

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

NRC Sealed Source and Device Program
Reporting Period: September 24, 2005 to October 23, 2009

NOTE: Not all questions are relevant to the sealed source and device (SSD) evaluation program. The NRC responses, where applicable, are shown in bold following the questions.

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.
 - **The last review made one recommendation (Page 6): "...adhere more closely to the document format and the guidance" in NUREG-1556, Vol. 3.**
 - **The review listed several specific examples regarding document formatting (in Section 3.2, Pp. 3-4):**
 - **Two documents were not in ADAMS but were found in the hard copy back-up files; on one occasion an engineering drawing was scanned unfolded – CORRECTIVE ACTION: we replaced the documents in ADAMS with complete sets.**
 - **Adherence more closely to the document format in Vol. 3, such as the use of extra line for the source/device type in SSD header – CORRECTIVE ACTION: We did not change the practice because we follow the provisions of Vol. 3. Specifically, Section 12.1 states that "[t]he header includes...the sealed source and device type," and similarly, the examples in Appendix D show the sealed source and**

¹ Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

device type in the header on every page of the sample certificates.

- In three cases, documents were missing from the electronic records - **CORRECTIVE ACTIONS:** (1) we placed electronic copies of the missing documents into the electronic records, and (2) to solve the problem permanently, we implemented two procedural changes: (a) we developed a checklist entitled “Folder Contents for SSD Case” which the reviewer fills out when closing out the SSD case in order to ensure that all relevant documents had been placed into the records, and (b) we implemented a policy to consistently use the technical checklist (Appendix A, Vol. 3) in cases where safety issues were reviewed; or to place a note to the file into the records in cases where the action consisted of administrative issues (such as name or address change) where safety issues were not reviewed.
- Dual units were not used in one case – **CORRECTIVE ACTION:** to address the issue, we reviewed SECY-96-098, the document that is referenced in the current guidance, NUREG-1556, Vol. 3, Rev. 1, Section 12.16. We found that a newer NRC guidance has been issued on the use of units: NUREG-1379, Rev. 2, dated May 2009, entitled “NRC Editorial Style Guide.” This document specifies (in Section 1, Page 1) that NRC uses the metric system and, in cases where nonmetric units must be used, the values in metric units should be stated first, followed by nonmetric units in parenthesis. We instructed the staff to follow the latter NRC guidance. We will also reference the new guidance in the next revision of NUREG-1556, Vol. 3.

B. COMMON PERFORMANCE INDICATORS

I. Technical Staffing and Training

2. Please provide the following organization charts, including names and positions:

- (a) A chart showing positions from Governor down to Radiation Control Program Director;

The organization chart of the NRC Office of Federal and State Environmental Management Programs (FSME) is attached (see Attachment A).

- (b) A chart showing positions of current radiation control program including management; and

The organization roster of the Division of Materials Safety and State Agreements (MSSA) lists the SSD review staff (see Attachment A). The accession number is ML003769707.

- (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

Please see response to Question B.I.2(b) above.

- 3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

<u>Name</u>	<u>Position</u>	<u>Area of Effort</u>	<u>FTE%</u>
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See Attachment B for a listing of professional efforts expended on SSD safety evaluations by staff members. Attachment B also shows the names of all staff who worked on SSD issues during the review period.

The staff time, listed in Attachment B, includes all activities that have been performed related to SSDs, i.e. direct case work, support work, event evaluations, generic issues, and related projects. The time also includes activities performed by staff not having signature authority, including reviews conducted as part of the training program.

- 4. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, as appropriate.

Staff members, who completed all training requirements in accordance with the NRC's applicable training procedure (i.e. MC 1246) and are SSD board certified reviewers:

- U. Bhachu, GG-13 engineer
- J. Jankovich, team leader, GG-15 sr. engineer

Both Mr. Bhachu's and Dr. Jankovich's academic training and professional qualifications have been reviewed in previous IMPEP audits.

Staff members who are currently in training:

- Stephen Poy, engineer, B.Sc. Mechanical Eng., M.Sc. Civil Eng., 17 yrs of engineering experience, no prior SSD experience, trainee, Dec. 2008 – present

-Lymari Sepulveda, B.Sc. Mechanical Eng., 2 yrs of engineering experience, no prior SSD experience, trainee, Oct. 2008 – present

- Candace Clemons-Webb, B.Sc. Chemistry, M.Sc. (candidate) Nuclear Eng., 6 yrs HP experience, no previous SSD experience, trainee, May 2009 - present

5. Please list all professional staff who have not yet met the qualification requirements for a license reviewer or materials inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

Stephen Poy and Lymari Sepulveda (see academic training above in Question 4) are in the process to fully qualify as SSD reviewers in accordance with the requirements of NRC MC 1246. Both still need to (1) take additional course work, timing depends on when the courses are offered, and (2) complete additional case work under supervision. We anticipate that they will be fully qualified within 12 months.

6. Identify any changes to your qualification and training procedure that occurred during the review period.

None.

7. Please identify the technical staff that left your program during the review period.

The following staff members left the program due to promotions or other assignments:

- N. Ashkeboussi, GG-13 engineer
- T. Herrera, GG-13 engineer
- Xiaosong Yin, GG-14 health physicist
- Joshua Palotay, M.Sc. Health Physics, no prior SSD experience, trainee, Aug. 2007 – April 2008

8. List any vacant positions in your program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

None.

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

There are no oversight boards over the SSD program.

Conflict of interest issues are addressed in the NRC's annual ethics training that all employees are required to take.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: licensee name, license number, your inspection interval, and rationale for the difference.
11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800; the number of initial inspections; and the number of increased controls inspections that were completed during the review period.
12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees, increased controls, and initial inspections that were conducted overdue per the applicable guidance. Priority 1, 2, and 3 licensees and initial inspections must be conducted at least as frequently as the inspection intervals established in IMC 2800. Increased controls inspections should be conducted at the intervals established in the Staff Requirements Memorandum for COMSECY-05-0028.

At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:

- (1) Licensee Name
- (2) License Number
- (3) Priority (IMC 2800)
- (4) Last inspection date or license issuance date, if initial inspection
- (5) Date Due
- (6) Date Performed
- (7) Amount of Time Overdue
- (8) Date inspection findings issued

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees, increased controls, and initial inspections that are currently overdue, per the applicable guidance. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection.
14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and the number of candidate licensee reciprocity inspections that were completed each year during the review period.

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?
16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<u>Inspector</u>	<u>Supervisor</u>	<u>License Category</u>	<u>Date</u>
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17. Describe or provide an update on your instrumentation, methods of calibration and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

IV. Technical Quality of Licensing Actions

NOTE: The responses below apply to the SSD evaluation program.

18. How many specific radioactive material licenses does the Program regulate at this time?

See listing of SSD actions in response to Question 31.

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

As unusual cases and, in addition to the case work, the staff completed the following significant actions related to SSDs during the review period:

- **we conducted an SSD workshop to train Agreement State and NRC staff to conduct SSD safety evaluations. The Workshop was held in Houston, TX, with 20 Agreement State and 4 NRC trainees participating, May 11-15, 2009;**
- **we conducted a safety evaluation for recycling/re-encapsulating previously used Cs-137 sources. Information is available in Case No. SSD-06-44, International Isotopes Idaho, Inc., NR-1235-S-103-S;**
- **we conducted a safety evaluation for a battery, containing Kr-85, designed to generate electric current. Information is available in Case No. SSD-07-38, Qynergy Corp., NR-1298-D-101-S;**
- **we issued a set of procedures for the conduct of SSD safety evaluations;**
- **we served as IMPEP team members for auditing the SSD programs in eight Agreement States: Arizona, California, Colorado, Florida, Maryland, Massachusetts, Ohio, and Texas, between 2005-2009;**

- an SSD staff served as member of the evaluation team for Pennsylvania's application to become an Agreement State;
- we conducted safety evaluations for Agreement States who did not have the skills for the type of devices that were to be registered:
 - high-dose-afterloader (HDR) evaluation for Louisiana (Oncology Systems, SSD Case 07-23),
 - beta-gauge evaluation for South Carolina (Mahlo-America, Inc., SSD Case 07-30),
 - development of a technical/regulatory position with North Carolina to approve moisture density gauges as generally licensed devices (May 2009),
 - determination of the leak test requirements for gamma gauges that use stacked check sources (currently under review) with Kentucky;
- the NRC team served as SSD resource on a nationwide basis through several interactions/week (61 cases in 2006, 73 cases in 2007, 52 cases in 2008, 57 cases in 2009): responded to e-mail questions, expressed opinions that the SSD Team prepared to outside inquiries. Specifically,
 - inquiries from A/S SSD reviewers
 - licensee inquiries (held public meetings, responded to e-mails, responded to telephone calls)
 - responded to questions from the NRC Regions
 - served as SSD resource in meeting with licensees, e.g. U.S. Army (Nov. 2008), Troxler Laboratories re. new exempt product licensing (Dec. 2008)
- the SSD staff served as NRC delegates on the Working Groups for the following standards related to sealed sources and devices:
 - ANSI N43.6, "Sealed Radiation Sources – Classification," issued in 2007
 - ANSI N43-9, "Specifications for Design and Testing Apparatus for Gamma Radiography," issued in 2009,
 - ANSI N42-40, "Technical Performance of Gamma-Ray Security Screening Equipment," a new standard, development started in May 2005,
 - ISO-2919, "Radiation protection – sealed radioactive sources – general requirements and classification," update completed, submitted for publication in 2009.
- To address new developments in standards relevant to SSD's, we issued NRC Regulatory Issue Summary 2007-03, "Ionizing Radiation Warning Symbol."

20. Identify any licensees or groups of licensees that were issued increased controls during the review period. Those licensees that were initially identified during the initial implementation of increased controls need not be listed.

N/A

21. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

No exemptions were granted during the review period.

22. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

We issued a set of Policy and Guidance Directives (i.e. procedures) in April 2006. The Directives were updated in September 2009, to reflect the name changes of new organizational units due to re-organization; no other changes were made.

23. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

V. Technical Quality of Incident and Allegation Activities

24. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
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The SSD staff participated in the resolution of the following incidents/events during the audit period:

- **We participated in May 2006, in an inspection of NDT Repair Service & Supply, Inc. (NDT), Morgan City, LA, conducted jointly by NRC Region IV and the State of Louisiana, regarding radiography cable-disconnects. We wrote the inspection charter, determined the root cause, and wrote the technical part of the inspection report.**
- **We participated in 2007, in an inspection of Varian Medical Systems, Charlottesville, VA, conducted jointly by NRC Region I and the States of California (licensing authority) and Virginia (site location), regarding failures of source withdrawals in the Varisource HDR devices. We participated in the determination of the root cause, and wrote the part of the inspection report. We issued, with the support of California, Information Notice 2007-35 regarding the failures (see listed in answer to Question 25).**

- **We participated in 2009, in an inspection of Varian Medical Systems, Charlottesville, VA, conducted jointly by NRC Region I and the State of Virginia, regarding residue build-up in the connecting tubes of the Varian HDR devices. We participated in the determination of the root cause, and wrote a significant part of the inspection report. We issued Information Notice 2009-35 regarding the failures (see listed in answer to Question 25).**
 - **We routinely monitor public sale sites such as eBay or Craig's List for sales that involve licensed materials or licensing requirements. We established procedures to inform the sellers about the regulatory requirements and the expected steps to take. We responded to numerous eBay sales during the review period. In July, 2009, we responded to an event particularly fast and effectively with results in three days: we received notification that a moisture density gauge was for sale on Craig's List in a pawn shop in California. We notified the State, the California staff went to the shop, picked up the gauge which - as it turned out - had been reported stolen, returned it to the rightful owner, and notified the State police about the person who pawned the stolen device.**
 - **The list of allegations that the SSD staff was involved is available in the files of the FSME Allegation Coordinator.**
25. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated? For Agreement States, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

The SSD program performed the following reviews regarding incidents/events involving sealed sources or devices:

- **The team leader receives and reviews the daily events report and determines whether the event is an SSD generic issue. The determination is based on the criteria in MD 6.4, "Generic Issues Program." The team leader maintains a log of the events that were reviewed.**
- **The Program conducts periodically an analysis of the Nuclear Material Events Database (NMED) to identify generic issues related to sources and devices. The outcome of the reviews of event reports:**
 - **we noted frequent leaks of thin walled sources. We conducted an NMED research and issued Information Notice 2009-05, "Contamination Events Resulting from Damage to Sealed Radioactive Sources During gauge Dismantlement and Non-Routine Operations," dated February 2009;**

- **we recorded the results, which did not result in generic communications, in periodic memoranda and e-mails to the Branch Chief and the Team Leader.**
 - **We identified, as an outcome of an inspection, that the issues regarding the source withdrawal failures in Varian HDR devices constituted a generic issue and issued Information Notice 2007-35, "Varian Medical Systems Varisource HDR Events: Iridium-192 Source Pulled from Shielded Position," dated October 17, 2007.**
 - **We identified, as an outcome of an inspection, that the issues regarding the material buildup that prevented source withdrawals in Varian HDR devices constituted a generic issue and issued Information Notice 2009-15, "Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Sources Retraction Problems," dated July 29, 2009.**
 - **In response to event reports, we issued Information Notice 2009-18, "Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures," dated September 18, 2009.**
26. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

None.

C. NON-COMMON PERFORMANCE INDICATORS

I. Compatibility Requirements

27. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.
28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.
29. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations, please describe their use.
30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

II. Sealed Source and Device (SS&D) Evaluation Program

31. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of devices issued during the review period. The table heading should be:

<u>SS&D Registry Number</u>	<u>Manufacturer, Distributor or Custom User</u>	<u>Product Type or Use</u>	<u>Date Issued</u>	<u>Type of Action</u>
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All cases that the Program completed since the previous IMPEP audit, i.e. from Oct. 1, 2005, through Sept. 4, 2009, are listed in Attachment C.

32. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

III. Low-Level Radioactive Waste Disposal Program

33. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

IV. Uranium Recovery Program

34. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9
Status of Materials Inspection Program - Questions 10-14
Technical Quality of Inspections - Questions 15-17
Technical Quality of Licensing Actions - Questions 18-23
Technical Quality of Incident and Allegation Activities - Questions 24-26

**MATERIALS REQUESTED TO BE AVAILABLE FOR
THE ON-SITE PORTION OF AN IMPEP REVIEW**

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of followup actions.
- List of licenses terminated during review period.
- Copy of current log or other document used to track licensing actions.
- List of all licensing actions completed during the review period (sorted by license reviewer, if possible).
- Copy of current log or other document used to track inspections.
- List of all inspections completed during the review period (sorted by inspector, if possible).
- List of inspection frequencies by license type.
- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.

ALSO, PLEASE HAVE THE FOLLOWING DOCUMENTS AVAILABLE:

- All State regulations
- Statutes affecting the regulatory authority of the State program
- Standard license conditions
- Technical procedures for licensing, model licenses, review guides
- SS&D review procedures, guides, and standards
- Instrument calibration records
- Inspection procedures and guides
- Inspection report forms
- Documented training plan, if applicable
- Records of results of supervisory accompaniments of inspectors
- Emergency plan and communications list
- Procedures for investigating allegations
- Procedures for investigating incidents
- Enforcement procedures, including procedures for escalated enforcement, severity levels, civil penalties (as applicable)
- Job descriptions