TEMPORARY INSTRUCTION 2800/033, REVISION 01

REVISED MATERIALS INSPECTION PROGRAM

PROGRAM APPLICABILITY: 2800

2800/033-01 OBJECTIVE

01.01 To test the proposed revisions to IMC 2800 incorporating the recommendations of the Phase II Byproduct Materials Review (August 13, 2001).

01.02 To test five inspection procedures which are used for routine inspections of medical licensees and are associated with IMC 2800.

2800/033-02 BACKGROUND

On November 14, 2000, the Mallinckrodt Lessons Learned Task Group Report (Phase I) recommended specific actions to NMSS as short-term changes, long-term changes, rulemaking, referral to the Phase II Byproduct Materials Review Group (Phase II) which reviewed the entire materials program, and referral to the National Materials Program Working Group. The Phase I recommendations addressed IMC 2800 and the associated inspection procedures that describe the materials inspection program.

On August 13, 2001, the Phase II report endorsed the majority of the recommendations that had been referred by Phase I, thereby encouraging NMSS to complete action on those items. Phase II recommended broad changes to NMSS policies, procedures, and processes to improve effectiveness and gain efficiencies to save NMSS resources for the materials program. Phase II recommendations addressed IMC 2800 changes and estimated resource costs and savings for implementation of each recommendation. With input from the Regional Administrators, NMSS considered this information and committed to implement the Phase II recommendations, including the endorsed Phase I recommendations in FY02.

On April 15, 2002, NMSS implemented Temporary Instruction 2800/033 (TI), Attachment A, which reflected IMC 2800 and included the Phase II recommendations listed in Section 03, below. In Temporary Instruction 2800/033 Revision 01 (revised TI), NMSS

is implementing further changes to conform Attachment A to the five, routine, medical, inspection procedures which are being tested during this revised TI.

2800/033-03 INSPECTION REQUIREMENTS

03.01 Attachment A (Revised Materials Inspection Program) incorporates the recommendations from Phase I and Phase II into the current IMC 2800. The recommendations are listed below.

a. Revise IMC 2800 and the current inspection priority structure based on current risk information and operational data. (Recommendation II-5)

b. Revise IMC 2800 and related inspection records to indicate that inspectors may sign clear inspection records and submit them to the official docket file without management review. (Recommendation II-9)

c. Revise IMC 2800 and its associated inspection procedures to require less intensive preparation for routine inspections. (Recommendation II-10)

d. Revise IMC 2800 requirements for conducting initial inspections to be more effective and efficient. (Recommendation II-11)

e. Revise IMC 2800 to provide greater flexibility for inspecting field office locations. (Recommendation II-12)

f. Revise IMC 2800 and the guidance to expand the use of NRC Form 591. (Recommendation II-16)

03.02 The following table indicates the inspection procedure numbers and titles for new (revised) items and de-listed items for the NRC Inspection Manual. For the duration of this TI, inspectors shall use the new (revised) inspection procedures in place of the de-listed inspection procedures. Hours of inspection shall be charged to the new inspection procedure numbers instead of the de-listed inspection procedure numbers.

Table 03.02

De-Listed Inspection Procedures	New (Revised) Inspection Procedures
Portions of TI 2800/029, Revision 2 (IP 87115), Nuclear Medicine Programs, which address low-risk, diagnostic nuclear medicine	IP 87130, Nuclear Medicine Programs–Written Directive Not Required
Portions of TI 2800/029, Revision 2 (IP 87115), Nuclear Medicine Programs, which address uses of sodium iodide-131 and therapeutic uses for nuclear medicine	IP 87131, Nuclear Medicine Programs–Written Directive Required
IP 87118, Brachytherapy Programs	IP 87132, Brachytherapy Programs
IP 87116, Medical Teletherapy Programs	IP 87133, Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
IP 87119, Medical Broad-Scope Programs	IP 87134, Medical Broad-Scope Programs

2800/033-04 INSPECTION GUIDANCE

This revised TI is consistent with the performance-based approach. The structure and emphasis of the inspection will be on the Focus Elements which describe the key aspects of a radiation safety program for use of byproduct material. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiological conditions at the facility, rather than exclusive reliance on a review of records.

04.01 Attachment A describes changes to the administrative aspects of the materials inspection program. It also contains conforming changes from the new (revised) inspection procedures listed in Table 03.02, as follows:

a. The following terms were removed throughout Attachment A: Program Code 06100 (New License), core inspections, non-core inspections, misadministration(s).

b. Attachment A, Section 04.01.b., includes paragraphs about safety culture and common elements that pertain to most routine inspections (i.e., entrance and exit meetings, follow up items, general overview, observations, measurements, special conditions).

c. Attachment A, Section 05.01.a., indicates reduction of the inspection interval to 1-year for well logging licensees if the current inspection was limited to an office inspection and no temporary job site inspection was completed.

d. Attachment A, Section 07.04, provides updated examples of violations cited on NRC Form 591X to indicate all the necessary elements of a complete violation. The examples involve 10 CFR 20.1101(c) and 10 CFR 34.29.

e. Attachment A, Section 10.02 addresses timeliness for input to the Nuclear Materials Event Database (NMED), annotated copies of all inspection documentation, and refers to instructions in Enclosure 6 for a “complete” NMED record.

f. The Enclosures to Attachment A were revised and are listed below.

1. Enclosure 1 contains revised inspection priorities by program code. The inspection priorities were unchanged for this revised TI. But, program code titles and descriptions were revised to reflect NUREG-1556, Volume 20, “Consolidated Guidance About Materials Licenses–Guidance About Administrative Licensing Procedures” (Final Report, December 2000), Appendix G, “LTS Program Code Descriptions.”

2. Enclosures 2, 3, 4, and 5 respectively contain revised telephone contact procedures, questionnaire, and model letters to be issued by an inspector. These items reflect the Focus Elements in the revised inspection procedures and empower inspectors to issue the letters.

3. Enclosure 6 outlines information the regional office must provide to NMSS for NMED, including basic information and additional information for specific event types. The former Enclosure 6, “Examples of Violations that can be Cited on NRC Form 591,” has been removed from Attachment A. All non-willful, non-repetitive, Severity Level IV violations may be cited on the revised NRC Form 591X.

4. Enclosure 7 contains the table of Manual Chapters (MC) and Inspection Procedures (IPs) that comprise the materials inspection program. Inspectors shall use the items as “Required” or “As Needed” to perform various inspections.

Six items were de-listed from the NRC Inspection Manual and were also removed from the table in Enclosure 7:

MC 1300	“Incident Response Actions–Responsibility and Authority”
IP 87101	“Performance Evaluation Factors”
IP 83726	“Control of Radioactive Materials and Contamination Surveys, and Monitoring”
IP 83750	”Occupational Radiation Exposure”
IP 83728	“Maintaining Occupational Radiation Exposures ALARA”
IP 86721	“Transportation–Basic”

Five items from the NRC Inspection Manual were added to the table in Enclosure 7 and designated “Required” (R) or “As Needed” (N):

MC 0620	”Inspection Documents and Records” (R)
MC 0330	“Guidance for NRC Review of Licensee Draft Documents” (N)
IP 40002	“Inspections to Review Allegations” (N)
MC 1303	“Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)” (N)
MC 2602	“Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees” (N)

5. Enclosure X contains the revised NRC Form 591X, “Safety Inspection Report,” which is to be used to document results of inspections, as directed in this revised TI. Parts 1, 2, and 3 of the form were slightly revised and re-formatted in response to earlier comments from inspectors.

6. Enclosure XX is unchanged and is to be used as directed in this revised TI. It contains the revised “Inspection Record” that replaces Appendix A of the current inspection procedures.

04.02 Table 03.02 indicates the de-listed and new inspection procedures (IPs). The de-listed IPs were revised and re-numbered. The formerly stated objectives (Section 01 in each IP) were retained. The requirements (Section 02 in each IP) were changed to implement the risk-informed Focus Elements that were developed by Phase II. The

guidance (Section 03 in each IP) supports the Focus Elements. The content of the guidance retains information that was formerly in Sections 02 and 03 of each IP, but the redundant material was removed and the retained material was re-arranged to follow the order of the Focus Elements. Focus Element 03 involves comprehensive safety measures, e.g., fire protection programs. Common elements in each IP were removed and inserted into Attachment A. Common elements included, e.g., entrance and exit meetings, follow up items, general overview, observations, independent confirmatory measurements, special license conditions.

2800/033-05 REPORTING REQUIREMENTS

To obtain labor rates (hours per inspection) inspectors shall report hours in the Human Resources Management System (HRMS), formerly Starfire or Resource Information Tracking System (RITS), to the new IPs that are used for the inspections; no time should be charged to this revised TI for inspection effort; and no time shall be charged to the de-listed IPs indicated in Table 03.02 of this revised TI. The regions should forward any qualitative comments on this revised TI from regional staff to the Point of Contact, listed below.

2800/033-06 SPECIAL REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY INSPECTIONS

06.01 For industrial radiography licensees 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), when possible, in addition to inspecting licensed activities at the licensee's principal place of business.

06.02 Through June 30, 2003, and at the completion of each industrial radiography inspection, the regions shall provide electronic copies of the inspection documentation (e.g., copies of Form-591X, cover letter and Notice of Violation, inspection reports, etc.) to the Point of Contact listed below.

2800/033-07 EXPIRATION

The new inspection procedures in Table 03.02 will be implemented in October 2002. Analysis of this revised TI will be completed in July 2003. Final versions of IMC 2800 and the inspection procedures will be effective in October 2003. This TI shall remain in effect until September 30, 2003 .

2800/033-08 CONTACT

Data reports and questions about this revised TI should be addressed to the Project Manager, Section A, Rulemaking and Guidance Branch, Division of Industrial and Medical

Nuclear Safety (Thomas Young, Mail Stop T9C24, NMSS/IMNS/RGB-A, 301-415-5795, www.tfy@nrc.gov)

2800/033-09 ORIGINATING ORGANIZATION INFORMATION

09.01 The RGB/IMNS/NMSS initiated this revised TI.

09.02 No additional time is necessary to complete this revised TI.

09.03 Specialized required training will be provided to each region to implement the provisions of this revised TI.

Appendix A, Revised Materials Inspection Program

END

ATTACHMENT A

REVISED 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 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 risk-informed 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 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. 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).

03.05 Reactive Inspection. A reactive inspection is a special inspection in response to an incident, allegation, or special information obtained by NRC (e.g., 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 frequency.

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

03.07 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.

03.08 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 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."

03.09 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 04.04], 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], or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts. Telephonic contacts are not inspections.

The Materials Inspection Program designates reactive inspections [see Section 04.02] as being of highest priority, followed by initial inspections and routine inspections for the Priority Codes (in ascending numeric order) listed in Enclosure 1. Telephonic contacts are designated to be the lowest priority, and should be performed as resources permit.

All routine materials inspections should be performed on an unannounced basis, with the following exception. 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. Some licenses authorize activities that can be classified under more than one program code, (i.e., limited scope medical institution with an HDR). 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 the above example, the licensee would be classified as Priority 2. 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.

04.01 Basic Inspection Process. The purpose of this MC is to describe the types of materials inspections and the general inspection program. Other than for elements that are common to all materials inspections, 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 Enclosure 7. To provide a reliable, uniformly implemented budgetary basis, the inspector shall charge inspection hours only to the program-specific inspection procedure (i.e., Inspection Procedures 87110, 87111, 87112, 87113, 87114, 87117, 87120, 87130, 87131, 87132, 87133, and 87134). Although the NRC conducts different types of materials inspections, all inspections encompass certain common activities, as described below.

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 determined based upon discussions with the supervisor.

Preparation includes reviewing 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), licensee's recent inspection and enforcement history (i.e., results of the last inspection and any outstanding open items), determining whether any events have been reported by the licensee during the current inspection cycle, reviewing any commitments made by the licensee or restrictions imposed by NRC as a result of a Confirmatory Action Letter or Order issued since the last inspection, and reviewing any notes in the file regarding special inspection emphasis. This approach will adequately prepare the inspector to review a licensee's program.

If an inspector identifies problems during the course of the inspection, it would then be appropriate to review procedures and backup licensing documents maintained by the licensee. For instances when these documents are not available to the inspector from the licensee, the inspector may need to contact the region for assistance. This practice would apply to routine inspections only.

For reactive inspections, inspectors should determine the information to be reviewed in advance of the inspection on a case-by-case basis [see Section 04.02].

In addition, 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. 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 09.02]. Finally, the inspector selects appropriate and calibrated radiation detection instrumentation to take and acquires the necessary inspection forms (such as an NRC Form 591X).

b. Inspection Activities

The inspector must be prepared to meet all entry requirements established by the licensee (e.g., 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.

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.

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 (e.g., 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 (e.g., there are an unacceptable number of occurrences with unacceptable health and safety consequences).

Common elements to every inspection are discussed below.

d. 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/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 apprize management that an exit meeting will be conducted, at the end of the inspection, that will 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 (e.g., 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.

d. 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 recommendations, outstanding safety items, and unresolved issues identified during the previous inspection.

d. General Overview

(a) 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).

(b) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc.

d. Observation of Actual Facilities and Licensed Activities

(a) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.

(b) Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.

(c) Perform routine inspections, when applicable, during first run operations.

(d) Make direct observations of radiation safety systems and practices in use.

(e) 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.

5. Independent and Confirmatory Measurements. 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 (e.g., 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. 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. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the

licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements.

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 office.

6. 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.

7. Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present at the facility. If a senior management representative is unavailable for the exit meeting, the inspector may hold a preliminary exit meeting with appropriate staff on site. However, there must be a formal exit meeting with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting) as soon as practical after the inspection. This meeting will usually be held by telephone conference call.

   During the exit meeting, the licensee representatives should be made aware of the preliminary inspection findings including any apparent violations of regulatory requirements, safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations. Significant safety concerns must receive immediate attention from the licensee.

   If safety concerns or violations of significant regulatory requirements are identified that affect safe operation of a licensee facility, prompt corrective action must be initiated by the licensee. 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 (e.g., 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.

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 and other chapters .

04.02 Reactive Inspections. Inspections performed to follow up on incidents (e.g., 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 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 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.

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. Enclosure XX may be completed to document inspection findings that were unrelated to the event [see Section 07.03.b].

04.03 Initial and Routine Inspections

a. Initial inspections of all licensees. Initial inspections of new licensees should be announced and completed within 12 months of the date the new license is 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 was issued. The “last inspection date” data element in the LTS shall be 0 (zero) or blank.

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 completing a Form 591X. The "program scope" description in the Form 591X 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 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.

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” data elements 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. The “last inspection date” and “next inspection date” data elements in the LTS should remain the same as for the licensee’s initial license.

e. Routine inspections 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 04.03(a)(1) through (4).

04.04 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, telephone contacts are useful for staying in touch with priority T licensees. Procedures for using the telephonic contacts are included as Enclosure 2. A telephone 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 telephone contact. The inspector shall brief the supervisor about the telephone contact.

2800-05 CHANGES IN INSPECTION FREQUENCY

05.01 Reduction of Inspection Frequency

a. The inspection interval may 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 (e.g., 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 2 or 3 years, rather than 5 years, depending on the scope of licensed activities. Or a priority 2 licensee with a Severity Level I, II, or III violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the Severity Level I, II, or III violation may have already been completed within 6 months [see Section 05.04]. 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.

The inspection interval shall be reduced to 1-year for well logging licensees (Program Codes 03110, 03111, 03112, and 03113) when the current inspection was limited to an office inspection (no temporary job site inspection).

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.

05.02 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 ± 25 percent. Inspection of priority 5 licensees and priority T licensees (telephone contacts) may vary around their due date by ± 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.

05.03 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.

05.04 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 I, II, or III 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 frequency [see Section 05.01(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.

05.05 Other Changes in Inspection Frequency. At the discretion of regional management, other changes in inspection frequency 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 frequency, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

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 and IP 87895.

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.

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. 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)].

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 the scheduling of the inspection of the Agreement State licensee operating under reciprocity.

NRC regional offices shall follow the policy and guidelines found in MC 1220, Appendix III, 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 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 shall make every reasonable attempt 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 identifying 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). 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.

b. Permanent Field Offices. If the license authorizes licensed activities to be conducted from two or three permanent field offices, only one location must be inspected at the frequency specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 3 to 10 permanent field offices, at least two field offices must be inspected at the frequency specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 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. If an inspection identifies significant program weaknesses (i.e., SL III or above violation(s), multiple SL IV violations indicative of poor program management/oversight), consideration should be given to expanding the initial review to include additional satellite locations to determine the extent of the weakness. In addition, routine inspections of licensees with multiple field offices should include a review of the licensee's audit program that assesses the performance of its field office activities.

   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.

c. Off-Shore Waters. 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.

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 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 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 coordinate through the 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 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 04.03. 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 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 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. 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."

c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.

d. Telephone contacts are not onsite inspections even though they involve direct inspection effort. 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. The Human Resources Management System (HRMS, formerly Resource 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 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.

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

a. Enclosure X provides the format for documenting inspections that result in the issuance of an NRC Form 591X. If an NRC Form 591X is not issued, then the inspection results will be documented on Enclosure XX 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 violation findings; (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 XX). 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.

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

a. NRC Form 591X, "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.

When the NRC Form 591X 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 591X:

1. Section 20.1101(c) requires the licensee to annually review the content and implementation of the radiation protection program. During years 2000 and 2001, the license did not complete the review. The licensee will complete the review in October 2002 for the period of January 2000 through September 2002. The licensee intends to complete future reviews in October of each year by completing NUREG-1556, Volume 2, Appendix I, Radiation Safety Program Audit.

2. As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2002, to October 24, 2002, 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.

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 591X 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 591X from the regional office. The responsible inspector will sign the cover letter transmitting the Form 591X from the regional office. All non-willful, non-repetitive Severity Level IV violations may be cited on NRC Form 591X.

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

c. 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 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 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.

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. For example, an inspector may conclude there is a lack of fire protection which compromises the safe, secure storage and use of materials that are under the control of the licensee. The conclusions were based on OSHA training provided to NRC inspectors and the inspector's observations and interviews of workers in restricted and controlled

areas of the facility. 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].

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, in accordance with MC 1007.

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. 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 describe the situation to OSHA as per MC 1007.

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, 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 program may be referred to the appropriate regional office.

2800-10 INPUT INTO NRC TRACKING SYSTEMS

10.01 Input into the Licensing Tracking System (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 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 05.01(b).

10.02 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, event (e.g., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor (INEEL at this time) and/or 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." 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 the NMED Project Manager.

2800-11 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).

a. "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, e.g., 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.

b. "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, "Followup 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 591X
9. XX. Inspection Record

INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users; 10 CFR 33.13
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 Broad	RSC-approved users
02120	5	Medical–Written Directive (WD) required	Hospitals
02121	5	Medical–WD not required	Hospitals
02200	5	Medical–WD required	Clinics
02201	5	Medical–WD not required	Clinics
02210	5	Eye Applicators Strontium-90 (Sr-90)	Hospitals or Clinics
02220	3	Mobile Nuclear Medicine Service	(Primary code)
02230	2	High-Dose Rate Remote Afterloaders (HDR)	
02231	2	Mobile HDR	
02240	3	Mobile Therapy–Not HDR	
02300	5	Teletherapy	Human subjects only
02310	2	Stereotactic Radiosurgery–Gamma Knife	
02400	5	Veterinary–Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.
02410	5	*In-Vitro* Testing Laboratories	
02500	2	Nuclear Pharmacies	
02511	5	Medical Product Distribution–32.72 Prepared Radiopharmaceuticals	
02513	5	Medical Product Distribution–32.74 Sources and Devices	Therapy sources, calibration and reference sources
03110	5	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	
03111	5	Well Logging Byproduct and/or SNM Sealed Sources Only	
03112	5	Well Logging Byproduct Only–Tracers Only	
03113	5	Field Flooding Studies	

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03120	5	Measuring Systems Fixed Gauges	
03121	5	Measuring Systems Portable Gauges	
03122	T[1]	Measuring Systems Analytical Instruments	e.g., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	
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 under10 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	
03218	3	Nuclear Laundry	
03219	3	Decontamination Services	
03220	T	Leak Test Service Only	
03221	5	Instrument Calibration Service Only, Source Less Than 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only, Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services	Commercial serving for teletherapy, irradiator, and gauge licensees
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

[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 Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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 *in-vitro* 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 *in vivo* diagnostic use authorized under 10 CFR 30.21
03310	1	Industrial Radiography Fixed Location	Permanent radiographic installation or designated field station
03320	1	Industrial Radiography Temporary Job Sites	Multiple temporary customer locations
03510	5	Irradiators Self Shielded Less Than 10,000 Curies	Not external beam
03511	5	Irradiators Other Less Than 10,000 Curies	Panoramic (in air or under water) units; includes converted teletherapy units

[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 Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03520	5	Irradiators Self Shielded Greater Than 10,000 Curies	Not external beam
03521	2	Irradiators - Other Greater than 370 TBq (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
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

[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 Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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 40.42
22110	3	Special Nuclear Material Plutonium - Unsealed, Less than Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22111	3	Special Nuclear Material, U-235 and/or U-333 - 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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
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 40.42
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
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

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:

a. licensee is unaware of licensed material or NRC regulations for possession, use, transfer, and disposal
b. change in ownership or bankruptcy proceedings
c. a qualified radiation safety officer or authorized user was not routinely involved
d. unsecured or unshielded material
e. doses in excess of 10 CFR Part 20 limits
f. excessive radiation levels or leaking sources
g. lost, stolen, or missing licensed material
h. any nonroutine event (e.g., 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.

TELEPHONE CONTACT QUESTIONNAIRE

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?	
6. Describe leak testing of the sealed source(s). How often and who analyzed the leak test samples? What were the most recent results?	

QUESTIONS	ANSWERS
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 (e.g., fire, explosion, natural disaster.)	

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

Licensee Name [License No.]
Address [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:

d. 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
d. maintain shielding of licensed material to reduce radiation exposure
d. 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
d. use properly calibrated survey instruments to monitor radiation levels
d. ensure that workers are knowledgeable, skilled, and empowered to implement the radiation protection program
d. 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]

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

Licensee Name [License No.]
Address [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. 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]

INFORMATION FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED)

The regional office shall forward copies of all documentation regarding a material incident (e.g., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor and/or the NMED Project Manager, 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 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.

<u>Basic Information</u>:
d. Essential Details
a.
1.narrative event description
a.
1.report identification number
a.
1.event date and notification date
a.
1.licensee/reporting party information (name, license number, and address)
a.
1.site of event
a.
1.whether the event is NRC reportable and the applicable reporting requirement
a.
1.cause and corrective actions

d. Source/Radioactive Material:
b.
2.isotope and activity
b.
2.manufacturer
b.
2.model and serial number

d. Device/Associated Equipment:
c.
3.manufacturer
c.
3.model and serial number

<u>Additional information is required for the specific event types listed below</u>:
d. Release of Licensed Material or Contamination (NMED CODE: RLM):
a.
1.release type (air or water)
a.
1.contamination (person or surface)
a.

1.isotope and activity released

d. Medical event (NMED CODE: MD2):
b.
2.procedure administered
b.
2.dose intended and dose administered
b.
2.isotope and activity administered
b.
2.organ targeted

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

INSPECTION MANUAL CHAPTERS (MCs) AND INSPECTION PROCEDURES (IPs)

MC/IP No.	MC/IP Title	Routine (R) or As Needed (N)
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
INSPECTIONS		
MC 0300	"Announced and Unannounced Inspections"	R
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 93800	"Augmented Inspection Team."	N
IP 93812	"Special Inspection."	N
INTERACTIONS WITH OTHER FEDERAL AGENCIES		
MC 1007	"Interfacing Activities between Regional Offices of NRC and OSHA"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
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/IP No.	MC/IP Title	Routine (R) or As Needed (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
MC 2602	"Decommissioning Inspection Program For Fuel Cycle Facilities and Materials Licensees"	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
IP 84900	"Low-Level Radioactive Waste Storage"	R
MATERIALS SAFETY PROGRAM		
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 Preoperational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
MC 2882	"Transfer of NRC License Files to Agreement State(s)	N
IP 87110	"Industrial/Academic/Research Programs"	R
IP 87111	"Materials Processor/Manufacturer Programs"	R
IP 87112	"Irradiator Programs"	R
IP 87113	"Well Logging Programs"	R
IP 87114	"Fixed and Portable Gauge Programs"	R
IP 87115	"Nuclear Medicine Programs"	R
IP 87116	"Medical Teletherapy Programs"	R
IP 87117	"Radiopharmacy Programs"	R
IP 87118	"Brachytherapy Programs"	R
IP 87119	"Medical Broad-Scope Programs"	R
IP 87120	"Industrial Radiography Programs"	R

MC/IP No.	MC/IP Title	Routine (R) or As Needed (N)
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
IP 87103	“Inspection of Material Licensees Involved in an Incident or Bankruptcy”	N
IP 87104	“Decommissioning Inspection Procedures for Materials Licenses”	N
IP 87250	"Locating Missing Materials Licensees"	N
RADIATION PROTECTION		
IP 83822	"Radiation Protection"	R
IP 83890	"Closeout Inspection and Survey"	N
IP 83895	"Radiation Protection - Followup on Expired Licenses"	N
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

NRC FORM 591X PART 1
(5-2002)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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)

STATEMENT OF CORRECTIVE ACTIONS

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			
NRC INSPECTOR			

NRC FORM 591X PART 1 (5-2002)

SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE REPORT		2. NRC/REGIONAL OFFICE
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION

(Continued)

NRC FORM 591X PART 3
(5-2002)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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

☐ Main Office Inspection — Next Inspection Date: _____

☐ Field Office _____

☐ Temporary Job Site _____

PROGRAM SCOPE

NRC FORM 591X PART 3 (5-2002)

INSPECTION RECORD

Region ___ Inspection Report No._____ License No. _____
Docket No. _____

Licensee (Name and Address):

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 frequency:

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:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT #	DATE	SUBJECT

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

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in the applicable inspection procedure(s) are required to be addressed during each inspection.

All areas covered during the inspection should be listed in Section 2. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. For any violations identified, Section 4 should state the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective actions. For an NCV, indicate why the violation was not cited. Attach copies of all licensee documents and records that are needed to support violations.

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. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED:

INSPECTION FOCUS AREAS:

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 requirement and how and when licensee violated the requirement. 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-