

NRC INSPECTION MANUAL

NMSS/RGB

MANUAL CHAPTER 2800

MATERIALS INSPECTION PROGRAM

2800-01 PURPOSE

To establish the inspection program for licensees authorized to possess, use, transfer, and dispose of radioactive material associated with various types of use, i.e., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (i.e., leak testing of sealed sources, calibration of instruments, servicing of devices, collection and repackaging of radioactive waste for final disposal), and transportation related thereto.

2800-02 OBJECTIVES

02.01 To establish the general policy for the materials inspection programs.

02.02 To describe a performance-based inspection approach and to identify specific conditions of poor performance which require the licensee to be inspected more frequently.

02.03 To place the major emphasis of the materials inspection program on timely and thorough follow-up of incidents and events.

02.04 To continue and enhance risk-informed, relative priorities for routine inspections of all licensees and a program of special inspection activities as specified by the Office of Nuclear Material Safety and Safeguards (NMSS).

02.05 To aid in the achievement of a consistent process of inspection for materials licensees.

2800-03 DEFINITIONS

03.01 Initial Inspection. The first inspection after a license is issued to a licensee.

03.02 Inspection. The act of assessing licensee performance to determine whether the licensee is using radioactive material safely and whether an individual or organization is in compliance with established standards, such as regulations, license conditions, and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions). Inspections involve a visit to a licensee's facility and/or temporary jobsite by

U.S. Nuclear Regulatory Commission (NRC) inspector(s), observations of licensed activities, interaction with licensee personnel, and transmission of the inspection findings. Pre-licensing visits and telephone contacts are not considered inspections.

03.03 Inspection Plan. An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

03.04 Inspection Priorities. An inspection priority code is assigned to a particular type of use which is authorized by a radioactive material license. The same priority code is assigned to all licenses which authorize that particular type of use. The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspections, expressed in years. Enclosure 1 lists the program codes (types of use) along with the assigned priority codes. The priority represents the relative risk of radiation hazard for the type of use. Priority Code 1 presents the greatest risk to the health and safety of workers, members of the public, and the environment. Priority Code 5 presents less potential risk to health and safety. Because a license may authorize multiple types of use, the priority codes are designated as primary and secondary codes, with the shortest routine inspection interval as the primary code.

03.05 Reactive Inspection. A reactive inspection is a special inspection in response to an incident, allegation, or special information obtained by NRC (i.e., report of a medical event, other Federal agency interests). Reactive inspections may focus on one or several issues, and need not examine the rest of a licensee's program. If the reactive inspection does not cover the activities normally reviewed on a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

03.06 Routine Inspection. Periodic, comprehensive inspections performed at a specified interval, as defined in Enclosure 1 of this Inspection Manual Chapter (MC).

03.07 Special Inspection Activities. Those inspection activities specified in Section 2800-0 7 of this MC where special guidance is needed. Those activities cover: 1) inspections of expired licenses, terminated licenses, and licensees undergoing decommissioning; 2) inspections of significantly expanded licensee programs; 3) reciprocity inspections; 4) temporary job-site or field site inspections; 5) team inspections; 6) inspections of abandoned licenses; and 7) general licensee inspections.

03.08 Team Inspections. For the purposes of this MC only, team inspections are defined as those inspections conducted by three or more inspectors, or any materials inspection that includes an inspector from outside NRC (other than members from a State's radiation control agency). Often, at least one of the inspectors is included on the team because of specialty in a particular field, or at least one of the team members comes from a different region or Headquarters. Team inspections can be routine inspections of a major licensee, or reactive inspections in response to a particular incident or event. Team inspections do not include those where a supervisor or program office staff member accompanies an inspector to evaluate the inspector's performance. In this context, team inspections are not meant to cover Augmented Inspection Teams (AITs) or Incident Investigation Teams(IITs), described in Management Directive 8.3, "NRC Incident Investigation Program."

03.09 Telephonic Contacts. These are contacts, made by telephone and documented in the docket file, to determine the status of licensees' activities, to assess compliance of

priority T licensees [see Section 05.05], or to exchange information with the licensee. Examples such as reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an inspection, or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts. Telephonic contacts are not inspections.

2800-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Director, Office of Nuclear Materials Safety and Safeguards (NMSS). Provides overall program direction for the NRC materials inspection program.

04.02 Regional Administrator. Oversees implementation of the materials inspection program within their respective region.

04.03 Director, Division of Industrial and Medical Nuclear Safety (IMNS)

- a. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to NRC jurisdiction.
- b. Assesses the effectiveness, uniformity, and completeness of implementation of the materials inspection program.
- c. Approves changes to the materials inspection program.
- d. Ensures that operating plans are consistent among the Regions responsible for materials inspections.

04.04 Director, Regional Division of Nuclear Materials Safety (DNMS)

- a. Manages the implementation of the inspection program elements performed by the Regional Office.
- b. Ensures, within budget limitations, that the Regional Office staff includes adequate numbers of inspectors to carry out the inspection program described in this chapter, including that which may be needed for reactive inspections.
- c. Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.
- d. Coordinates, with IMNS, to obtain technical assistance, as necessary.
- e. Recommends changes to the materials inspection program to the Director, IMNS.

04.05 Chief(s), Regional Inspection Branch(es)

- a. Proposes changes to the materials inspection program.
- b. Implements the Regional materials inspection program.

- c. Reviews and approves inspection schedules.
- d. Ensures that Regional inspectors achieve and maintain qualifications, in accordance with IMC 1246.
- e. Appraises the performance of each inspector during actual inspections at least once during each fiscal year.

2800-05 BASIC REQUIREMENTS

The Materials Inspection Program designates reactive inspections [see Section 05.02] as the highest priority, followed by initial inspections [see Section 05.03] and routine inspections [see Section 05.04] for the Priority Codes (in ascending numeric order) listed in Enclosure 1. Telephonic contacts [see Section 05.05] are not inspections and are performed as resources permit.

All routine materials inspections should be performed on an unannounced basis, with the following exceptions.

Since considerable travel is required, inspectors may telephone licensees located in Guam, American Samoa, Hawaii, Alaska, or other remote locations to verify that a routine inspection can be performed before undertaking such travel.

For inspection of Master Materials Licensees (MML), the lead region shall notify the MML of the dates of the inspection and the documentation that the MML should have available for the inspectors to review. [See IMC 2810] The lead region should also request assist inspections (i.e., accompaniment inspections and independent inspections) to be completed by the regional offices. The accompaniment inspections will be completed according to the MML's audit schedule with NRC inspectors accompanying the MML's staff during the radiation safety audits of the MML permittees. [See IP 87129] NRC inspectors will complete the independent inspections according to the request from the lead region by using the program-specific inspection procedures in Enclosure 7. The independent inspections will be unannounced just as routine inspections of other NRC licensees are unannounced. [See Section 07.08]

The regional license reviewer shall assign a primary program code which sets the inspection priority for each new license. Some licenses authorize activities that can be classified under more than one program code. If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority. For example., a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate (HDR) remote afterloader unit (Program Code 02230, Priority Code 2). The licensee's primary program code would be Program Code 02230. The HDR-related activities would be inspected during every routine inspection while the other portions of the licensee's program would be inspected during every other routine inspection.

Inspection plans should be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections, as decided by the region. After the inspection, the inspection plan may be discarded. It need not be filed or kept by the region.

05.01 General Inspection Process. The purpose of this MC is to describe the types of materials inspections and the general inspection program. For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. The IPs listed in Enclosure 7 provide more specific guidance for onsite inspection activities. Section 2800-08 provides guidance for documentation of inspection results.

To provide a reliable, uniformly implemented budgetary basis, the inspector shall charge inspection hours in the Human Resources Management System (HRMS, formerly the Resource Information Tracking System [RITS]). For routine inspections, the inspector shall designate the hours for the license docket number only to the program-specific inspection procedure (i.e., Inspection Procedures 87121, 87122, 87123, 87124, 87125, 87126, 87127, 87129, 87130, 87131, 87132, 87133, and 87134 [See paragraph 10.01.c.3 for OSHA Interface activities]) within the Task Codes for preparation and documentation, direct inspection onsite activities, enforcement activities, and time spent in travel status. There are separate Task Codes for reactive inspections, routine inspections, allegation follow up. Telephonic contacts are not inspections. As such the inspector shall charge time for activities described in Enclosures 2, 3, 4, and 5 to HRMS as direct inspection effort under Program Code PA No. 203232E, (generic TAC No. A10159).

- a. Pre-inspection activities. The goal of inspection preparation is to ensure that the inspector is sufficiently familiar with the types of uses and the generic requirements applicable to the licensed program. The effort expended on inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector. The extent to which an inspector prepares for routine inspections should be based on discussions with the supervisor.

To adequately prepare, an inspector shall review:

1. the license to determine if it has any unusual license conditions that would affect the approach to the inspection, i.e., authorization for an incinerator, authorization for use of material at temporary job sites,
2. the licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items and determining whether any events have been reported by the licensee during the current inspection cycle,
3. any commitments made by the licensee or restrictions imposed by NRC as a result of a Confirmatory Action Letter or an Order issued since the last inspection,
4. any notes in the file regarding special inspection emphasis, i.e., license reviewer's note to request a near term inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of the amendment [see Section 07.02.b].

It is not necessary for the inspector to review all the current licensing documents and procedures from the docket file. For problems identified during the course of the routine inspection, the inspector should ask the licensee for pertinent procedures and backup licensing documents maintained onsite by the licensee. If the documents are not available from the licensee, the inspector should contact the region for assistance. This practice would apply to routine inspections only.

To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and his or her supervisor on a case-by-case basis [see Section 05.02].

Inspectors should anticipate whether or not they will encounter protected information during inspection of a licensee. Inspectors should be aware of minimum handling requirements for sensitive—unclassified information, i.e., Safeguards Information, Official Use Only, and Proprietary Information. For current instructions, contact the regional security advisor or refer to the security services web page, <http://www.internal.nrc.gov/ADM/DFS/dfs.html>.

The inspector should identify the location of the licensee, make travel arrangements, discuss special aspects of the inspection with his or her supervisor (i.e., inspection of temporary job sites), and obtain the supervisor's approval for the travel itinerary. At least one week in advance of the inspection trip, the inspector shall convey the itinerary to the State radiation control agency to give the State personnel an opportunity to observe the routine inspections [see Section 10.02].

Finally, the inspector selects appropriate and calibrated radiation detection instrumentation for the inspection and obtains the necessary inspection forms (such as NRC Form 591M).

- b. Onsite Inspection Activities. Based on the pre-inspection activities, the inspector should be prepared to evaluate a licensee's performance of the licensee's radiation safety program. Inspection activities described below include: focus areas, performance-based approach, necessary review and retention of copies of a licensee's records, communication of findings during an inspection, awareness of a licensee's safety culture, and common elements to every inspection.
 - 1. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus areas:
 - (a) security and control of licensed material;
 - (b) shielding of licensed material;
 - (c) comprehensive safety measures;
 - (d) radiation dosimetry program;
 - (e) radiation instrumentation and surveys;
 - (f) radiation safety training and practices; and
 - (g) management oversight.

These focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material. The focus areas are described in Section 3 of each program-specific IP.

If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus area, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.

2. The inspector should use a performance-based approach to evaluate the focus areas. A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiological conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should provide an inspector with reasonable assurance of a licensee's ability to safely use byproduct material and is preferable to a review of selected records alone.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Observations of licensee operations, interviews with staff, review of licensee documents to complement and support inspector observations, and radiation surveys to obtain independent and confirmatory measurements should then be conducted. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety.

The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's

presence does not interfere with licensed activities. For example, an inspector should not insist on interviews when:

- (a) a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site)
- (b) a worker is preparing or administering dosages or doses,
- (c) a worker is providing patient care, or
- (d) a licensee is dealing with customers or members of the public.

3. Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the information reviewed or gathered has been declared as proprietary information by the licensee.

In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.

In all cases where licensee documents are retained beyond the inspection, inspectors must follow the requirements of MC 0620. Inspectors shall ensure that the licensee understands that the retained record will become publicly available, and shall give the licensee the opportunity to provide redacted copies or to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

4. The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensee's understanding and agreement that a violation occurred, preferably before leaving the site.

Whenever possible the inspector should keep NRC regional management informed of significant findings (i.e., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.

5. To have a positive impact on maintaining safety and effectiveness, the inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a "questioning attitude" and generally

adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns). The inspector's conclusions about safety culture may only be useful when violations are identified and linked to significant risk (i.e., there are an unacceptable number of occurrences with unacceptable health and safety consequences).

6. Common elements to every inspection are discussed below.

- (a) Entrance Meeting. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observations of licensed activities currently in progress.

The purpose of the entrance briefing is to inform licensee management that an inspection is being conducted and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of NRC's presence on site, and apprise management that an exit meeting will be conducted at the end of the inspection to detail the inspection findings.

This is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

The licensee representative should be asked to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (i.e., excessive personnel exposures, unexpected releases to the environment, QA problems, etc.). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

When an inspection is likely to involve proprietary information, given the technical area or other considerations of inspection scope, the inspector should discuss with licensee management during the entrance meeting how the information will be handled during the inspection.

- (b) Follow up on Previous Items. Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took the corrective actions as described in its response to the NOV and followed-up on safety concerns and unresolved issues identified during the previous inspection.

- (c) General Overview. The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.
 - (1) Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management, the Radiation Safety Officer (RSO), and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).
 - (2) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc., and anticipated changes in the range of the radiation use program. Determine if the licensee possesses material in accordance with a general license.
- (d) Observation of Actual Facilities and Licensed Activities. Ideally, the inspector should observe work in progress that involves NRC-regulated activities. If there is no opportunity, then the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites [see Section 07.04].
 - (1) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.
 - (2) Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.
 - (3) Perform routine inspections, when applicable, during first run operations.
 - (4) Make direct observations of radiation safety systems and practices in use.
 - (5) The walk-through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.
- (e) Independent and Confirmatory Measurements. Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory

measurements are those whereby the inspector compares his or her measurements with those of the licensee's.

- (1) The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e., inspector's detection equipment malfunctions during an inspection trip). Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.
 - (2) Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.
 - (3) The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation. However, the inspector must use NRC's instruments for independent verification of the licensee's measurements. The inspector's instruments must be in current calibration and source checked before they leave the regional office.
- (f) Special License Conditions. If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions.
- (g) Exit Meeting. At the conclusion of the inspection the inspector should conduct an exit meeting with the most senior licensee representative present at the facility. As appropriate, the inspector should prepare NRC Form 591M before the exit meeting so that the form can be properly executed during the exit meeting. [See Section 08.04]

If a senior management representative is unavailable for the exit meeting, the inspector should hold a preliminary exit meeting with appropriate staff onsite. As soon as practical after the inspection, the inspector shall hold an exit meeting directly with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting). This meeting involving the licensee's management and RSO will usually be held by telephone conference call.

- (1) For initial and routine inspections, the inspector should request the meeting and control the meeting for purposes of the inspection. During the meeting, the inspector shall explain any cited violation of NRC requirements and the inspector's understanding of the licensee's corrective action plan for each violation [See Section 05.01.b.4 about keeping the licensee informed of apparent violations during the inspection].

To avoid the formal disputed violation process [See NRC Enforcement Manual], the inspector should confirm the licensee's agreement and mutual understanding of cited violations and associated corrective action plans. If the licensee disagrees with a violation, the inspector should contact his or her supervisor before leaving the site to obtain further instructions. It may be necessary to continue the inspection or modify the cited violation. Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, the inspector should inform the licensee about the next steps in the enforcement process.

The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (i.e., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation (NOV).

At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature. If so, the inspector should assure proper handling of the information.

- (2) For a reactive inspection, the inspector should refer to IP 87103 for specific instructions about the exit meeting. It is particularly important that the inspector keep regional management informed of the inspection details and explain the exit meeting strategy with his or her supervisor before beginning the meeting. During

the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to regional management. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to regional management. The licensee's next opportunity to discuss the findings will be after the regional management has reviewed these matters.

- c. Post-inspection activities. After returning from an inspection trip, the inspector shall discuss the results of the inspection trip with his or her supervisor. This discussion should be sufficient to alert management to significant enforcement, safety, or regulatory issues. This meeting need not be documented, but it should be held in all cases. To complete the inspection, the inspector documents the inspection results in accordance with guidance in this MC [See Section 2800-08] and other chapters, as appropriate.

05.02 Reactive Inspections. Inspections performed to follow up on incidents (i.e., medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. Regional management shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. Regional management, in consultation with IMNS, shall also determine if the event warrants the recommendation for an AIT or IIT, rather than a reactive inspection. The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. Generally, issues of compliance will be addressed after all safety issues and program weaknesses are identified and clearly understood.

Inspections resulting from allegations will be documented in accordance with Management Directive (MD) 8.8, "Management of Allegations."

Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program." All other reactive inspections will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

A narrative inspection report will be written for all reactive inspections. The narrative report will include a discussion of the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The inspector shall annotate inspection reports with the NMED Event No. if the reactive inspection was initiated by an NMED reportable event. Enclosure 6 provides instructions to properly

“complete” the record for NMED. Enclosure 9 may be completed to document inspection findings that were unrelated to the event [see Section 08.03.b].

05.03 Initial Inspections: Initial inspections of a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy–Other Emerging Technology) shall be announced and completed within 12 months of the date the new license or amendment was issued by a Regional Office. To schedule the initial inspection, the date in the “next inspection date” data element in the Licensing Tracking System (LTS) shall be 12 months from the date the new license or amendment was issued. The “last inspection date” data element in the LTS shall be 0 (zero) or blank.

- a. Initial inspections of all licensees. Once onsite, the inspector should interview licensee staff (management and technical) to determine if licensed material has been possessed or licensed operations have been performed. Methods for determining if licensed activities have been performed include, but are not limited to the following: performing a site tour, performing confirmatory measurements, and/or contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed licensed operations, then the inspector should conduct an inspection in accordance with Section 05.01 and other applicable guidance.

If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

1. Determine the licensee's plans for future possession of licensed material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.
2. Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions.
3. Request that the licensee notify the NRC before receipt of licensed material or initiation of licensed operations.
4. Document the onsite inspection by completing a Form 591M. The “program scope” description in the Form 591M should include the licensee's plans for future possession of material or plans to perform licensed operations.
5. Ensure that the date in the “next inspection date” data element in the LTS is 12 months from the date of the onsite visit.

- b. New licenses excepted from an initial inspection. There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.

1. New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" data elements in the LTS should remain the same as for the licensee's previous license.
2. New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:
 - (a) the organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);
 - (b) the licensee significantly increases the types, quantities, or forms of radioactive materials on the license;
 - (c) the licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);
 - (d) the licensee significantly increases the number of authorized users; or
 - (e) the new license authorizes one or more new facilities.

If none of these conditions applies, then the "last Inspection date" and "next inspection date" data elements in the LTS should remain the same as for the previous license.

3. New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" data elements in the LTS should remain the same as for the licensee's initial license.

05.04 Routine Inspections. Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority listed in Enclosure 1. If the licensee has possessed material or performed licensed operations since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program-specific inspection procedure. If the licensee has not possessed material or performed licensed operations since the last inspection, the inspector should follow the instructions in Section 05.03(a)(1) through (4).

05.05 Telephonic Contacts (Priority T). For certain licensees, the regions shall use telephone contacts at 5-year intervals in lieu of an onsite inspection, with the exception of initial or reactive inspections. Enclosure 1 designates these licensees as priority T. As defined in Section 2800-03, telephonic contacts are useful for staying in touch with priority T licensees. Procedures for using the telephonic contacts are included as Enclosure 2. A telephonic questionnaire is attached as Enclosure 3 and standard

responses back to licensees contacted by telephone are included as Enclosures 4 and 5. This questionnaire should be completed, signed by the inspector, and placed in the docket file, and the "next inspection date" data element in the LTS shall be changed to indicate the date of the next telephonic contact. The inspector shall brief the supervisor about the telephonic contact. The inspector shall charge time to HRMS as direct inspection effort under Program Code PA No. 203232E, (generic TAC No. A10159).

2800-06 INSPECTION INTERVALS

06.01 Scheduling Inspections. To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled within a window around their inspection due date. Inspection of licensees in priorities 1, 2, and 3 may vary around their due date by ± 25 percent. Inspection of priority 5 licensees and telephonic contact of priority T licensees may vary around their due date by ± 1 year. Inspections will not be considered "overdue" until they exceed the scheduling window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

06.02 Combining Inspections. If a licensee holds several licenses with different Program Codes that are assigned different Priority Codes in Enclosure 1, a single inspection may be scheduled whenever practicable to aid in more effective use of the inspector's time spent in travel status. In the determination to combine inspections on a continuing basis, consideration should be given to not "over-inspect" a lower-priority license versus the need and desirability to inspect a licensee's total activities for a more complete assessment of its safety and compliance performance. The priority designations of the lower-priority licenses shall not be changed in these cases; the more frequent inspections of lower-priority licenses shall be handled only in the scheduling process.

06.03 Inspections After Escalated Enforcement. If escalated enforcement action has taken place for a particular licensee, a follow-up inspection to focus on the Severity Level III or above violation(s) shall be scheduled and conducted within 6 months of the last inspection or sooner, in accordance with the guidance in this MC regarding reduction of inspection interval, after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous violations. Regions may perform this follow-up inspection as a part of a routine inspection.

06.04 Reduction of Inspection Interval

- a. The inspection interval shall not be extended beyond that specified by the priority system indicated in Enclosure 1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation safety program. Poor compliance history is one indicator of such problems. Lack of management involvement or control over the radiation safety program is another indicator. Specifically, licensees that meet the following conditions shall be considered for reduction in inspection interval if:

1. A Severity Level I, II, or III violation results from the most recent inspection;
or
2. Issuance of an Order as a result of the most recent inspection; or
3. A "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (i.e., a paragraph that requires the licensee to address adequate management control over the licensed program); or
4. An event requires a reactive inspection; or
5. Repetitive violations occur.

The above list is not exhaustive; the inspection interval can and should be reduced for any other reason deemed pertinent by regional management. An example would be an enforcement conference where the outcome did not include escalated enforcement action, but did indicate the need for the licensee to improve some aspect(s) of its compliance program.

Another example would be an industrial radiography licensee or a well logging licensee which is authorized to use byproduct material at temporary job sites and the current inspection was limited to an office inspection and no temporary job site inspection was completed during the current inspection. [See Section 07.04.]

A licensee that meets the above criteria may have its inspection interval reduced by any length. For example, a priority 5 licensee with a poor performance record could be rescheduled for its next inspection in 2 or 3 years, rather than 5 years, depending on the scope of licensed activities. Or a priority 2 licensee with a Severity Level III or above violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the Severity Level III or above violation may have already been completed within 6 months. [See Section 06.03] The reduction shall be valid only until the next inspection, but regional management shall consider the results of the next inspection when determining whether the reduced interval should be continued, changed, or returned to normal.

- b. The designated inspection priority for these licensees should not be changed in the LTS. However, the "next inspection date" field in the LTS should be changed to contain the reduced date for the next inspection. To identify the reduced inspection date in the LTS, the letter "R" shall be entered under Special Inspection Codes on the Inspection and Enforcement Screen of the LTS.
- c. To document the reduction in the interval between inspections, a brief note (i.e., in the inspection records) should be written by the inspector, approved and signed by the inspector's immediate supervisor, and placed in the docket file.

06.05 Other Changes in Inspection Interval. At the discretion of regional management, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently

observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

2800-07 SPECIAL INSPECTION ACTIVITIES

07.01 Expired and Terminated Licenses and Decommissioning Activities. Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys. The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the NRC on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule.

Specific guidance for performing closeout inspections is outlined in IP 83890.

07.02 Significantly Expanded Programs. During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspectors and the reviewers should make the inspection and licensing supervisors aware of the following changes in a licensee's scope of use.

- a. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:
 1. the licensee has recently increased the types, quantities, and uses of radioactive material;
 2. the license authorizes a physical move of a facility or a new use at a temporary jobsite;
 3. the license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;
 4. the licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material; and

5. the number of authorized users has significantly increased or decreased.

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor.

- b. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded. [See the 5 points in the preceding paragraph.] In that case, the license reviewer shall ensure that the "next inspection date" data element in the LTS is changed and shall post a notice in the docket file for the inspector [see NUREG-1556, Volume 20, Section 4.12 (Significant Licensing Actions that Warrant Onsite Inspection) and Appendix C (Checklist C.5)].

For example, an amendment issued for a new medical therapy modality under 10 CFR 35.1000 (Program Code 02240) shall be inspected within 12 months of the date of the amendment. The reviewer shall ensure that the next inspection date data element in the LTS was appropriately changed, the docket file was posted with a paper copy of the memo in Appendix C of the NUREG-1556 (Volume 20), and the inspection and licensing supervisors were notified accordingly.

07.03 Reciprocity Inspections. Section 150.20 grants a general license to any person, with a specific license from an Agreement State authorizing use at temporary job sites, to conduct the same activity in areas under Federal jurisdiction. The licensee must submit an NRC Form 241, "Report of Proposed Activities in Non-Agreement States" 3 days before engaging in the licensed activity.

- a. The recipient of the NRC Form 241 is the NRC region in which the Agreement State that issued the license is located (licensing region).
- b. MC 1220 details the process for scheduling the inspection of the licensee operating under reciprocity. The licensing region shall take immediate action to enter information from the form into the Reciprocity Tracking System. Before reciprocity work begins, the licensing region shall forward the form to the NRC regional office having jurisdiction in the area of the licensee's proposed activities (inspecting region).
- c. The inspecting region shall follow the policy and guidelines found in MC 1220, Appendix III, for performing inspections of reciprocity licensees. MC 1220 details the percentage of reciprocity licensees to be inspected each year. The inspectors shall use the program-specific procedures which are used for equivalent NRC-licensed activities.
- d. The inspecting region is responsible for initiating enforcement action and taking other follow-up actions, as appropriate for the inspection. In addition, the inspecting region shall send copies of inspection and enforcement documentation to the licensing region and to the Agreement State radiation control agency which issued the license that is the basis for the general license under 10 CFR 150.20.

07.04 Temporary Job Site or Field Office Inspections

- a. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).
 1. During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).
 2. The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.
 3. If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).
 4. If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" data element in the LTS may indicate a reduced inspection interval. [See Section 06.04]
- b. Permanent Field Offices. Each licensing region is responsible for requesting an assist inspection (i.e., an inspection conducted by one region at the request of another region) at each permanent field office to be inspected, if these locations are outside the geographical area of the licensing region. The inspecting region should provide complete documentation and recommend enforcement action to the licensing region, which will distribute the documentation, initiate enforcement action, and take other follow-up actions, as appropriate to the case. [See Section 09.02]
 1. If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or more field offices), only one location must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.
 2. If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.

3. If an inspection identifies significant program weaknesses (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the licensing region should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.
- c. Off-Shore Waters. For a licensee working in off-shore waters, the regional staff should either make travel arrangements to accompany another federal agency to the rig to complete an unannounced inspection or contact the rig operators, or appropriate licensee contact, to request the licensee to provide travel arrangements to the rig when work is in progress. Before accepting transportation or lodging from the licensee, staff should obtain approval from the individual's immediate supervisor. This approval should be documented with a brief statement in the inspection records. NRC should reimburse the provider for the cost of transportation, lodging, or other services accepted during the course of inspections.

07.05 Team Inspections. [NOTE: This section is included solely for team inspections of materials licensees. The term "team inspections" is used here only for the purposes of this MC. The requirements of other MCs or IPs for team inspections or team assessments of nuclear reactors and fuel cycle facilities do not apply.]

Regional offices shall conduct team inspections of major licensees within the region on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside NRC (other than State radiation control agencies) shall be made by regional management, in consultation with IMNS. Examples of situations where team inspections may be appropriate are:

- a. Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processor/manufacturers). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.
- b. Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors). Also, reactive inspections of any licensee where at least one of the three or more inspectors is from another region or from Headquarters.
- c. Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess licensees' strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, pre-licensing visits are not considered inspections, and team inspections should not take the place of pre-licensing visits.
- d. Inspections of any type (routine or reactive) that include team members from outside the NRC and the State radiation control agencies, such as members from

the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). For inspections of any type that involve participation by outside agencies (other than State radiation control agencies), the region should coordinate through the NRC Regional State Liaison Officer with the outside agency.

At regional management discretion, inspection plans may be developed for all team inspections. Inspection plans should be considered for team inspections of major, broad-scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the NRC (other than State radiation control agencies) are involved. [See examples (a) and (d) in this section]

07.06 Abandonment of Licensed Activities. Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The regional decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

07.07 Inspection of Generally Licensed Devices. Routine inspections of general licensees [other than reciprocity (10 CFR 150.20)] are not normally performed. However, if a specific licensee also possesses generally licensed devices that require registration under 10 CFR Part 31, the inspector should verify the adequacy of the licensee's control and accountability of the devices [See IP 87124, Focus Element 1]. Inspections of general licensees shall also be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

07.08 Inspection of Master Materials Licenses. A Master Materials License (MML) is a multi-site, multi-regional materials license (Program Code 03613) to authorize possession, use, disposal, etc., of byproduct, source, and/or special nuclear material. The MML authorizes the MML's central radiation control program which includes internally managed licensing and inspection programs that are similar to NRC's licensing and inspection programs. The NRC inspection of an MML is a comprehensive evaluation of the MML's central radiation control program.

IMC 2810 specifically describes the NRC's organization and administrative procedures for oversight of the MMLs. IP 87129 provides specific guidance for NRC's inspection of an MML.

Each licensing region (Lead Region) has assigned the project management responsibilities for the MML to a designated NRC staff member (NRC MML Project Coordinator). One of the coordinator's responsibilities is the routine inspection of the MML. As such, the Lead Region requests other of the NRC's regional offices (Assisting Regions) to complete assist inspections (accompaniment inspections and independent inspections).

- a. For accompaniment inspections, the Assisting Region's inspectors shall implement IP 87129 while accompanying the MML's staff during routine radiation safety audits of the MML's permittees. The purpose of the accompaniment inspection is to determine whether or not the MML's staff are inspecting the permittees in

accordance with NRC's inspection policies and procedures [See Enclosure 7]. In addition, the inspectors shall obtain information deemed necessary by the Lead Region for special issues relating to the inspection.

1. IP 87129 includes forms to document the accompaniment inspections.
 2. The inspector shall provide the completed forms to the Lead Region's MML Coordinator as per the established timeliness goal.
- b. For independent inspections, the Assisting Region's inspectors shall implement the program-specific guidance contained in the inspection procedures in Enclosure 7. In addition, the inspectors shall obtain information deemed necessary by the Lead Region for special issues relating to the inspection.
1. The inspections shall be unannounced by NRC or the MML.
 2. Inspection report numbers will be provided by the Lead Region.
 3. Inspectors will provide completed inspection documentation to the Lead Region MML Coordinator within the established timeliness goal. [See Section 2800-08]
 - (a) NRC Form 591M shall not be issued to the MML permittee's management.
 - (b) The Lead Region shall issue all inspection-related correspondence to the MML.

All allegations received by NRC inspectors shall be forwarded to the Lead Region MML Coordinator and Office Allegation Coordinator for action by the Lead Region. If independent follow up by NRC is needed, the Lead Region may request the Assisting Region to assist with the follow up for the allegation.

2800-08 DOCUMENTATION OF INSPECTION RESULTS

08.01 What Constitutes an Inspection. The following guidance is provided to assist in determining when activities constitute an inspection.

- a. An inspection will be considered to have been performed if:
 1. the inspection involves a licensee that possesses or has possessed licensed material since the last inspection, including material possessed under a "possession-only license" or that is performing or has performed licensed activities since the last inspection; or
 2. the inspection is an initial inspection that has been performed in accordance with Section 05.03.

If it is possible to inspect records or other items according to license conditions or NRC regulations, such activities should be inspected and be recorded as an inspection, whether the radiation safety officer (RSO) is present or not, including those licenses that have expired or are being processed for termination.

If the RSO is not onsite, the inspector shall make a telephone call to contact the RSO about the inspection. At the conclusion of the inspection, the inspector shall re-contact the RSO to explain the inspection results. If the inspector is unsuccessful in announcing the inspection to the RSO, the inspector shall make a follow-up telephone call to the RSO as soon as possible after the onsite inspection.

- b. An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector will document the on-site activities by placing a note in the docket file, signed by the inspector, that briefly summarizes the attempted inspection. Together, the inspector and his or her supervisor should determine when another attempt will be made to inspect the licensee and the "next inspection date" data element in the LTS should be changed to reflect the new date. The region should not record an attempted inspection in the LTS as "an inspection."
- c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.
- d. The HRMS allows the time spent in gathering factual material to be charged against the time budgeted for performing routine inspections. Telephone contacts are not onsite inspections even though they involve direct inspection effort. The inspector should charge their time to HRMS, Program Code PA No. 203232E, (TAC No. A10159). The fact that a telephone contact of a Priority T licensee was made should not be entered into the LTS as an inspection; however, the date of the next telephone contact should be indicated in the "next inspection date" data element in the LTS.
- e. A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

08.02 Allegations. Allegations will be followed up and the results documented and transmitted in accordance with NRC Management Directive 8.8, "Management of Allegations." No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, or other documents that will be filed in the docket file for the licensee. Following is further guidance about "chilling" effect.

- a. In conducting interviews or other activities with licensee personnel, inspectors should be sensitive to areas where employees may be reluctant to raise concerns about the licensee's program. Even if the licensee addresses an employee's concern regarding safety issues, there could be underlying factors that could produce a "chilling" effect or reluctance for employees to report such issues. For example, the following questions will help an inspector determine if problems exist in the licensee's safety program:

1. Has there been an unexplained change in the number or nature of valid concerns that employees have raised with the licensee or the NRC?
 2. Have there been interactions with NRC personnel that suggest that some employees may be hesitant to raise concerns or present information to NRC?
 3. Are employee concerns addressed by licensee management in a timely manner?
 4. Is the licensee's corrective action successful in addressing employees' concerns?
- b. If any indication of a "chilling" effect is found, the inspector shall inform regional management for further review and follow-up.

08.03 Methods of Documenting Inspection Results. Inspections shall be initially documented by completing inspection records or a narrative report.

- a. Enclosure 8 provides the format for documenting inspections that result in the issuance of an NRC Form 591M. If an NRC Form 591M is not issued, then the inspection results will be documented on Enclosure 9 or in a narrative report as described below, and the region will communicate the inspection findings to the licensee in a formal letter with a Notice of Violation, if appropriate. The inspection records do not have to be typed, but should be legible and should contain:
1. the procedure(s) used;
 2. the focus areas examined;
 3. the status of follow-up items involving prior enforcement or reported licensee events;
 4. sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection;
 5. description of completed and anticipated corrective actions to any identified violations; and
 6. a succinct description of the scope of the licensee's program.

A different inspector should be able to use the inspection records in preparing for a subsequent inspection, and to determine whether corrective actions have been taken.

- b. A narrative report is required for all team inspections and actions involving an enforcement conference or escalated enforcement. For escalated cases, the narrative report need address only the areas in which safety concerns and violations are identified (all other areas may be documented using Enclosure 9). All inspection documentation shall be filed in the licensee's docket file. For medical events, the narrative report must follow the guidance in Management Directive 8.10. Additional guidance on inspection reports can be found in MC 0610, "Inspection Reports." Narrative inspection reports may be used to document other types of inspections at the discretion of regional management.

08.04 Methods of Transmitting Inspection Results. Results of inspections may be reported to the licensee by either issuing an NRC Form 591M , or a regional office letter either with or without a Notice of Violation (NOV) to the licensee.

a. NRC Form 591M, "Safety Inspection Report", shall be used:

1. to document clear inspections and inspections resulting in Severity Level IV violations (that are neither willful nor repetitive) that can be corrected while the inspector is present, or that the licensee is able to correct easily; and
2. to document non-cited violations (NCVs), as discussed in the Enforcement Manual.
3. When the NRC Form 591M is used to document the results of an inspection, the inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met, reference to the regulation or license condition that was violated, and a description of the licensee's corrective actions. Following are examples of cited violations on an NRC Form 591M:
 - (a) Section 20.1101(c) requires the licensee to annually review the content and implementation of the radiation protection program. During years 2002 and 2003, the license did not complete the review. The licensee will complete the review in October 2004 for the period of January 2002 through September 2004. The licensee intends to complete future reviews in October of each year by completing NUREG-1556, Volume 2, Appendix I, Radiation Safety Program Audit.
 - (b) As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2003, to October 24, 2003, to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system to notify the Radiation Safety Officer to perform the inventories.
4. The inspector must also ensure that the findings are documented in the inspection records in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. If the licensee provides corrective action for the violations, this information should also be included in the inspection records.
5. For NCVs, the inspection records should document why the violation was not cited and the corrective action taken or planned.
6. The inspector will present NRC Form 591M to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with regional management is necessary, the inspector may transmit NRC Form 591M from the regional office by facsimile. Other forms of distribution, i.e., electronic mail, may be used at the discretion of regional management. All non-willful,

non-repetitive Severity Level IV violations may be cited on NRC Form 591M.

7. The NRC Form 591M, "Safety Inspection Report", shall include the name of the responsible inspector. The inspector shall sign the completed Form 591M and will usually provide the signed form to the administrative staff without further management review, unless instructed otherwise by the supervisor.

b. A letter, signed by regional management, shall be used:

1. for repetitive violations;
2. for violations involving willfulness;
3. where an apparent Severity Level I, II, or III violation or problem is indicated;
4. when an enforcement conference or a management meeting is to be held;
5. where the licensee needs to take extensive corrective action or make programmatic changes to address the violation;
6. where the licensee needs to perform further evaluations before taking corrective action;
7. where the corrective action includes a request for an amendment to the license;
8. when a specific message should be provided to the licensee;
9. if the inspector questions the effectiveness of the licensee's planned action or the ability of the licensee to carry out the corrective action; or
10. where it is appropriate to request a written response to the violation.

If a regional office letter and NOV are to be issued, NCVs, if any, are to be documented in the inspection records.

2800-09 COORDINATION OF REGIONAL RESPONSIBILITY FOR INSPECTIONS

09.01 General. When a license authorizes operations in more than one region, the responsibility for inspection shall reside with the regional office in which the licensee's main office is located. The main office means the corporate office, normally the street address listed in item 2 of the license.

09.02 Assistance in Inspections. In the interest of efficiency in use of travel time and funds, the responsible regional office may request another regional office to conduct inspections (assist inspections) of the activities of such licensees when the licensee is operating outside the geographical area of the responsible region. [See Section 07.04(b)]

Because of the close proximity of a licensed facility to the responsible region's boundary, the responsible region's personnel may perform the inspection activity themselves rather than request assistance from another region. In such cases, these activities should be coordinated between regions.

09.03 Transfer of Responsibility. Notwithstanding the above (Sections 09.01 and 09.02), when a license has an address that places the inspection responsibility in one region, and operations under the license routinely or predominantly occur within another region, the inspection responsibility may be transferred to the region in which the operations are performed. This transfer shall be done with mutual agreement of the regional offices involved. The regional offices should ensure that the appropriate changes are made to the LTS to show which office has the overall responsibility for inspection and enforcement.

2800-10 COORDINATION WITH OTHER AGENCIES

10.01 Federal Agencies. NRC does not conduct inspections of licensee compliance with the requirements of other Federal agencies, except the U.S. Department of Transportation (DOT). However, NRC inspectors may identify concerns that are within another agency's regulatory authority. If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the NRC regional office, in coordination with NMSS, should inform the appropriate liaisons within the other agency about the concerns.

Except for DOT regulations, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. Thus, in discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness. For example, if an inspector identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation. The inspector would also advise the licensee of the inspector's obligation to inform the NRC supervisor who may coordinate the information with OSHA as per MC 1007.

In the case of complaints or allegations involving another federal agency's jurisdiction, the inspector should withhold the information from the licensee and elevate the concerns to the attention of NRC regional management while the inspector is still onsite. [see Section 08.02]

NRC has entered into several Memoranda of Understanding (MOUs), with other Federal agencies, that outline agreements regarding items such as exchange of trade-secret information and evidence in criminal proceedings. These MOUs are published in the NRC Rules and Regulations (Volume IV) and copies may be obtained from the regional office or IMNS. The following MOUs contain information that is relevant to inspection activities:

- a. U.S. Department of Transportation (DOT). The NRC/DOT MOU, "Transportation of Radioactive Materials" - published in the Federal Register July 2, 1979, delineates DOT's and NRC's respective responsibilities for regulating safety in transportation of radioactive materials.

b. U.S. Department of Justice (DOJ)

1. The NRC/DOJ–Federal Bureau of Investigation (FBI) MOU, "Cooperation Regarding Threat, Theft, or Sabotage in U.S. Nuclear Industry" - published in the Federal Register May 16, 2000, provides a basis for contingency response planning, coordination, and cooperation between the FBI and the NRC, to deal effectively with threats, and with acts associated with theft or sabotage attempts against NRC-licensed nuclear facilities and activities.
2. The NRC/DOJ MOU published in the Federal Register December 14, 1988, provides for coordination between the two agencies for matters that could lead to NRC enforcement action, as well as DOJ criminal prosecution. The MOU also facilitates exchange of information on matters within their respective jurisdictions.

c. U.S. Department of Labor (DOL)

1. The NRC/DOL MOU, "Cooperation Regarding Employee Protection Matters" published in the Federal Register October 27, 1998, provides coordination of employee protection provisions in Section 211 of the Energy Reorganization Act of 1974. Section 211 prohibits a licensee, applicant, or contractor or subcontractor of same from discriminating against any employee who assisted or participated, or is about to assist or participate, in an NRC inspection.
2. The NRC/DOL–Mine Safety and Health Administration (MSHA) MOU, "Facilitation of Coordination and Cooperation in Areas of Mutual Jurisdiction and Concern," published in the Federal Register January 4, 1980, clarified the regulatory roles for NRC and MSHA for milling of source material, including inspection of an operating uranium mill.
3. The NRC/DOL–Occupational Safety and Health Administration (OSHA), MOU, "Worker Protection at NRC-licensed Facilities" - published in the Federal Register October 31, 1988, was designed to ensure that there will be no gaps in the protection of workers at NRC-licensed facilities where the OSHA also has health and safety jurisdiction. At the same time, the MOU is designed to avoid NRC and OSHA duplication of effort in those cases where it is not always practical to sharply identify boundaries between the NRC's responsibilities for nuclear safety and the OSHA's responsibilities for industrial safety.

Specific guidance on the responsibilities and interfacing activities for reporting non-radiological hazards to OSHA can be found in MC 1007. There are 4 categories of hazards that may be associated the licensed materials:

- (a) radiation risk from radioactive materials,
- (b) chemical risk from radioactive materials,

- (c) facility conditions that affect the safety of radioactive materials and thus present a risk to workers or members of the public, and
- (d) facility conditions that result in an occupational risk but do not affect the safety of licensed materials.

Generally, NRC has jurisdiction over categories (a), (b), and (c). OSHA has authority and responsibility for category (d). Through this MOU, NRC supports OSHA by reporting category (d) conditions to the licensee, NRC, and OSHA so appropriate action(s) can be taken.

Time spent on meeting the requirements of MC 1007 for category (d) conditions are to be charged to IP 93001, "OSHA Interface Activities." Time spent on category (a), (b), and (c) conditions are to be charged to the program-specific inspection procedure.

d. U.S. Environmental Protection Agency (EPA)

1. The NRC/EPA MOU, "Regulation of Radionuclide Emissions", published in the Federal Register November 3, 1980, defines in general terms the respective roles of the two agencies and establishes a framework of cooperation for avoiding unnecessary duplication of effort and for conserving resources in establishing, implementing, and enforcing standards for airborne radionuclide emissions from sources and facilities licensed by the NRC.
2. The NRC/EPA MOU published in the Federal Register November 16, 1992, was designed to foster NRC/EPA cooperation in protecting health and safety and the environment on issues relating to the regulation of radionuclides in the environment.
3. The NRC/EPA MOU published in the Federal Register December 22, 1992, concerns "Clean Air Act Standards for Radionuclide Releases from Facilities Other than Nuclear Power Reactors Licensed by NRC or its Agreement States." The MOU was designed to ensure that facilities other than nuclear power reactors, licensed by the NRC, will continue to limit air emissions of radionuclides to levels that result in protection of the public health with an ample margin of safety.

e. U.S. Department of Health and Human Services (DHHS)

The NRC/DHHS–FDA MOU published in the Federal Register December 23, 2002, renewed with minor changes the MOU signed by NRC and FDA on August 26, 1993. The MOU coordinates existing NRC and FDA regulatory programs for medical devices, drugs, and biological products using byproduct, source, or special nuclear material.

f. U.S. Department of Energy (DOE)

The NRC/DOE–Office of Waste Management MOU, “Concerning the Management of Sealed Sources,” published in the Federal Register January 7, 2000, addresses the problem of unwanted and uncontrolled radioactive materials (“orphan” sources) and defines agreed-upon roles and responsibilities of the NRC and DOE in situations where the NRC is the lead Federal agency, where immediate health and safety hazards have been addressed, and where assistance with the transfer of radioactive material is determined to be necessary for continued protection of public health and safety and the environment.

10.02 State Agencies. For routine NRC inspections in both Agreement and non-Agreement States, State radiation control program personnel shall be notified of the inspection at least 1 week in advance, by telephone, e-mail, or facsimile.

State personnel interested in participation may do so as observers as long as their presence does not affect NRC's inspection program. State personnel should be informed that information gathered during the inspection is confidential and predecisional and shall not be disclosed.

Whenever possible, for reactive inspections in Agreement States, State radiation control program personnel should be notified before the start of the inspection so that any public inquiries that may come to the State radiation control agency may be referred to the appropriate regional office.

2800-11 INPUT INTO NRC TRACKING SYSTEMS

11.01 Input into the Licensing Tracking System (LTS). Enclosure 1 provides a listing of license program codes with the associated inspection priorities. Regions should enter data promptly into the LTS at the time a new license is issued or an inspection has been performed, including the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are made to the next inspection date (reductions in the inspection intervals), regions should enter the data for the correct next inspection date into the LTS and enter the Special Inspection Code on the Inspection and Enforcement Screen, as described in Section 06.04(b).

11.02 Input into the Nuclear Materials Events Database (NMED). NMSS manages NMED for all material-related incidents and events. The regional office is responsible for ensuring that NMSS is notified of all material-related incidents. The regional office shall also forward annotated copies (NMED Event No. shall be on each document) of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor (INEEL at this time) and the NMED Project Manager, NMSS.

The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." For documents that are publicly available, entry into ADAMS meets the requirement for forwarding documents. For documents that are not

publicly available, the regional office must forward paper copies to the NMED contractor and the NMED Project Manager, NMSS.

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The regional office shall provide the information outlined in Enclosure 6 to classify a record as "complete." If there is a reason that the regional office can not obtain the required information, that reason should be forwarded to the NMED contractor and to the NMED Project Coordinator, NMSS.

2800-12 INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM

The Inspection Manual Chapters (MCs) and Inspection Procedures (IPs) listed in Enclosure 7 comprise the inspection program for material licensees. This list is organized into various topics. 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. In performing an inspection, a MC in addition to several specific procedures, may be needed to adequately evaluate the licensee's program.

MCs and IPs in this section are classified into two categories: Routine (R) and As-Needed (N). "Routine" (R) means those MCs and IPs that are generally used to evaluate licensee performance. For example, the IP 87100-series includes procedures for routine inspections of certain types of use of byproduct material, i.e., industrial/academic, medical, industrial radiography, gauges, etc. However, all "routine" MCs and IPs are not appropriate for each inspection. For example, IP 84900, "Low-Level Waste Storage," would not be appropriate for inspection of a fixed or portable gauge licensee that stores devices, unless the devices were designated for disposal. "As-Needed" (N) means those MCs and IPs that are specifically used for a certain situation. For instance, MC 1120, "Preliminary Notifications," is classified "as-needed," because it only applies to certain events. Similarly, IP 92703, "Follow Up of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to a licensee who has been issued a CAL.

END

Enclosures:

1. Inspection Priority by Program Codes
2. Telephone Contact Procedures for Priority T Licenses
3. Evaluation of Priority T Licensees Possession and Use of Byproduct Material
4. Standard Response to Licensees Contacted by Telephone (Violations)
5. Standard Response to Licensees Contacted by Telephone (No Violations)
6. Information for the Nuclear Materials Events Database (NMED)

7. MCs and IPs for the Materials Inspection Program
8. NRC Form 591M
9. Inspection Record

ENCLOSURE 1
INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES

Program	Priority	Category Title	Remarks
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users; 10 CFR
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 10 CFR 33.14
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 10 CFR 33.15
02110	2	Medical Institution Broad	RSC-approved users for possession and use of a wide range of radionuclides in medical research, diagnosis, and therapy and research and development.
02120	3	Medical Institution–Written Directive (WD) Required	Includes “hybrid broad” licenses. Used as primary code for <i>only</i> nuclear medicine or types of use under 10 CFR 35.1000. The secondary codes for research and development may be used, i.e., 3610, 3611, 3612, as appropriate. Used as secondary code when the license also authorizes medical therapy modalities.
02121	5	Medical Institution–WD Not Required	Used as primary code <i>only</i> for nuclear medicine or for uses authorized under 10 CFR 35.1000. Used as secondary code when the license also authorizes medical therapy modalities.
02200	3	Medical Private Practice–WD Required	[same remark as 02121]
02201	5	Medical Private Practice–WD Not Required	[same remark as 02121]
02210	3	Eye Applicators Strontium-90 (Sr-90)	Institution or Private Practice
02220	3	Mobile Medical Service–WD Not Required	Use as a primary code if the license authorizes the mobile service <i>only</i> . Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.
02230	2	High-Dose Rate Remote After loader (HDR)	Use as a primary code.

Program	Priority	Category Title	Remarks
02231	2	Mobile Medical Service–WD Required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 10 CFR Part 35
02240	2	Medical Therapy–Other Emerging Technology	Medical therapy modalities used under 10 CFR 35.1000, i.e., liquid sources, microspheres, and intravenous brachytherapy devices.
02300	5	Teletherapy	Treatment of human subjects <i>only</i>
02310	2	Gamma Stereotactic Radiosurgery (GSR)	Treatment of human subjects <i>only</i>
02400	5	Veterinary–Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.
02410	5	<i>In-Vitro</i> Testing Laboratories	Licenses are issued to individuals or facilities which are not included in larger programs described by Program Codes 02110 or 02120.
02500	2	Nuclear Pharmacies	Receive bulk material used to prepare single use dosages or multi-dose products which are distributed to authorized medical licensees. Sealed sources are re-distributed in the original packaging to authorized clients.
02511	5	Medical Product Distribution–32.72 Prepared Radiopharmaceuticals	Distribution of prepared radiopharmaceuticals to authorized medical licensees.
02513	5	Medical Product Distribution–32.74 Sources and Devices	Therapy sources, calibration and reference sources
03110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells.
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers.
03112	3	Well Logging Byproduct Only–Tracers Only	Exploration of oil, gas, or minerals in wells
03113	3	Field Flooding Studies	Injection of unsealed byproduct materials for tracing oil and gas reservoirs
03120	5	Measuring Systems Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness, or weight, etc.

Program	Priority	Category Title	Remarks
03121	5	Measuring Systems Portable Gauges	Moisture/density gauges contain gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials.
03122	T ¹	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.
03124	T	Measuring Systems Other	instrument calibrators, Krypton-85 (Kr-85) leak detectors
03211	2	Manufacturing and Distribution Broad-Type A	RSC-approved users under 10 CFR 33.13
03212	5	Manufacturing and Distribution Broad-Type B	RSO-approved users under 10 CFR 33.14
03213	5	Manufacturing and Distribution Broad-Type C	Authorized Users specifically named in the license under 10 CFR 33.15
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials.
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results.
03221	5	Instrument Calibration Services Only—Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only—Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services—Source Less Than Or Equal To 100 Curies	Commercial servicing for teletherapy, industrial gauge, and HDR licensees
03226	2	Other Services—Source Greater Than 100 Curies	Commercial servicing for teletherapy and GSR units, and irradiators.

¹

Priority T denotes a telephone contact made by an inspector to evaluate the radiation protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone contact interval is 5 years.

Program	Priority	Category Title	Remarks
03231	2	Waste Disposal (Burial)	Commercial and non-commercial
03232	3	Waste Disposal Service Prepackaged Only	pick up, transfer, and storage; opening packages not authorized
03233	2	Waste Disposal Service Incineration	Commercial operation
03234	2	Waste Disposal Service Processing and/or Repackaging	receipt, open, compact, re- package, and transfer to authorized burial
03235	- ²	Incineration, Non-Commercial	(Secondary Code)
03236	2	Waste Treatment Service (Other Than Compaction)	Includes multiple, complex physical and chemical waste treatment processes
03240	5	General License Distribution - 32.51	For fixed gauges authorized under 10 CFR 31.5
03241	5	General License Distribution - 32.53	For luminous aircraft safety devices authorized under 10 CFR 31.7
03242	5	General License Distribution - 32.57	For calibration and reference sources authorized under 10 CFR 31.8
03243	5	General License Distribution - 32.61	For ice detection devices authorized under 10 CFR 31.10
03244	5	General License Distribution - 32.71	For certain <i>in-vitro</i> clinical testing kits authorized under 10 CFR 31.11
03250	5	Exempt Distribution-32.11: Exempt Concentrations and Items	For residual material in a product authorized under 10 CFR 30.14
03251	5	Exempt Distribution-32.14: Certain Items	For manufactured products authorized under 10 CFR 30.15
03252	5	Exempt Distribution-32.17: Resins	For synthetic plastic resins authorized under 10 CFR 30.16
03253	5	Exempt Distribution-32.18: Small Quantities	For individual quantities authorized under 10 CFR 30.18
03254	5	Exempt Distribution-32.22: Self- Luminous Products	For devices authorized under 10 CFR 30.19
03255	5	Exempt Distribution-32.26: Smoke Detectors	For devices authorized under 10 CFR 30.20
03256	5	Exempt Distribution - 32.21 - Carbon-14 Urea Capsules	For <i>in vivo</i> diagnostic use authorized under 10 CFR 30.21
03310	2	Industrial Radiography Fixed Location	Permanent radiographic installation (PRI) or designated field station. Use as secondary code, except when the license authorizes the PRI <i>only</i> .

² Program Code 03235 is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste

Program	Priority	Category Title	Remarks
03320	1	Industrial Radiography Temporary Job Sites	Use as primary code for multiple temporary customer locations
03510	5	Irradiators Self Shielded Less Than Or Equal To 10,000 Curies	Not external beam
03511	5	Irradiators Other Less Than Or Equal To 10,000 Curies	Panoramic (in air or under water) units; includes converted teletherapy units
03520	5	Irradiators Self Shielded Greater Than 10,000 Curies	Not external beam
03521	2	Irradiators - Other Greater than 10,000 curies	Panoramic (in air or under water) units; includes sterilization (mega-curie) units
03610	3	Research and Development Broad-Type A	RSC-approved users under 10 CFR 33.13
03611	5	Research and Development Broad-Type B	RSO-approved users under 10 CFR 33.14
03612	5	Research and Development Broad-Type C	Authorized users specifically named in the license under 10 CFR 33.15
03613	2	Research and Development Broad-Multisite-Multiregional	Master Materials Licenses
03620	5	Research and Development Other	Non-human research subjects
03710	5	Civil Defense	Instrument calibration and training
03800	3	Byproduct Material Possession Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
03810	3	Byproduct Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
03900	D ³	Decommissioning of Byproduct Material Facilities	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 30.36
11200	5	Source Material Other Less than 150 Kilograms	Research or manufacturing of consumer products
11210	T	Source Material Shielding	Possession and use

³ The Priority D denotes a decommissioning inspection as determined under MC 2602, Decommissioning Inspection Program, for Program Codes 03900, 11900, 21325, and 22200. These inspections are scheduled at times when the licensee is performing decommissioning activities at the site.

Program	Priority	Category Title	Remarks
11220	5	Source Material Military Munitions Indoor Testing	Depleted Uranium (DU); results in fragmentation of DU
11221	5	Source Material Military Munitions Outdoor Testing	DU
11230	5	Source Material General License Distribution - 40.34	DU products and devices authorized under 10 CFR 40.25
11300	5	Source Material Other Greater than 150 Kilograms	Research or manufacturing of consumer products
11700	5	Rare Earth Extraction and Processing	Generates waste products containing source material not related to the nuclear fuel cycle
11800	2	Source Material Possession Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
11810	2	Source Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
11900	D	Decommissioning of Source Material Facilities	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 40.42
21310	5	Critical Mass Material - University	Greater than 350 grams of enriched Uranium-235 (U-235), greater than 300 grams of Uranium-233 (U-233), greater than 200 grams of Plutonium, or any combination thereof
21320	5	Critical Mass Material - Other Than Universities	Greater than 350 grams of enriched U-235, greater than 300 grams of U-233, greater than 200 grams of Plutonium, or any combination thereof
21325	D	Decommissioning of Critical Mass - Other Than Fuel Fabrication	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38
22110	3	Special Nuclear Material Plutonium - Unsealed, Less than Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration

Program	Priority	Category Title	Remarks
22111	3	Special Nuclear Material, U-235 and/or U-233 - Unsealed, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22120	5	SNM Plutonium - Sealed Neutron Sources, Less than 200 Grams	Plutonium-beryllium howitzer for instrument calibration, teaching and demonstration purposes, and industrial applications
22130	T	Power Sources with Byproduct and/or Special Nuclear Material	Heat or power generators for remote locations
22140	5	Special Nuclear Material Plutonium - Sealed Sources in Devices	Gauges
22150	5	Special Nuclear Material Plutonium - Sealed Sources Less than a Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22151	5	Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22160	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Medical Institution	Surgical implantation, follow up, recovery, and disposal of devices
22161	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Individual	Possession of a surgically implanted device by the recipient while in the United States
22162	2	Pacemaker–Byproduct and/or Special Nuclear Material - Manufacturing and Distribution	
22170	5	Special Nuclear Material General License Distribution (70.39)	Includes calibration or reference sources authorized under 10 CFR 70.19
22200	D	Decommissioning of Other SNM Facilities - Less than Critical Mass	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38
23300	2	SNM Possession Only (Non-Fuel)-Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized

Program	Priority	Category Title	Remarks
23310	2	SNM Standby (Non-Fuel)-No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized

END

TELEPHONE CONTACT PROCEDURES FOR PRIORITY T LICENSEES

1. PROGRAM OBJECTIVES: The NRC developed telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection was completed and the inspector determined that the licensee had satisfactorily implemented the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at 5-YEAR intervals for the duration of the license.
2. PROCEDURES
 - a. Using the LTS report of licensees due for inspection, select a Priority T licensee to interview by telephone [see Section 04.04].
 - b. Obtain the license file and identify the licensee's point of contact and review pertinent details of the license that will be needed to evaluate the licensee's responses to the interview questionnaire (Enclosure 3.)
 - c. Telephone the licensee and complete each item of Enclosure 3, as appropriate for the type of use authorized by the license. If a question is not applicable for the type of use, then indicate "N.A." for the answer.
 - d. The interviewer should promptly notify their supervisor if the licensee describes any problem listed below:
 1. licensee is unaware of licensed material or NRC regulations for possession, use, transfer, and disposal
 2. change in ownership or bankruptcy proceedings
 3. a qualified radiation safety officer or authorized user was not routinely involved
 4. unsecured or unshielded material
 5. doses in excess of 10 CFR Part 20 limits
 6. excessive radiation levels or leaking sources
 7. lost, stolen, or missing licensed material
 8. any non-routine event (i.e., special maintenance or handling; fires, explosions, or natural disasters resulting in decommissioning)

The supervisor should determine if an inspection of the facility is required, or if a letter transmitting regulatory concerns is needed. If an inspection is required, the inspector should note that decision on Enclosure 3 and provide the completed questionnaire and license file to the supervisor for further action. If a letter is needed, the inspector should use Enclosure 4, "Standard Response to Licensees Contacted by Telephone (Concerns.)"

 - e. If no problem is evident from the licensee's responses, the inspector should use Enclosure 5, "Standard Response to Licensees Contacted by Telephone (No Concerns/Violations.)"
 - f. With the supervisor's concurrence, the inspector may sign the letter and provide the package to the administrative staff.

ENCLOSURE 3

TELEPHONE CONTACT QUESTIONNAIRE

[See Enclosure 2, Objectives and Procedures]

Name and title of Interviewer Signature of Interviewer	
Date of this Interview Date of Previous Interview	
QUESTIONS	ANSWERS
Licensee Name, Address, and URL	
Licensee's Point of Contact (Name, Address, Phone and FAX Numbers, and URL)	
License Number Docket Number	
1. Name and Title of person responsible for radiation safety program:	
2. Describe how you prevent: (a) use by unauthorized personnel and (b) loss or theft.	
3. Describe how you maintain shielding, restrict access, and control contamination from unsealed material to prevent individuals from becoming exposed to radiation.	
4. Describe how you determine radiation doses to workers and members of the public from licensed activities. What was the maximum dose received since the last NRC telephone contact or inspection?	
5. Describe radiation area surveys around licensed activities. What survey instrument (SI) was used? SI's last calibration date? What were the typical radiation levels and at what distance?	

QUESTIONS	ANSWERS
6. Describe leak testing of the sealed source(s). How often and who analyzed the leak test samples? What were the most recent results?	
7. Describe physical inventory of all byproduct material in your possession. When was the last inventory completed? Were all the sources located?	
8. Describe your provisions for repair and maintenance of your device or source holder.	
9. Describe any unusual events involving the byproduct material or the device(s) in which it is used (i.e., fire, explosion, natural disaster.)	

ENCLOSURE 4

STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE
(CONCERNS, INSPECTION TO FOLLOW)

Licensee Name
Address

[License No.]
[Docket No.]

ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY
PROGRAM

Sir or Madam:

This refers to an interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the U. S. Nuclear Regulatory Commission (NRC) rules and regulations and with the conditions of your license. As a result of this examination of your licensed activities, we noted regulatory concerns that are specified below. These concerns may be further evaluated during an onsite inspection at your facility in the near future.

(List regulatory concerns. For any concern that appears to rise to a violation or otherwise to indicate lack of programmatic oversight, the region should promptly conduct an inspection and take enforcement action, as appropriate, based on the results of the inspection.)

In particular, you should examine your license and the NRC's regulations to determine how you can correct the apparent regulatory concerns listed above. The points listed below are especially important for your radiation safety program:

1. control access to and prevent loss of licensed material, ensure proper transfers and disposal of licensed material, and promptly report to NRC loss or theft of licensed material
2. maintain shielding of licensed material to reduce radiation exposure
3. implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material evaluate radiation exposures to workers and members of the public
4. use properly calibrated survey instruments to monitor radiation levels
5. ensure that workers are knowledgeable, skilled, and empowered to implement the radiation protection program
6. ensure that upper level managers are aware of the radiation protection program, that annual audits of the program are completed, and that appropriate action is taken for past performance, present conditions, and future needs

If you have any questions about this matter, please contact me at [phone, fax, email address].

Sincerely, [Inspector Name, Title]

ENCLOSURE 5

STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE
(NO CONCERNS/VIOLATIONS)

Licensee Name
Address

[License No.]
[Docket No.]

ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY
PROGRAM

Sir or Madam:

This refers to an interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the U. S. Nuclear Regulatory Commission rules and regulations and with the conditions of your license. No regulatory concerns were identified.

If you have any questions about this matter, please contact me at [phone, fax, email address].

Sincerely,

[Inspector Name, Title]

ENCLOSURE 6

INFORMATION FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED)

The regional office shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor and the NMED Project Manager, NMSS. For publicly available documents, entry into ADAMS meets the requirement for forwarding the documents. For documents that are not publicly available, the regional office must forward paper copies to the NMED contractor and the NMED Project Coordinator, NMSS.

The NMED Event No. must be annotated on each document. The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." The basic information along with the additional specific information for certain types of events, outlined below, constitutes the "complete" record.

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The information identified below must be provided to classify a record as "complete." If there is a reason that required information can not be obtained, that reason should be forwarded to the NMED contractor and the NMED Project Manager.

Basic Information:

1. Essential Details
 - a. narrative event description
 - b. report identification number
 - c. event date and notification date
 - d. licensee/reporting party information (name, license number, and address)
 - e. site of event
 - f. whether the event is NRC reportable and the applicable reporting requirement
 - g. cause and corrective actions
 - h. number of persons involved, consequences
 - i. notifications: local police, FBI, other States, as needed
 - j. identify any possible generic safety concerns/potential for others to experience the same event
2. Source/Radioactive Material:
 - a. isotope and activity

- b. manufacturer
 - c. model and serial number
3. Device/Associated Equipment:
- a. manufacturer
 - b. model and serial number

Additional information is required for the specific event types listed below:

- 1. Release of Licensed Material or Contamination (NMED CODE: RLM):
 - a. release type (air or water)
 - b. contamination (person or surface)
 - c. isotope and activity released

- 2. Medical event (NMED CODE: MD2):
 - a. procedure administered
 - b. dose intended and dose administered
 - c. isotope and activity administered
 - d. organ targeted
 - e. notifications: patient, physician

- 3. Overexposure (EXP):
 - a. radiation source and activity
 - b. exposure dose
 - c. exposure type (whole body, extremity, etc.)

- 4. Transportation (TRS):
 - a. type of transport
 - b. identity of shipper
 - c. package type and ID number

ENCLOSURE 7

INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
MATERIALS SAFETY PROGRAMS		
MC1220	"Processing of NRC Form 241, 'Inspection of Agreement State Licensees Operating Under the Reciprocity Provisions of 10 CFR 150.20"	N
MC2810	"Materials Inspection Programs for Multi-Site and Multi-Regional Broad Licensees"	N
MC2815	"Construction and Pre-Operational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
MC 2882	"Transfer of NRC License Files to Agreement State(s)"	N
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging Programs"	R
IP 87124	"Fixed and Portable Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Industrial/Academic/Research Programs"	R
IP 87127	"Radiopharmacy Programs"	R
IP 87129	"Master Programs"	N
IP 87130	"Nuclear Medicine Programs–Written Directive Not Required"	R
IP 87131	"Nuclear Medicine Programs–Written Directive Required"	R
IP 87132	"Brachytherapy Programs"	R
IP 87133	"Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"	R
IP 87134	"Medical Broad-Scope Programs"	R
CONDUCT OF INSPECTIONS		
MC 0300	"Announced and Unannounced Inspections"	R

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
MC 0330	"Guidance for NRC Review of Licensee Draft Documents"	N
MC 0312	"Technical Assistance for Radiation Safety Inspections at Nuclear Fuel Facilities and Materials Licensees"	N
MC 1246	"Formal Qualification Programs in Nuclear Material Safety and Safeguards Program Area."	R
IP 40002	"Inspections to Review Allegations"	N
IP 87250	"Locating Missing Materials Licensees"	N
IP 93800	"Augmented Inspection Team."	N
IP 93812	"Special Inspection."	N
INCIDENT RESPONSE		
MC 1301	"Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Center"	N
MC 1302	"Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public"	N
MC 1303	"Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)"	N
MC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
MC 1360	"Use of Physician and Scientific Consultants in the Medical Consultant Program"	N
IP 87103	"Inspection of Material Licensees Involved in an Incident or Bankruptcy"	N
LOW-LEVEL WASTE/WASTE MANAGEMENT		
MC 2401	"Near-Surface Low-Level Radioactive Waste Disposal Facility Inspection Program"	N
IP 84750	"Radioactive Waste Treatment and Effluent and Environmental Monitoring"	R
IP 84850	"Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"	R

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
IP 84900	"Low-Level Radioactive Waste Storage"	R
DECOMMISSIONING INSPECTIONS		
MC 2602	"Decommissioning Inspection Program For Fuel Cycle Facilities and Materials Licensees"	N
IP 83890	"Closeout Inspection and Survey"	N
IP 87104	"Decommissioning Inspection Procedures for Materials Licenses"	N
RADIATION PROTECTION		
IP 83822	"Radiation Protection"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
TRANSPORTATION		
MC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 86740	"Inspection of Transportation Activities"	R
IP 86750	"Solid Radioactive Waste Management and Transportation of Radioactive Materials"	R
REPORTS/COMMUNICATIONS/FOLLOW-UP		
MC 0230	"Morning Report"	N
MC 0610	"Inspection Reports"	R
MC 0620	"Inspection Documents and Records"	R
MC 0720	"NRC Bulletins and Information Notices"	N
MC 0730	"Generic Communications Regarding Material and Fuel Cycle Issues"	N
MC 1120	"Preliminary Notifications"	N
IP 92701	"Follow-up"	R
IP 92703	"Follow-up of Confirmatory Action Letters"	N
INTERACTIONS WITH OTHER FEDERAL AGENCIES		
MC 1007	"Interfacing Activities between Regional Offices of NRC and OSHA"	R
IP 93001	"OSHA Interface Activities"	N

ENCLOSURE 8

NRC FORM 591M PART 1

U.S. NUCLEAR REGULATORY COMMISSION

(10-2003)

10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

2. NRC/REGIONAL OFFICE

REPORT

3. DOCKET NUMBER(S)

4. LICENSEE NUMBER(S)

5. DATE(S) OF INSPECTION

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- ☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR			

NRC FORM 591M PART 1 (10-2003)

**SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION**

1. LICENSEE

2. NRC/REGIONAL OFFICE

REPORT

3. DOCKET NUMBER(S)

4. LICENSE NUMBER(S)

5. DATE(S) OF INSPECTION

(Continued)

(10-2003)
10 CFR 2.201

Docket File Information
**SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION**

1. LICENSEE REPORT NUMBER(S)		2. NRC/REGIONAL OFFICE	
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)		5. DATE(S) OF INSPECTION
6. INSPECTION PROCEDURES USED		7. INSPECTION FOCUS AREAS	
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
<input type="checkbox"/> Main Office Inspection	Next Inspection Date: _____		
<input type="checkbox"/> Field Office _____			
<input type="checkbox"/> Temporary Job Site _____			

PROGRAM SCOPE

ENCLOSURE 9

INSPECTION RECORD

Region ____ Inspection Report No. _____ License No. _____

Licensee (Name and Address): _____ Docket No. _____

Location (Authorized Site) Being Inspected

Licensee Contact: _____ Telephone No. _____

Priority: _____ Program Code: _____

Date of Last Inspection: _____ Date of This Inspection: _____

Type of Inspection: () Initial () Announced () Unannounced
() Routine () Special

Next Inspection Date: _____ () Normal () Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

- () No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Followup on previous violations

Inspector(s) _____ Date _____
(Name(s))

(Signature(s))

Approved _____ Date _____
(Name)

(Signature)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
0 (License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

2. SCOPE OF INSPECTION:

(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used:

Focus Areas Evaluated:

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at exit meeting

-END-