

NRC INSPECTION MANUAL

NMSS

INSPECTION PROCEDURE 87103

INSPECTION OF MATERIAL LICENSEES INVOLVED IN AN INCIDENT OR BANKRUPTCY FILING

PROGRAM APPLICABILITY: MC 1301

87103-01 INSPECTION OBJECTIVES ≡≡

01.01 This inspection procedure is applicable to the inspection of incidents that occur at nuclear materials facilities and for those cases where the NRC is concerned that material may not be properly controlled, such as when a licensee files for bankruptcy. According to U. S. Nuclear Regulatory Commission (NRC) Inspection Manual Chapter 1300, "Incident Response Actions," NRC management must determine the need to dispatch one or more regional inspectors to conduct a special inspection following occurrence of an incident, either immediately following notification, or before the next routine inspection. This procedure is intended for use in such special inspections. The incidents to be inspected under this procedure include those that are considered serious enough to warrant a special inspection to determine causes and corrective actions, but are not of such a nature as to require an Incident Investigation Team (IIT) or an Augmented Inspection Team (AIT). Typically, the procedure will be used in response to misadministrations, overexposures, losses or releases of significant quantities of radioactive materials, and situations where the NRC is concerned that material may be abandoned, such as in cases where the licensee has filed for bankruptcy, but it is not limited to these type of incidents. In instances where the material has been abandoned, the guidance in Policy and Guidance Directive PG 9-12, "Reviewing Efforts to Dispose of Licensed Material and Requesting DOE Assistance," and Inspection Manual Chapter 1303, "Requesting Emergency Acceptance of Radioactive Material by DOE," should be followed.

Most of this Inspection Procedure places emphasis on regional inspectors and regional management. Nonetheless, headquarters inspectors or staff may also be involved in these inspections due to the nature of some type of licensee activities, like uranium recovery facilities. ≡≡
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01.02 The objective of the procedure is to assist headquarters or regional inspectors in analyzing the sequence of events leading to the incident, and the conditions that existed at the time these ≡≡
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events occurred. This analysis should lead to the identification of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. The primary emphasis of the inspection is safety, not compliance. Issues of compliance are addressed after all safety issues and program weaknesses are identified and clearly understood. This procedure is also an ~~essential~~ step in ensuring that the NMSS/IMNS database contains complete and accurate event information.

01.03 The steps presented in the procedure should be followed in the order they are presented; some of the steps may be repeated in alternating fashion as data accumulates and hypotheses are refined. Experience shows that accidents generally have multiple contributing factors that are interconnected in complex ways. Therefore, a disciplined, organized, and thorough approach to the inspection are essential. Organization and correlation of the findings should start early in the inspection. Charts should be used if the data is complex. The initial organization of the data will necessarily be sketchy and incomplete, but this early start will help direct the inspection and also help identify areas where data is lacking or is inconsistent.

87103-02 DEFINITIONS

02.01 Cause. The action or condition that led to the occurrence of the incident. Causes are labeled, according to their proximity to the incident, as direct, contributing, or root causes.

02.02 Direct Cause. This is the event or failure that led directly to the incident, without any additional intervening action or failure. An example is a technician improperly measuring a dose in a dose calibrator. A possible direct cause for the incorrect dose is improper setting of the radionuclide or energy selection dial on the calibrator.

02.03 Contributing Cause. This is a cause that does not necessarily lead to an incident, but it does make the incident more probable. In the example of the dose calibrator mentioned in the Direct Cause definition, a contributing cause may have been a radionuclide or energy selection dial with illegible markings at the various settings. This does not in itself necessarily lead to errors in measuring doses, since a trained and attentive technician may know from experience where the settings are, without reference to the markings. However, the fact that the markings are not legible makes it much easier to make an error, and hence may be a contributing factor, or cause, when an error does occur.

02.04 Root Cause. This is the cause whose existence establishes the conditions that allow contributing causes to develop and which, in turn, increases the probability of the occurrence of an incident. In the example of the calibrator mentioned in the Direct Cause definition, a root cause may be an organization with a poor maintenance program. The poor maintenance program may be due to an unqualified maintenance manager who fails to set routine maintenance schedules, set maintenance priorities, or respond to maintenance requests. In this case, the root cause may be the

presence of the unqualified manager, which results in a poor maintenance program.

87103-03 INSPECTION REQUIREMENT

03.01 Conduct an inspection to: 1) determine the causes of the incident and the corrective actions, taken or planned, to prevent recurrence; or 2) address the accountability and control and health and safety issues associated with a licensee filing for bankruptcy or instances where material may have been abandoned.

87103-04 GENERAL GUIDANCE

04.01 Pre-Inspection Notifications. NRC regional management and staff involvement early in the incident assessment is critical in determining the scope of the proposed inspection activities and future actions. Contact should be made with State and local authorities, and public affair representatives to coordinate follow-up actions. As soon as the decision is made to inspect the incident, notify the licensee's management that an inspection of the incident is to be conducted. When notifying the licensee, make sure that the incident has been brought under control and that there are no ongoing safety issues. If there are, immediately notify regional management of the situation. Request that the licensee preserve any physical evidence connected with the incident, if that is possible. Request in advance that the licensee be prepared to submit the necessary documents at the initial licensee meeting.

04.02 Pre-Inspection Preparations. Prepare all materials and documents that may be needed during the inspection, based on your knowledge of the nature of the incident, types of exposures, and the availability of technical support and equipment at the site.

04.03 Initial Licensee Meeting. Meet with the licensee's management as soon as possible upon reaching the site. Explain the purpose of the inspection, the techniques to be used in conducting the inspection, the scope of the work, and the expected duration.

04.04 Facility Inspections. A tour of the facility or a specific area should be performed at the beginning of the inspection since it may be necessary for the NRC inspector to observe proper control of licensed material affected by the incident. If possible have licensee representatives guide the tour, then arrange personnel interviews when the tour is completed. Inspect equipment, tools, work areas, storage areas, and anything else directly or indirectly involved in the incident.

04.05 Interviews. Interview all personnel directly or indirectly involved in the incident, as well as all levels of management whose area of responsibility is in any way connected with the persons

involved in the incident or who have any responsibility for the facilities or equipment connected with the incident.

04.06 Documentation. Obtain copies, or originals if copies are not available, of all documentation that may be needed in the inspection. Ensure that proprietary materials are appropriately safeguarded and original material handled carefully and returned at the end of the inspection. In any case where documentation supports or is needed to support an inspection finding, the inspector must make a copy of the document and include it as an attachment to the inspection report. The licensee should be advised of each document that will be included as part of the report.

04.07 Review of the Data. Review the notes of the interviews and tours, and the relevant documents. Establish a time line for the incident. If the data does not produce a coherent, internally consistent narrative, repeat interviews, tours, and document reviews until all inconsistencies and information gaps are addressed.

04.08 Establishing Causes. Once satisfied that all the relevant information has been obtained, ordered in proper temporal and logical sequence, and verified to be consistent, technically correct, and coherent, identify contributing factors and root causes. Correlate these findings with weaknesses in the licensee's program, and formulate ideas on what the appropriate corrective actions to prevent recurrence should be. Compare with the licensee's corrective actions and evaluate their adequacy. If the licensee's corrective actions are determined to be acceptable, a commitment and schedule for implementation should be made by the licensee and submitted to the cognizant NRC region.

04.09 Licensee Briefings. Meet periodically with the licensee's management and key personnel involved in the incident. Review the sequence of events and specify the suspected causes. Provide the licensee with opportunities to modify or correct the data, sequence of events, or conclusions. Obtain further data if warranted by the discussions, and make corrections to the conclusions, as necessary.

04.10 Event Analysis Data. Make sure that as much as possible of the data needed by NMSS/IMNS is available to you before the exit meeting (see Section 5.12).

04.11 Exit Meeting. Prepare notes summarizing the sequence of events and the conclusions. Identify possible items of noncompliance. Meet with the licensee's management and present these findings.

~~04.12~~ Post Inspection Actions. Any follow-up actions that the inspector takes on a reported incident should be summarized in writing, discussed with his/her appropriate NRC supervisor, and maintained in an official regional file (the docket file for an incident involving a licensee). A formal report of the results of the inspection should be prepared and distributed in accordance with the standard distribution list (see Inspection Manual Chapter

(MC) 0610, "Inspection Reports"). Each incident must be evaluated to determine if it meets the criteria for an Abnormal Occurrence Report (see Management Directive (MD) 8.1, "Abnormal Occurrence Reporting Procedure").

Inspectors will also meet with regional licensing staff when any pertinent licensing issues are raised during the inspection, when inspection findings impact on any licensing actions, or to give feedback on how the licensee has addressed special license amendments or recent licensing actions. This meeting will be documented in the inspection record.

Additionally, in some instances, inspection findings will warrant communication with NRC Enforcement staff, Office of Investigations staff, State liaison staff, or other Federal agencies with whom NRC has Memoranda of Understanding (MOUs). In the latter case, ensure that the exchange of information is made in accordance with the appropriate MOU.

The inspector will ensure that inspection findings are clearly documented and reported to the licensee as appropriate. The inspector will also follow the requirements of MC 0620, "Inspection Documents and Records," regarding notifying the licensee that information that is retained by the inspector is subject to public disclosure and giving the licensee the opportunity to request withholding it (see MC 0620, Section 04.06.b.).

87103-05 DETAILED GUIDANCE

05.01 Pre-Inspection Notifications. As soon as the decision is made to travel to the licensee's facility to conduct an inspection, call the licensee to notify them of the upcoming inspection. Make sure to speak with a licensee official who is high enough in the organization to ensure prompt execution of any necessary arrangements. During this call, provide the licensee with the following information:

- a. Expected time of arrival at the licensee's facility.
- b. Purpose of the inspection.
- c. Expected duration of the inspection.
- d. Request a meeting with appropriate staff, including the responsible licensee management, very soon after the anticipated arrival time.
- e. Identify individuals to be interviewed. Have the licensee make arrangements for these persons to be available when needed, and ensure that the radiation safety officer (RSO) will be available. If the licensee uses a consultant, request that the consultant be present during part of the inspection. If that is not possible, then arrangements should be made for him/her to be available by telephone during a specified time period.

- f. Specify a time and date on which the exit meeting is expected to be held. Make it clear that this is a rough estimate that depends on the course of the inspection. Also make it clear that the highest level of facility management (e.g., the company president, CEO, or plant manager) is expected at this meeting, including the RSO.
- g. Request that copies or, if not possible, originals of all documents that may be needed during the inspection be prepared and ready following the initial meeting. These documents usually include data on surveys and various radiological measurements, log books, calibration and traceability records, training and qualification records, an organization chart, procedures, and any other documents that may seem relevant (see also Section 05.07). If in doubt about the utility of a document, request it anyway. Emphasize the importance of providing all the requested documents as soon as you arrive at the facility.
- h. Request that a knowledgeable person be available to accompany you on a tour of the facility.
- i. Request that physical evidence connected with the incident be preserved, if possible. Examples of physical evidence may include: a survey instrument that gave erroneous readings or malfunctioned (useful in determining why the instrument malfunctioned); a dosimeter that gave a much higher than expected dose reading (may be tested to determine if the dosimeter is defective); contamination smears and air sample filters (may be recounted or subjected to more sophisticated analysis, if necessary); instrument settings as they were found after the incident, etc.
- j. Make sure that access is available to any part of the licensee's facility that is involved in any way, directly or indirectly, with the incident. If there appear to be any difficulties, stress to the licensee that unescorted access must be arranged, escorted if need be. Notify regional management immediately of any potential difficulties in gaining access to areas or information. If a certain level of security clearance is required and you do not have that clearance, or if you do not have the required unescorted access training, immediately inform regional management and request guidance.

05.02 Pre-Inspection Preparations. Before leaving on the inspection, make sure to take all documents, calculators, computer disks, references, radiation safety equipments, etc., that may be needed. A portable computer may be very useful, as would a small hand-held tape recorder to record observations and ideas (not interviews). Arrange for regional or Headquarters personnel to provide technical assistance over the telephone, in case information that is needed, is not available at the site, or if it is desirable to run a computer program on a regional computer, to check calculations. When preparing for the inspection, consider taking at least the following items:

- a. Writing pads, notebooks, and other stationary needed to record interviews, data, and findings, and to perform calculations and draw charts.
- b. Calculator.
- c. Computer discs with programs to perform various radiological calculations, if available, and if the licensee can provide the necessary computer, or a portable computer with the necessary software. Word processing software may be helpful if you can type at a reasonably rapid pace. ≡≡≡
- d. References, handbooks, etc., that contain the basic radiological equations and the values of frequently used constants. For example, if the incident involved external radiation exposures, equations to convert fluence to dose may be needed. A variety of source geometries should be anticipated, such as a point, line, disk, sphere, or cylinder, etc. Quantities normally needed in such calculations include attenuation and energy absorption coefficients at various energies, densities of a variety of materials, buildup factors, organ depths, and so on. Skin dose calculations require skin dose equations applicable to a variety of source geometries. Internal dose calculations will require organ masses, intake retention functions, intake to committed dose conversion factors for organs, and so on. In addition to the technical references, regulatory references should also be taken, including at least the parts of Chapter I (The parts of Title 10 that pertain to the NRC) that apply to the licensee, as well as other regulations that may apply, such as transportation regulations for transportation-related incidents. ≡≡≡
- e. Appropriate radiation safety equipment (instrument, dosimetry) to ensure areas are safely controlled. ≡≡≡

05.03 Initial Licensee Meeting. Upon arrival at the site, meet with licensee management. If a sufficiently high level of management commensurate with the severity of the incident is not present, explain the situation to the licensee, terminate the meeting, and contact regional management immediately. Await instructions from the region before proceeding. The importance of this step is that it is necessary to ensure that a licensee representative who has the authority to make changes in the program has first-hand knowledge of the inspection and its findings. During the initial meeting, present the following items briefly, but clearly: ≡≡≡

- a. The purpose of the inspection.
- b. The expected duration of the inspection.
- c. The level of support you expect from the licensee.

Request a brief description of the incident including the names of the personnel directly involved. Request that the licensee make

available the personnel to be interviewed. Request that the interviews start immediately after the meeting. Set an approximate time and date for the exit meeting. Make it clear that this is tentative and may change, depending on the progress of the inspection. Request that the licensee provide you with the documents you requested during the pre-inspection telephone conversation described in section 04.01. Find out the name of the person to accompany you on the tours. Request the name of a management person to contact in case you experience difficulties or you do not get the necessary level of support.

05.04 Interviews. Interview everyone connected in any way with the incident, either directly or indirectly. The interviews should follow a widening circle, from the small number of people directly involved, to an increasing number of people less and less directly involved. Persons directly involved are those whose actions directly led to the incident, such as, for example the person who dropped the syringe, or the person who was using the radiography source when it got stuck in the unshielded position. Persons indirectly involved are usually a larger class, but no less important. These include the assistants to the directly involved persons, supervisors of those persons, maintenance people, health physics or safety people, warehouse personnel, drivers, and so on. Also included in persons indirectly involved are the supervisory and management staff whose responsibilities are connected in any way with the persons directly or indirectly involved in the incident or to the facilities, hardware, software, supplies, or anything else involved in the incident. This list can be very long, but the depth of the interviews will vary depending on the closeness of the person's activities or responsibilities to the incident.

Although some of the personnel indirectly involved may not know much about the incident itself, they may contribute invaluable information about the morale of the staff, the quality of management at the facility, the level of training, the degree of attention to detail normally observed at the facility, audit and appraisal practices, involvement of consultants and the quality of their work, the quality of procedures in general, and the degree to which management insists that personnel adhere to applicable procedures. During these interviews, try to get a clear impression of the extent to which the persons interviewed are aware of the circumstances directly or indirectly connected to the incident, and whether their knowledge and awareness are commensurate with their responsibilities in the organization.

When conducting the interviews, observe the following guidelines:

- a. Interview only one or, at most, two people at a time. A worker's union representative may be present if the worker requests it. However, unless there is a compelling reason, avoid interviewing people in the presence of the supervisors.
- b. Start the interview by stating clearly, but not too specifically, what you expect to learn from the person.

- c. Make it clear that the purpose of the interview is not to find fault or assign blame, but to learn what happened and if there were any contributing factors so that any weaknesses in the program may be corrected. Be very courteous and realize that the person being interviewed is helping you in your inspection. ≡≡
- d. Do not interrupt, but ask questions when a statement is not clear. Ask questions that elicit useful details rather than questions that call for yes or no answers. Also, do not ask leading questions, i.e., questions that imply the expected answer, such as "you did follow proper procedure, didn't you?". As long as the person is talking about issues relevant to the incident, let the person talk. Keep the conversation focused and end the interview as soon as it becomes clear that no further useful information can be obtained. ≡≡
- e. Make sure to ask open-ended questions that will produce all the information the person being interviewed is expected to provide. The person interviewed may forget something or may believe that a piece of information is not relevant and may therefore not state it. You must be alert to this selectivity and ask questions to compensate. ≡≡
- f. Write down all information discussed during the interviews, such as times, places, recalled conversations, names of people, equipment, sources, reagents, supplies used, procedures involved, surveys done, and any information presented, even if it does not seem to be very relevant at the time. Keep the notes clear and orderly so that they may be used later to reconstruct the information obtained in the interview. ≡≡

05.05 Facility Inspections. The purpose of a facility inspection is to help reconstruct the events leading to the incident, to place all items and persons involved in proper spatial perspective, and to attempt to identify any factors, relating to the facility or equipment, that may have contributed to the incident. Have a knowledgeable licensee representative take you on a tour of the facility. Ask that person to point out all relevant items involved in the incident and to show you the path followed by the persons involved, the layout of equipment and materials at the time of the incident, and any equipment settings that may be relevant to the inspection.

Upon arrival at the facility, proceed to make a tour of the facility or the area and remind the licensee of the need to provide unescorted access (escorted, if need be) to NRC inspectors according to the Pre-Inspection Notification (see 5.01j). Keep in mind that you must abide by all of the licensee's rules and procedures as provided in their site access training. Take time to absorb all detail, and retrace the paths followed by the persons involved in the incident. Remember, however, that this is an event follow-up inspection, and includes only those items that may have a bearing on the event. ≡≡

~~During~~ these tours, look for the following, among other things:

- ~~a.~~ Postings and Access Control: Are all radiation areas properly posted with the correct postings? Are radiation postings clearly visible and clean, and do they provide the necessary information? Is access to restricted areas properly controlled? Are dosimeters issued to the proper personnel, and are they worn properly?
- ~~b.~~ Equipment and Facilities: Does the equipment, including radiation measuring instruments, look well maintained and properly handled? Do instruments have calibration stickers showing valid calibration dates? Is shielding provided where needed?

05.06 Reenactment of the Incident. Incidents that involved a complicated series of movements may be difficult to visualize on the basis of descriptions provided by the licensee. In this case, a reenactment may prove very helpful. The reenactment consists in having the persons directly involved in the incident go through all ~~the~~ motions that ultimately led to the incident. NRC regional ~~management~~ and staff should encourage the licensee to perform and ~~record~~ on videotape the event reenactment for later and repeat ~~viewing~~. Prior arrangements and authorizations by the licensee and regional management must be made to record the reenactment on ~~videotape~~. In any case, where the licensee records the reenactment on videotape, the inspector should obtain a copy of the licensee's videotape.

If the equipment or facility involved in the incident is no longer available, or is unsafe for use in the reenactments, a mockup of the equipment or facility may be used, if warranted. A mockup is a model that is used in place of the equipment during the reenactment. The mockup does not have to be an exact replica of the equipment, but should include the essential features that are significant in determining the outcome of the incident, such as the ~~general~~ shape or size, distances, and the weight if carrying the item was involved.

Reenactments are very important, and sometimes essential, in cases where exposures at high dose rates in complicated configurations were involved. In such cases, differences of a few seconds in the estimated exposure times can result in large differences in the doses assessed for the persons involved. Reenactments, with time-and-motion studies, allow refinement of estimates of exposure times, and also provide the basis for calculating the dose rates at different phases of the incident by observation of the relative positions of the personnel and radiation source during the incident.

If the dose calculations show that any person involved in the ~~incident~~ was exposed to high doses (i.e., above 20 Rem), regional ~~management~~ should contact the appropriate Headquarters management to consider the need for cytogenetic studies. Such studies may ~~confirm~~, in some cases, that a high dose was received. (See also MC 1302, "Action levels for Radiation Exposures and Contamination

Associated with Events Involving Members of the Public" for additional guidance.)

05.07 Documentation. The documentation needed for the inspection includes documents that indicate the overall quality of the licensee's operation, as well as those that are directly related to the incident. Obtain for review at least the following documents:

- a. Procedures for all activities directly and indirectly related to the incident. If applicable, review these procedures and determine their adequacy in terms of clarity of presentation, completeness of information, logical flow of steps to accomplish the desired end, and clarity of decision points. If the procedures are found to be weak, determine who wrote them, the qualifications of those persons, and how the procedures were tested to ensure that they are correct and complete. If availability of procedures appears to be a problem, verify that there are procedures for all of the important activities. Check on the method used by the licensee to keep all procedure copies in the facility updated, and how controlled and uncontrolled procedures are used. Check on the availability of copies of relevant procedures at the locations where they are supposed to be used. Determine the procedure review schedule and verify that procedures were reviewed on schedule by qualified personnel.
- b. Training and Qualifications Records. Obtain records of the qualifications of all persons directly or indirectly connected with the incident, including technicians, safety personnel, supervisors, and managers. Review these records and verify that all personnel meet at least the minimum qualification requirements for their positions and are qualified for their respective functions. Review training records and check the training schedules to verify that they meet minimum training requirements. Verify that persons scheduled for training within the past year or two have attended that training. Review the qualifications of the persons who provide the training, and review some of the lesson plans. Review some examination questions and some answers to these questions.
- c. Calibration and Quality Control Records. Check the calibration records and verify that all equipment that should have been calibrated was indeed calibrated. Check that all instruments scheduled for calibration during the past year or two have been calibrated at the proper time, using approved procedures and sources. Check records of traceability of calibration sources or instruments. Verify that personnel performing the calibrations are properly qualified and trained for the job. Check the quality control program and schedules. Verify that daily or periodic quality control checks were made as scheduled, that the results of these checks were recorded, that instruments that did not pass the tests were taken out of service, and that these checks are

routinely reviewed and signed by a sufficiently high level of management.

- d. Records of the Incident. Obtain and review all records that bear directly and indirectly on activities leading to the incident. These include the names of persons involved, the dates and times they entered and left the relevant areas, the type of dosimetry and the readings of these dosimeters, any protective clothing worn, and any equipment or sources issued to them. Check log books to determine the record of activities that were performed and that eventually led to the incident. Check the records of any radiation surveys that may have been made before, during, or after the incident.
- e. Records of Recovery. Obtain all records that show the activities taken to recover from the incident. Check on whom initiated corrective actions, who was notified, who responded and how, who came to the site of the incident, what they did, and when an investigation was initiated. Determine the scope of the licensee's investigation, who was in charge of it and who was involved, who reviewed and approved the results, and what corrective actions were recommended and what actions were actually implemented.

~~05.08~~ Review of the Data. A final reconstruction of the incident must now be attempted, and must include all available details. Start as far back in time from the incident as may seem relevant to the ensuing events. Note where the staff members were at the time, what they were doing, and what was said. Proceed forward in this manner until the time of the incident, and then proceed to the recovery phase in the same manner. Note on a time line all relevant detail, such as what doors were open or closed, what ~~postings~~ were in the area, instrument readings, room occupancy, clothing worn, procedures and equipment used, when equipment was turned on or off, and what the thoughts of the persons involved were, relevant to the events that were taking place (e.g., the technician might have thought that the source was in the shield, but, in fact it was not). Try to note why certain actions were taken and certain others were not. For example, the technician did not perform the required survey because he thought the room had been surveyed by someone else, or because the battery in the survey instrument was dead, etc.

At the end of this review, the inspector should understand the incident and relevant factors as well as, if not better than, anyone on site. All detail must fall in place, and the flow of decisions, actions, and responses must be quite clear. If any gaps exist, or if any item is not quite clear, return to the notes or documents, interview more people, or interview again some of those already interviewed, tour the facility again, or request additional records. If the data and events are complex, consider using charts. Make up your own system or use standard charting techniques, such as those used in event and causal factors analysis.

The inspector can refer to NUREG-1303, "Incident Investigation Manual," as a guide on how to collect data. Although primarily used for an Incident Investigation Team, NUREG-1303 is the reference document based on inspection experience that provides good follow-up information on how to conduct an investigation and interview, collect information, write a preliminary notification, and prepare a report.

05.09 Establishing Causes. Most incidents usually have direct causes, as well as several contributing causes, and one or more root causes. Direct causes are the obvious ones that led directly to the incident. Contributing causes are those that facilitated, or did not prevent, the direct cause. Direct causes usually point to contributing causes which in turn point to root causes. A common direct cause is failure to follow procedures or good practices. Failures to follow procedures may have a number of causes, including, lax discipline, poor management supervision, poorly written procedures, procedures that are difficult or impractical to implement, unavailability of procedures, and so on. These contributing causes may point to other contributing causes, such as poor training, poor morale, no management oversight, etc. For incidents involving a complex interaction of events, or a long sequence of events, charts may prove to be very useful in identifying causes. It should be remembered that causes must be sought not only for the direct causes, but also for every contributing factor. One may view the incident as a series of incidents, each with its own set of causes, and each leading to, or failing to prevent, the subsequent action. All these contributing causes may have one or a few root causes in common, such as, for example, an unqualified program manager, or poor management practices.

After identifying the causes, express them in a logical hierarchy, one leading to the next. State the cause in a manner that suggests how the action should have proceeded if it had been done properly. For example, it is better to say that the bottle slipped out of the technician's hand because the technician was not wearing gloves, causing his or her hand to be slippery, rather than that the bottle slipped because the technician's hand was slippery. The incorrect action is in this way directly tied to the consequence of that action, and at the same time clearly implies the correct action that should have been taken, in this case, to wear gloves. Finally, the inspector should review the direct and root causes against the licensee's causes and corrective actions to determine whether the licensee's response was appropriate.

05.10 Licensee Briefings. Once the events and data are properly ordered and understood, and causes identified, discuss with the licensee, at a preestablished time, the status of findings and communicate the issues as they develop. Schedule a brief meeting that includes all persons directly and indirectly involved in the incident. Ensure that key licensee staff is represented in the meeting, and certainly the supervisory and management personnel directly responsible for the area involved in the incident. If brief meetings are held with the licensee to discuss issues as they

~~Develop~~, reasonable assurance can be made that the licensee will be ~~aware~~ of problematic areas at the time the exit meeting is held.

~~Present~~ your findings in a clear, and logical order. Review your understanding of the incident, the sequence of events that led to it, the persons involved, their actions, and how these actions contributed to the incident.

After your presentation, which should not last more than 30 minutes for a complex incident, allow the licensee to comment and to express disagreement. Make sure you understand the reasons for the disagreement, and clearly separate those that stem from differences of opinion from those that arise out of disagreements on matters of fact. For the former, try to understand the licensee's point of view and note it for later consideration. For the latter, ensure that disagreements on fact are resolved, either at the meeting, or later. All factual disagreements must be resolved at this stage. If factual disagreements are extensive, reschedule the meeting and allow time to review and correct any factual errors. This phase of the inspection should not end until all disagreements on matters of fact are resolved to the extent possible and to your satisfaction.

05.11 Management Briefing. Keep regional management informed of the progress of the inspection. Periodically, summarize the findings and call the appropriate NRC supervisor, usually the branch chief, and discuss the findings. This is especially important if there are, or are expected to be, controversial issues arising from the findings. It is also important to discuss the merits of any items of apparent noncompliance with regional management before discussing them with licensee representatives. Notify regional management of any suspected falsification of records, providing false information to the NRC, or any other ~~willful~~ wrongdoing. If the inspector identifies serious or ~~controversial~~ issues which cannot be immediately resolved then NRC ~~regional~~ management should consider if their on-site presence is ~~warranted~~.

05.12 Event Analysis Data. In accordance with its responsibility for evaluating and analyzing operational data for material ~~licensees~~, NMSS/IMNS collects, reviews, and codes material license event data, and maintains a database - the Nuclear Material Events ~~Database~~ (NMED) - of non-reactor events. The purpose of reviewing operational event data is to identify systemic causes of licensee problems that are significant to licensee and public health and safety. In addition to maintaining this incident database, ~~NMSS/IMNS~~ also provides computer programs to search the database and classify incidents in a variety of ways, depending on the user's needs. For example, incidents may be classified by dose received, body part exposed, type of license, and many other ~~variables~~. To accomplish this goal, NMSS/IMNS must be provided with a minimum amount of information for each incident. This minimum information is shown in Appendix A in the form of a listing of the variables needed. Review the list and record the data for each variable, as it pertains to the incident. At this stage of the inspection, all listed information should be readily available to you. If not, attempt to obtain any missing information from the

licensee before the exit meeting. All documents created related to the event, such as the inspection report, letters to the licensee or trustee, etc., should have the NMED event number in a clearly visible location. This will ensure that all documents related to the event are identified in the database.

05.13 Exit Meeting. The exit meeting is the concluding meeting of the inspection, and its purpose is to provide the licensee with a summary of the findings and any items of noncompliance. Schedule the meeting for a time just before leaving the site, and leave immediately after the meeting. Make sure the meeting is attended by a sufficiently high level of management, including the RSO. Make sure the meeting is attended by the highest level of facility management (e.g., the company president, CEO, or plant manager), including the RSO. The exit meeting is your meeting, held at your request, and you must conduct the meeting. Open the meeting by explaining the reasons for coming on site, what you did, and what were your findings. Explain what you believe were the causes of the incident and the program weaknesses that they indicate. Present your conclusions regarding contributing and root causes. List the potential violations of regulatory requirements or license conditions, and note that these are apparent violations to be reviewed and approved by regional management. Ask if everything is clear and if there are any questions. Do not enter into any discussions but note any disagreements and inform the licensee that you will convey their disagreements to regional management. Thank the licensee for their cooperation during the inspection, end the meeting, and leave site.

05.14 Post Inspection Actions. The inspector will review his or her inspection findings with NRC regional management following the guidance in MC 1301, "Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan," to determine what follow-up actions must be taken. The inspector should discuss the findings in detail, commensurate with the scope of the licensee's program. Violations, items of concern, and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

Discussion of the inspection findings with licensing staff can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that NRC has entered into several MOUs, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings.

The inspector will prepare a formal report of the results of the inspection following the guidance of MC 0610, "Inspection Reports." The findings should be documented in the inspection record, 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. Copies of all licensee documents needed to support the violation should be attached to the inspection record. The inspection record should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.~~

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- VARSKIN, for skin dose calculations.
- MICROSHIELD, for external dose and shielding calculations.

END

Attachments:

Appendix A, Information Needed For Nuclear Materials Events Database (NMED) Database
Appendix B, Guidance for Inspection of Materials Licensees Who Have Filed for Bankruptcy.



APPENDIX A

INFORMATION NEEDED FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED) DATABASE



General Information - All Events

License Number
Additional license numbers, if multiple licenses
Docket number
Licensee's name*
Licensee's city of record*
Licensee's county of record*
Licensee's state of record*
Licensee's telephone number*
City where the event occurred
State where the event occurred
Agreement State (Y/N)
NRC region number
Reportable event?
Date event occurred
Date event reported to NRC or state
Time of event
Was a consultant hired to investigate?
License number of additional involved party
Additional licensee's name
Additional licensee's city of record
Additional licensee's county of record
Additional licensee's state of record

* If a non-licensee is involved, note that fact and enter the marked items.

General Information - All Medical Misadministrations

Type of misadministration (Part 35)
Dose prescribed
Dose received
Percent under prescribed dose
Percent over prescribed dose
Intended target organ or site
Actual target organ or site
Was patient notified of the misadministration?
Was patient's family notified of the misadministration?
Was the patient's referring physician notified?
Number of people who received a misadministration

Specific Data on Teletherapy Events

Source of radiation prescribed
Source of radiation administered
Model number of teletherapy unit
Manufacturer's name
Serial number of teletherapy unit
Model number of teletherapy unit's source
Manufacturer's name
Serial number of teletherapy unit's source

Teletherapy source activity
Teletherapy source assay date
Teletherapy source radionuclide

Specific Data on Brachytherapy Events

Radionuclide of source prescribed
Radionuclide of source utilized
Activity of source prescribed
Activity of source utilized
Model number of source utilized
Manufacturer's name
Serial number of source utilized

Specific Data on Radiopharmaceutical Events

Radionuclide of pharmaceutical prescribed
Radionuclide of pharmaceutical administered
Activity of pharmaceutical prescribed (mCi)
Activity of pharmaceutical administered (mCi)
Chemical form of pharmaceutical prescribed
Chemical form of pharmaceutical administered
Manufacturer's and/or supplier's name

Specific Data on Radiation Overexposure Events

Number of people who received overexposures
Dose received from the overexposure
Were members of the public overexposed?
Were radiation (occupational) workers overexposed?
Were overexposed persons notified of their exposures?
Source of radiation causing the overexposure
Model number of device causing the overexposure
Manufacturer's name
Serial number of device causing the overexposure
Model number of sealed source causing the overexposure
Manufacturer's name
Radionuclide that caused the overexposure
Activity of the source that caused the overexposure
Assay date of the source

Specific Data on Lost, Abandoned, or Stolen Radioactive Material Events

Model number of the lost or stolen device, instrument, or gauge
Manufacturer's name
Serial number of the lost or stolen device, instrument, or gauge
Model number of the lost, stolen, or abandoned sealed source
Manufacturer's name
Serial number of the lost, stolen, or abandoned sealed source
Radionuclide in the lost, stolen, or abandoned source
Activity in the lost or stolen source
Assay date of source

Specific Data on Leaking Sealed Source Events

Model number of the leaking source

Manufacturer's name
Serial number of the leaking source
Radionuclide of the leaking source
Activity of the leaking source
Assay date of source
Leak test results?
What kind of leak test?

Specific Data on Release of Radioactive Material Events

Radionuclide that was released
Activity of the material released

Specific Data on Radiography Equipment Malfunction or Failure Events

Model number of the equipment that failed or is defective
Manufacturer's name
Serial number of the equipment that failed or is defective
Accessory equipment
Manufacturer's name

Specific Data on Damaged Industrial Gauging Device Events

Model number of the damaged gauge housing
Manufacturer's name
Serial number of the damaged gauge housing
Model number of the sealed source in the damaged gauge
Manufacturer's name
Serial number of the sealed source in the damaged gauge
Activity of the sealed source
Assay date
Source radionuclide

Specific Data on Consultants

Was a consultant hired?
Consultant's name
Name of consultant's company
Who hired the consultant?
What is the consultant's specialty?

Specific Data on Licensee Corrective Actions

Licensee corrective actions

END

APPENDIX B

GUIDANCE FOR INSPECTION OF MATERIALS
LICENSEES WHO HAVE FILED FOR BANKRUPTCY

Note: The inspector should be aware that NUREG-1556, Vol.15 "Program-Specific Guidance about changes of control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," has been issued in draft form. When this draft report is issued in final form, PG 8-11 "NMSS Procedures for Reviewing Declarations of Bankruptcy," will be considered superseded and NUREG-1556, Vol. 15 should be used as guidance for inspection of materials licensees who have filed for bankruptcy.

Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," requires that, after receiving a report that a licensee has filed for bankruptcy or that an involuntary petition has been filed against it, NRC licensing staff verify that all licensed material possessed by the licensee is being adequately controlled. If it is determined that licensed material may not be adequately controlled, a special inspection should be conducted. The special inspection should be conducted in accordance with this Inspection Procedure.

Policy and Guidance Directive PG 8-11 also requires that a Bankruptcy Response Team (BRT) be formed. A BRT consists of representatives from various NRC offices, whose purpose is to provide a coordinated response to declarations of bankruptcies, to assess whether there are any current public health and safety concerns at the facility, and to determine any impacts the bankruptcy could have on licensed operations. The results of the special inspection, if conducted, will assist the BRT with their duties.

Any steps to secure the site should be taken only after consultation with the Office of the General Counsel, to ensure that NRC's rights to compel the debtor to satisfy its public health, safety, and environmental obligations, or to pursue any claim against the assets of the bankruptcy estate would not be unnecessarily prejudiced.

NRC staff performing the assessment of material control and special inspection should take into consideration the following guidance:

1. When determining the adequacy of material control and preparing for an inspection, NRC staff should verify:
 - a. the Radiation Safety Officer remains in the position; and
 - b. access to the licensed material is under positive control (i.e., the facility has not been abandoned);and review NRC license files for:
 - a. reports of leaking sealed sources;

- b. disposition of any identified leaking sealed sources;
 - c. reports of facility contamination;
 - ~~→~~ d. reports of possible inventory discrepancies; and
 - e. history of violations, specifically those related to performing leak tests, inventories, and facility surveys.
2. While performing the special inspection at the licensee's facility, inspectors should review records for:
- a. definitive inventory of licensed radioactive material;
 - b. leak test records;
 - ~~→~~ c. facility surveys; and
 - ~~→~~ d. shutter checks of fixed gauges (this will help to determine the status of the device whether locked out or not).
3. While performing the special inspection at the licensee's facility, inspectors should also:
- a. direct an inventory of licensed and unlicensed radioactive material to be performed, as necessary¹;
 - b. direct leak tests to be performed, as necessary²;
 - ~~→~~ c. direct facility surveys to be performed, as necessary³; and
 - ~~→~~ d. perform a survey.

~~→~~ Inspectors should consider whether control of licensed material has been maintained and will continue to be maintained, especially in cases where operations have ceased or will cease. Considerations of such cases may include:

- ~~→~~ a. the likelihood of inadvertent releases due to cessation of operations;
- ~~→~~ b. adequate control of licensed material in the event a closed facility is accessed in an unauthorized manner; and
- ~~→~~ c. degradation of material control over time in a prolonged shutdown condition.

4. Upon completion of the special inspection, the inspector should provide documentation of the findings to the BRT leader.

Even though the licensee has filed for bankruptcy, the licensee remains responsible for all regulatory requirements. The inspector's role is to make necessary confirmatory measurements. However, if the licensee has abandoned the material and the trustee ~~→~~ cannot perform these measurements, the inspector shall perform them to evaluate the health and safety consequences.

By completing the above actions, all entities involved (licensee, BRT, trustee, etc.) are aware of the situation and health and safety issues may be resolved before bankruptcy actions are completed.

¹ If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing inventories, then an inventory should be completed.

² If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing leak tests, then the

sealed sources should be leak tested. In addition, consideration should be given to leak testing sources that have been in storage for greater than one year. The inspector should consider the former use of the source(s), the current physical condition of the source(s) (e.g., visible damage, corrosion, etc.), and the past history of the licensee's performance of leak testing.

³ If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing surveys, then a basic facility survey should be conducted.

END