MANUAL CHAPTER 2601

TEAM ASSESSMENTS OF FUEL CYCLE AND MATERIALS LICENSEES

2601-01 PURPOSE

To establish a system for in-depth evaluations of major fuel cycle and materials licensees' radiological and non-radiological programs, using a team of inspectors. Radiological programs to be assessed may include criticality controls and radiological contingency planning, as well as general radiation safety issues. Non-radiological programs to be assessed may be in areas related to chemical safety, fire protection, industrial safety, and management controls. This chapter promulgates guidelines and requirements for team assessment preparation, scheduling, interaction with other participating agencies, areas to be observed, prioritization, tracking, reporting, followup, fees, and resources.

2601-02 OBJECTIVES

The objectives of the team assessment are:

02.01 To identify and focus increased inspection effort on those facility operating conditions and those specific parts of the licensee's processes and facilities that could pose radiological and non-radiological hazards.

02.02 To determine whether licensees are implementing their NRC-approved radiation safety programs, consistent with NRC regulations and industry safety standards.

02.03 To determine whether licensees have developed appropriate operating procedures, have provided training to their employees, and are ensuring that licensed operations are conducted in a safe manner in accordance with approved operating procedures and requirements.

02.04 To determine whether contingency planning is sufficient to protect health and safety of the public and employees and meets applicable requirements of the regulations and facility license conditions.

02.05 To determine whether the licensee is exercising sufficient management involvement and oversight for licensed activities, and whether adequate routine audits of facility operations are performed.

02.06 To make regional and headquarters management aware of any situation observed in a facility that may involve a previously unevaluated radiological or non-radiological accident potential or an accident potential for which current NRC requirements do not appear adequate.

02.07 To provide information based on onsite observations by NRC inspectors and others that will help develop improvements to the fuel cycle and materials licensing and inspection programs.

02.08 To provide operational and safety information, to the NRC licensing staff, that should be considered during the license renewal process.

2601-03 DEFINITIONS

03.01 Concern. A team assessment finding which raises issues that the NRC believes the licensee first should review and then should determine which changes should be included in their program.

03.02 Other Participating Agencies. Agencies, either Federal or State, or consultants invited to participate in the team assessment. Other participating Federal agencies may send a team member from their national or regional offices. Examples of "other participating agencies" include the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the State radiation protection program office, the Food and Drug Administration (FDA), the Federal Emergency Management Agency (FEMA), and consultants from Oak Ridge National Laboratory or other national labs.

03.03 Team Assessment. The systematic assessment, using a team of inspectors, of a major fuel cycle or materials licensee's radiological and non-radiological safety programs. Team assessments are expanded inspections that emphasize safety, rather than violations and include other participating agencies.

2601-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Deputy Director, Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS)

a. Select the materials licensees for team assessments during the following fiscal year from the regions' lists of candidates. Reply to the regions not later than September 30 of each year, with a list of selected materials licensees.

b. Provide team members from IMNS to participate on the team assessment, when requested by the regions.

04.02 Director, Division of Radiation Safety and Safeguards (DRSS), Regions I - V

a. Recommend candidate materials licensees for team assessments during the next fiscal year, in writing, not later than July 31.

b. Identify and select the fuel cycle licensees to be assessed during the following fiscal year. Seek an exception to the provisions on identifying fuel cycle licensees in Subsection 2601-05.01.b., if needed.

c. Schedule team assessments as described in Subsection 2601-05.01.c.

d. Designate the team leader and team participants.

e. Invite the agencies specified in Subsection 2601-05.01.e.1. (and Subsection 2601-05.01.e.2., if appropriate) to participate in each team assessment. Make the requests at least two months in advance of the starting date for the onsite team assessment.

f. Inform NMSS if invited agencies reject an offer to participate on the team assessment.

g. Assign priority to team assessments over the priority for other routine inspections defined in Manual Chapters (MC) 2600 and 2800.

h. Provide a copy of the final team assessment report with a cover memorandum, in accordance with Subsection 2601-05.04.h., to the Deputy Director, IMNS/NMSS.

i. Issue the final team assessment report, as described in Subsection 2601-05.04.i.

j. Follow up on violations identified in the team assessment, in accordance with Subsection 2601-05.05.a.

k. Request licensees to respond to concerns, and follow up on concerns, in accordance with Subsection 2601-05.05.b.

l. Take appropriate action and coordinate with IMNS/NMSS on any further action necessary, if a licensee refuses to respond to or act on NRC concerns.

m. Obtain copies of followup documentation between participating agencies and licensees, when possible, as described in Subsection 2601-05.05.d.

n. Send a letter to the licensee that discusses topics in Subsection 2601-05.06.a.

o. Forward copies of all contractor business letters claiming team assessment time to the License Fee and Debt Collection Branch, Division of Accounting and Finance, Office of the Controller (LFDCB/OC) every quarter, in accordance with Subsection 2601-05.06.f.

p. Forward quarterly inspection staff-hour reports to LFDCB/OC every quarter, in accordance with Subsection 2601-05.06.g.

04.03 Director, Program Management, Policy Development and Analysis Staff (PMDA), NMSS

a. Enter team members' and team leaders' names (when appropriate) into the Regulatory Information Tracking System (RITS) for automatic fee recovery.

b. Provide team members and team leaders (when appropriate) with inspection activities report sheets.

04.04 Director, Division of Resource Management and Administration (DRMA), Regions I - V

a. Enter team members' and team leaders' names (when appropriate) into RITS automatic fee recovery.

b. Provide team members and team leaders (when appropriate) with inspection activities report sheets.

04.05 Chief, Fuel Cycle Safety Branch (IMSB), IMNS/NMSS.

a. Approve (or disapprove) exceptions to the provisions given in Subsection 2601-05.01.b. for regional identification and selection of fuel cycle licensees to receive team assessments during the following fiscal year.

04.06 Chief, License Fee and Debt Collection Branch (LFDCB), Office of the Controller (OC)

a. Bill the licensee for the team assessment, when applicable, in accordance with Subsections 2601-05.06.b. through 2601-05.06.g. and applicable regulations.

04.07 Team Leader

a. Coordinate and direct team activities.

b. Plan in coordination with each team member the role and scope of his or her assessment.

c. Meet with all participants from outside agencies before the team assessment to discuss issues identified in Subsection 2601-05.01.e.4.

d. Assemble background information on the facility and license and provide that information to team members well in advance of the assessment.

e. Encourage team members from outside agencies to fulfill the roles given in Subsection 2601-05.01.e.5. Advise team members from outside agencies who choose to take a different approach than described in Subsection 2601-05.01.e.5. of the bounds of NRC's regulatory mandate and the need to follow up directly with the licensee.

f. Ensure that the team assesses overall operational safety of the licensee. Violations are secondary to larger safety issues. However, if team members observe violations, ensure that appropriate action is taken.

g. Ensure that the team assessment is entered as a replacement for the routine inspection in the Licensing Tracking System (LTS).

h. Decide on the date that the next routine inspection should be performed and receive approval from immediate supervisor.

i. Ensure that appropriate information, as described in Subsection 2601-05.03.b., is entered into the LTS and the Master Inspection Planning System (MIPS).

j. Set standards for a draft team assessment report, as described in Subsection 2601-05.04.a.

k. Set a schedule for completion of the draft report during the planning and scheduling phase of the team assessment.

l. Arrange (or have a regional management representative arrange) an exit meeting with the licensee's management. Brief the licensee's management on issues covered in Subsection 2601-05.04.b. at the exit meeting.

m. Ensure that a final assessment report, with transmittal letter, is prepared by the team in accordance with Subsections 2601-05.04.c. through 2601-05.04.g.

n. Review the final assessment report, after the team members' review, for accuracy and control of information, as described in Subsection 2601-05.04.c.

o. Delineate, before the conclusion of the onsite assessment, which findings will be addressed in the NRC final report and which will be handled directly between the participating agency and the licensee.

p. Reach an agreement with participating agency team members on a scheduled date for the participating agency to submit a copy of it own report or other material to be included in the NRC report.

q. Inform the licensee that verbal or written communication on outside agency issues must be handled directly between the licensee and the other agency.

r. Include a copy of the participating agencies' reports or findings in or as an attachment to NRC's final report, in accordance with Subsection 2601-05.04.f.

s. Proceed with arrangements to issue NRC's final report if the participating agency does not meet the established schedule, in accordance with Subsection 2601-05.04.f.

t. Instruct NRC contractors participating in the team assessment about their requirement to provide a business letter claiming time spent on team assessment efforts.

u. Report all the team leader's professional staff time (when applicable) spent on team assessment efforts, on inspection activities report sheets, as indicated in Subsections 2601-05.06.g. and 2601-06. (Note: check with DRMA, or PMDA, and LFDCB/OC to determine applicability, in each case. The team leader's time may not be fee-chargeable if the team leader is an NRC manager.)

v. Coordinate with DRMA, or PMDA, to ensure that the team leader's name is entered into the RITS for automatic fee recovery, when applicable. (See above note in Subsection 2601-04.07.u. concerning applicability.)

w. Ensure that the final NRC report is given a report number.

x. Instruct each participating agency team member that NRC will not bill the licensee for participating agency efforts, and that their agency should use its own standards, regulations, and procedures, if it chooses to bill the licensee.

04.08 Team Members

a. Assess overall operational safety of the licensee. Consider violations to be secondary to larger safety issues. However, if violations are observed, take appropriate action.

b. Identify those parts of the NRC-regulated processes and associated conditions that could present a hazardous condition to the facility's workers or to members of the public, in accordance with requirements in Subsection 2601-05.02.b.

c. Assess facility operations and the effectiveness of measures to prevent accidents which could produce a significant release of radioactive material or significant threat to worker health and safety, in accordance with requirements in Subsection 2601-05.02.c.

d. Base any findings on operating procedures (Subsection 2601-05.02.c.3.) on direct observation of selected work activities.

e. Prepare detailed exit notes or a draft report outline before the exit meeting.

f. Prepare a draft assessment report.

g. Prepare a final assessment report, in accordance with Subsections 2601-05.04.c. through 2601-05.04.g.

h. Review the final assessment report for accuracy and for control of information, as described in Subsection 2601-05.04.c.

i. Recognize licensee strengths and weaknesses, as well as concerns and violations, in NRC's report. Refrain from violation/no-violation types of findings.

j. Report all NRC professional staff time spent on team assessment efforts on inspection activities report sheets, as indicated in Subsections 2601-05.06.g. and 2601-06.

k. Coordinate with DRMA, or PMDA, to ensure that the team member's name is entered into RITS for automatic fee recovery.

l. Use the references in 2601-07 as guidance for team assessments.

2601-05 BASIC REQUIREMENTS

05.01 Preparation

a. Identification of Materials Licensees (Non-Fuel Cycle)

1. Materials licensee candidates for team assessments shall be identified through consideration of the following factors:

- Type and quantity of radioactive and chemical materials
- Potential for fire and explosion
- Potential for adverse impact of radioactive materials on the public, due to licensee misuse, poor product, or uncontrolled effluent releases
- Past performance of licensee
- Degree of diversity of licensee operations
- Upcoming license renewal date or five years since the last team assessment

Regions may also recommend materials licensees as candidates for team assessments, based on NRC managers identifying the licensees as potential problem facilities, during the NRC Senior Management Meeting.

2. Regional offices shall identify candidate materials licensees for team assessments during the next fiscal year, in writing, to the Deputy Director, IMNS, not later than July 31. Normally, a materials licensee should not be identified as a candidate for a team assessment if an assessment has been conducted in the previous five years.

3. In consultation with the regions, IMNS/NMSS will select the materials licensees to be assessed during the following fiscal year from the lists of candidates. A reply will be sent to the regions, not later than the end of each fiscal year (September 30), specifying the selected materials licensees that should receive team assessments during the next fiscal year. The number of materials licensees identified for team assessments among

all regions during a fiscal year will generally not exceed three.

b. Identification of Fuel Cycle Facility Licensees. The regions will identify and select the fuel cycle licensees to be assessed during the next fiscal year. In general, major fuel cycle facilities will be selected for team assessments approximately every five years with an assessment one year before license renewal and four years after license renewal. Exceptions to this provision shall be approved by IMSB.

c. Scheduling of Team Assessments

1. The regions shall schedule team assessments as announced assessments. Regions shall schedule team assessments of fuel cycle facility licensees to take place approximately every five years, with an assessment one year before license renewal and four years after license renewal. Where possible, Regions should also attempt to schedule team assessments of materials licensees approximately one year before license renewal.

2. The onsite team assessment effort should generally be completed within five working days at each facility. Regions may pursue followup actions beyond the recommended five-day onsite time, when needed, and are not required to carry out the assessment over consecutive work days.

d. Team Assessment Approach.

1. The region shall designate the participants on each assessment team, based on the licensee's past performance. The assessment team should consist of NRC and other staff with the proper technical expertise (e.g., health physics, industrial safety, chemical safety, fire protection, criticality assessment, radiological contingency planning, hazard analysis, management controls, maintenance, etc.) to cover the broad scope of each assessment. All the above technical areas need not be examined in each team assessment. Some team members may specialize in multiple technical areas. A team leader, who will principally coordinate and direct team activities shall be appointed by the region. The team should be limited to about six members (including the team leader); however, the region may alter team size, as needed. Headquarters and inter-regional participation is encouraged. The role of each NRC member on the team assessment shall be planned in coordination with the team leader and agreed on in advance of the onsite assessment.

2. Team assessments at non-fuel cycle materials facilities (such as universities, major laboratories, broad-scope medical licensees, etc.) need not include the full complement of inspectors noted above. Regions should

construct teams for materials facility team assessments based on the major safety hazards at the facility.

e. Interface with Other Participating Agencies.

1. The regional office shall invite the following agencies to participate in each team assessment:

- OSHA at the Federal (regional) or State level, whichever is appropriate.

- EPA at the Federal (regional) or State level, whichever is appropriate.

- The State radiation protection program office, for both Agreement and non-Agreement States.

- FDA, for team assessments of radiopharmaceutical manufacturers only.

A request for participation shall be made at least two months in advance of the starting date for the onsite team assessment. Either the State or Federal (regional) office, but not both, of OSHA and EPA shall be invited. The FDA's Center for Drug Evaluation and Research, Office of Compliance in Rockville, MD, shall be invited to send a participant for radiopharmaceutical manufacturer team assessments. Participating agencies will be requested by the regional office to provide one person to take part in the team assessment. Participating agency team members need not stay for the entire assessment.

2. Other Federal or State agencies, such as FEMA, or consultants may be included on the assessment team at the discretion of the regional Director, Division of Radiation Safety and Safeguards.

3. Although the agencies specified in this section will be invited to participate, their acceptance or rejection of such an offer is outside of NRC control. If outside agencies reject the offer or fail to act upon it, then the region will proceed to conduct the team assessment without that agency's participation. Regions need not take extraordinary steps to include outside agencies which rebuff or fail to show interest in the offer. However, NMSS should be informed as soon as practical following such a rejection.

4. The assessment team leader appointed by the region, should meet with all participants from outside agencies before the team assessment. During this meeting, the team leader should determine that outside agency participants understand the assessment's scope, team members' roles, and the mechanics for reporting and following up on outside agency findings. Background information on the facility and license should be

assembled and provided to team members well in advance of the assessment.

5. The scope of the team assessment will be to assess the safety of NRC-licensed activities, including the impact of both radiological and non-radiological safety on NRC licensed activities. The role of outside agency team members is to provide expertise in areas not covered by NRC staff; that is, primarily non-radiological areas that impact on radiological safety. FDA participants on team assessments of radiopharmaceutical manufacturers also fulfill the role of assessing the licensee's good manufacturing practices. Team leaders will encourage participating team members from outside agencies to fulfill those roles. However, if the participating team members choose to take a different approach, the team leader will advise them of the bounds of NRC's regulatory mandate and that areas outside of NRC's purview can be followed up only by direct communication between the participating agency and the licensee. In the spirit of interagency cooperation, the role of each team member and the scope of his or her assessment must be planned in coordination with the team leader and agreed on in advance of the onsite assessment.

6. Non-NRC members of the assessment team shall augment, not replace, the core NRC team members.

05.02 Conducting the Team Assessment

a. Assessing Safety. The team assessment is an assessment of the overall operational safety of major non-reactor NRC licensees. It is an expanded inspection with an emphasis on safety. Violations shall be considered secondary to larger safety issues. However, if a team member observes violations during the assessment, the region shall take appropriate action.

b. Identification of Potentially Hazardous Conditions. Based on direct observations in the facility and review of the license and its supporting documentation, identify those parts of the NRC-regulated processes and associated conditions that could present a hazardous condition to the facility's workers or to members of the public. Special emphasis should be given to situations that could produce a release of radioactive material. In determining the significance of a hazardous condition, the region should take into account the non-radiological (e.g., chemical toxicity of the radioactive material) as well as radiological hazards. If the licensee has performed safety hazard analyses or identified critical processes and conditions, then the licensee's documentation should be used to assist, but not replace, the team's assessment of potentially hazardous conditions. In particular, the team assessment should identify:

1. Conditions that could result in a fire or explosion affecting an NRC-regulated process that could produce a release of radioactive material, cause a criticality

excursion, or present other hazardous conditions for worker or public health and safety.

2. Processes where overheating or overpressurization might cause a process component or confinement barrier to fail, with subsequent release of radioactive material, criticality excursion, or other hazardous conditions for worker or public health and safety.

3. Electrical failures or equipment malfunctions that could result in loss of control of the process and that could produce the potential for a release of radioactive material, potential for criticality accident, or other hazardous conditions for worker or public health and safety.

4. Critical valves, pressure or temperature sensors, and flow and volume control instrumentation that are important to safe operation of the process and whose failure could result in a possible release of radioactive material, criticality, or other hazardous conditions for worker or public health and safety.

c. Facility Operations. By assessment determine whether:

1. The licensee has a program for establishing operating procedures, for revising those procedures, and for management approval of new or revised procedures.

2. The licensee has a formal program for training employees in its operating procedures and whether that training program is being followed. Do all employees receive the training needed for performance of their job responsibilities? Is employee retraining part of the program? Are the training and retraining adequate and appropriate for the intended audiences? Are employees receiving sufficient procedural and safety training/retraining for their specific job situations?

3. The licensee's work activities are being performed in accordance with the approved operating procedures and whether those procedures adequately deal with potentially unsafe conditions.

4. The licensee has implemented adequate contingency planning for emergencies (both radiological and non-radiological) and whether training is provided for employees and others designated to act under these plans. Are drills and exercises (rather than formal classes) practiced during contingency planning training?

5. The licensee has a management oversight (audit) program for all phases of its operation, and whether the findings of the audits are promptly resolved.

6. The licensee has a management system implemented by appropriately trained personnel for hazard analysis of licensee processes and systems.

7. The licensee has established and implemented a maintenance program, including preventive and on-going maintenance, and is documenting the maintenance with appropriate records. Are calibrations, functional testing, and maintenance management controls (e.g., tag out, rip-out control, restoration turnover, etc.) in use?

8. The licensee has implemented an "As Low As Is Reasonably Achievable" (ALARA) program to review programs impacting radiation protection and to identify and correct causes of unnecessary radiation exposure.

9. The licensee has sufficient, qualified staff to manage and carry out licensee safety programs.

The team should normally examine all of the aforementioned technical areas for each team assessment.

Any findings concerning operating procedures (Subsection 2601-05.02.c.3.) should be based on direct observation of selected work activities. Special emphasis should be placed on those activities that might potentially create a condition where a large release of radioactive material could credibly take place under adverse conditions. Based on its assessment in particular facility operations areas, the team should judge the effectiveness of the procedures, training, work control, contingency planning, maintenance, and/or overall management controls at preventing accidents which could produce a significant release of radioactive material or significant threat to worker health and safety.

05.03 Assessment Priority.

a. Assigning Priority. The team assessment activities required by this manual chapter have priority over other routine inspections defined in Manual Chapters (MC) 2600 and 2800.

b. Updating the LTS and MIPS Systems. The team assessment will be entered as a replacement for the routine inspection in the LTS. The team leader will decide upon the date that the next inspection should be performed, as approved by the immediate supervisor. On completion of the team assessment, the region shall enter the assessment onsite starting date into the LTS (under "Inspection Date") and manually enter the "Next Inspection Date," which probably will not be a team assessment, to reflect the team leader's decision. The Region shall also enter other pertinent information on inspection report number and team leader's name (under "Inspection Name"). The MIPS shall be similarly updated with all necessary assessment characteristics (dates, report number, team leader, etc.).

05.04 Team Assessment Reporting.

a. Draft Report. Before the assessment team's exit meeting with the licensee, the team should prepare detailed exit notes or a draft report outline. The team leader will set standards for the degree of specificity, formality, and completeness of the draft report, which will be prepared later and based on the exit notes and/or outline. A schedule for completion of the draft report shall be set during the planning and scheduling phase of the team assessment.

b. Exit Meeting. The team leader or a regional management representative shall arrange an exit meeting with the licensee's management to discuss preliminary findings and concerns. During the exit meeting, licensee's management shall also be briefed on followup procedures by NRC and participating agencies.

c. Final Report. On completion of the team's onsite time, the team shall prepare a final assessment report. The final report format, with the addition of specific requirements given below, shall be prepared in accordance with MC 0610, "Inspection Reports." The report will, as a minimum, contain the following descriptive data:

- Report Number
- Docket Numbers
- License Numbers
- Program Codes
- Licensee's Name and Address
- Facility's Name (may be same as Licensee's Name)
- Location of Facility Assessed (Town, State)
- Dates of Assessment ("from" and "to" Onsite Dates)
- Names, Titles, and Agencies of Assessment Team Members

After the descriptive data, the final report shall provide an "Assessment Summary," describing facility areas assessed and including a brief description of the results. After the assessment summary, the final report shall provide details of the entire assessment. The "Details" shall include names of key licensee personnel contacted and those present at the exit meeting, as well as narrative, detailed discussions of the assessment's scope, findings, and meetings with licensee management. The final report shall include, as an enclosure, a sheet that lists the specific topical areas assessed by the team that are not covered by a particular inspection procedure (IP). Once completed, the report will be reviewed for accuracy by the team members. This review will be made in accordance with MC 0610 and MC 0611, "Review and Distribution of Inspection Reports." Reviewers shall ensure that classified, safeguards, and proprietary information and information concerning investigations (either contemplated or under way) by the Office of Investigations (OI) are controlled under the procedures given in MC 0610 and MC 0611.

d. Categories of Findings. Results of the team assessment shall be categorized in all reports and discussions with the licensee as "apparent violations," if the findings indicate

a violation of regulations or license conditions, in accordance with MC 0610. (After a Notice of Violation (NOV) is issued, or escalated enforcement action is taken, the cited "apparent violations" become "violations.") Any adverse findings that team members make that are not apparent violations shall be characterized as "concerns." Concerns may include items that are not specifically addressed by regulations or license conditions, but which may impact on radiological safety. Concerns fill the gap between reporting safe operations and citing outright violations. Licensees cannot be required to respond to concerns since they are not violations. However, licensees will be requested to address and resolve concerns. In addition, if the licensee agrees to a particular plan of action to resolve concerns, then the licensee may be bound to that plan through issuance of a Confirmatory Action Letter. See Subsection 2601-05.05.b. "`Concerns' Follow Up."

e. Findings from Participating Agencies. The findings of other agencies shall be included in the NRC report of the assessment. In addition, any apparent violations of participating agency regulations and any concerns from participating agency team members that do not impact on radiological safety shall be acted on by the agency responsible for making that finding. The final NRC report need only mention that a problem was observed and name the agency to whom the finding was referred. The team leader shall inform the licensee that verbal or written communication on these outside agency issues must be handled directly between the licensee and the other agency. The transmittal letter accompanying the final report to the licensee shall repeat this information concerning how the licensee should follow up on outside agency issues. The NRC report should request the licensee to respond to all issues in the report, with a response to any other agency is findings made separately to that agency, as well.

f. Reports from Participating Agencies. The NRC regional office shall include a copy of the participating agency's report or findings in or as an attachment to NRC's final reports. However, timeliness of the issuance of the final NRC report shall not be compromised due to lateness of participating agency reports. Care must be taken to delineate, before the conclusion of the onsite assessment, which findings will be addressed in the NRC final report and which will be handled directly between the participating agency and the licensee. In this manner, the region will not have to rewrite, edit, or prioritize findings from other agencies. Participating agencies' reports and findings need not conform to NRC's style or format.

Concerns that impact on radiological safety shall be written by the region into the final report. Concerns that do not impact on radiological safety will be handled by the other agency, with a copy attached to NRC's final report. The team leader and participating agency team members shall reach an agreement on a scheduled date for the participating agency to

submit a copy of its own report or other material to be included in the NRC report. If the agency does not meet the established schedule, the team leader shall proceed with arrangements to issue NRC's final report. Any late participating agency reports shall be issued as supplemental attachments to NRC's report.

g. Breadth of Findings. The NRC report shall recognize strengths and weaknesses, as well as concerns and violations, in the licensee's program. The strength of the team assessment report lies in its wide range of options for findings. The team is not limited to and should refrain from violation/no-violation types of findings. If the licensee demonstrates operational or management strengths, those should be stated. If the licensee exhibits inadequacies or weaknesses, those should also be stated. The result should be a complete, accurate picture of the licensee's safety program and safety culture regarding licensed operations.

h. Distribution of Final Report to Headquarters. Once the final report is prepared, reviewed, and signed within the region, a copy shall be provided directly to the Deputy Director, IMNS/NMSS, for Headquarters' information. A cover memorandum accompanying the copy from the regional Division Director to the Deputy Director, IMNS/NMSS, shall identify any significant items found by the assessment team.

i. Issuance of Final Report. The final report shall be distributed in accordance with MC 0611, "Review and Distribution of Inspection Reports," with particular attention paid to the procedures for controlling exempt information. A copy of the final report shall be sent to the licensee with a cover letter briefly describing the assessment and followup procedures.

05.05 Team Assessment Followup

a. Violation Followup. Violations will be followed up in the traditional manner by issuing an NOV or initiating escalated enforcement action and tracking the item through to completion.

b. "Concerns" Followup. Licensees shall be requested to respond to NRC concerns given in the final report and indicate how the concerns will be resolved. Licensees shall be requested to resolve immediate, specific (non-programmatic) concerns and describe their actions in the response. The regions shall determine what type of response format is needed from the licensee. Licensees may be permitted to resolve programmatic-type concerns through the license renewal or license amendment process, if licensing actions will resolve the concerns in a timely manner. The region shall determine which concerns are immediate and which may be deferred to licensing actions.

c. Coordination with NMSS. If a licensee refuses to respond to or act on NRC concerns, the region will take appropriate

actions and coordinate with IMNS/NMSS on any further action necessary.

d. Participating Agency Followup. Violations and concerns addressed by other participating agencies (i.e., findings not impacting on radiological safety) should be documented in the participating agencies' reports and should also be followed up directly with the licensee by the agency issuing the finding. Copies of the followup documentation to and from the licensee should be provided, as a courtesy, by the participating agency, to the NRC regional office.

05.06 Inspection Fees.

a. Licensee Notification. The region shall send a letter to the licensee before the team assessment, informing the licensee of the date that the onsite team assessment will begin and also stating that the licensee will be billed for the team assessment, if applicable (see Subsection 2601-05.06.b. "Applicability of Team Assessment Fees"). Regional staff and team members should not attempt to estimate fees for the licensee.

b. Applicability of Team Assessment Fees. All licensees undergoing team assessments that are regularly billed for inspections shall also be billed for team assessments, since the team assessment is considered to be an expanded routine inspection. Licensees shall be billed the inspection fee for that category of license under 10 CFR Part 170, Section 170.31.

c. Exempt Licensees. Licensees that are exempt from inspection fees shall also be exempt from fees for a team assessment.

d. "Full-Cost" Fees. For licensees that may be billed for the full cost of conducting inspections, the fee for a team assessment shall be based on the NRC professional staff time and appropriate contractual support services expended to conduct the assessment, including time spent in preparation, travel, onsite, and documenting the team assessment. "NRC professional staff time" shall apply to all NRC professional employees, regardless of location of assignment.

e. Capped Fees. For licensees that may not be billed for "Full Cost" of inspections, the fee for a team assessment shall be that given for a routine inspection in the Schedule of Fees in 10 CFR Part 170, Section 170.31, for the appropriate category of licensee.

f. Recovering Fees for NRC Contractors' Services. NRC contractors that provide appropriate support services to conduct team assessments shall send a business letter to the regional office in order to claim time spent on fee-chargeable assessment activities. The team leader shall instruct any NRC contractor participating in the team assessment about the requirement to provide a business letter claiming time spent on team assessment efforts. The regional office shall forward

copies of all contractor business letters claiming team assessment time to the LFDCB/OC every quarter, along with the quarterly inspection staff-hour reports, so that costs may be recovered from the licensee, when applicable. All license fee billing documentation should be referenced by docket number and report number.

g. Automatic Cost Recovery through RITS. All NRC professional staff shall report time spent on team assessment efforts on inspection activities report sheets, as indicated in 2601-06 "Inspection Resources," so that costs may be automatically processed through the RITS and efficiently recovered from the licensee. Team members who do not routinely participate in fee-chargeable inspections shall ensure, through coordination with their PMDA office or DRMA office, that their names are entered into the RITS system for automatic fee recovery. The inspection activities report sheets shall be completed for all team assessments, regardless of whether the licensee's fees are full cost, capped, or exempt. LFDCB/OC bills licensees upon completion of the assessment report. The report must be given a report number for LFDCB/OC to track NRC staff effort through RITS and bill the licensee. NRC efforts expended on the team assessment, and tracked by RITS, beyond the report issue date, are not fee-chargeable. Every quarter, inspection staff-hour reports are generated so that all inspection costs may be billed to the licensee.

h. Other Participating Agencies' Fees. Any fees for assessment efforts of team members from any other participating agency shall be handled entirely by that agency. NRC shall not bill the licensee for participation of any other agency team members. The team leader shall instruct team members from other participating agencies that NRC will not bill the licensee for their efforts, and that each agency should use its own standards, regulations, and procedures, if it chooses to bill the licensee.

2601-06 RESOURCES

The NRC Five Year Plan notes that NRC will conduct approximately five enhanced operational safety assessments each year in FY 1990-1994 at large, non-reactor facilities. Resources have been appropriately budgeted for these team assessments. Although the resources have been included under the "Fuel Facility Inspections (Activities)" program element of the Five Year Plan, these resources shall be regarded as applying to team assessments for both fuel facility licensees and materials licensees. Staff time spent while conducting or in professional support of team assessments for both fuel cycle facility licensees and materials licensees shall be charged specifically to the Items of Major Interest (IMI) code for team assessments (IMI code = IOSU) and to the Inspection Program Element (IPE) code for "Core Inspection Program" (IPE code = CO). In addition, inspection activities report sheets shall indicate the procedure numbers for the specific inspection procedures performed on the team assessment, under the "Description" column. Headquarters and interregional participants on the assessment team

shall also complete and submit inspection activities report sheets, logging time for the same above IMI code, IPE code, and procedure numbers.

2601-07 REFERENCES

The program areas that this chapter applies to are MC 2600, MC 2800, and associated procedures. The procedures listed below are health and safety related. They shall be used as guidance for team assessments, particularly for team members who do not perform inspections on a regular basis. Also, NRC procedures for fire safety and environmental surveillance may be used; but if OSHA, FDA and EPA personnel participate, they should use their own procedures for fire safety and environmental analyses.

MC 0610	Inspection Reports
MC 0611	Review and Distribution of Inspection Reports
MC 2820	Followup Actions to Incidents Involving Fuel Facility or Materials Licensees
IP 83822	Radiation Protection
IP 84850	Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61
IP 86740	Inspection of Transportation Activities
IP 87100	Licensed Materials Programs
IP 88005	Management Organization and Controls
IP 88010	Operator Training/Retraining
IP 88015	Criticality Safety
IP 88020	Operations Review
IP 88025	Maintenance and Surveillance Testing
IP 88035	Radioactive Waste Management
IP 88045	Environmental Protection
IP 88050	Emergency Preparedness

EPA Procedure

FDA Procedures

OSHA Procedures

END