (non-minor) of NRC requirements by the MML's RSC.
 4. NRC identification of willful violations of NRC safety requirements, material false statements, or falsification of records, with the intent to indicate that NRC requirements are being fulfilled, when in fact, they are not. NRC will maintain and consider the option of reviewing and citing similar licensee-identified violations, on a case-by-case basis.
- b. The NRC will not issue violations to the MML under the following circumstances:
 1. Violations meeting the requirements in Section VII.B(1) or (2) of the Enforcement Policy. The intent is that the 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 by the MML's RSC; or minor violations that are identified by the NRC.

2. Identification of non-conformance with conditions placed on permits by the licensee's RSC, when the non-conformance does not constitute an apparent violation of NRC requirements. Such non-conformance, if safety-related, should be identified to the permittee during the exit meeting, and documented in the field notes. Also, if the non-conformance is safety-related, the MML's Licensee Coordinator shall notify the MML's RSC. Non-conformance with permit conditions should not be characterized as violations, at this time.

END