

NRC INSPECTION MANUAL

IMNS/RGB

INSPECTION PROCEDURE 87129

MASTER MATERIALS PROGRAM

PROGRAM APPLICABILITY: 2810

87129-01 INSPECTION OBJECTIVES

01.01 To establish the inspection process for the Master Materials License (MML) biennial review.

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 in regard to 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 Preparation. 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 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 Entrance Briefing. When the inspection team arrives at the MML licensee's facility, they will inform an available senior management official of the inspection.

02.03 Focus Elements

- a. Management Oversight. 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. Technical Staffing and Training. 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. Status of Materials Inspections. 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. Technical Quality of Materials Inspection. 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. Technical Quality of Materials Permitting Actions. 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)

87129-04 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.

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

APPENDIX A

MML Biennial Review Questionnaire

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

I. Management Oversight

- ☐ Organizational chart that includes the Senior Executive Management through the Radiation Control Program staff (current and changes since last biennial inspection).
- ☐ Internal management audits or reviews that have been performed to assess the MML Radiation Control Program, the audit or review findings and their resolutions.
- ☐ Current internal regulations, policies and/or operating procedures that affect the MML Radiation Control Program.
- ☐ 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.
- ☐ Prepare a summary of the status of the MML licensee's actions taken in response to NRC's comments and recommendations following the last biennial review.
- ☐ Describe any recent efforts, or future plans, on your part to improve the safety performance of permittees operating below acceptable levels for ensuring public health and safety.
- ☐ Description of your perspective of your 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 permit list sorted by NRC program code, by inspection due date, and by priority if possible. Include the following information:

Name	Permit #	Location	NRC prog. code	Priority	Last inspection date	Inspection due date

II. Technical 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 heading should be:

Name	Position	Area of Effort	FTE%
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- ☐ List all new professional personnel hired since the last review, 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 technical staff who left your program during this period.
- ☐ List the vacant positions in each program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

III. Status of Materials Inspections

- ☐ Prepare a table identifying the permits with inspections that were/are overdue by more than 25% of the scheduled frequency at any time 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 MC2800. Further, unless the MML licensee requests and receives approval from NRC (or has been asked by NRC and agreed) to follow a temporary instruction, the MML will be inspected in accordance with the current inspection procedure and not a temporary instruction.) The list should include initial inspections that are overdue. Include the following information:

Permittee Name	Insp. Frequency	Due Date	Time Overdue
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- ☐ Do you currently have an action plan for completing overdue inspections? If so, describe the plan.
- ☐ Copy of current log or other document used to track inspections.

- ☐ List of Inspection frequency and program code by permit type.
- ☐ List individual permittees or groups of permittees that you are inspecting at a different frequency than called for in NRC Inspection Manual Chapter 2800 and state the reason for the change.

IV. Technical Quality of Inspections

- ☐ 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:

Inspector	Supervisor	NRC Program Code	Date
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- ☐ 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:

Permittee	Program code	Date of inspection	Severity Level
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V. Technical Quality of Permitting Actions

- ☐ List any major, unusual, or complex permits issued such as amendments, terminations, new permits, decommissioning, or renewals. 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.
- ☐ List pending licensing actions, include the following information:

Permittee	Program Code	Action Type	Date Received
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VI. Responses to Events or Incidents and Safety Concerns or Allegations

- ☐ 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:

Permittee Name	Permit #	Date of Incident/Report	Type of Incident	Status	Reported to NRC
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- ☐ 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 of 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 Coordinator 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";
- b. 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 among executive management, the RCP Office, the MRSC, and 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 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.
 - c. 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.

VI. Reference and Resource Materials.

1. NUREG 1556, Volume 10, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance about Master Material Licenses."
2. Title 10 Code of Federal Regulations (10 CFR)

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.
- 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) 1246. The MML licensee should have established, documented training and qualification requirements that are equivalent to IMC 1246.

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 Coordinator 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:

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 Coordinator 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. Probable cause and 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 1246.

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

VI. APPENDICES

Not Applicable

VII. REFERENCES

Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

NUREG-1556, Vol. 10, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Master Materials Licenses."

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

- 1. 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 Coordinator 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 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area, for a Materials Radiation Specialist Inspector," and have at least 5 years of inspection experience.

- 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.

e. Guidance

A. Guidance Evaluation Procedures

- a. 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 overdue inspections is the number of overdue inspections (as defined in IMC 2800) conducted over the review period divided by the total number of routine inspections completed. Overdue inspections include: (1) Priority 1 inspections completed more than three months past the inspection due date; (2) Priority 2 inspections completed more than six months past the inspection due date; (3) Priority 3 inspections completed more than nine months past the inspection due date; and (4) initial inspections completed more than 12 months after permit issuance.
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 Coordinator.
4. The principal reviewer should examine any printouts listing information on inspections completed by the MML licensee during the review period. If such lists cannot be provided, the reviewer should examine a representative number of core and initial inspections, as well as documents involving inspection findings.
5. 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 Coordinator, 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 (available on the NRC external homepage) 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 25% 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.

VI. APPENDICES

Not applicable.

VII. REFERENCES

- A. Inspection Manual Chapter 1246, "Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."
- B. Inspection Manual Chapter 2800, "Materials Inspection Program."
- C. NUREG-1556, Vol. 10, "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Master Materials Licenses."
- D. MD 5.6

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 Coordinator 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 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," for a Materials Radiation Specialist Inspector. This individual should also have at least 5 years of inspection experience.

B. The principal reviewer in conjunction with the MML Project Coordinator is responsible for selecting permit files/inspection reports to be reviewed, 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."
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 Coordinator 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 Coordinator 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 permitting action 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. operations observed.
 - e. 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. 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 an 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

- A. Inspection File Review Checklist
- B. Inspector Accompaniment Checklist

VII. REFERENCES

Inspection Manual Chapter 1246, "Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

Inspection File Review Checklist
PAGE 2

MML INSPECTOR: _____ OFFICE: _____

MML SUPERVISORY REVIEW BY: _____ DATE: _____

“MML BIENNIAL REVIEW” REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____ ON: _____

ITEM	O.K.	COMMENTS OR QUESTIONS
ACTION DATES:		
PREVIOUS INSPECTION:		
INSPECTION DATE:		
ENFORCEMENT LETTER: SHORT FORM <input type="checkbox"/>		
PERMITTEE RESPONSE:		
FOLLOW-UP:		
ACKNOWLEDGMENT LETTER:		
CLOSE-OUT:		
DOCUMENTED EVIDENCE OF:		
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		

Inspection File Review Checklist
PAGE 3

OPERATING PROCEDURES	
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	

Inspection File Review Checklist
PAGE 4

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		

[illegible]

INSPECTOR ACCOMPANIMENT CHECKLIST

MML:	DATE:
INSPECTOR:	NRC REVIEWER:
PERMITTEE:	PERMIT NO:
LOCATION:	INSPECTION TYPE:
PERMIT TYPE:	ANNOUNCED <input type="checkbox"/> UNANNOUNCED <input type="checkbox"/>

PRELIMINARY DISCUSSION WITH INSPECTOR

DONE

EXPLAIN THE EXTENT OF THE REVIEWER'S PARTICIPATION IN INSPECTION.

☐

DISCUSS PROCEDURE FOR INTRODUCING REVIEWER TO
PERMITTEE AND EXPLAINING HIS PART IN INSPECTION.

☐

EXPLAIN METHOD TO BE USED IN EVALUATING INSPECTOR'S PERFORMANCE.

☐

SUMMARY OF EVALUATION

INSPECTOR'S PERFORMANCE:

ADEQUATE ☐

NEEDS IMPROVEMENT ☐

COMMENTS: _____

THE INSPECTOR WOULD BENEFIT FROM ADDITIONAL TRAINING IN _____

EVALUATION DISCUSSED WITH _____ **ON** _____
(SUPERVISOR) (DATE)

INSPECTOR ACCOMPANIMENT CHECKLIST
PAGE 2

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 <input type="checkbox"/>		
SUPPLEMENTAL MATERIALS: REGS <input type="checkbox"/> ID <input type="checkbox"/> FORMS <input type="checkbox"/> DOSIMETRY <input type="checkbox"/> SOURCES <input type="checkbox"/> ANEMOMETER <input type="checkbox"/>		
ENTRANCE		
INTERVIEW CONDUCTED AT APPROPRIATE LEVEL		
EXPLANATION OF INSPECTION PURPOSE, SCOPE, METHOD		
INSPECTION		
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 <input type="checkbox"/> ANCILLARY WORKERS <input type="checkbox"/>		
WIPES, SURVEYS, MEASUREMENTS TAKEN		
ADHERENCE TO ALARA EVALUATED		

INSPECTOR ACCOMPANIMENT CHECKLIST
PAGE 3

REVIEW OF INCIDENTS, OVEREXPOSURES, ETC.		
ORAL INTERVIEWS AND IF NECESSARY RECORDS VERIFICATION FOR: <ul style="list-style-type: none"> SECURITY <input type="checkbox"/> PROCUREMENT & INVENTORY <input type="checkbox"/> RECEIPT & TRANSFER OF MATERIAL <input type="checkbox"/> INTERNAL AUDITS <input type="checkbox"/> SURVEYS & MONITORING <input type="checkbox"/> PERSONNEL DOSIMETRY, BIOASSAY <input type="checkbox"/> QUALIFICATION AND TRAINING OF PERSONNEL <input type="checkbox"/> EMERGENCY PLAN & PROCEDURES <input type="checkbox"/> COMMITTEE MEETINGS, MINUTES <input type="checkbox"/> AUTHORIZED USERS <input type="checkbox"/> INSTRUMENT CALIBRATION <input type="checkbox"/> DOSE CALIBRATOR TESTS; UTILIZATION LOG <input type="checkbox"/> LEAK TESTS <input type="checkbox"/> GENERATOR - ASSAY, MOLY <input type="checkbox"/> BREAKTHROUGH, LOGS <input type="checkbox"/> WASTE MANAGEMENT, DISPOSAL <input type="checkbox"/> RELEASE OF AIR & SEWER EFFLUENTS <input type="checkbox"/> QA & QC; MAINTENANCE <input type="checkbox"/> 		
INSPECTION CONDUCTED IN SUFFICIENT SCOPE & DEPTH		
INSPECTION FOCUS ON PERMITTEE 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.)		

INSPECTOR ACCOMPANIMENT CHECKLIST
PAGE 4

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	

INSPECTOR ACCOMPANIMENT CHECKLIST
PAGE 5

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.

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 Coordinator 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 1246, "Formal Qualification Programs

in the Nuclear Material Safety and Safeguards Program Area,” for a Materials License Reviewer. This individual should also be a Senior Radiation Specialist/Health Physicist or a Radiation Specialist/Health Physicist with at least 5 years of licensing experience.

- B. The principal reviewer is responsible for selecting permits to be reviewed, and for maintaining a summary of all permits 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 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.

1. 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 Coordinator 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 with regard to permit conditions, issue and expiration dates.
2. Applications are properly completed and signed by an authorized official.
3. 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

A. Permit File Review Checklist

VII. REFERENCES

- A. Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."
- B. NUREG-1556 Series, "Consolidated Guidance About Materials Licenses."
- C. List of MML permitting actions received by NRC during the review period.

PERMIT FILE REVIEW CHECKLIST
PAGE 1

ATTACHMENT A

PERMIT FILE REVIEW CHECKLIST

MML:

FILE #	
PERMITTEE: _____	PERMIT # _____
LOCATION: _____	PERMIT TYPE _____
TYPE OF PERMITTING ACTION: NEW <input type="checkbox"/> RENEWAL <input type="checkbox"/> AMENDMENT <input type="checkbox"/> TERMINATION <input type="checkbox"/>	
DATE OF ACTION: _____	AMENDMENT # _____

[illegible]

PERMIT FILE REVIEW CHECKLIST
PAGE 2

PERMIT REVIEWER: _____

SUPERVISORY REVIEW BY: _____ DATE: _____

MML Biennial REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH _____ ON: _____

PERMIT FILE REVIEW CHECKLIST
PAGE 3

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

Item	OK	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		

PERMIT FILE REVIEW CHECKLIST
PAGE 4

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		
Item	OK	Comments or Questions
Permit File		
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		
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 FILE REVIEW CHECKLIST
PAGE 5

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.		

PERMIT FILE REVIEW CHECKLIST
PAGE 6

Terminated Permits		
Item	OK	Comments or Questions
Application for Termination		
Acceptable Method of RAM Disposal <input type="checkbox"/>		
Transfer to Another Licensee or permittee <input type="checkbox"/> Return to Manufacturer	<input type="checkbox"/>	
Shipment to Burial Site or Other	<input type="checkbox"/>	
Supporting Documents		
SS&D Leak Tests		
Current Copy of Recipient's Permit		
Permittee's Close-out Survey Make, Model, S/N of Instrument <input type="checkbox"/> Dates of Survey and Calibration <input type="checkbox"/> Identification of Person Making Survey <input type="checkbox"/> All Readings, Including Background <input type="checkbox"/>		
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 <input type="checkbox"/> Dates of Survey and Calibration <input type="checkbox"/> Identification of Person Making Survey <input type="checkbox"/> All Readings, Including Background <input type="checkbox"/>		

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 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. One MML licensee has a formal allegation program that is modeled after NRC's program. The other licensees' programs differ in structure or documentation. Nonetheless, whether these licensees have had safety concerns raised to them, and how they have handled these concerns, should still be reviewed. Where the programs are not well defined, the inspector should determine if the MML licensee's program is equally as effective as NRC's.

"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.
- 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 alleged is protected, a safety concern or allegation is closed in a timely manner, feedback is provided to the concerned individual or alleged, 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.

IV. ROLES AND RESPONSIBILITIES

- A. The MML Project Coordinator 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 Coordinator. 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).
10. Individuals interviewed

The data should be redacted or prepared in a manner that does not compromise the confidentiality of alleged, 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 alleged.

C. Review Guidelines

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 Coordinator 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:
 - a. Reports to NRC were made in accordance with NRC regulations.

- 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. Whether the MML licensee determined the root cause.
 - 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.
 - i. A printout of the NMED data should be obtained to determine that the number and type of event or incident reports recorded in NMED are identical to those recorded by the MML licensee.
 - j. 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 allegor.
 - c. The safety concern or allegation is discussed with the concerned individual or allegor, if known, to obtain additional information.
 - d. In accordance with the MML licensee's rules and policy, allegors' 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.

- i. Notification is made to concerned individual or alleged that the safety concern or allegation is closed, and that alleged 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.
 - l. 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

Attachment A - Event and Incident Review Checklist

Attachment B - Safety Concern or Allegation Review Checklist

VII. REFERENCES

Management Directive 8.8, Management of Allegations

Management Directive 5.6

Inspection Procedure 87103, Inspection of Material Licensees Involved in an Incident

EVENT AND INCIDENT REVIEW CHECKLIST

ATTACHMENT A

NRC REVIEW BY: _____ DATE: _____ MML: _____

MML EVENT /INCIDENT FILE IDENTIFICATION NUMBER: _____

PERMITTEE: _____ PERMIT # _____

LOCATION OR SITE OF EVENT: _____

DATE OF 1ST CONTACT: _____ DATE OF INCIDENT: _____

DATE OF INVESTIGATION: _____ INVESTIGATION TYPE: SITE ☐ PHONE ☐

NEXT INSP ☐ NONE ☐

☐ OVEREXPOSURE

☐ DAMAGE TO EQUIPMENT OR FACILITY

☐ RELEASE OF RAM

☐ EQUIPMENT OR PROCEDURE FAILURE

☐ LOST/STOLEN/ABANDONED RAM

☐ LEAKING SOURCE

☐ CONTAMINATION EVENT

☐ TRANSPORTATION

☐ LOSS OF CONTROL

☐ MEDICAL EVENT

☐ DOSE TO EMBRYO/FETUS

☐ OTHER: _____

BRIEF SUMMARY OF INCIDENT _____

EVENT MET NRC REPORTING REQUIREMENTS? Y N

POSSIBLE GENERIC PROBLEM? Y N

MML'S ACTION: _____

FINAL DISPOSITION: _____

NO.	COMMENTS FOR REPORT APPENDIX

Event and Incident Review Checklist
PAGE 2

INVESTIGATOR _____

SUPERVISORY REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED 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		
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		
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		

Event and Incident Review Checklist
PAGE 4

OTHER:	
QUESTIONS FOR INVESTIGATOR OR SUPERVISOR:	

SAFETY CONCERN OR ALLEGATION REVIEW CHECKLIST

NRC REVIEW BY: _____ DATE: _____ MML: _____

MML SAFETY CONCERN OR ALLEGATION FILE IDENTIFICATION NUMBER: _____	
PERMITTEE: _____	PERMIT # _____
LOCATION: _____	
DATE OF 1ST CONTACT: _____	DATE OF CONCERN/ALLEGED EVENT: _____
DATE OF INVESTIGATION: _____	INVESTIGATION TYPE: SITE <input type="checkbox"/> PHONE <input type="checkbox"/>
NEXT INSP <input type="checkbox"/> NONE <input type="checkbox"/>	
SAFETY CONCERN/ALLEGATION PERTAINING TO POSSIBLE:	
<input type="checkbox"/> UNREPORTED OVEREXPOSURE	<input type="checkbox"/> FAULTY EQUIPMENT
<input type="checkbox"/> UNREPORTED RELEASE OF RAM	<input type="checkbox"/> FALSE STATEMENTS OR RECORDS
<input type="checkbox"/> UNQUALIFIED USERS OR INADEQUATE TRAINING	
<input type="checkbox"/> DELIBERATE VIOLATION	
<input type="checkbox"/> INADEQUATE PROCEDURES OR POSTINGS	<input type="checkbox"/> DISCRIMINATION
<input type="checkbox"/> OTHER: _____	

BRIEF SUMMARY OF SAFETY CONCERN/ALLEGATION

RULE OR PERMIT CONDITION SAFETY CONCERN/ALLEGEDLY VIOLATED: _____

MML'S ACTION: _____

FINAL DISPOSITION: _____

EVIDENCE OF CHILLING EFFECT ON CONCERNED INDIVIDUAL/ALLEGOR OR OTHERS: _____

Safety Concern or Allegation Review Checklist
PAGE 2

NO.	COMMENTS FOR REPORT

INVESTIGATOR _____

SUPERVISORY REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH _____ ON: _____

Safety Concern/Allegation review checklist

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?)		
CONFIDENTIALITY 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 SUPERVISOR:	