NRC INSPECTION MANUAL

NMSS/MSST

INSPECTION PROCEDURE 87129

MASTER MATERIALS PROGRAM

Effective Date: 10/29/2021

PROGRAM APPLICABILITY: IMC 2810 and 2800

87129-01 INSPECTION OBJECTIVES

- 01.01 To establish the inspection process for the Master Materials License (MML) biennial inspection.
- 01.02 To provide a systematic and integrated approach to determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.
- 01.03 To provide a systematic and integrated approach to determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements, the MML, and the Letter of Understanding (LOU).

87129-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of MML licensees. Review of the licensed activities will be commensurate with the scope of the MML licensee's program. The evaluation of the MML licensee's program will be based on routine communication with the MML licensee's Radiation Control Program (RCP) and review of its performance regarding management oversight, inspection, permitting, and event or incident and safety concern or allegation response programs. This also includes a review of the radiation safety performance of permittees during NRC's independent inspections. NRC's independent inspections shall be conducted in accordance with Inspection Manual Chapter (IMC) 2810.

In reviewing the MML licensee's performance, the inspection should cover the period from the last inspection forward. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as to ensure follow-up on previous violations, events or incidents, non-compliance, allegations, or overexposures.

02.01 <u>Preparation</u>. Preparation will include reviewing results of routine communications with the MML licensee, independent and accompaniment inspection reports, Master Radiation Safety Committee (MRSC) meeting minutes and other appropriate documents; identifying team members; coordinating with appropriate staff; and notifying and coordinating site access with the MML licensee. The inspector shall also review regional event logs and files to determine if the licensee has had any incidents or events since the last inspection. The letter notifying the

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licensee of the biennial review with the MML Biennial Review Questionnaire (see Appendix A) will be sent to the licensee 60 days before the inspection date.

02.02 <u>Entrance Briefing</u>. An entrance meeting should be scheduled prior to arrival on site to ensure senior management's availability for participation. The team should conduct the entrance briefing to inform senior management of the scope of the inspection soon after arrival on site.

02.03 Focus Elements

- a. <u>Management Oversight</u>. The MML licensee has centralized control over its radiation control program through management's oversight and control of licensed activities, its MML RCP office and MRSC. This focus element is used to determine if the MML licensee's performance is adequate to assure the public health and safety and if the licensee operates as described in its license commitments and LOU. This focus element also includes the results of NRC's independent inspections. (See Appendix B)
- b. <u>Technical Staffing and Training</u>. This focus element is used to evaluate whether staffing and training for the MML RCP office and MRSC are adequate for the scope of the program and license commitments. (See Appendix C)
- c. <u>Status of Materials Inspections</u>. MML permittees are inspected by MML RCP staff at regular intervals. This focus element is used to evaluate inspection frequency deviations, rescheduling, and timely communication of inspection findings to permittees. (See Appendix D)
- d. <u>Technical Quality of Materials Inspection</u>. This focus element is used to determine if inspections performed by the licensee's RCP office focus on health and safety, the inspectors follow NRC inspection policies and procedures, and findings are well-founded and well-documented. This focus element includes the results of NRC's accompaniment inspections. (See Appendix E)
- e. <u>Technical Quality of Materials Permitting Actions</u>. This focus element is used to determine whether permitting actions performed by the licensee's RCP office are performed in accordance with NRC's policy and guidance. This focus element includes reviewing the licensee's permit tracking system and permitting documentation. (See Appendix F)
- f. Response to Events or Incidents and Safety Concerns or Allegations. This focus element is used to determine whether events or incidents and safety concerns or allegations are reviewed, assessed and processed in a manner consistent with NRC's regulations, policies and guidance, and in accordance with license commitments. (See Appendix G)

87129-03 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800 and 2810. These documents are to be used as guidelines for inspectors in

determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

IMC 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs"

IMC 2800, "Materials Inspection Program"

IP 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing"

NUREG 1556, Volume 10, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance about Master Material Licenses"

MD 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)"

MD 8.8, "Management of Allegations"

END

Appendices:

- A. MML Biennial Review Questionnaire
- B. Management Oversight
- C. Technical Staffing and Training
- D. Status of Materials Inspections
- E. Technical Quality of Materials Inspection
- F. Technical Quality of Materials Permitting Actions
- G. Response to Events or Incidents and Safety Concerns or Allegations

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APPENDIX A

MML Biennial Review Questionnaire

Please send the checked information to the NRC MML Project Manager. The unchecked items should be available for inspection during the biennial review.

l.	<u>Mana</u>	lanagement Oversight								
		Organizational chart that includes the Senior Executive Management through the Radiation Control Program staff (current and changes since last biennial inspection).								
						en performed to as gs and their resolu				
		Current inter Control Prog		and/or operat	iing procedures	s that affect the Mi	VIL Radiation			
		List of reportable events or incidents that have occurred since last biennial inspection, include any actions taken to address the problems.								
		Current membership of the Master Radiation Safety Committee, including new members, vacancies and actions to fill those positions.								
		Minutes of Master Radiation Safety Committee meetings, including dates of meetings, attendance, issues discussed (e.g., MML licensing, program, oversight, inspection, enforcement issues; Master Radiation Safety Committee initiatives and activities; or unique permitting requests/actions, decommissioning activities, enforcement cases, allegations, incidents and events) and their resolutions.								
		•		of the MML's ac ring the last bid		response to NRC'	's comments and			
						nprove the safety uring public health				
		Description of the program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems, or difficulties which occurred during this review period.								
_		Updated per	mit list that i	ncludes the fo	ollowing informa	ntion:				
	Name	ne Permit#	Location	NRC prog. code	Priority	Last inspection date	Inspection due date			

II.	<u>Tec</u>	hnical Staffing and Training									
		Provide a staffing plan or complete a listing of personnel using the suggested format below, that provides the professional (technical) person-years of effort applied to the MML program by individual. Include the name, position, and the fraction of time spent in the following areas: administration, materials permitting & inspection activities, event response, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the MML radiation control program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. The table headings should be:									
	Nan	ne	Position	Area of Effort	FTE%						
		List all new professional personnel hired since the last review. For each, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.									
		List technical staff who have not yet met the qualification requirements of permit reviewer/materials inspection staff. For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.									
		List the number of	of technical staff who left	the program during this	period.						
		•	ositions in each program of summary of efforts to	, the length of time each fill the vacancy.	position has been						
Ш	. <u>Sta</u>	tus of Materials Ins	pections								
	Prepare a table identifying the permits with inspections that were/are passed due date by more than 50% for Priority 1 and 2 permittees and 1 year for Priority 3, 4, 5, and 5R permittees during the review period. The schedule for inspection frequency is set out in NRC Inspection Manual Chapter 2800. (Note: Although the licensee may be more restrictive and perform inspections more frequently, the list should be based on the inspection frequency in IMC2800, including temporary instructions. The list should include initial inspections that are overdue. Include the following information:										
	Р	Permittee Name Insp. Priority Pass Due Date Date performed									
		Are there current this.	ly any overdue inspectio	ons? If so, describe the a	action plan to address						
		Copy of current log or other document used to track inspections.									
		List of Inspection frequency and program codes by permit type.									

		frequency than called for in NRC Inspection Manual Chapter 2800 and state the reason for the change.									
IV	IV. <u>Technical Quality of Inspections</u>										
		List changes made to your written inspection procedures during the review period.									
		Prepare a table showing the number and types of supervisory accompaniments made during the review period, and results of those accompaniments. Include the following information:									
	Inspe	ector	Date								
_	 Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. 										
		Describe the type of instrumentation used during inspections and methods/frequency of calibration. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available through the review period?									
_		List of inspections that resulted in violations. Include the following information:									
	Perm	nittee	Program code	Date of inspection	Severity Level						
V.	<u>Tech</u>	nical Quality of Pe	ermitting Actions								
		List all permit actions completed during the review period, and highlight any major, unusual, or complex permits issued. Also identify any new or amended permits that now require emergency plans.									
		Discuss any variances from NRC licensing policies and/or procedures during the review period.									
		List changes made in your written permitting procedures (new procedures, updates, policy memoranda, etc.) during the review period.									
		Copy of current log or other document used to track licensing actions.									
		List non-standard	permit conditions used	during the review period	l.						
		List pending licen	nsing actions, include the	e following information:							
	Perm	nittee	Program Code	Action Type	Date Received						

I. <u>Responses to Events or Incidents and Safety Concerns or Allegations</u>								
	List reportable events or incidents (e.g., medical events, doses to embryo/fetus or nursing child, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc.) that were ongoing or occurred during the review period. Show whether the incident is open or closed and whether it was reported to the NRC. The list should be in the following format:							
Perm	Permittee Name							
	During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other permittees who might be affected notified? Was timely notification made to NRC?							
	For incidents involving failure of equipment or sources, was information on the incident provided to NRC for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.							
	List any changes to procedures for investigating incidents and events made during the review period.							
	List any changes to your procedures for handling safety concerns or allegations made during the period of this review.							
	List of all safety concerns or allegations received during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.							
	List of all wrongdoings identified during the review period. Show whether the action is open or closed.							

APPENDIX B

Management Oversight

I. INTRODUCTION

This document describes the procedures for conducting the review of the licensee's centralized control program.

II. OBJECTIVES

- A. To verify that the Master Materials Licensee has centralized control over its materials use program.
- B. To verify that the Master Materials License (MML) management's oversight and control of licensed activities, through its Radiation Control Program (RCP) office and Master Radiation Safety Committee (MRSC), operate as described in the MML licensee's commitments, are adequate to assure the public health and safety.
- C. To determine if the licensee's organization and structure is as described in the license.
- D. To confirm that the MML management and MRSC conduct internal audits and self-assessments as required by regulations (i.e., 10 CFR Part 20) or additional commitments in the license. In addition, to confirm that the licensee implements adequate corrective actions in response to safety and non-compliance issues and programmatic weaknesses identified as a result of these audits and assessments.
- E. To verify that the MML licensee has established and implemented radiation control program policies and standard operating procedures and that these procedures are consistent with NRC regulations, policies, guides and procedures.
- F. To integrate the results of independent inspections in evaluating the licensee's oversight of its permittees' safe use of radioactive materials.
- G. To integrate the results of routine communications and document reviews to assess the licensee's oversight.
- H. To confirm that the MML licensee has effectively implemented its radiation control program at all licensee levels and safely uses NRC regulated materials at all these levels.

III. BACKGROUND

This procedure only applies to the MML licensee's oversight and radiation control program procedures for byproduct, source, and special nuclear materials as identified on the license.

IV. ROLES AND RESPONSIBILITIES

The NRC MML Project Manager should be responsible for this focus element. This includes conducting staff discussions, and reviewing relevant documentation, MRSC meeting minutes, policies and procedures, internal audit reports, and other evidence of centralized control of the program.

V. GUIDANCE

A. Evaluation Procedures

The information used to assess the licensee's performance in this area will be obtained by:

- 1. Review of records pertaining to specific areas described in the review details section below. The information obtained from the records review should be discussed with MML personnel to ensure that the reviewer has a complete understanding of how the MML licensee has established and implemented its centrally controlled radiation control program, maintained oversight of its program, and exercised its centralized control over the program.
- 2. Interviews with MML personnel (i.e., members of the MRSC, RCP Office, permittee staff and permittee Radiation Safety Officers (RSO), observations at MRSC meetings, inspection accompaniments with MML staff, and independent inspections.
- 3. Review of responses to questions in the MML Biennial Review questionnaire. (See Appendix A)

B. Review Details

1. Centralized Control

Interview the radiation control program staff, use information obtained from independent inspections, and integrate the results of appendices C through G to evaluate the licensee's centralized control of the program.

2. Management Oversight

Executive management exercises its oversight of the RCP primarily through the MRSC. The reviewer should examine the MRSC charter and the minutes of its meetings since the last MML Biennial Review to determine if:

- a. The MRSC is composed of the required membership, has met at the required frequency, has been attended by the required members when meetings were conducted, and has discussed topics related to those in the "Management Oversight" section of Appendix A, "MML Biennial Review Questionnaire."
- The MRSC has been proactive in seeking out areas needing improvement, rather than just responding to events and information from outside sources;
- c. The committee has recommended any specific actions and assessed the implementation of those recommendations;

- d. The committee has demonstrated an ability to identify, assess and resolve issues and documents decisions;
- e. The MRSC effectively communicates the results of audits and trending analyses to appropriate personnel performing licensed activities.

3. Organization

- a. Review the reporting structure from the executive management, down through the permittees, and determine through record reviews and interviews the effectiveness of communication within the reporting structure.
- b. Determine whether the RCP Director has sufficient access to the MML licensee senior executive management.
- c. If the individuals appointed as the RCP Director and/or the Chairman of the MRSC changed since the last inspection, determine if the NRC was notified of these changes, and whether these changes impacted the program.

4. RCP Office

- a. Determine if the RCP Director/RCP Office have adequately assisted the MRSC in ensuring that radiation safety issues are addressed in a comprehensive and timely manner, audits are conducted as required, feedback mechanisms are in place to correct deficiencies, and that adequate resources are provided for implementing the radiation safety program or when modifications of the RCP are needed.
- b. Determine if the RCP Director has performed the duties and responsibilities as described in the license for this position or if these duties and responsibilities have been delegated to other individuals. If some have been delegated, ensure that the delegations were properly authorized and that the RCP Director has implemented measures to ensure that the delegated activities were adequately performed.
- c. Verify that inspection and permitting documents are received and processed in an effective and timely manner, that there is a means to track the status and location of each document, and that these documents are maintained such that they are readily retrievable.

5. Internal audits and self-assessments

- a. Determine if the MML licensee has performed the internal audits and self-assessments described in its license commitments.
- b. Review the results of these internal audits and self-assessments to determine if they were timely, comprehensive, performed by qualified

- individuals, and assessed the appropriate radiation safety program elements
- Based on the results of the audits and assessments, determine if the MML licensee took appropriate corrective actions in response to identified deficiencies.

6. RCP Procedures

- a. Determine if the MML licensee has established and implemented the RCP procedures as described in the license.
- b. Verify that the means used to develop, update, approve and disseminate these procedures are consistent with the procedures described in the license.

7. Effective Implementation of the RCP

- a. Review the results of NRC inspections performed at MML facilities. Review the actions the MML licensee took in response to violations identified as a result of the NRC inspections and determine if these actions were timely, comprehensive and effective.
- b. Review the results of MML licensee's inspections performed at its facilities. Review the actions the MML licensee took in response to violations identified as a result of its inspections and determine if these actions were timely, comprehensive and effective.
- c. Review the MML licensee's efforts to effectively communicate with its permittees in order to ensure that the permittees have a clear understanding of the RCP procedures and are aware of its requirements.
- d. Review and assess the MML licensee's efforts to receive and resolve technical questions from the permittees and how generic safety and health issues were addressed.
- e. Integrate the results of the above review to determine if all licensee levels are safely using licensed materials.

APPENDIX C

Technical Staffing and Training

I. INTRODUCTION

This document describes the procedures for evaluating the Master Materials License (MML) licensee's technical staffing and training.

II. OBJECTIVES

- A. To confirm that the staffing strategy described in its license commitments has been implemented by the MML licensee throughout the review period.
- B. To verify that qualification criteria for hiring new technical staff are established and are being followed.
- C. To ensure that vacancies, especially at the senior-level positions, are filled in a timely manner in accordance with the LOU.
- D. To confirm that the current staffing (management, technical and administrative) is adequate to support the MML licensing, permitting, and inspection programs.
- E. To determine that management is committed to training and staff qualification (e.g., is committed to and implemented a program for planned training and refresher training with an adequate training and travel budget to assure individual staff members are qualified).
- F. To verify that Radiation Control Program (RCP) permit reviewers and inspectors are trained and qualified in a timely manner (with allowance for availability of courses).
- G. To verify that Radiation Control Program (RCP) permit reviewers and inspectors receive training in revisions to NRC regulations, licensing and inspection policies and procedures related to the permitting and inspection activities performed.
- H. To evaluate the MML inspector and permit reviewer technical training and qualification program. The NRC requirements are established in NRC Inspection Manual Chapter (IMC) 1248. The MML licensee should have established, documented training and qualification requirements that are equivalent to IMC 1248.

III. BACKGROUND

- A. With respect to staffing, this procedure applies only to technical and management personnel in the nuclear materials safety program.
- B. This procedure only applies to the licensing, permitting, and inspection of byproduct, source, and special nuclear materials as identified on the license.

IV. ROLES AND RESPONSIBILITIES

A. Selection of a Principal Reviewer.

The MML Project Manager will determine which team member is assigned lead review responsibility for this focus element.

- B. The principal reviewer for this indicator is responsible for determining whether the program is being implemented safely by evaluating the following:
 - 1. Whether the full-time equivalents (FTEs) budgeted for the radioactive materials program are sufficient to complete the required work;
 - 2. Whether vacancies are filled promptly;
 - 3. Whether the licensee has assessed the impact of expected staff turnover;
 - 4. If not, whether program performance has been adversely affected;
 - 5. Whether changes in workload lead to changes in staffing; and
 - 6. Whether those individuals performing materials permitting and inspection activities are adequately qualified and trained to perform their duties.

V. GUIDANCE

A. Prior Information

Staffing and training records as well as organizational charts, as appropriate, should be reviewed based on the MML Biennial Review Questionnaire (see Appendix A) responses prior to the review, so that issues can be identified and questions formulated prior to the on-site portion of the review.

The MML Project Manager will provide the principal reviewer with feedback on staff activities from the results of independent inspections, accompaniment inspections, and routine communications with the licensee. Feedback on the MML staff permitting and inspection performance will also be provided during the biennial review from the principal reviewers evaluating other focus elements.

B. Review Details

The principal reviewer should evaluate and document the following:

- 1. Adequacy of personnel dedicated to the materials program for properly implementing the regulatory program, including the number and type of full-time and part-time positions allocated to the program.
- 2. Impact of any positions that are currently unfilled, or which were unfilled for a significant amount of time during the review period.

- 3. Timeliness and effectiveness of the MML management's actions to adjust workloads, or to recruit or reassign personnel to fill vacancies.
- 4. Impact of any observed differences between authorized staffing and budget, as well as any impacts which may occur due to recent changes in approved staffing levels or workload.
- 5. The results of whether an assessment of the impact of expected staff turnover was needed and if so, if it was adequate.
- 6. A balance among FTE assigned to permitting, inspection, and incident response exists
- 7. Minimum documented training and qualification requirements for personnel in the program as well as how actual training and qualification of personnel compare to those requirements.
- 8. Attendance of permit reviewers and inspectors at NRC regional/headquarters/stakeholder training sessions on implementation of new regulations, and NRC licensing, inspection, incident response/reporting and allegation handling policies and procedures appropriate for the types of MML permittees.
- 9. Whether there are established documented training qualification requirements equivalent to IMC 1248.

The reviewer should analyze any trends or developments over the entire review period, not merely those present at the time of the review.

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APPENDIX D

Status of Materials Inspection Program

I. INTRODUCTION

This document describes the procedure for conducting reviews of the Master Materials License (MML) licensee inspection activities.

II. OBJECTIVES

- A. To verify that MML permittees are inspected by Radiation Control Program (RCP) staff at intervals in accordance with frequencies prescribed in Inspection Manual Chapter (IMC) 2800.
- B. To ensure that inspections of new permittees are conducted within the inspection frequency specified for new licensees in IMC 2800.
- C. To confirm that inspection findings are communicated to permittees in a timely manner (30 calendar days as specified in IMC 2800).

III. BACKGROUND

- A. This procedure only applies to the MML licensee's oversight and radiation control program procedures for byproduct, source, and special nuclear materials as identified on the license.
- B. This procedure evaluates the quantitative performance of the MML licensee over the period of time since the last MML biennial review.
- C. While this indicator focuses primarily on quantitative performance, it also includes a qualitative evaluation that examines the justifications for the MML licensee if it revises its internal inspection frequencies.

IV. ROLES AND RESPONSIBILITIES

A. Selection of the Principal Reviewer.

The NRC's MML Project Manager will determine which team member is assigned lead review responsibility for this focus element. The principal reviewer should meet the appropriate requirements specified in IMC 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs, for a Materials Radiation Specialist Inspector," and have related inspection experience¹.

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¹ The MML Project Coordinator will determine which team member is assigned lead review responsibility for this focus element. This individual should have inspection experience in the program codes associated with the MML. Inspectors who have been involved in the MML program are preferred since they are familiar with the nuances of the MML program.

- B. The principal reviewer is responsible for reviewing relevant documentation, conducting staff discussions, and maintaining a summary of all statistical information received. At a minimum, this summary will include a tally of:
 - 1. All inspections, except initial inspections, that were completed late during the review period or are overdue.
 - 2. The amount of time past the proper inspection date that these overdue inspections were completed.
 - 3. Initial inspections that were completed late during the review period or are overdue
 - 4. The amount of time past the proper inspection date that the late initial inspections were completed.
 - 5. Inspection findings that were sent to the permittee late during the review period or are overdue.
 - 6. The amount of time past the required date the inspection findings should have been sent to the permittee.
 - 7. Any MML licensee inspection frequencies that do not match those detailed in IMC 2800.

V. GUIDANCE

A. Guidance Evaluation Procedures

- The principal reviewer should refer to Part III (Evaluation Criteria) of Management Directive 5.6 for specific evaluation criteria. These criteria should be applied to the data on inspections during the entire review period, not to the status of the MML inspection program at the time of the review only. The Directive's Glossary defines the terms "Materials Inspections" and "Overdue Inspections."
- 2. The percentage of exceeding due date inspections (Priority 1, 2, 3, and initial inspections) is the number of inspections exceeded due date (as defined in IMC 2800) conducted over the review period divided by the total number of routine inspections completed.
- 3. In applying the criteria, some flexibility may be used to make a determination of the significance of the findings for this indicator. If flexibility is being considered, it should be discussed with the NRC's MML Project Manager.

The principal reviewer should use a risk-informed methodology to select a representative number of MML permittees inspections completed during the review period, as well as documents involving inspection findings. That is, emphasis should be placed on permittees where the licensed activities have a higher potential for health and safety problems.

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4. If any significant problems or issues are identified (e.g., a preliminary finding that one or more large categories of permits are not being inspected at the appropriate interval), the principal reviewer should discuss this preliminary finding with the NRC's MML Project Manager, who will instruct the reviewer how best to obtain additional information from the RCP staff that might explain the situation.

B. Review Guidelines.

The response generated by the MML licensee to relevant questions in the MML Biennial Review questionnaire should be used to focus the review.

The principal reviewer should be familiar with IMC 2800 (https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/) which describes core inspections. Use inspection data provided by the MML licensee from the questionnaire. The principal reviewer may comment on the MML licensee's failure to meet more aggressive internally-developed inspection schedules than those specified in IMC 2800, but should not cite the MML licensee unless the licensee does not meet the criteria in IMC 2800. In addition, the reviewer should be sure that overdue inspections are tallied in a consistent fashion, (i.e. those more than 50 percent past the frequency specified in IMC 2800.)

C. Review Details

For the status of materials inspection, the principal reviewer should evaluate the following:

- 1. Number of overdue inspections.
- 2. The amount of time past the proper inspection date that any overdue inspections were completed.
- 3. Reason inspections were completed overdue.
- 4. Safety significance of canceling or deferring any overdue inspections.
- 5. Whether reports were issued in a timely fashion.
- 6. Whether the inspection frequencies used by the MML licensee are at least as frequent as those listed in IMC 2800.
- 7. Whether or not the MML licensee is counting inspections in a manner consistent with IMC 2800.
- 8. Whether an appropriate protocol is employed by the MML licensee to reduce inspection frequencies.

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APPENDIX E

Technical Quality of Materials Inspections

I. INTRODUCTION

This document describes the procedure for conducting reviews of the Master Materials License (MML) licensee inspection activities.

II. OBJECTIVES

- A. To ensure that inspection findings of noncompliance and health and safety matters are well-founded and well-documented.
- B. To verify that inspections, inspection results, and inspection reports are complete and reviewed promptly by supervisors or management.
- C. To determine that procedures are in place and used to help identify root causes and poor permittee performance.
- D. To confirm that follow-up inspections address previously identified open items and/or past violations.
- E. To verify that inspection findings lead to appropriate and prompt regulatory action.
- F. To confirm that supervisors conduct annual accompaniments of each inspector to assess performance and assure application of appropriate and consistent policies and guides.
- G. To verify that procedures are established and followed to provide feedback information from the inspector to the permit reviewers.
- H. To determine that inspection guides are consistent with NRC guidance, and that they are being used consistently by inspectors to assure uniform and complete inspection practices.
- I. To verify that permittees respond to MML inspector identified violations and concerns in an effective and timely manner and that the MML RCP staff response to the permittee's response is accurate and timely.
- J. To verify during the accompaniment process that the MML licensee's inspectors perform inspections in a manner consistent with the procedures in the license and NRC inspection policies and procedures.

III. BACKGROUND

A. This procedure applies to inspection accompaniments and the review (for adequacy, accuracy, completeness, clarity, specificity, and consistency) of the technical quality of completed materials inspection actions taken by the MML licensee in the review period.

B. This procedure only applies to the inspections of byproduct, source, and special nuclear materials as identified on the license.

IV. ROLES AND RESPONSIBILITIES

A. Selection of the Principal Reviewer.

The MML Project Manager will determine which team member is assigned lead review responsibility for this focus element. The principal reviewer should meet the appropriate requirements specified in Inspection Manual Chapter 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs," for a Materials Radiation Specialist Inspector. This individual should also have related inspection experience.

- B. The principal reviewer in conjunction with the MML Project Manager is responsible to use a risk-informed methodology to select a representative number of MML permittees inspections completed during the review period, as well as documents involving inspection findings. That is, emphasis should be placed on permittees where the licensed activities have a higher potential for health and safety problems. The reviewer is also responsible for reviewing relevant documentation, conducting staff discussions, and maintaining a reference summary of all those reviewed. At a minimum, this summary will include:
 - 1. The permittee name and address.
 - 2. A numerical file reference (such as permit number, or inspection report number).
 - 3. The inspection priority.
 - 4. The type of permit operation (e.g., program code or permit category).
 - 5. The MML licensee's inspector's initials.
 - 6. The type of inspection (e.g., routine, reactive, closeout, announced, unannounced, team, other, etc.).
 - 7. The date of inspection.
 - 8. The date inspection findings were issued.

V. GUIDANCE

- A. Evaluation Procedures.
 - 1. The principal reviewer should refer to MD 5.6, Part III, "Evaluation Criteria," for specific evaluation criteria. The Directive's Glossary defines the terms "Materials Inspection" and "Overdue Inspection."

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- 2. All materials inspections conducted by the MML licensee's inspectors since the last MML Biennial Review are potential candidates for review. Inspections of permit terminations and decommissioning will be treated as a subset of this focus element.
- 3. Depending upon the size of the MML licensee's program under review, the principal reviewer should select 10-25 inspection casework examples for review. Whenever possible, the selected casework should represent a cross-section of the MML licensee's workload, including as many different inspectors, permit categories, and geographic locations as practical. Inspections of decommissioning activities should also be included.
- 4. If the initial review indicates a systematic weakness on the part of one MML inspector, or problems with respect to one or more inspection procedures, additional similar inspection files should be obtained and reviewed, in order to determine the magnitude of the programmatic weakness.
- 5. If the evaluation of the 10-25 casework examples does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.
- 6. The casework should be reviewed to determine if the MML licensee was required to notify the NRC and if the notification was made in accordance with NRC regulations.

B. Review Guidelines.

- 1. The response generated by the MML licensee to relevant questions in the MML Biennial Review questionnaire should be used to focus the review.
- 2. The MML Project Manager will provide the principal reviewer with feedback from the results of independent inspections, accompaniment inspection and routine communications with the licensee.
- 3. The principal reviewer should work with the MML Project Manager in selecting inspection files for review.
- 4. The inspection files reviewed should include clear inspections, violations documented on the licensee's form equivalent to NRC's Form 591, and full inspection reports.

C. Review Details.

Attachment A, "Inspection File Review Checklist," was developed to assist in reviewing certain completed inspection reports. However, the principal reviewer is not required to address every item in the checklist, or to use the checklist for each type of inspection selected for review.

For the technical quality of inspections, the principal reviewer should evaluate the following:

- 1. That the correct inspection procedure was used.
- 2. For each compliance action selected, that the inspection report adequately documents:
 - a. The scope of the inspection and the permitted program.
 - b. The permittee organization and the persons contacted.
 - c. The permittee's administrative controls and procedures; facilities and equipment; radiation safety procedures for procurement, use, transfer and disposal; posting and labeling; personnel monitoring, gaseous and liquid effluents, surveys and bioassay, events or incidents, overexposures, and radioactive waste packaging and shipping.
 - d. The operations observed.
 - e. The interviews of workers.
 - f. Independent measurements.
 - g. Status of previous noncompliance items.
 - h. New items of noncompliance noted.
 - i. The exit interview with management.
 - j. The substance of discussions with permittee management.
 - k. The permittee's response to any items of noncompliance.

Note: Violations documented on the licensee's form equivalent to NRC Form 591 will not include all the details described above.

- 3. Whether any information is missing from the file (e.g., documents, letters, file notes, and telephone conversations).
- 4. Inspection reports are sufficiently detailed to show that each inspection was complete.
- 5. All items of noncompliance and safety recommendations were identified and substantiated.
- 6. Correct action was taken for items of noncompliance.
- 7. The documentation of items of noncompliance is written in the correct regulatory language and dispatched in a timely manner.
- 8. Any unresolved items or misunderstandings by the permittee were pursued to a satisfactory conclusion.

- 9. The inspection report was reviewed by management.
- 10. Management notes report deficiencies (such as unsupported conclusions and opinions in the report, noncompliance items not properly substantiated, apparent items of noncompliance not cited, etc.) and brings these deficiencies to the attention of the inspector.
- 11. The permittee's response was reviewed for adequacy and any subsequent action taken by management.
- 12. The effectiveness of the RCP's internal program to evaluate its inspectors in the field. RCP supervisors should evaluate all inspectors on at least one inspection in the field per year.
- 13. If the MML licensee was required to notify the NRC, the notification was made in accordance with the regulations (e.g., decommissioning notification).
- D. Inspector Accompaniments/Field Evaluations.

In addition to performing a file review of the selected inspections, this focus element includes a sufficient number of accompaniments of the MML inspectors to observe, on a first-hand basis, the inspectors' demonstration of proper inspection techniques, and areas of emphasis. Accompaniments should include a broad sample of permittee types. Scheduling of accompaniments should be in accordance with the MML licensee's work schedules. Attachment B, "Inspector Accompaniment Checklist," was developed to assist in documenting the inspection accompaniments.

VI. ATTACHMENTS

- 1. Inspection File Review Checklist
- 2. Inspector Accompaniment Checklist

APPENDIX E - ATTACHMENT 1

INSPECTION FILE REVIEW CHECKLIST

*NOTE: not all items in checklist are applicable to all MMLs.

FILE#_								
PERMIT	TEE:		PERMIT #					
LOCATIO	ON:	PERM	IIT TYPE:					
INSPEC ⁻	TION DATE:		PI	RIORITY:				
ANNOUN	ICED 🗆	UNANNOUNCED 🗆	COMPLETE		PARTIAL			
ROUTINE		INITIAL 🗆	IR:	OFFICE	FIELD			
FOLLOW	/-UP □	SPECIAL □	OTHER					
INSPECT	TION COND	UCTED WITHOUT GOIN	IG OVERDUE?	Y N N/A				
NO.		СОММЕ	ENTS FOR REF	PORT				
MML INSPE	CTOR:			OFFICE:				
MML SUPER	RVISORY RE	EVIEW BY:		DATE:				

"MML BIENNIAL REVIEW" REVIEW BY:	DATE:	
FINDINGS DISCUSSED WITH:		ON:

ITEM	0.K.	COMMENTS OR QUESTIONS
ACTION DATES:		
PREVIOUS INSPECTION:		
INSPECTION DATE:		
ENFORCEMENT LETTER: SHORT FORM □		
PERMITTEE RESPONSE:		
FOLLOW-UP:		
ACKNOWLEDGMENT LETTER:		
CLOSE-OUT:		
DOCUMENTED EVIDENCE OF:	ı	
CLOSEOUT OF PREVIOUS VIOLATIONS		
REVIEW & CLOSEOUT OF PREVIOUS INCIDENTS		
EXIT MEETING ATTENDEES & TITLES SUBSTANCE OF DISCUSSIONS		
OBSERVED OPERATIONS		
WORKER/USER INTERVIEWS		
ANCILLARY WORKER INTERVIEWS		
INDEPENDENT MEASUREMENTS		
REPORT DOCUMENTS REVIEW OF:		
PERMIT EXPIRATION DATE OR RENEWAL STATUS		
CONDITION, LOCATION OF FACILITIES & EQUIPMENT		
ALARA PROGRAM, ACTION LEVELS, INTERNAL AUDITS		
OPERATING PROCEDURES		

	1
MANAGEMENT, ORGANIZATION, RSO, RSC, USERS	
EMERGENCY PLAN OR PROCEDURES	
INCIDENT FILE	
TRAINING PROGRAM - USERS & ANCILLARY WORKERS	
INSTRUMENTS, CALIBRATION	
POSTING, LABELING, REGULATIONS	
SECURITY	
PROCUREMENT, RECEIPT, INVENTORY	
USE, TRANSFER, SHIPPING	
MONITORING & SURVEY PROGRAM	
RSC MINUTES, COMMITTEE COMPOSITION	
DOSIMETRY & BIOASSAY RECORDS	
LEAK TESTS, MAINTENANCE, QA, QC	
GAS & LIQUID EFFLUENT RECORDS	
WASTE DISPOSAL	
USE OF FIELD OR TEMP JOB SITES AS APPROVED	
INSPECTION FINDINGS (REPORT)	
CONDUCTED IN SUFFICIENT DEPTH & SCOPE	
REPORT COMPLETE AND IN STANDARD FORMAT	
REPORT CLEARLY IDENTIFIES VIOLATIONS	
EXIT MEETING AT APPROPRIATE MANAGEMENT LEVEL	
FINDINGS INDICATIVE OF NEED FOR PERMIT CHANGES RELAYED TO PERMITTING STAFF (VERIFY IN FILE)	
ENFORCEMENT	
VIOLATIONS PROPERLY CITED	

	 1
REPEATED VIOLATIONS TAKEN INTO ACCOUNT	
LETTER CLEARLY IDENTIFIES VIOLATIONS	
PROPER REGULATORY LANGUAGE IN LETTERS	
SUITABLE FOLLOW-UP TO PERMITTEE'S RESPONSE	
ENFORCEMENT ACTION APPROPRIATE	
POTENTIAL SEVERITY LEVEL I-III VIOLATIONS REPORTED TO NRC	
WILLFUL/WRONG DOING VIOLATIONS REPORTED TO NRC	
PERMIT FILE (INSPECTION SECTION)	
FILE ORDERLY AND COMPLETE	
ADEQUATE SUPERVISORY REVIEW OF REPORTS, LETTERS AND PERMITTEE RESPONSES	
SUPERVISORY REVIEW	
DEFICIENCIES IDENTIFIED AND DOCUMENTED BY SUPERVISOR	

COMMENTS FOR DISCUSSION WITH STAFF

APPENDIX E ATTACHMENT 2

INSPECTOR ACCOMPANIMENT CHECKLIST

MML:	DATE:	
INSPECTOR:	NRC REVIEWER:	
PERMITTEE:	PERMIT NO:	
LOCATION:	INSPECTION TYPE:	
PERMIT TYPE:	ANNOUNCED	UNANNOUNCED
PRELIMINARY DISCUSS	SION WITH INSPECTOR	DONE
EXPLAIN THE EXTENT OF THE REVIEWE INSPECTION.	R'S PARTICIPATION II	1
DISCUSS PROCEDURE FOR INTRODU PERMITTEE AND EXPLAINING HIS PA		
EXPLAIN METHOD TO BE USED IN EVAL PERFORMANCE.	UATING INSPECTOR'S	;

SUMM	1ARY OF EVALUATION		
INSPECTOR'S PERFORMANCE:			
ADEQUATE NEEDS IMPROVEMENT			
COMMENTS:			
THE INSPECTOR WOULD BENEFIT	FROM ADDITIONA	AL TRAINING	6 IN
EVALUATION DISCUSSED WITH _	(SUPERVISOR)	ON	(DATE)

ITEM	.O.K.	COMMENTS OR QUESTIONS
INSPECTOR'S PREPARATION		
ADEQUATE REVIEW OF PERMIT AND COMPLIANCE HISTORY		
INSPECTION PLAN OR FIELD FORM		
APPROPRIATE SURVEY INSTRUMENTS CALIBRATED INSTRUMENT RESPONSE CHECK		
SUPPLEMENTAL MATERIALS: REGS		
ENTRANCE	_	
INTERVIEW CONDUCTED AT APPROPRIATE LEVEL		
EXPLANATION OF INSPECTION PURPOSE, SCOPE, METHOD		
INSPECTION	1	
USE OF APPROPRIATE FORM OR CHECKLIST		
"WALK THROUGH" AT BEGINNING OF INSPECTION		
OBSERVATION OF OPERATION AND HANDLING OF RAM		
FACILITIES CHECKED FOR PROPER POSTING, LABELING		
SECURITY VERIFIED		
WORKERS CHECKED FOR PERSONAL DOSIMETRY		
WORKER INTERVIEWS RAM USERS □ ANCILLARY WORKERS □		
WIPES, SURVEYS, MEASUREMENTS TAKEN		
ADHERENCE TO ALARA EVALUATED		
REVIEW OF INCIDENTS, OVEREXPOSURES, ETC.		

ORAL INTERVIEWS AND IF NECESSA	RY		
RECORDS VERIFICATION FOR:			
SECURITY			
PROCUREMENT & INVENTORY	Ш		
RECEIPT & TRANSFER OF MATERIAL	Ш		
INTERNAL AUDITS			
SURVEYS & MONITORING			
PERSONNEL DOSIMETRY, BIOASSAY			
PERSONNEL DOSIMETRY, BIOASSAY	Ш		
QUALIFICATION AND TRAINING OF			
PERSONNEL	П		
T ENCOMMEE	ш		
EMERGENCY PLAN & PROCEDURES	П		
COMMITTEE MEETINGS, MINUTES			
AUTHORIZED USERS	H		
NOTITO NIZZB GOZING	ш		
INSTRUMENT CALIBRATION	П		
DOSE CALIBRATOR TESTS;	_		
UTILIZATION LOG			
LEAK TESTS	\exists		
GENERATOR - ASSAY, MOLY			
BREAKTHROUGH, LOGS			
WASTE MANAGEMENT, DISPOSAL	\Box		
, -	_		
RELEASE OF AIR & SEWER			
EFFLUENTS			
QA & QC; MAINTENANCE			
INSPECTION CONDUCTED IN			
SUFFICIENT SCOPE & DEPTH			
	- _F		
INSPECTION FOCUS ON PERMITTE PERFORMANCE AND SAFETY			
SIGNIFICANCE			
VERIFICATION OF CORRECTIONS	TO		
PREVIOUS VIOLATIONS			
OTHER			

IDENTIFIED POTENTIAL SL I-III VIOLATIONS/REPORTED TO NRC	
IDENTIFIED WILLFUL/WRONGDOING VIOLATIONS - REPORTED TO NRC	
IDENTIFICATION/HANDLING OF SAFETY CONCERNS/ALLEGATIONS	

INSPECTOR'S PROFESSIONALISM	
USE OF PROPER HEALTH PHYSICS TECHNIQUES (SELF MONITORING, ETC.)	
ACCURATE EVALUATION OF RADIATION SAFETY	
KNOWLEDGE OF HEALTH PHYSICS & REGULATIONS	
APPROPRIATE APPEARANCE FOR PERMIT TYPE	
SKILL IN WORDING QUESTIONS	
SUITABLE RAPPORT WITH MANAGEMENT AND WORKERS	

ITEM	O.K.	COMMENTS OR QUESTIONS
EXIT		
PREPARATION FOR EXIT INTERVIEW; ASSEMBLY OF SUPPORTING MATERIAL		
EXIT CONDUCTED AT APPROPRIATE MANAGEMENT LEVEL		
VIOLATIONS FULLY EXPLAINED; PERMIT CONDITION OR REG CITED		
RECOMMENDATIONS CLEARLY DISTINGUISHED FROM VIOLATIONS		
IMPENDING ENFORCEMENT ACTIONS EXPLAINED		
PERMITTEE ADVISED OF EXPECTED RESPONSE AND REQUIREMENTS FOR CHANGE		

ITEMS OF NON-COMPLIANCE	O.K.	
	+	
	+	
	1	
	<u> </u>	
ADDITIONAL COMMENTS		

APPENDIX F

Technical Quality of Materials Permitting Actions

I. INTRODUCTION

This document describes the procedure for reviewing the Master Materials License (MML) licensee's permitting program.

II. OBJECTIVES

- A. To ensure that all permitting actions are reviewed.
- B. To verify that permit reviews are thorough, complete, consistent, and of acceptable technical quality; health and safety issues are properly addressed; and decisions regarding the review are technically sound and consistent with approved NRC guidance (e.g., NUREG 1556 Series).
- C. To verify that essential elements of permit applications have been submitted and that these elements meet current regulatory guidance for describing the isotopes and quantities used, qualifications of personnel who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permitting actions.
- D. To verify that all deficiency correspondence (e.g., e-mail, fax, phone, etc.) clearly state regulatory positions and are used at the proper time, and that all deficiency responses are in writing and signed by the permittee.
- E. To verify, through site visits of the RCP offices, that permitting actions and documents are handled and processed as described in the MML licensee's commitments for permitting procedures and policies.
- F. To determine if the MML licensee has a means of tracking and accounting for all permitting actions and associated documents received.
- G. To verify that applicable licensing guidance documents are available to reviewers and are followed.

III. BACKGROUND

- A. This procedure applies to review (for adequacy, accuracy, completeness, clarity, specificity, and consistency) of the technical quality of completed materials permitting actions issued by the MML licensee in the review period, and the permit tracking system.
- B. This procedure only applies to the permitting of byproduct, source, and special nuclear materials as identified on the license.

IV. ROLES AND RESPONSIBILITIES

A. Selection of the Principal Reviewer.

The MML Project Manager will determine which team member is assigned lead review responsibility for this focus element. The principal reviewer should meet the appropriate requirements specified in Inspection Manual Chapter 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs," for a Materials License Reviewer. This individual should also be a Senior Radiation Specialist/Health Physicist or a Radiation Specialist/Health Physicist with related licensing experience.

- B. The principal reviewer in conjunction with the MML Project Manager is responsible to use a risk-informed methodology to select a representative number of MML permittees actions completed during the review period, covering renewals, amendments and terminations. That is, emphasis should be placed on permittees where the licensed activities have a higher potential for health and safety problems. The reviewing is also responsible for reviewing relevant documentation, conducting staff discussions, and maintaining a reference summary of all those reviewed. At a minimum, this summary will include:
 - 1. The permittee name and address.
 - 2. A numerical file reference (such as permit number).
 - 3. The permit reviewer's initials.
 - 4. The type of permitting action (i.e. new, amendment, renewal, termination, etc.).
 - 5. The date the permitting action was issued.
 - 6. The type of permit operation (i.e. program code or permit category).

V. GUIDANCE

- A. Evaluation Procedures.
 - 1. All permitting actions since the last MML biennial review are potential candidates for review. Reviews of permit terminations and complex decommissioning will be treated as a subset of this common focus element.
 - 2. Depending upon the size of the MML licensee's program, the principal reviewer should select between 10-25 permitting actions for review. Whenever possible, the selected permits should represent a cross-section of the MML licensee's workload, including as many different permit reviewers and permit categories as practical. A mix of medical and academic uses (hospitals, teletherapy licenses, broad scope facilities, etc.) and industrial use permits (radiography, irradiators, gauges, measuring devices, etc.) should be sought. Whenever possible, the selected permits should include at least 2 new permits, at least 3 major program amendments, at least 3 permit renewals, and at least 1 permit termination or

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denial. Permits authorizing activities with potential for significant environmental impact should be included whenever possible. Complex decommissioning permitting activities should also be included.

- 3. If the initial review indicates a systematic weakness on the part of one MML reviewer, or problems with respect to one or more type(s) of permitting action, additional similar permit files should be obtained and reviewed, in order to determine the magnitude of the programmatic weakness. If previous reviews indicate a programmatic weakness in a particular area, additional files should be reviewed to assure this weakness has been addressed.
- 4. If the evaluation of the 10-25 permitting actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.
- 5. Permitting actions pending completion for unusually long periods of time (e.g. amendments not completed for periods greater than six months or renewals not completed for periods over one year), should be identified specifically, in order to determine whether or not there have been any safety-significant impacts on each permittee's program.

B. Review Guidelines.

- The response generated by the MML licensee to relevant questions in the MML Biennial Review Questionnaire (see Appendix A) should be used to focus the review.
- 2. The MML Project Manager should consider the quantitative and qualitative responses to the questionnaire as well as general knowledge about the nature and scope of the specific program under review in determining the permit files to be reviewed on site.

C. Review Details.

Attachment A, "Permit File Review Checklist," was developed to assist in reviewing certain completed permitting actions. However, the principal reviewer should not feel compelled to address every item in the checklist or to use it for each type of permitting action selected for review.

For the technical quality of permitting actions, the principal reviewer should evaluate the following:

- 1. Technical correctness regarding permit conditions, issue and expiration dates.
- 2. Applications are properly completed and signed by an authorized official.
- Any significant errors, omissions, deficiencies or missing information in permitting action files (i.e., documents, letters, file notes, and telephone conversations).
 Permits should be properly supported by information in the file. Any significant deficiencies related to health and safety should be noted.
- 4. Whether there are improper and/or illegal permit authorizations.

- 5. Any pre-permitting visits completed for complex and major permitting actions.
- 6. Procedures for reviewing permits prior to renewal to assure that supporting information in the file reflects the current scope of the permitted program.
- 7. Permitting guides, checklists, and policy memoranda consistent with current NRC practice.
- 8. Appropriate use of signature authority.
- 9. Consideration of the present compliance status of the permittees in the permitting actions.
- 10. Use of NRC standard license conditions to expedite and provide uniformity to the permitting process, whenever practicable.

VI. ATTACHMENT

3. Permit File Review Checklist

APPENDIX F ATTACHMENT 3 PERMIT FILE REVIEW CHECKLIST

MML: FILE# PERMITTEE: ______PERMIT #_____ LOCATION: _____PERMIT TYPE TYPE OF PERMITTING ACTION: NEW _ RENEWAL _ AMENDMENT _TERMINATION _ DATE OF ACTION: _____AMENDMENT # _____ NO. **COMMENTS FOR REPORT** QUESTIONS FOR REVIEWERS PERMIT REVIEWER: SUPERVISORY REVIEW BY: ______DATE_____ MML Biennial REVIEW BY: ______DATE:

FINDINGS DISCUSSED WITH ON: ON:

Tie-down Document Description (Letter, Telcon, Fax, E-mail, Etc.)	Date	ок	Or Comments
1. APPLICATION			
2. DEFICIENCY LETTER RESPONSE			
3.			
4.			
5.			
6.]
7.			
8.			
9.			
10.			

Item	ок	Comments or Questions
Application Deficiencies Identified by Reviewer:	_	
Senior Management Signature, Date		
Isotope, Form, Quantity, Authorized Use		
Places of Use (Including Temp Job Site, Field, Etc.)		
Description of Facility (Hoods, Shielding, Etc.)		
ID & Duties of Authorized Users, RSO, RSC		
User Qualifications, Training, Supervision		
Instruments & Calibration		
SS&D Identification; Leak Test Procedures		

Service Procedures (Dose Calibrator Tests, IR, Etc.)		
Personnel Monitoring, Bioassays		
Operating Procedures		
Emergency Procedures or Plan		
Security of RAM		
Posting Requirements		
Procurement, Receipt Procedures		
Inventory, Record Keeping Requirements		
Transportation of RAM		
Waste Disposal (Incineration, Compacting, Etc.)		
Effluent Release & Records		
Special Authorization		
Monitoring and Survey Program		
Internal Audits		
Financial Security Requirement If Needed		
QA/QC/QM		
ALARA, Action Levels		
lt a ma	OK	Commonto en Overtione
Item	OK	Comments or Questions
Permit File	Ī	
File orderly; complete with application, deficiency letters, tie-downs documents, all amendments, etc.		
Telcons, e-mails, faxes, and checklists included		
Peer Review Documented		
Permitting Process	ı	
Deficiencies Clearly Stated		
Applicant Response Adequate or Followed-up		

Exemption Request Identified/Request Sent to NRC	
Technical Assistance Requested from NRC	
Pre-permitting Visit Conducted and Documented	
Permittee's Compliance History Considered	
Supervisory Review Corrected All Problems	
Request for exemption identified	
Permit	
Permit Correctly Lists Materials to Be Possessed and Authorized Use	
Standard Conditions for Permit Type Included	
Special or Modified Conditions Proper	
Tie-down Condition Complete	
Correct regulations Cited	
Expiration Date Correct	
Signature Line, Date O.K.	

Terminate	ed Perr	nits
Item	ОК	Comments or Questions
Application for Termination		
Acceptable Method of RAM Disposal Transfer to Another Licensee or permittee Return to Manufacturer Shipment to Burial Site or Other		
Supporting Documents		
SS&D Leak Tests		
Current Copy of Recipient's Permit		
Permittee's Close-out Survey Make, Model, S/N of Instrument Dates of Survey and Calibration Identification of Person Making Survey All Readings, Including Background		
Verification of Receipt by Recipient for Transfer		
MML Licensee's Actions		
NRC Notified of Termination If Required and Timeliness Issues Appropriately Addressed		
Permittee's Statements Verified		
Necessary Action Taken Promptly to Prevent Abandonment of RAM		
Termination Inspection Conducted and Properly Documented If Required		
Review of Receipts		
Transfer and/or Disposal Records		
Verification of Transfer and Disposal		
Facility Survey Documentation Make, Model, S/N of Instrument Dates of Survey and Calibration Identification of Person Making Survey All Readings, Including Background		

APPENDIX G

Response to Events or Incidents and Safety Concerns or Allegations

I. INTRODUCTION

This document describes the procedures for reviewing the Master Materials License (MML) licensee's response to events or incidents and safety concerns or allegations.

Investigation of allegations is a shared responsibility between NRC and the MML licensee. Objective B below recognizes differences exist between MML licensee commitments, and other statements are included to focus NRC's review of the MML licensee's handling of safety concerns and allegations from a performance-based rather than prescriptive perspective.

"Safety concerns" are included in this section because the MML licensee may recognize a safety concern quicker than an allegation. Further, handling safety concerns in a manner in which a concerned individual feels his/her concern was considered and he/she is comfortable with the process could resolve issues before they become allegations.

The MML licensee, like other licensees, should ensure that all personnel involved in licensed activities are aware of their right to express their safety concerns directly to the NRC. MML licensees should have a program to receive and respond to safety concerns, and they should do so in a manner that does not result in a negative impact on the individual expressing the concern or cause a "chilling effect" on others. The NRC's expectation is that once a safety concern is brought to the licensee's attention, the licensee should investigate the concern and take action as appropriate for the nature and validity of the concern. The NRC should review the handling of safety concerns from a performance-based perspective.

II. OBJECTIVES

- A. To assure that actions taken in response to events, incidents, safety concerns, or allegations are appropriate to the nature of the situation, well-coordinated, timely and in accordance with the license application.
- B. To verify that the MML licensee has established and implemented effective event, incident, safety concerns, and allegation response procedures in accordance with the license applications and Letter of Understanding.
- C. To confirm that corrective actions taken in response to events, incidents, safety concerns, or allegations are adequately implemented by the Radiation Control Program (RCP) and permittees, that correct follow-up measures are taken to ensure compliance and that the issue is closed.
- D. To verify through telephonic contacts with individuals at several permittee facilities that they are familiar with the RCP event or incident, and safety concern or allegation procedures and discuss any experiences they may have had with these procedures.
- E. For events or incidents:

- 1. To assure that the level of effort in responding to an event or incident is commensurate with potential health and safety significance.
- 2. To confirm that follow-up inspections are scheduled and completed, if necessary.
- 3. To confirm that notification to the RCP office and NRC is performed in accordance with the license application and specific regulations for the particular type of incident or event.
- 4. To verify that the information provided by the MML licensee on events or incidents is complete and accurate.

F. For safety concerns or allegations:

To verify that the MML licensee is properly handling all safety concerns and allegations (e.g., the evaluation is of sufficient depth and scope, root causes and generic implications are considered, safety issues are properly addressed, identity of the concerned individual or alleger is protected, a safety concern or allegation is closed in a timely manner, feedback is provided to the concerned individual or alleger, and corrective actions are sufficient).

III. BACKGROUND

- A. This procedure applies to all event or incident responses and safety concern or allegation activities that are ongoing or occurred during the review period.
- B. This procedure only applies to events or incident responses and safety concerns or allegations involving byproduct, source, and special nuclear materials as identified on the license.
- C. As used in this procedure, the term "incident" or "event" applies to an occurrence that may have caused, or threatens to cause, conditions described in 10 CFR 20.2202 through 20.2204, 10 CFR 30.50, 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 36.83, 10 CFR 40.60, or 10 CFR 70.50.
- D. As used in this procedure "safety concern" means an individual's concern associated with the safe use of NRC regulated materials.
- E. As used in this procedure, the term "allegation" means a declaration, statement, or assertion of impropriety or inadequacy associated with regulated activities, the validity of which has not been established. This term includes all concerns identified by sources such as the media, individuals or organizations. If the MML licensee defines this term in a different fashion, this should be noted during the course of the review.

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IV. ROLES AND RESPONSIBILITIES

- A. The MML Project Manager will determine which team member is assigned lead review responsibility for this focus element.
- B. The principal reviewer is responsible for reviewing relevant documentation, conducting staff discussions, and maintaining a reference log of all permitting, inspection, safety concern, and allegation files reviewed and MML personnel interviewed.

V. GUIDANCE

A. Review Scope

The principal reviewer will determine the scope of the review based on preliminary discussions with the MML Project Manager. At a minimum, for each event, incident, safety concern, and allegation reviewed, the principal reviewer shall document the following:

- 1. Permittee name:
- 2. Permittee address:
- 3. A numerical file reference (such as permit number, or inspection report number);
- 4. Inspection priority of the permit;
- 5. The lead inspector (if any);
- 6. Type of inspection (i.e., reactive, announced, unannounced, team, other, etc.);
- 7. Date of inspection;
- 8. Date issued;
- 9. Type of permit operation (i.e., program code or permit category); and
- 10. Individuals interviewed.

The data should be redacted or prepared in a manner that does not compromise the confidentiality of allegers, or others. (Note: Data for the allegation reviews will not be part of the MML biennial review report).

B. Evaluation Procedures

The principal reviewer should refer to Part III, Evaluation Criteria of Management Directive 5.6, for specific evaluation criteria.

At the MML Project Coordinator's discretion, the reviewer should examine a representative number of significant materials program event and incident response and safety concern and allegation activities conducted by the MML licensee. Priority should be given to evaluating in detail all allegations referred to the MML licensee from the NRC.

The reviewer will need to consult with the MML licensee as to the existence of confidentiality agreements (or other similar mechanisms) in place that may limit the review of specific files. The MML licensee may have to remove certain information from documents to protect the identity of allegers.

C. Review Guidelines

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The responses generated by the MML licensee to relevant questions in the Master Materials License Biennial Review Questionnaire should be used to focus the review.

A detailed printout of all Nuclear Material Events Database (NMED) data related to the MML licensee for the review period should be obtained.

The principal reviewer should work with the Regional MML Project Manager in obtaining the listing of safety concerns or allegations transferred from the NRC to the MML licensee for response in selecting the appropriate files for review.

Any events, incidents, safety concerns, or allegations identified for follow-up from the last periodic meeting should be reviewed.

D. Review Details

The review of each file and interview with the staff should be made in conjunction with the reference and resource materials specified in Section VII of this focus element.

Attachment A, "Event and Incident Review Checklist," was developed to assist in reviewing the licensee's program for events and incident responses. Attachment B, "Safety Concern or Allegation Review Checklist," was developed to assist in reviewing the licensee's response to reported safety concerns and allegations. However, the principal reviewer is not required to address every item in the checklist.

- 1. For event or incident responses, the principal reviewer should evaluate the following:
 - Reports to NRC were made in accordance with NRC regulations.
 Compare the MML records against the data in NMED to verify that a complete and timely report was made for all reportable events.
 - b. Promptness of inquiries made to evaluate the need for on-site inspections.
 - c. Promptness of on-site inspections of events or incidents requiring reporting to NRC in less than 30 days.
 - d. As warranted on a case-by-case basis follow up of events or incidents was performed during the next scheduled inspection, including ensuring the adequacy, accuracy, and completeness of permittee-provided information.
 - e. Inclusion of in-depth reviews of events or incidents during inspections on a high-priority basis, as warranted. When warranted on a case-by-case basis, follow-up activities should include re-enactments and time-study measurements (normally within a few days). Inspection results should be documented and enforcement action taken in accordance with NRC policies and procedures.
 - f. Event/incident follow-up included determining whether the permittee identified, commiserate with the event's safety significance, the cause(s) and developed adequate corrective actions to prevent reoccurrence.

- g. Pertinent information about events or incidents which could be relevant to other permitted operations (e.g., equipment failure, improper operating procedures) is provided to permittees and the NRC.
- h. Information on events or incidents involving equipment failure is provided to the NRC for an assessment of possible generic design deficiency.
- Information obtained during the MML licensee's review is compared with other information obtained from the permittee to identify and resolve any differences.
- 2. For safety concerns or allegations, the reviewer should evaluate the following during the records review and staff interviews:
 - a. Priority is given to safety concerns or allegations with potential safety significance.
 - b. Receipt of a safety concern or allegation is acknowledged to the concerned individual or alleger.
 - c. The safety concern or allegation is discussed with the concerned individual or alleger, if known, to obtain additional information.
 - d. In accordance with the MML licensee's rules and policy, allegers' identities are successfully protected.
 - e. The individual conducting the investigation is independent of the organization affected by the concern and competent in the specific functional area,
 - f. The evaluation/inspection of the safety concern or allegation is adequate to assess its validity and whether permittee's health and safety issues are present, and of sufficient depth and scope to substantively address the concern.
 - g. Root causes and generic implications are considered if the concern was substantiated.
 - h. Appropriate regulatory action is taken and the corrective actions, if necessary, are sufficient.
 - Notification is made to concerned individual or alleger that the safety concern or allegation is closed, and that allegers are informed of the progress of allegations every six months for unresolved allegations.
 - j. The length of time to close safety concerns or allegations is appropriate to the circumstances.
 - k. For allegations referred to an MML licensee from the NRC, that the MML licensee's procedures for handling allegations are comparable to guidance

in Management Directive 8.8, documenting any significant differences and determining if the MML licensee's procedures are equally as effective as NRC's.

- I. Whether the program for processing safety concerns or allegations encourages those with safety concerns to express those concerns to the MML program office or has a chilling effect on others.
- m. The MML licensee's policies and procedures and the implementation of these policies and procedures do not have a chilling effect on others or discourage permittee employees from reporting safety concerns directly to the NRC.
- 3. In addition to other items mentioned above, the reviewer should determine that:
 - a. Appropriate regulatory action was taken for items of noncompliance.
 - b. Letters to permittees are written in correct regulatory language, and they specify the time period for permittee response indicating corrective actions and actions taken to prevent recurrence.
 - c. The permittee's response was reviewed for adequacy and/or whether subsequent action was taken by the MML licensee to prevent recurrence and assure compliance.

VI. ATTACHMENTS

- 4. Event and Incident Review Checklist
- 5. Safety Concern or Allegation Review Checklist

APPENDIX G ATTACHMENT 4 EVENT AND INCIDENT REVIEW CHECKLIST

MML EVENT /INCIDENT FILE IDENTIFIC PERMITTEE:	ATION NUMBER:
T LINWITTEE.	
	PERMI
DATE OF 1ST CONTACT:	
	DATE O
	IDENT:
	NVESTIGATION TYPE: SITE PHONE
	NEXT INSP □ NONE □
□ OVEREXPOSURE	□ DAMAGE TO EQUIPMENT OR FACILITY
☐ RELEASE OF RAM	☐ EQUIPMENT OR PROCEDURE FAILURE
☐ LOST/STOLEN/ABANDONED RA	AM ☐ LEAKING SOURCE
☐ CONTAMINATION EVENT	☐ TRANSPORTATION
□ LOSS OF CONTROL	☐ MEDICAL EVENT
□ DOSE TO EMBRYO/FETUS	
☐ OTHER:	

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	NO.	COMMENTS FOR REPORT APPENDIX					
L							
IN	VESTIGAT	OR					
Sl	JPERVISOF	RY REVIEW BY:		DATE:			
FII	NDINGS DI	SCUSSED WITH			ON:		

EVENT AND INCIDENT REVIEW CHECKLIST

ITEM	O.K.	COMMENTS
INITIAL RESPONSE		
PROMPTNESS		
APPROPRIATE TYPE OF RESPONSE (ON- SITE, TELCON, NEXT INSPECTION, ETC.)		
INVESTIGATION	ı	
DEPTH OF INVESTIGATION		
DOCUMENTATION OF INVESTIGATION (REPORTS, TELCON DOCUMENTATION, ETC)		
REGULATORY ACTIONS (CITATIONS, LICENSE RESTRICTIONS, CORRECTIVE REQUIREMENTS)		
SUPERVISORY OVERSIGHT OF INVESTIGATION		
FOLLOW THROUGH AND CLOSE OUT	Г	
INVESTIGATION ENTERED AND CLOSED OUT IN MML'S TRACKING SYSTEM		
PERMITTEE'S REPORTS AND CORRECTIVE ACTIONS REVIEWED AND/OR VERIFIED		
CLOSE-OUT DOCUMENTATION COMPLETE WITH DATE AND SIGNATURE		
INCIDENT REVIEWED AT NEXT INSPECTION		
INCIDENT REPORT CROSS REFERENCED TO PERMIT/COMPLIANCE FILE		
REPORTING REQUIREMENTS		
NRC		
REPORTED ACCORDING TO CRITERIA		
MEDICAL EVENT REPORT CRITERIA MET		
DOSE TO EMBRYO/FETUS OR NURSING CHILD CRITERIA MET		

OTHER:		
QUESTIONS FOR INVESTIGATOR OR SUPERV	VISOR:	

APPENDIX G ATTACHMENT 5

SAFETY CONCERN OR ALLEGATION REVIEW CHECKLIST

NRC REVIEW BY:	DATE: ML:
MML SAFETY CONCERN OR AL	LLEGATION FILE IDENTIFICATION NUMBER:
PERMITTEE:	
	PERMIT #
LOCATION:	·
DATE OF 1ST CONTACT:	DATE OF CONCERN/ALLEGED
	EVENT:
DATE OF INVESTIGATION: INV	
NEXT	ΓINSP □ NONE □
SAFETY CONCERN/ALLEGATION	ON PERTAINING TO POSSIBLE:
☐ UNREPORTED OVEREX	KPOSURE ☐ FAULTY EQUIPMENT
☐ UNREPORTED RELEAS	E OF RAM ☐ FALSE STATEMENTS OR RECORDS
☐ UNQUALIFIED USERS C	OR INADEQUATE TRAINING
□ DELIBERATE VIOLATIO	N
_	URES OR POSTINGS DISCRIMINATION
☐ OTHER:	
BRIEF SUMMARY OF SAFETY CO	ONCERN/ALLEGATION
KULE OR PERMIT CONDITION SA	AFETY CONCERN/ALLEGEDLY VIOLATED:

MM	IL'S ACTIC	DN:	
FIN	IAL DISPO	SITION:	
EV	IDENCE O	F CHILLING EFFECT O	N CONCERNED INDIVIDUAL/ALLEGER OR OTHERS:
Γ		T	
	NO.		COMMENTS FOR REPORT
ŀ			
INI\	/ESTIGAT		
			DATE:
			ON:

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ITEM	O.K.	COMMENTS
INITIAL RESPONSE	_	
SAFETY CONCERN/ALLEGATION HANDLED PROFESSIONALLY		
PROMPTNESS (PRIORITY GIVEN TO SERIOUS SAFETY CONCERNS/ ALLEGATIONS)		
APPROPRIATE TYPE OF RESPONSE (ON- SITE, TELCON, NEXT INSPECTION, ETC.)		
DOCUMENTATION OF SAFETY CONCERN/ALLEGATION		
DETAILS OF SAFETY CONCERN/ALLEGATION (WHAT, WHERE, WHEN, WHO?)		
CONFIDENTIALLY OF ALLEGER PRESERVED		
INVESTIGATION		
INDIVIDUAL CONDUCTING THE INVESTIGATION IS INDEPENDENT OF THE ORGANIZATION AFFECTED BY THE SAFETY CONCERN/ALLEGATION,		
INDIVIDUAL CONDUCTING THE INVESTIGATION IS COMPETENT IN THE SPECIFIC FUNCTIONAL AREA		
DEPTH OF INVESTIGATION		
DOCUMENTATION OF INVESTIGATION REPORTS, TELCON DOCUMENTATION, ETC)		
DESCRIPTION OF EVIDENCE EXAMINED		
ROOT CAUSES AND GENERIC IMPLICATIONS CONSIDERED		
REGULATORY ACTIONS (CITATIONS, LICENSE RESTRICTIONS, CORRECTIVE REQUIREMENTS)		
SUPERVISORY OVERSIGHT OF INVESTIGATION		
FOLLOW-THROUGH AND CLOSE OUT		

		_			
CONCERNED INDIVIDUAL/ALLEGER PROVIDED WITH RESULTS OF INVESTIGATION					
INVESTIGATION ENTERED AND CLOSED OUT IN MML'S TRACKING SYSTEM					
PERMITTEE'S REPORTS AND CORRECTIVE ACTIONS REVIEWED AND/OR VERIFIED					
CLOSE-OUT DOCUMENTATION COMPLETE WITH DATE AND SIGNATURE					
SUBSTANTIATED SAFETY CONCERN/ALLEGATION REVIEWED AT NEXT INSPECTION					
SAFETY CONCERN MEETING DEFINITION OF ALLEGATION IDENTIFIED AS ALLEGATION					
ALLEGATION IS REPORTED TO NRC IN TIMELY MANNER FOR ACTION OR MONITORING, AS REQUIRED					
SAFETY CONCERN/ALLEGATION OR INCIDENT REPORT CROSS REFERENCED TO PERMIT/COMPLIANCE FILE					
INCIDENT REPORTING REQUIREMENTS MET IF APPLICABLE					
OTHER:					
QUESTIONS FOR INVESTIGATOR OR SUPERV	/ISOR:				

Attachment 6: Revision History for IP 87129

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	ML032810328 09/15/03 CN 03-034	Initial issuance.	N/A	N/A
N/A	ML21137A349 10/29/21 CN 21-036	This was issued in September 2003. 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 Inspection Procedures has been updated in 2017 and again in 2020. Therefore, staff determined that some revisions beyond editorial changes are needed for this Inspection Procedures. This is a Major revision.	N/A	N/A