

### MATERIALS INSPECTION PROGRAM

#### 2800-01 PURPOSE

To establish the inspection program for licensees authorized to possess and use licensed radioactive material for: radiography; medical programs; academic, research, and industrial uses; waste disposal operations; manufacturing and distribution of products; leak-testing, calibration, and other types of services; and transportation related thereto.

#### 2800-02 OBJECTIVES

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

02.02 To define specific requirements for a performance-based materials inspection program that gives licensees credit for good performance by extending the interval of the next inspection and requires poor performers to be inspected more frequently.

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

02.04 To establish core and non-core inspection priorities for all licensees and a program of special inspection activities to be 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 Core Inspection. All initial inspections (priorities 1, 2, 3, 5, and 7) and all routine inspections of priority 1, 2, or 3 licensees. Note: The use of priorities 4 and 6 frequencies has been discontinued.

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

03.03 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 or telephonic communications are not considered inspections.

03.04 Inspection Plan. A written outline listing the licensee's activities and programs that will be covered during an inspection.

03.05 Inspection Priorities. The inspection priority assigned to a license is the frequency of routine inspections, expressed in years. For example, a priority 2 means that the licensed program is routinely inspected every other year. The priority is based on the potential radiation hazard of the licensee's programs. A licensee with an inspection priority 1 presents the greatest risk to the health and safety of the public and the environment; this priority requires the most frequent inspections (every year) because of the nature of the operations. A licensee with an inspection priority 5 involves much less potential for risk to health and safety and requires less frequent inspection (every 5th year).

03.06 Non-Core Inspection. All routine inspections of priority 5 or 7 licensees, other than initial inspections.

03.07 Reactive Inspection. A special inspection in response to an incident, allegation, or special information obtained by NRC (e.g., misadministration reports, 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 frequency.

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

03.09 Special Inspection Activities. Those inspection activities specified in Section 2800-06 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.

03.10 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 State Radiation Protection Organizations). 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."

03.11 Telephonic Contacts. These are contacts, made by telephone and documented in the docket file, to determine the status of licensees' activities, to assess compliance, 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 (see Section 2800-05, "Changes in Inspection Frequency"), or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts. Telephonic contacts are not considered inspections.

## 2800-04 INSPECTION PRIORITIES

The Materials Inspection Program designates reactive inspections as being of highest priority, followed by core inspections. Non-core inspections are designated to be the lowest priority inspections, and should be performed as resources permit.

All routine materials inspections should be performed on an unannounced basis, with the exception noted below. 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.

Each new license issued by the regional office shall be assigned a primary program code by the license reviewer, which sets the inspection priority. If a license involves more than one type of use, the type associated with the highest priority (most frequent) inspection shall establish the inspection priority.

Inspection plans shall be developed for all routine inspections of major licensees and all team inspections. Major licensees include those programs that routinely use large quantities of radioactive material, such that special facilities and procedures are necessary for handling and control (i.e., broad-scope academic, broad-scope medical licensees, and large manufacturers). Inspection plans may also be developed for any other inspections, as decided by the region. The inspection records should be documented (a checkoff will suffice) to indicate whether an inspection plan was prepared. After the inspection, the inspection plan may be discarded. It need not be filed or kept by the region.

04.01 Basic Inspection Process. The purpose of this MC is to describe the types of materials inspections and the general inspection program. It is not within the scope of this MC to provide detailed guidance on conducting the inspection itself. That type of guidance can be found in the referenced manual chapters and inspection procedures listed in Section 2800-11. Although the NRC conducts different types of materials inspections, as described in this MC, all inspections contain certain routine steps, as described below.

- a. First the inspector prepares for the inspection by reviewing appropriate background material [e.g., license, quality management program (QMP), past inspection reports, incident files, related allegations, Nuclear Materials Events Database (NMED) and other pertinent information]. The inspector identifies the location of the licensee and works out travel arrangements. The inspector should have the itinerary approved and discuss special aspects of the inspection with his or her supervisor. Finally, the inspector selects appropriate and calibrated radiation detection instrumentation to take and acquires the necessary inspection forms (such as blank inspection records and an NRC Form 591).
- b. Next, the inspector conducts the onsite inspection. This usually begins with an entrance meeting with appropriate licensee personnel. Inspectors should ensure that licensee management is made aware of the inspection. Observations of licensee operations, interviews with staff, document review 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. 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. Finally, the inspection concludes with an exit meeting with licensee management.

- c. 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 and other chapters and inspection procedures.

04.02 Reactive Inspections. Inspections performed to follow up on incidents (e.g., misadministration, 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 the Division of Industrial and Medical Nuclear Safety (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.

Reactive inspections involving medical misadministration 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.

Inspections resulting from allegations will be documented in accordance with Management Directive 8.8.

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. All inspection reports for reactive inspections initiated by an NMED reportable event will have the NMED event No. affixed to the report.

04.03 Core Inspections. These are comprised of routine and initial inspections.

- a. Initial inspections of all licensees in any priority. The time interval from license issuance to an onsite inspection is based on whether the licensee has possessed material or performed operations under the license (i.e., initiated licensed activities). Initial inspections of new licensees should be announced. Initial inspections of licensees shall be performed within 6 months of receipt of licensed material, within 6 months of beginning licensed activities, or within 1 year of license issuance, whichever comes first.

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 04.01 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 placing a note in the docket file, signed by the inspector and the inspector's supervisor, that briefly summarizes the following: individuals contacted, actions taken by the inspector to verify license status, and the licensee's plans for future possession of material or plans to perform licensed operations.
  5. Provide written acknowledgment to the licensee documenting the inspection. This correspondence should restate the licensee's plans for future possession of material or plans to perform licensed operations and request that the licensee inform the NRC when licensed activities have been initiated.
  6. Record this onsite visit as an inspection in the Licensing Tracking System (LTS). After an initial inspection in which no material was possessed or received, an inspection shall be scheduled at the routine frequency as described in Enclosure 1; however, on notification from the licensee that licensed material has been received, another inspection shall be performed within 1 year of receipt of licensed material.
- b. 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" fields in the LTS should remain the same as for the licensee's previous license.
- c. 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: (1) the organization controlling the licensed activities changes substantially (e.g., changes in key personnel, authorities, or resources associated with the radiation safety program); (2) the licensee significantly increases the types, quantities, or forms of radioactive materials on the license; (3) the licensee significantly increases the different uses authorized on the license (e.g., adds brachytherapy to a diagnostic nuclear medicine license); (4) the licensee significantly increases the number of authorized users; or (5) the new license authorizes one or more new facilities. If none of these conditions applies, then the "last inspection date" and "next inspection date" fields in the LTS should remain the same as for the previous license.
- d. 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.



Priority 5 increased up to 7 years

For instance, a radiographer (priority 1) who meets the above criteria may have his/her next inspection due date lengthened to 2 years from the last inspection. A portable gauge licensee (priority 5) that meets the above criteria may have its next inspection due date lengthened to 7 years from the last inspection (rather than 5). The extension shall be valid only until the next inspection, but may be renewed on the basis of repeated favorable findings.

- b. The designated inspection priority for these licensees should not be changed in the LTS. However, the inspector is responsible for initiating the change in the "next inspection date" field in the LTS, which will contain the extended date for the next inspection. To identify the extended inspection date in the LTS, the letter "E" shall be entered under "Special Inspection Codes" on the "Inspection and Enforcement Screen" of the LTS.
- c. To document the extension in the interval between inspections, a brief note (e.g., 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.
- d. The decision to extend the inspection should be made immediately after each routine inspection.

#### 05.02 Reduction of Inspection Frequency

- a. 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 is on the most recent inspection; or
  2. Issuance of an Order or escalated enforcement occurs on 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 frequency 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.

A licensee that meets the above criteria may have its inspection interval reduced by any length. For instance, a priority 5 licensee with a poor performance record could be rescheduled for its next inspection in 3 years, rather than 5. Or a priority 1 licensee with

a Severity Level III violation could be rescheduled for its next inspection in 6 months. 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 frequency 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 (e.g., 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.

05.03 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 through 3 may vary around their due date by  $\pm 25$  percent. Inspection of priority 5 licensees may vary around their due date by  $\pm 1$  year. Inspections will not be considered "overdue" until they exceed the open window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

05.04 Combining Inspections. If a licensee holds more than one kind of license (that is, of different priorities), 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 picture 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.

05.05 Inspections After Escalated Enforcement. If escalated enforcement action has taken place for a particular licensee, a follow-up inspection 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 frequency [Section 05.02(a)], 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.

## 2800-06 SPECIAL INSPECTION ACTIVITIES

06.01 Expired and Terminated Licenses. 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. 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. 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. Specific guidance for performing closeout inspections is outlined in IP 83890.

06.02 Significantly Expanded Programs. During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. This can be done by determining (through interviews of licensee staff or observations of licensed activities), if: (a) the licensee has recently increased the types, quantities, and uses of radioactive material; (b) the license authorizes a physical move of a facility or a new use at a temporary jobsite; (c) the license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored; (d) the licensee has increased the types of uses or disposal (e.g., incineration or decay-in-storage) of radioactive material; and (e) 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 inspector's immediate supervisor [see Policy & Guidance Directive 1-20 (94-04)].

A special inspection should be considered if, during the licensing review process, it is determined that the licensee's program has significantly expanded.

06.03 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. The NRC region in which the Agreement State that issued the license is located is the recipient of the NRC Form 241. That regional office shall take immediate action on the report, enter the information into the Reciprocity Tracking System, and forward the NRC Form 241 to the NRC regional office having jurisdiction in the area of the Agreement State licensee's proposed activities, before reciprocity work begins. MC 1220 details the processing of reciprocity requests and inspection of Agreement State licensees operating under reciprocity.

NRC regional offices shall follow the policy and guidelines found in MC 1220, Appendix II, for performing inspections of reciprocity licensees. Agreement State licensees are to be inspected using the same guidelines and procedures used for equivalent NRC-licensed activities. The percentage of reciprocity licensees to be inspected each year is delineated by program code and priority in MC 1220.

#### 06.04 Temporary Job-site or Field Office Inspections

- a. Temporary Job-sites. For a licensee authorized to work at a temporary job-site, inspectors should plan to include an unannounced inspection of licensed activities at such a location(s), when possible, in addition to inspecting licensed activities at the licensee's principal place of business. 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). To assist the inspector in locating these locations, the customer of the licensee may be contacted and the temporary job-site inspection scheduled when the licensed activities are in progress. The licensee's customer should be requested not to notify the licensee of the inspection. 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).

- b. Permanent Field Offices. If the license authorizes licensed activities to be conducted from multiple permanent field offices (satellite locations of use identified on the license), at least 50 percent of the field offices should be inspected at the frequency specified in this chapter for the type of license. Consideration should be given to rotating the inspection of various field offices to assess the licensee's entire program over several inspection cycles. Each licensing region will be 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. These last two actions shall be completed by mutual agreement of the regional offices involved.

At the beginning of each fiscal year, the licensing region will provide, to the other regions, a list of the field offices to be inspected during that year. Included with this list will be a copy of each license and supporting documentation. Assist inspections that are not conducted within the frequency required by this chapter will be considered overdue inspections for the assisting region where the field office is located.

For Master Material Licenses (i.e., Navy, Air Force, Department of Agriculture), the licensing region will be responsible for requesting assist inspections, in accordance with MC 2810.

- c. For a licensee working in off-shore waters, the regional staff should contact the rig operators, or appropriate licensee contact, to schedule inspections when work is in progress and transportation is available. 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.
- d. 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.

06.05 Team Inspections. [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 Protection Organizations) 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 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, core 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 protection programs, 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 Protection Organizations), the region should contact IMNS before making the first contact with the outside agency.

Inspection plans shall be developed for all routine 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 Protection Organizations) are involved [i.e., examples (a) and (d) in this section].

06.06 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.

06.07 General Licensee Inspections. Routine inspections of general licensees [other than reciprocity (10 CFR 150.20)] are not required. Inspections shall be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

## 2800-07 DOCUMENTATION OF INSPECTION RESULTS

07.01 What Constitutes an Inspection. The following guidance is being 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 04.02. 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 available during the inspection, a follow-up telephone call should be made to that individual as soon as possible after the onsite inspection.]
- b. An inspection will not be considered to have been performed if: (1) the licensee or licensee's representatives are not available to assist with the inspection, and the inspector

is unable to perform inspection activities; or (2) the follow-up is solely in response to an allegation and is not part of a routine inspection. If item (1) above applies, the inspector will document the on-site activities by placing a note in the docket file, signed by the inspector and approved by the inspector's supervisor, that briefly summarizes the attempted inspection. Regional management will determine when a subsequent inspection will be performed, and the "next inspection date" data element in the LTS should be changed to reflect the new date. The region should not record the attempted inspection in the LTS as "an inspection." If item (2) above applies (i.e., the onsite visit is in response to an allegation), then the inspector will document the on-site visit in accordance with Section 07.02.

- c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection. If the assist inspection involves a core inspection (see Section 04.03) or a non-core inspection (i.e., priority 5 licensee), then the region will receive credit toward the operating plan goal for core or non-core inspections, as appropriate.
- d. Telephone contacts are not onsite inspections even though they involve direct inspection effort. The fact that a telephone contact of a Priority 7 licensee was made should not be entered into the LTS as an inspection; however, the inspection date (next telephone contact) should be changed in the LTS. The Regulatory Information Tracking System allows the time spent in gathering factual material to be charged against the time budgeted for performing routine inspections.
- e. A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

07.02 Allegations. Allegations will be followed up 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.

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?

If any indication of a "chilling" effect is found, the inspector shall inform regional management for further review and follow-up.

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

- a. Formats for inspection records can be found in Appendix A of IP 87110 through 87120. The inspection records do not have to be typed, but should be legible and should contain: (1) sufficient detail to describe the inspection that was conducted, including operations observed; (2) the compliance status of topics examined during the inspection; (3) the status of follow-up items involving prior enforcement or reported licensee events; (4) sufficient information to support violation findings; (5) description of completed and anticipated corrective actions to any identified violations; and (6) sufficient detail for management, license reviewers, and other inspectors to evaluate the licensee's overall safety 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 reactive inspections and for team inspections involving agencies outside the NRC (other than State Radiation Protection Organizations), 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 should be covered in the inspection records). Inspection records must document routine inspection activities that are not covered in the narrative report. 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."

07.04 Methods of Transmitting Inspection Results. Results of inspections may be reported to the licensee by either issuing an NRC Form 591 (i.e., in accordance with the guidance in MC0610 and the Enforcement Manual), or a regional office letter either with or without a Notice of Violation (NOV) to the licensee.

- a. NRC Form 591, "Safety Inspection," shall be used: (a) 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, Section 4.3. When the NRC Form 591 is used to document the results of an inspection, the inspector must ensure that for each cited and non-cited violation, 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, and reference to the regulation or license condition that was violated. The following are examples of how to document citations on an NRC Form 591:
  1. Dose calibrator linearity was not performed during the third quarter of 1992 and the first quarter of 1994. [10 CFR 35.50(b)(3)]
  2. Physical inventories were not performed at 6-month intervals to account for all sealed sources during the period from January 9, 1993 to July 10, 1994. (License condition 15)

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. In addition, for NCVs, the inspection records should document why the violation was not cited and the corrective action taken or planned. The inspector will present NRC Form 591 to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with regional management is necessary, the inspector may

mail NRC Form 591 from the regional office. Enclosure 6 provides examples of violations that may be cited on NRC Form 591.

- b. A regional office letter 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 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 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.

## 2800-08 REGIONAL RESPONSIBILITY FOR LICENSES

08.01 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.

08.02 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. Because of the close proximity of a licensed facility to a region, 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.

08.03 Transfer of Responsibility. Notwithstanding the above (Sections 08.01 and 08.02), 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.

## 2800-09 OTHER AGENCY COORDINATION

09.01 Federal Agencies. Although NRC does not conduct inspections of licensee compliance with the requirements of other Federal agencies (with the exception of DOT), NRC inspectors may identify concerns regarding another agency's areas of regulatory concern. In such instances, the inspector should bring the matter to the attention of licensee management. In the case of complaints or allegations, the inspector should withhold the information from the licensee and elevate the concerns to the attention of NRC regional management (see Section 07.02, "Allegations"). If significant concerns are identified or if the licensee demonstrates a pattern of unresponsiveness to identified concerns, the NRC regional office, in coordination with IMNS, should inform the appropriate liaisons, within the other agency, of the concerns.

With the exception of 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.

Additionally, inspectors should be aware that 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. The following are MOUs that contain information relevant to inspection activities:

a. U.S. Department of Transportation (DOT)

The DOT and NRC MOU, "Transportation of Radioactive Materials" - published in the Federal Register July 2, 1979. The MOU 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 DOJ, Federal Bureau of Investigation (FBI), and NRC MOU for "Cooperation Regarding Threat, Theft, or Sabotage in U.S. Nuclear Industry" - published in the Federal Register December 20, 1979. The MOU 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 and the DOJ MOU published in the Federal Register December 14, 1988. The MOU 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 DOL, Mine Safety and Health Administration (MSHA), and NRC MOU - published in the Federal Register January 4, 1980. The MOU was written to facilitate coordination and cooperation in areas of mutual jurisdiction and concern.
2. The NRC and DOL MOU, "Employee Protection" - published in the Federal Register December 3, 1982. The MOU was written to facilitate coordination and cooperation concerning the employee protection provisions of Section 211 of the Energy Reorganization Act of 1974.
3. The NRC and DOL, OSHA, MOU, "Worker Protection at NRC-licensed Facilities" - published in the Federal Register October 31, 1988. The MOU 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.

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

1. The EPA and NRC MOU, "Regulation of Radionuclide Emissions", published in the Federal Register November 3, 1980. The MOU 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 EPA and NRC MOU, published in the Federal Register November 16, 1992. The MOU 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 EPA and NRC 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 (HHS)

The NRC and HHS, FDA, MOU, published in the Federal Register September 8, 1993. The MOU coordinates existing NRC and FDA regulatory programs for medical devices, drugs, and biological products using byproduct, source, or special nuclear material.

These MOUs are published in the NRC Rules and Regulations, and copies may be obtained from the regional office or IMNS.

09.02 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 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 should 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 radiation control program may be referred to the appropriate regional office.

## 2800-10 INPUT INTO NRC TRACKING SYSTEMS

### 10.01 Input into the LTS

- a. Enclosure 1 provides a listing of license program codes with the associated inspection priorities.
- b. 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.

- c. When changes are made to the next inspection date (reductions or extensions in the inspection frequency), 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 2800-05.

10.02 Input into 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, event, or misadministration (e.g., "Preliminary Notifications," reports of misadministrations, follow-up inspection reports) to the NMED Project Manager, NMSS.

## 2800-11 IMCs and IPs FOR MATERIALS PROGRAM

The IMCs and IPs listed in this section comprise the inspection program for material licensees. This list is divided into various subject categories. 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, an 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).

- a. "Routine" (R) means those MCs and IPs that are used to evaluate licensee performance on a routine basis. For instance, MC 0610, "Inspection Reports" is classified as "routine" because the guidance in MC 0610 should be used routinely on all materials inspections. Not all areas in inspection records are required to be addressed on each inspection; consequently, some IPs may not need to be used on a routine basis (e.g., IP 84900, IP 86740, etc.). Specific requirements for individual licensed materials programs (e.g., radiography, nuclear medicine, industrial/academic, etc.) can be found in IPs 87110 through 87120 respectively.
- b. "As-Needed" (N) means those IMCs and IPs that can be used on an as-needed basis for evaluation of licensee performance. For instance, MC 1300, "Incident Response Actions - Responsibility and Authority," is classified "as-needed," because it only applies to reactive inspections that follow up on incidents. Similarly, IP 92703, "Followup of Confirmatory Action Letters (CALs)," is classified "as-needed" because it only applies to licensees who have been issued CALs.

MCs and IPs are grouped by general subject area as shown on the following pages.

END











## INSPECTION PRIORITY BY PROGRAM CODES (CONT.)

Program	Category Title	Remarks	Priority
03121	Measuring Systems, Portable Gauges (includes Industrial Lixiscope)		5
03122	Measuring Systems Analytical Instruments		7
03123	Measuring Systems Gas Chromatographs		7
03124	Measuring Systems Other		7
03211	Manufacturing and Distribution Type A Broad		1
03212	Manufacturing and Distribution Type B Broad		3
03213	Manufacturing and Distribution Type C Broad		5
03214	Manufacturing and Distribution Other		3
03218	Nuclear Laundry		2
03219	Decontamination Services		2
03220	Leak Test Services Only		7
03221	Instrument Calibration Services Only - Self- Shielded		5
03222	Instrument Calibration Services Only - Other		3
03225	Other Services - includes teletherapy, irradiator, and gauge services		3
03231	Waste Disposal - Burial		1
03232	Waste Disposal Service Prepackaged Only		2
03233	Waste Disposal Service Incineration		1
03234	Waste Disposal Service Processing and/or Repackaging		1
03235	Incineration-Noncommercial (Secondary Code)		
03240	General License Distribution - 32.51	Generally licensed gauges, other	5
03241	General License Distribution - 32.53	Hydrogen-3(H-3), Promethium-147 (Pm-147) signs or markers	5
03242	General License Distribution - 32.57	Americium-241 (Am-241) calibration sources	5
03243	General License Distribution - 32.61	Sr-90 ice detection	5
03244	General License Distribution - 32.71	In-vitro kits	5
03250	Exempt Distribution-32.11	Exempt concentrations. Includes broad	5

INSPECTION PRIORITY BY PROGRAM CODES (CONT.)

Program	Category Title	Remarks	Priority
03251	Exempt Distribution-32.14	H-3, Pm-147, and other isotopes in 10 CFR 30.15	5
03252	Exempt Distribution, Resins - 32.17	Scandium-46(Sc-46) resins	5
03253	Exempt Distribution-32.18 Small Quantities	Byproduct material in processed chemicals, elements, compounds, mixtures, tissue samples, etc.	5
03254	Exempt Distribution-32.22	Self-luminous products	5
03255	Exempt Distribution-32.26	Smoke detectors	5
03310	Industrial Radiography, Fixed		1
03320	Industrial Radiography, Temporary Jobsites		1
03510	Irradiators Self-Shielded Less Than 370 TBq (10,000 curies)	Includes blood irradiators	5
03511	Irradiators - Other Less than 370 TBq (10,000 curies)	Panoramic; includes converted teletherapy units	3
03520	Irradiators Self-Shielded Greater than 370 TBq (10,000 curies)		3
03521	Irradiators - Other Greater than 370 TBq (10,000 curies)		1
03610	Research and Development, Type A Broad	Committee-approved users	2
03611	Research and Development, Type B Broad	RSO-approved users	3
03612	Research and Development, Type C Broad	Named users	5
03613	Research and Development, Broad - Multisite-Multiregional		1
03620	Research and Development, Other		5
03710	Civil Defense		5
03800	Byproduct Material Possession-Only - Permanent Shutdown		2
03810	Byproduct Material Standby - No Operations		2
03900	Decommissioning of Byproduct Material Facilities		1
11200	Source Material - Other Less than 150 Kilograms		5
11210	Source Material- Shielding		7
11220	Source Material- Military Munitions-Indoor Testing		5
11221	Source Material- Military Munitions-Outdoor Testing		3
11230	Source Material General License Distribution - 10 CFR 40.34		5

INSPECTION PRIORITY BY PROGRAM CODES (CONT.)

Program	Category Title	Remarks	Priority
11300	Source Material - Other Greater than 150 Kilograms	Includes munition production, subcritical assembly, and other	3
11700	Rare-Earth Extraction and Processing		3
11800	Source Material Possession-Only - Permanent Shutdown		2
11810	Source Material Standby - No Operations		2
11900	Decommissioning of Source Material Facilities		1
21310	Critical Mass Material - University		5
21320	Critical Mass Material - Other Than Universities		5
21325	Decommissioning of Critical Mass - Other Than Fuel Fabrication		1
22110	SNM Plutonium - Unsealed Less than Critical Mass		2
22111	SNM U-235 and/or U-233 - Unsealed Less than Critical Mass		2
22120	SNM Plutonium - Sealed Neutron Source Less than 200 Grams		5
22130	Power Sources with Byproduct and/or SNM		7
22140	SNM Plutonium - Sealed Sources in Devices		5
22150	SNM Plutonium - Sealed Sources Less than Critical Mass		5
22151	SNM U-235 and/or U-233 Sealed Sources Less than Critical Mass		5
22160	Pacemaker Byproduct, and/or SNM - Medical Institution		7
22161	Pacemaker Byproduct, and/or SNM - Individual		7
22162	Pacemaker Byproduct and/or SNM - Manufacturing and Distribution		1
22170	SNM General License Distribution - 70.39		5
22200	Decommissioning of Other SNM Facilities - Less than Critical Mass		1
23300	SNM Possession-Only (Non-Fuel)-Permanent Shutdown		2
23310	SNM Standby (Non-Fuel)-No Operations		2





STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE (CONCERNS)

License No. \_\_\_\_\_  
Docket No. \_\_\_\_\_

Sir or Madam:

This refers to a telephone contact conducted on \_\_\_\_\_, 20\_\_.

The contact was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The contact consisted of discussions with \_\_\_\_\_.

As a result of this examination of activities, regulatory concerns were noted and are specified below. These may be evaluated at an onsite inspection at your facility soon.

As you described on the telephone, the following regulatory concerns were identified:

*(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.)*

You should examine your license and Nuclear Regulatory Commission regulations to determine how you can correct the apparent regulatory concerns that were discussed on the telephone. In addition, we would like to highlight the following items that licensees should pay particular attention to, as follows:

- a. Maintaining awareness and control of licensed material;
- b. Proper transfers and disposal of radioactive sources; and
- c. Promptly reporting losses or thefts of licensed materials.

If you have any questions about this contact, you may contact us at (\_\_\_\_)\_\_\_\_\_.

Sincerely,

\_\_\_\_\_, Chief  
Nuclear Material Safety and

Safeguards (Branch or Section)

bcc  
DCS/RSB (RIDS)  
(NOTE: THIS FORM SHOULD NOT BE USED TO DISPENSE VIOLATIONS)

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

License No. \_\_\_\_\_

Docket No. \_\_\_\_\_

**Sir or Madam:**

This refers to a telephone contact conducted on \_\_\_\_\_, 20\_\_.

The contact was an examination of activities conducted under your license, as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The contact consisted of discussions with \_\_\_\_\_.

No regulatory concerns were identified.

If you have any questions about this contact, you may contact us at  
(\_\_\_\_)\_\_\_\_\_.

Sincerely,

\_\_\_\_\_, Chief  
Nuclear Material Safety and  
Safeguards (Branch or Section)

bcc  
DCS/RSB (RIDS)

