Integrated Materials Performance Evaluation Program (IMPEP)

Directive 5.6

Contents

Integrated Materials Performance Evaluation Program (IMPEP) Directive 5.6

Policy
(5.6–01)

It is the policy of the U.S. Nuclear Regulatory Commission to evaluate the NRC regional materials programs and Agreement State radiation control programs in an integrated manner, using common and non-common performance indicators, to ensure that public health and safety is being adequately protected.

Objectives
(5.6–02)

- To establish the process by which the Office of Nuclear Material Safety and Safeguards and the Office of State Programs conduct their periodic assessments to determine the adequacy of their programs in the NRC regions and Agreement States. (021)
- To provide NRC and Agreement State management with a systematic and integrated approach to evaluate the strengths and weaknesses of their nuclear material licensing and inspection programs. (022)
- To provide significant input to the management of the regulatory decision-making process, and indicate areas in which NRC and the Agreement States should dedicate more resources or management attention. (023)

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Organizational Responsibilities and Delegations of Authority
(5.6–03)

Deputy Executive Director for Materials, Research and State Programs (DEDMRS)
(031)

- Oversees the integrated materials performance evaluation program (IMPEP). (a)
- Chairs management review boards (MRBs). (b)
- Signs final reports issued to each region and Agreement State. (c)

Director, Office of Nuclear Material Safety and Safeguards (NMSS) and Director, Office of State Programs (OSP)
(032)

- Implement the IMPEP within NMSS and OSP. Provide staffing support and training for review teams. (a)
- Establish a schedule and develop a detailed review regimen for conducting the reviews in each region and Agreement State. (b)
- Monitor the IMPEP process; evaluate and develop IMPEP policy, criteria, and methodology, and assess the uniformity and adequacy of the implementation of the program. (c)
- Issue draft reports and prepare final reports for each region and State for consideration by the MRB and signature by the DEDMRS. (d)
- Participate on MRB. (e)
- Coordinate with Agreement States to provide appropriate representatives for IMPEP reviews and MRB meetings. (f)

General Counsel
(033)

Participates on MRBs.

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Regional Administrators
(034)

- Implement the IMPEP within their respective regions. (a)
- Provide staffing support for review teams, as needed. (b)

Applicability
(5.6–04)

The policy and guidance in this directive and handbook apply to all NRC employees who are responsible for and participate in the IMPEP.

Handbook
(5.6–05)

Handbook 5.6 describes the performance indicators that will be used, the performance standards against which these indicators will be evaluated, and the frequency and process sequence to be employed. The "Glossary" to the handbook also defines the most commonly used key terminology.

References
(5.6–06)

Code of Federal Regulations, Title 10 (10 CFR), "Energy."

NRC "Statement of Principle and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs," 62 FR 46517, September 3, 1997.

NRC Inspection Manual, Chapter 0610, "Inspection Reports."

—, Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

—, Chapter 2600, "Fuel Cycle Facility Operational Safety and Safeguards Inspection Program."

—, Chapter 2604, "Licensee Performance Review."

—, Chapter 2605, "Decommissioning Procedures For Fuel Cycle and Materials Licensees."

References
(5.6–06) (continued)

—, Chapter 2800, "Materials Inspection Program."

—, Chapter 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program."

—, Inspection Procedure 87104, "Decommissioning Inspection Procedure For Materials Licensees."

—, Inspection Procedure 88104, "Decommissioning Inspection Procedure For Fuel Cycle Facilities."

NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs."

NRC Office of State Programs Procedure SA-113, "Placing an Agreement State on Probation."

— SA-114, "Suspension of a Section 274b Agreement."

— SA-115, "Termination of a Section 274b Agreement."

— SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

— SA-201, "Reviewing State Regulations."

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Integrated Materials Performance Evaluation Program (IMPEP)

Handbook 5.6

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Part III (continued)

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Part III (continued)

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Part IV

Part I
Evaluation

Evaluation Frequency (A)

NRC will review the performance of each region and each Agreement State on a periodic basis. The schedule for conducting each regional or Agreement State visit will be developed by the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs (OSP) in coordination with the regions and States. Approximately 10 to 12 reviews will be scheduled in most years. Under normal conditions, this would allow evaluations of NRC regions every 2 years, and Agreement States every 4 years. However, these frequencies can be adjusted downward on the basis of the findings from the last review, or in light of significant program changes in a particular State or region. In addition, this schedule provides for review of certain NMSS headquarters functions on an as-needed basis.

Evaluation Process Sequence (B)

The typical evaluation process sequence for the integrated materials performance evaluation program (IMPEP) reviews is summarized below:

- Develop the review schedule for the year. (1)
- Assemble and train team members. (2)
- Designate a team leader and members for each scheduled review. (3)
- Transmit questionnaires to affected regions and States. (4)
- Provide to team members a copy of questionnaire responses and most current information on the region or Agreement State. (5)
- Assess a sample of inspections at different types of licensed facilities by accompanying inspectors. (6)

Evaluation Process Sequence (B) (continued)

- Conduct the onsite portion of IMPEP, using the criteria specified in this handbook and applicable performance review procedures. (7)
- Prepare draft IMPEP report, with recommendation for overall performance evaluation, for office director's signature. (8)
- Issue the draft report to the appropriate regions or States. (9)
- Review and consider written comments received from the regions or Agreement States. (10)
- Prepare proposed final report for consideration by the management review board (MRB). (11)
- Conduct MRB meeting. (12)
- Issue final reports; include the written comments received from the regions or Agreement States and any change to the report based on resolution of those comments and a summary of MRB findings. (13)

Part II
Performance Indicators

General (A)

A description of the common and non-common performance indicators to be evaluated, as appropriate, for each region and each Agreement State is given in (B) and (C) of this part. The evaluation criteria (i.e., performance standards) against which these indicators are to be assessed are described in Part III of this handbook. These reviews ensure regional programs provide adequate public health and safety and determine program adequacy and compatibility in the Agreement States. The reviews are instrumental in improving State and NRC regional performance, thus ultimately leading to improved licensee performance. (1)

The performance indicators should be used as a starting point of inquiry. This, in turn, should lead program evaluators to a more careful examination of the underlying conditions, or "root causes" of potential problem areas. Evaluators may find correlations exist between two or more performance indicators. In this situation, the impact of individual performance symptoms could be compounded when combined with others. Conversely, a regulatory program measured as potentially weak against one particular indicator could, nonetheless, be rated as strong overall, if there are sufficient mitigating factors with respect to other indicators. (2)

Certain non-reactor functions that continue to be conducted from NRC headquarters, such as fuel cycle licensing, uranium and thorium milling licensing, sealed source and device reviews, and low-level radioactive waste disposal licensing, are excluded from the set of common indicators because they are not common to the activities of the NRC regions and Agreement States. These functions are incorporated, as appropriate, as non-common indicators contributing to a performance-based evaluation of a program. (3)

General (A) (continued)

For Agreement States, the non-common indicators are legislation and program elements required for compatibility, the sealed source and device evaluation program, low-level radioactive waste disposal program, and uranium recovery program. (4)

Common Performance Indicators (B)

Common Performance Indicator 1—Status of Materials Inspection Program (1)

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in NRC Inspection Manual, Chapter 2800, and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program. (a)

Information regarding the number of overdue inspections is a significant measure of the status of an Agreement State's or NRC region's materials inspection program; reviews also should examine specific cases in detail where the inspection frequency has been significantly exceeded (i.e., by more than 50 percent). The terms "materials inspection" and "overdue inspection" are defined in the Glossary to this handbook. (b)

Common Performance Indicator 2—Technical Quality of Inspections (2)

This performance indicator provides the qualitative balance to Performance Indicator 1 above, which looks at the status of the inspection program on a quantitative basis. Review team members will accompany a sample of inspectors at different types of licensed facilities to evaluate the knowledge and capabilities of regional and Agreement State inspectors. These accompaniments will usually occur at a time other than the onsite review of the region or Agreement State to afford the review team sufficient time to observe inspectors at different types of licensee facilities. These reviews focus on the scope, completeness, and technical accuracy of completed inspections and related documentation. Review teams will conduct indepth, onsite reviews of a cross-section of completed inspection reports performed by different inspectors. In addition, review teams will verify that

Common Performance Indicators (B) (continued)

Common Performance Indicator 2—Technical Quality of Inspections (2) (continued)

supervisors generally conduct accompaniments of inspectors on an annual basis to provide management quality assurance.

Common Performance Indicator 3—Technical Staffing and Training (3)

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and thus could affect public health and safety. (a)

For this performance indicator, qualitative as well as quantitative measures must be considered. In particular, the reason for apparent trends in staffing must be explored, for example—(b)

- Is the rate of turnover and the degree of understaffing symptomatic of a chronic problem or is it merely a short-term phenomenon? (i)
- Why is turnover high? (ii)
- What steps are being taken to address this? (iii)
- What impact is it having on other performance indicators? (iv)

Review of staffing also requires a consideration and evaluation of the levels of training and qualification of the technical staff. Newly hired employees must be technically qualified. Professional staff should normally have a bachelor's degree or equivalent training in the physical and/or life sciences. Training requirements for NRC license reviewers and inspectors are specified in NRC Inspection Manual, Chapter 1246. The requirements include a combination of classroom requirements and practical on-the-job training. Some NRC regions impose additional requirements on certain license reviewers or inspectors, depending on their individual responsibilities and the types of licenses they review and/or inspect. (c)

Common Performance Indicators (B) (continued)

Common Performance Indicator 3—Technical Staffing and Training (3) (continued)

In addition, the qualification process for NRC materials program inspectors includes demonstration of knowledge of relevant sections of the *Code of Federal Regulations*, completion of a qualifications journal, and appearance before a qualifications board. Although Agreement States need not follow NRC Inspection Manual, Chapter 1246, they should have an equivalent program for training and qualification of personnel, and it should be present and adhered to in Agreement State programs. (d)

The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel. The staff should be afforded opportunities for training that are consistent with the needs of the program, such as attendance at counterpart meetings, university programs, technical workshops, and conventions. (e)

Common Performance Indicator 4—Technical Quality of Licensing Actions (4)

An acceptable program for licensing radioactive material includes: preparation and use of internal licensing guides and policy memoranda to ensure technical quality in the licensing program (when appropriate, NRC guides may be used); pre-licensing inspection of complex facilities; and supervisory review, when appropriate. (a)

This performance indicator evaluates the technical quality of the licensing program, on the basis of an indepth, onsite review of a representative cross-section of licensing actions, including license terminations, decommissioning actions and bankruptcies, and various types of licenses. Technical quality includes not only the review of the application and completed actions, but also an examination of any renewals that have been pending for more than a year because the failure to act on such requests may have health and safety implications. To the extent possible, the onsite review also should capture a representative cross-section as completed by each of the reviewers in the region or State. (b)

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Common Performance Indicators (B) (continued)

Common Performance Indicator 5—Response to Incidents and Allegations (5)

The quality, thoroughness, and timeliness of a regulator's response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. A careful assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup procedures and actions will be a significant indicator of the overall quality of the program.

Non-Common Performance Indicators (C)

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (1)

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses. State statutes should be consistent with Federal statutes, as appropriate. (a)

In accordance with Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," and the current revisions of OSP Procedures, SA-201, "Reviewing State Regulations," and SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," the State shall adopt legally binding requirements, such as regulations and other necessary program elements consistent with the above guidance. (b)

NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule. (c)

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (1) (continued)

Other program elements that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months following NRC designation. (d)

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program[1] (2)

Adequate technical evaluations of sealed source and device (SS&D) designs are essential to ensure that SS&Ds used by both licensees and persons exempt from licensing will maintain their integrity and that the design features are adequate to protect public health and safety. Three sub-elements will be evaluated to determine if the SS&D program is adequate.

- Technical Quality of the Product Evaluation Program (a)

  The technical quality of the product evaluation program, on the basis of an indepth onsite review of a representative cross-section of evaluations performed, includes various types of products and types of actions: (i)

  - Product evaluations should be technically accurate and ensure that proper prototype tests or analyses have been performed and passed for the normal and likely accidental conditions of use and that the safety features of the device are adequate to protect public health and safety. (*a*)

  - Completed registration certificates, and the status of obsolete registration certificates and registration certificates for products having defects or involved in incidents, must be clearly and promptly transmitted among various interested parties. (*b*)

  - Vendors' quality assurance and control programs should be evaluated to ensure that products are built to the same

[1]Agreement States with authority for sealed source and device evaluation programs that are not performing SS&D reviews are requested to commit in writing to having an SS&D evaluation program in place (as described in Section (C)(2) of this part) before performing evaluations.

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (2) (continued)

specifications as those listed on the registration certificate. The commitments made in the registrant's application and referenced in the registration certificate must be enforceable. (*c*)

To the extent possible, the onsite review also should capture a representative cross-section as completed by each of the State reviewers. (ii)

- Technical Staffing and Training (b)

Evaluation of SS&D review staffing and training should be conducted in the same manner and as part of the Common Performance Indicator 3 (Sections (B)(3)(a) and (b) of this part), except with a focus on training commensurate with the conduct of the SS&D reviews. (i)

A staffing review also requires a consideration and evaluation of the levels of training and qualification of the technical staff. Newly hired employees need to be technically qualified. Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Both initial and concurrence reviewers should be able to—(ii)

- Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal, and likely accidental conditions of use (*a*)
- Understand and interpret test results (*b*)
- Read and understand blueprints and drawings (*c*)
- Understand how the device works and how safety features operate (*d*)
- Understand and apply the appropriate regulations (*e*)
- Understand the conditions of use (*f*)
- Understand external dose rates, source activities, and nuclide chemical form (*g*)

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (2) (continued)

- Understand and utilize basic knowledge of engineering materials and their properties (*h*)

- Evaluation of Defects and Incidents Regarding SS&Ds (c)

  Reviews of SS&D incidents should be conducted in the same manner and as part of the Common Performance Indicator 5 (Section (B)(5) of this part) to detect possible manufacturing defects and the root causes of these incidents. The results should be evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications should take place.

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (3)

Five sub-elements will be evaluated to determine if an Agreement State's performance of its low-level radioactive waste disposal program is adequate.

- Status of Low-Level Radioactive Waste Disposal Inspection (a)

  Periodic inspections of low-level radioactive waste disposal facilities, from the pre-operational through the post-closure phase, are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. (i)

  - Inspections during siting and construction phases are essential to ensure the facility is being sited and constructed in accordance with regulatory and license requirements. (*a*)

  - Operational phase inspections are essential for ensuring that disposal activities are being conducted in accordance with license conditions and regulatory requirements. (*b*)

  - Closure and post-closure inspections are essential to ensure activities at closure are being conducted in compliance with the regulatory requirements and the facility is performing as expected. (*c*)

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (3) (continued)

The frequency of inspections for operating low-level radioactive waste disposal facilities is specified in NRC Inspection Manual, Chapter 2800, as yearly. Inspection frequencies for non-operational phase inspections should be established. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program for the low-level radioactive waste disposal program. (ii)

- Technical Quality of Inspections (b)

  This sub-element provides the qualitative balance to sub-element 1 above, which looks at the status of the inspection program on a quantitative basis. Review team members will accompany Agreement State inspectors, including onsite resident inspectors, to evaluate their knowledge and capabilities at low-level radioactive waste disposal facilities during the inspections discussed in sub-element 1 above. These accompaniments will usually occur at a time other than the onsite review of the region or Agreement State. Reviews in this area focus on the scope, completeness, and technical accuracy of inspections and related documentation. Review teams will conduct indepth, onsite reviews of completed inspection reports.

- Technical Staffing and Training (c)

  Evaluation of staffing and training should be conducted in the same manner and as part of the Common Performance Indicator 3 (Sections (B)(3)(a)-(d) of this part), unless the low-level radioactive waste program is organizationally separate from the materials program. The staffing (which can include contractual support or support from other State agencies) should be sufficient to enable the program to complete review of a new application within 15 months, if practicable, per the Low-Level Radioactive Waste Policy Amendments Act. Professional staff should normally have bachelor's degrees or equivalent training in the physical, life or earth sciences, or engineering. Staff and support contractors qualifications, training, and experience also should include the disciplines of health physics, civil or mechanical engineering, geology, hydrology and other earth sciences, and environmental science.

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (3) (continued)

- Technical Quality of Licensing Actions (d)

  An acceptable program for licensing low-level radioactive waste disposal facilities ensures that the proposed waste disposal facilities will meet State licensing requirements for waste product and volume, qualifications of personnel, site characterization, performance assessment, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures, and institutional arrangements in a manner sufficient to establish a basis for licensing action. This may be accomplished through the preparation and use of internal licensing guides, policy memoranda, or use of NRC equivalent guides. Licensing decisions should be adequately documented through safety evaluation reports, or similar documentation, of the license review and approval process. Opportunities for public hearings are provided in accordance with applicable State administrative procedure laws during the process of licensing a low-level radioactive waste disposal facility. Pre-licensing interactions with the applicant should be conducted to ensure clear communication of the regulatory requirements. (i)

  To evaluate the technical quality of the licensing program, a review of a technical aspect of a radioactive waste disposal licensing action (e.g., health physics, hydrology, and structural engineering) will be conducted in addition to an evaluation of the license review process. Technical quality includes not only the review of completed actions, but also an examination of any ongoing requests for licenses or renewals that may have health and safety implications. (ii)

- Response to Incidents and Allegations (e)

  Reviews of low-level radioactive waste program incidents and allegations of safety concerns should be conducted in the same manner and as part of Common Performance Indicator 5 (Sections (B)(3)(a)-(d) of this part), unless the low-level radioactive waste program is organizationally separate from the materials program.

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 4—Uranium Recovery Program (4)

Five sub-elements, as appropriate, will be evaluated to determine if the performance of the Region IV or an Agreement State's uranium recovery program is adequate.

- Status of Uranium Recovery Inspection Program (a)

  Periodic inspections of licensed uranium recovery operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in the NRC Inspection Manual, Chapter 2600, for insitu leach mining facilities, and in Chapter 2801 for conventional uranium and thorium mills. Uranium recovery facilities that are on standby or under decommissioning also should be inspected at that frequency. Inspections should occur more frequently if significant regulatory concerns develop, before major changes are made to operations, or if generic problems are identified. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program for the uranium and thorium program.

- Technical Quality of Inspections (b)

  This sub-element provides the qualitative balance to sub-element 1 above, which looks at the status of the inspection program on a quantitative basis. Review team members will accompany the region and Agreement State inspectors to evaluate their knowledge and capabilities at uranium recovery facilities. These accompaniments will usually occur at a time other than the onsite review of the region or Agreement State. An acceptable program for conducting inspections for radioactive material licenses includes preparation and use of internal inspection guides and policy memoranda to ensure technical quality in the inspection program (when appropriate, NRC guidance may be used). Reviews of this sub-element focus on the scope, completeness, and technical accuracy of completed inspections and related documentation. Review teams will conduct indepth, onsite reviews of completed inspection reports. In addition, review teams will verify that supervisors generally conduct accompaniments of inspectors on an annual basis to provide management quality assurance.

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 4—Uranium Recovery Program (4) (continued)

- Technical Staffing and Training (c)

  Evaluation of staffing and training should be conducted in the same manner and as part of Common Performance Indicator 3 (Sections (B)(3)(a)-(d) of this part), unless the uranium recovery program is organizationally separate from the materials program. Professional staff normally should have bachelor's degrees or equivalent training in the physical sciences, life or earth sciences, or engineering. Staff and support contractors qualifications, training, and experience should include the disciplines of health physics; civil or mechanical engineering; geology, hydrology and other earth sciences; and environmental science.

- Technical Quality of Licensing Actions (d)

  An acceptable program for licensing uranium recovery activities ensures that essential elements of NRC licensing requirements for radiation protection, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualification and assurance, closure and decommissioning procedures, and institutional arrangements are met in a manner sufficient to establish a basis for licensing action. This may be accomplished through the preparation and use of internal licensing guides, policy memoranda or use of NRC equivalent guides to ensure technical quality in the licensing program. Pre-licensing inspection of complex facilities are conducted, when appropriate. (i)

  To evaluate the technical quality of the Agreement State licensing program, an indepth review of an aspect of the uranium recovery license (e.g., radiation protection, hydrology, or geotechnical engineering) will be conducted. Technical quality includes not only the review of completed actions, but also an examination of any ongoing requests and license renewals that may have health and safety implications. Technical quality includes review of the State's compliance with the statutory requirements or prohibitions in Section 274 of the Atomic Energy Act, as amended. (ii)

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 4—Uranium Recovery Program (4) (continued)

- Response to Incidents and Allegations (e)

  Reviews of uranium recovery program incidents and allegations of safety concerns should be conducted in the same manner and as part of Common Performance Indicator 5 (Sections (B)(3)(a)-(d) of this part), unless the uranium recovery program is organizationally separate from the materials program.

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5)

Five sub-elements, as appropriate, will be evaluated to determine if the performance of the regional fuel cycle inspection program is adequate.

- Status of Fuel Cycle Inspection Program (a)

  Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and license commitments, and in an overall safe and adequate manner. (i)

  The appropriate frequencies of inspections for established procedures are discussed in NRC Inspection Manual, Chapter 2600. NRC Inspection Manual, Chapter 2600-04.02, provides the responsible headquarters and regional offices flexibility to adjust the frequencies, focus, and intensiveness of inspections for different functional areas at a licensed facility, taking into account the complexity, risk level, and previous operating history of the facility. These adjustments are generally determined by consensus of headquarters and regional management during the licensee performance review (LPR) process, or in response to significant facility events or conditions between LPRs. (ii)

  The level of resources provided for an inspection also may be adjusted. Unexpected external influences (e.g., turnover of key staff, diversion of staff for augmented inspection team (AIT), incident investigation teams, or other inspections in response to incidents, accretion of new regulatory responsibilities without timely provision of additional resources) may occasionally affect the frequencies with which routine inspections can be conducted,

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) (continued)

or the level of resources available for routine inspections. These influences should be documented and reviewed on a regular basis and integrated into each facility's portion of the fuel cycle master inspection plan. The master inspection plan also should include scheduling of LPRs according to the frequencies specified in NRC Inspection Manual, Chapter 2604. (iii)

Inspection scheduling and planning should consider the resource requirements for both routine and reactive inspection efforts, preparation for and documentation of inspections, and participation in other programmatic duties (e.g., training, licensee performance reviews, licensing support, or participation in or support for enforcement conferences). This planning should permit adequate time for inspectors to complete inspection reports so that the reports can be issued in accordance with the timeliness requirements contained in NRC Inspection Manual, Chapter 0610. Other planning and scheduling factors include concern for unusual impacts on licensees and exchanges of inspection resources between different regions. The established fuel cycle inspection schedule for the region should reflect these considerations. (iv)

Regional management should monitor the region's inspection program to determine that the current program is being implemented in accordance with the requirements of the fuel facility inspection program described in NRC Inspection Manual, Chapter 2600, the documented inspection plan for each facility, and overall regional objectives. There should be a capability for maintaining and readily retrieving (without additional analytical effort) the necessary information for demonstrating the extent to which established inspection program objectives are being met. (v)

There should be a means for maintaining and readily retrieving regional performance information for each facility. This information may reside in inspection reports, correspondence files, the inspection followup system, or the nuclear materials events database (NMED). Where there are several different inspectors inspecting each facility, the region may find it more practical to maintain its own summary information files (e.g., site issues matrices, incident analysis summaries, enforcement histories), to

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) (continued)

assemble the kind of information needed to support the fuel cycle licensee performance review program and to justify any changes in the inspection program for a facility as they occur. (This would prevent the loss of summary information valuable to the LPR, which is normally provided by the inspectors, if they are not available at the time the LPR is conducted.) Such programmatic changes should be documented at the time they are made. LPRs should be conducted in cooperation with headquarters according to the schedule included in the fuel cycle master inspection plan. (vi)

The reviewer should examine specific instances in which established inspection program objectives appear not to be met, and determine if mitigating circumstances may have been documented to offer justification for departures from the established plans. (vii)

- Technical Quality of Inspections (b)

  This sub-element provides the qualitative balance to the sub-element 1 above, which looks at the status of the inspection program on a quantitative basis. (i)

  Reviews of programs under this sub-element focus on the scope, completeness, and technical accuracy of completed inspections and related documentation. The reviewer will conduct indepth, onsite reviews of a cross-section of completed inspection reports, selecting from among those performed by different inspectors, if applicable. The reviewer also may interview the respective inspectors, if available. (ii)

  The reviewer will verify that supervisors accompany inspectors on an annual basis to provide management quality assurance. (iii)

  Inspection efforts should focus on the licensee's performance in ensuring the safety and safeguarding of operations. Inspection reports should reflect this focus by addressing licensee performance issues regarding plant operations posing the greatest safety or safeguards risks and where previous performance issues have been identified as requiring greater attention, consistent with the inspection program previously documented for the facility. (iv)

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) (continued)

Conversely, the results of inspections should be summarized and appropriately documented for later reference (e.g., for support of the licensee performance review program). (v)

Only qualified NRC inspectors are to conduct inspections on their own. When inspector trainees or contractors are included in an inspection visit, at least one qualified NRC inspector should be designated to lead the inspection. In these cases, the qualified inspector should provide guidance to such personnel trainees or contractors to ensure that their activities are appropriate to an NRC inspection. (vi)

- Technical Staffing and Training (c)

The ability to conduct effective inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Fuel cycle inspectors generally require extensive training in specialized technical areas, in addition to meeting academic requirements. This often results in significant time delays before newly hired inspectors can become certified as qualified NRC fuel cycle inspectors. Under certain conditions, staff turnover could have an adverse effect on the implementation of a region's fuel cycle inspection program, and thus could affect public health and safety. For small programs, their viability may depend upon the continued availability of a single individual with skills and experience that would be difficult to replace with another individual. (i)

Plans should be in place to replace the functional capabilities required for each aspect of the program (perhaps by contributions from several different individuals), in case a key inspector becomes unavailable (e.g., cross-training of other staff in the same organization, identification of individuals with required skills and qualifications in other NRC organizations, identification of possible outside contractors with suitable experience or expertise to augment specified types of inspections, if needed). (ii)

Qualitative as well as quantitative measures must be considered; in particular, the reason for apparent trends in staffing must be explored: (iii)

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) (continued)

- Is the rate of turnover or the degree of under-staffing symptomatic of a chronic problem, or is it merely a short-term phenomenon? (*a*)
- Why is turnover high? (*b*)
- Are inspectors being overburdened? (*c*)
- Is high turnover related to a morale problem? (*d*)
- What steps are being taken to address the basic problem? (*e*)
- What impact is high turnover having on other performance indicator sub-elements? (*f*)

Review of staffing also requires a consideration and evaluation of the levels of training and qualification of the technical staff and management. New hires need to be technically qualified. Professional staff normally should have bachelor's degrees or equivalent training in the physical and/or life sciences, or related engineering fields. Training requirements for NRC fuel facility specialist inspectors are specified in NRC Inspection Manual, Chapter 1246. The requirements include a combination of classroom requirements and practical on-the-job training. In addition, the qualification process includes demonstration of knowledge of relevant sections of the *U.S. Code of Federal Regulations*, completion of a qualifications journal, and satisfactory review before a qualifications board. There also are refresher training and retraining requirements, including taking new fuel cycle courses as they are developed. (iv)

The small number of fuel cycle facility inspectors who may need training at any one particular time pose unique challenges to arranging for the proper training of these individuals on a cost-effective basis. The region may have to seek outside training opportunities to provide inspectors with specific safety knowledge needed for unique aspects of their facilities (e.g., heavy duty overhead cranes). (v)

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) (continued)

After an inspector is trained and initially qualified to perform inspections in a specific technical area, providing additional cross-training opportunities for inspectors will increase the ability of the inspection organization to better respond to facility incidents, unexpected staff turnover, or other unusual situations. (vi)

- Response to Incidents and Allegations (d)

The quality, thoroughness, and timeliness of a regulator's response to incidents and allegations can have a direct bearing on public health and safety. (i)

Significant indicators of the overall quality of the fuel cycle facility inspection program will include detailed written procedures for incident response and the maintenance of records and reports of actual incidents, focusing on internal and external coordination, and analytical, investigative, and followup procedures. (ii)

The region should exhibit a readiness to respond, in conjunction with Headquarters, to major incidents that may arise at a facility. This will include a review of preparations in place at the region's incident response center (e.g., identification of individuals with required skills, facility data for use during emergencies, detailed preparations for responding to the highest risk types of incidents postulated for the facility, on the basis of known facility processes and source terms, etc.). (iii)

The region, possibly in coordination with headquarters, should conduct, or participate in, documented followup self-assessments of drills and responses to any major incidents that involved activation of the region's incident response center. (iv)

The region's responses to any allegations involving fuel cycle facilities should be grounded in established inspection procedures and good technical and regulatory analysis to determine if regulations were followed or may be deficient and in need of revision with regard to a significant safety issue brought to light by the allegation. (v)

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Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (6)

Six sub-elements, as appropriate, will be evaluated to determine if the performance of the regional site decommissioning management plan (SDMP) is adequate.

- Quality of SDMP Decommissioning Reviews (a)

  NRC staff reviews and approves planned, significant decommissioning actions at facilities that are listed on the SDMP in advance of decommissioning. Decommissioning plan reviews are conducted in accordance with NRC Inspection Manual, Chapter 2605, current NRC policies, standard review procedures, and other regulatory guidance. Reviews are documented as outlined in Chapter 2605, using environmental assessments, environmental impact statements, safety evaluation reports, checklists, interrogatories, and other written correspondence, as appropriate.

- Financial Assurance for Decommissioning (b)

  Adequate financial assurance for the decommissioning of SDMP sites has been established in accordance with regulatory requirements and applicable guidance. Financial assurance is provided for estimated costs for an independent, third party to perform decommissioning with the objective of releasing the site, unless alternative arrangements have been approved by the regulator. Financial assurance mechanisms are reviewed and maintained to ensure that they would be executable and provide sufficient funding for decommissioning in the event that the licensee liquidates or is otherwise unable to pay for decommissioning.

- Termination Radiological Surveys (c)

  Sufficient radiological surveys are required before license termination and site release, as outlined in NRC Inspection Manual, Chapter 2605, to ensure that residual radioactivity levels comply with release criteria. Licensee survey results are validated through a closeout inspection or confirmatory survey, also outlined in Chapter 2605, given the extent and significance of any residual contamination.

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (6) (continued)

- Inspections (d)

  Decommissioning projects are inspected in accordance with established frequencies and with written inspection procedures to confirm the safety of decommissioning procedures. Inspections are documented and carried out in accordance with NRC Inspection Procedures 87104 and 88104. Inspections focus on safety of licensee procedures, release of effluents to the environment, public and worker exposure, and suitability of decontaminated areas and structures for release.

- Staff Qualifications (e)

  License reviewers and inspectors are qualified through training and experience to review the safety of decommissioning. Qualifications for license reviewers and inspectors are established and reviewed. Staff members are qualified to perform licensing reviews and inspections related to decommissioning through training and documented work experience. Non-qualified staff members are subject to the direct supervision of qualified managers; this supervision is evidenced by concurrence on inspection reports and licensing documentation.

- SDMP Milestones (f)

  The decommissioning milestones summarized in the SDMP are being met. If not, delays are identified and there is a mechanism in place to ensure that any appropriate corrective actions are taken. Policy issues affecting the decommissioning of SDMP sites are being identified. Staff is updating the SDMP database in a timely manner.

Part III
Evaluation Criteria

NRC regions and Agreement States will be evaluated in their ability to conduct effective licensing and inspection programs using the common and non-common performance indicators, described in Part II of this handbook, as appropriate. The evaluation criteria for each performance indicator are given below. These criteria do not represent an exhaustive list of the factors that may be relevant in determining performance. In some cases, there may be additional considerations not listed here that are indicative of a program's performance in a particular area.

Common Performance Indicator 1—Status of Materials Inspection Program (A)

Satisfactory (1)

- Core licensees (those with inspection frequencies of 3 years or less) are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual, Chapter 2800. (a)
- Deviations from these schedules are normally coordinated between working staff and management. Deviations are generally the result of joint decisions that consider the risk of licensee operation, past licensee performance, and the need to temporarily defer the inspection(s) to address more urgent or more critical priorities. (b)
- There is a plan to reschedule any missed or deferred inspections or a basis established for not rescheduling. (c)
- Inspections of new licensees are generally conducted within 6 months of license approval, or in accordance with NRC Inspection Manual, Chapter 2800 Section 04-03, for those new licensees not possessing licensed material. (d)
- A large majority of the inspection findings are communicated to licensees in a timely manner (30 calendar days as specified in NRC Inspection Manual, Chapter 0610-10). (e)

Common Performance Indicator 1—Status of Materials Inspection Program (A) (continued)

Satisfactory With Recommendations for Improvement (2)

- More than 10 percent of the core licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. (a)
- Inspections of new licensees are frequently not conducted within 6 months of license approval. (b)
- Many of the inspection findings are delayed, or not communicated to licensees within 30 days. (c)

Unsatisfactory (3)

- More than 25 percent of the core licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. (a)
- Inspections of new licensees are frequently delayed, as are the inspection findings. (b)

Category N (4)

Special conditions exist that provide adequate justification for withholding a rating. For example, an unforeseen event or emergency with significant health and safety consequences may have required a temporary diversion of resources from the core inspection program. However, these programmatic adjustments are well-thought out, and properly coordinated with Office of Nuclear Material Safety and Safeguards (NMSS) or Agreement State management.

Common Performance Indicator 2—Technical Quality of Inspections (B)

Satisfactory (1)

- Review team members accompanying inspectors combined with an onsite review of a representative cross-section of completed inspection reports indicates inspection findings are usually well-founded and well-documented throughout the assessment. (a)
- A review of inspector field notes or completed reports indicates that most inspections are complete and reviewed promptly by supervisors or management. (b)

Common Performance Indicator 2—Technical Quality of Inspections (B) (continued)

Satisfactory (1) (continued)

- Procedures are in place and normally used to help identify root causes and poor licensee performance. (c)
- In most instances, followup inspections address previously identified open items and/or past violations. (d)
- Inspection findings generally lead to appropriate and prompt regulatory action. (e)
- Supervisors accompany nearly all inspectors on an annual basis. (f)

Satisfactory With Recommendations for Improvement (2)

- Review indicates that some inspections do not address potentially important health and safety concerns or it indicates periodic problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality, and consistency. (a)
- Review indicates that findings in inspection reports and inspection files are, on occasion, not well-founded or well-documented. (b)
- Review does not demonstrate an appropriate level of management review. (c)
- Accompaniment of inspectors by supervisors is performed non systematically. (d)
- Followup actions to inspection findings are often not timely. (e)

Unsatisfactory (3)

- Review indicates that inspections frequently fail to address potentially important health and safety concerns or it indicates chronic problems exist with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency. (a)
- Supervisors infrequently accompany inspectors. (b)
- Followup actions to inspection findings are often not timely and appropriate. (c)

Common Performance Indicator 2—Technical Quality of Inspections (B) (continued)

Category N (4)

Not applicable.

Common Performance Indicator 3—Technical Staffing and Training (C)

Satisfactory (1)

Review indicates implementation of a well-conceived and balanced staffing strategy throughout the assessment period, and demonstrates the qualifications of the technical staff. This is indicated by the presence of most of the following features:

- There is a balance in staffing the licensing and inspection programs. (a)
- There are few, if any, vacancies, especially at the senior-level positions. (b)
- There is prompt management attention and review, such as development of a corrective action plan to address problems in high rates of attrition or positions being vacant for extended periods. (c)
- Qualification criteria for hiring new technical staff are established and are being followed. (Staff would normally be expected to have bachelor's degrees or equivalent training in the physical and/or life sciences. Senior personnel should have additional training and experience in radiation protection commensurate with the types of licenses they issue or inspect.) (d)
- License reviewers and inspectors are trained and qualified in a reasonable time period.[1] (e)
- Management commitment to training is clearly evident. (f)

[1]For the regions, this means there has been, and continues to be, a clear effort to adhere to the requirements and conditions specified in NRC Inspection Manual, Chapter 1246, and the applicable qualifications journals, or to receive equivalent training elsewhere. For the Agreement States, equivalent requirements should be in place and followed.

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Common Performance Indicator 3—Technical Staffing and Training (C) (continued)

Satisfactory With Recommendations for Improvement (2)

Review determines the presence of some of the following conditions:

- Some staff turnover that could adversely upset the balance in staffing the licensing and inspection programs. (a)
- Some vacant positions not readily filled. (b)
- Some evidence of lack of management attention or actions to deal with staffing problems. (c)
- Some of the licensing and inspection personnel not making prompt progress in completing all of the training and qualification requirements. (d)
- The training and qualification standards include areas needing improvement. (e)
- Some of the new staff is hired with little education or experience in physical and/or life sciences, or materials licensing and inspection. (f)

Unsatisfactory (3)

Review determines the presence of chronic or acute problems related to some of the following conditions, which cause concerns about their likely effects on other performance indicators:

- There is significant staff turnover relative to the size of the program. (a)
- Most vacant positions are not filled for extended periods. (b)
- There is little evidence of management attention or actions to deal with staffing problems. (c)
- Most of the licensing and inspection personnel are not promptly completing all of the training and qualification requirements. (d)
- New staff members are hired without having scientific or technical backgrounds that would equip them to receive technical training. (e)

Common Performance Indicator 3—Technical Staffing and Training (C) (continued)

Category N (4)

Special conditions exist that provide justification for withholding a rating. For example, there has been a substantial management effort to deal with staffing problems. NMSS or OSP has been kept informed of the situation, and discernable recent progress is evident.

Common Performance Indicator 4—Technical Quality of Licensing Actions (D)

Satisfactory (1)

- Review of completed licenses and a representative sample of licensing files indicates that license reviews are generally thorough, complete, consistent, and of acceptable technical quality. (a)
- Health and safety issues are properly addressed. (b)
- License reviewers have the proper signature authority for the cases they review independently. (c)
- Special license tie-down conditions are usually stated clearly and are inspectable. (d)
- Deficiency letters clearly state regulatory positions and are used at the proper time. (e)
- Reviews of renewal applications demonstrate thorough analysis of a licensee's inspection and enforcement history. (f)
- Applicable guidance documents are available to reviewers and are followed. (g)

Satisfactory With Recommendations for Improvement (2)

Review indicates that some licensing actions do not fully address health and safety concerns or indicates repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance in licensing actions.

Common Performance Indicator 4—Technical Quality of Licensing Actions (D) (continued)

Unsatisfactory (3)

Review indicates that licensing actions frequently fail to address important health and safety concerns or indicates chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance in licensing actions.

Category N (4)

Not applicable.

Common Performance Indicator 5—Response to Incidents and Allegations (E)

Satisfactory (1)

- Incident response and allegation procedures are in place and followed in nearly all cases. (a)
- Actions taken are appropriate, well coordinated, and timely in most instances. (b)
- Level of effort is usually commensurate with potential health and safety significance of an incident. (c)
- Investigative procedures are appropriate for an incident. (d)
- Corrective (enforcement or other) actions are adequately identified to licensees promptly and appropriate followup measures are taken to ensure prompt compliance. (e)
- Followup inspections are scheduled and completed, if necessary. (f)
- Notification to NMSS, OSP, Incident Response Operations (IRO), and others as appropriate, is usually performed in a timely fashion. (g)

Satisfactory With Recommendations for Improvement (2)

- Incident response and allegation procedures are in place but occasionally not practiced in a detailed fashion. (a)

Common Performance Indicator 5—Response to Incidents and Allegations (E) (continued)

Satisfactory With Recommendations for Improvement (2) (continued)

- Performance is marginal in terms of resolving potential public health and safety issues, but not as well coordinated, complete or timely as would be required under the "Satisfactory" performance standard. (b)
- Infrequent failure to notify NMSS, OSP, IRO, and others, as appropriate, of incidents. (c)

Unsatisfactory (3)

- Review indicates frequent examples of response to incidents or allegations to be incomplete, inappropriate, poorly coordinated, or not timely. As a result, potential health and safety problems persist. (a)
- Failure to notify NMSS, OSP, IRO, and others, as appropriate, of incidents. (b)

Category N (4)

Not applicable.

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (F)

Satisfactory (1)

- State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. (a)
- The statutes authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health and safety. (b)
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses. (c)
- State statutes are consistent with Federal statutes, as appropriate. (d)

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (F) (continued)

Satisfactory (1) (continued)

- The State has existing legally enforceable measures such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety in the regulation of agreement material. (e)

- The State has adopted legal binding requirements, regulations, and other program elements in accordance with Management Directive (MD) 5.9, "Adequacy and Compatibility of Agreement State Programs," and the current revisions of OSP Procedures SA-201, "Reviewing State Regulations," and SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," with only minor discrepancies. (f)

- NRC regulations, that should be adopted by an Agreement State for purposes of compatibility or health and safety, are adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of NRC's final rule. (g)

- Other program elements that have been designated as necessary for maintenance of an adequate and compatible program should be adopted and implemented by an Agreement State within 6 months of such designation by NRC. (h)

Satisfactory With Recommendations for Improvement (2)

- The State has adopted legal binding requirements, regulations, and other program elements in accordance with MD 5.9 and the current revisions of OSP Procedures SA-201 and SA-200 but there are compatibility or health and safety discrepancies that need to be addressed. (a)

- Several NRC regulations that should be adopted by an Agreement State are adopted in a time frame such that the effective date of the State requirement is greater than 3 years after the effective date of NRC's final rule. (b)

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (F) (continued)

Satisfactory With Recommendations for Improvement (2) (continued)

- Several program elements that have been designated as necessary for maintenance of an adequate and compatible program have been adopted and implemented by the Agreement State in a time frame greater than 6 months of such designation by NRC. (c)

Unsatisfactory (3)

- State no longer has statutes that authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. (a)
- The State is not authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses. (b)
- State statutes are in conflict with, or do not sufficiently reflect, scope of Federal statutes. (c)
- The State does not have existing legally enforceable measures such as generally applicable rules, license provisions, or other appropriate measures, necessary to allow the State to ensure adequate protection of public health and safety in the regulation of agreement material. (d)
- The State has not adopted significant legal binding requirements, regulations, and other program elements in accordance with MD 5.9 and the current revisions of OSP Procedures SA-201 and SA-200. (e)
- Most NRC regulations that should be adopted by an Agreement State are consistently adopted in a time frame so that the effective date of the State requirement is significantly greater (many months or years) than 3 years after the effective date of NRC's final rule. (f)
- Most program elements that have been designated "as necessary" for maintenance of an adequate and compatible program have been adopted and implemented by the Agreement States in a time frame significantly greater (many months or years) than 6 months of such designation by NRC. (g)

Non-Common Performance Indicator 1—Legislation and Program Elements Required for Compatibility (F) (continued)

Category N (4)

Not applicable.

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G)

Technical Quality of the Product Evaluation Program (1)

Satisfactory (a)

- Review of a representative sample of SS&D evaluations completed during the review period indicates that product evaluations are thorough, complete, consistent, of acceptable technical quality, and adequately address the integrity of the products in use and likely accidents. (i)
- Health and safety issues are properly addressed. (ii)
- All initial and concurrence reviews[2] are performed by persons having adequate training. (iii)
- All registrations clearly summarize the product evaluation and provide license reviewers with adequate information to license possession and use of the product. (iv)
- Deficiency letters clearly state regulatory positions and are used at the proper time. (v)
- An independent technical review of the application and proposed certificate of registration is performed by a second individual and supports the finding that the product is acceptable for licensing purposes. (It is important to keep in mind that the independent technical reviewer must concur with the initial review.) (vi)
- Applicable guidance documents are followed, unless approval to use alternate procedures is obtained from management. (vii)

[2]A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, and prototype testing), but the concurrence review is not to the same level of detail as the initial review (i.e., it is not necessary to review every page of the applicant's submittal). The concurrence review must be focused on ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices.

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G) (continued)

Technical Quality of the Product Evaluation Program (1) (continued)

- Completed registration certificates, and the status of obsolete registration certificates, are clear and are promptly transmitted to interested parties. (viii)
- Reviewers ensure that registrants have developed and implemented adequate quality assurance and control programs. (ix)
- There is a means for enforcing commitments made by registrants in their applications and referenced in the registration certificates by the program. (x)

Satisfactory With Recommendations for Improvement (b)

- Review indicates that some SS&D evaluations do not fully address important health and safety concerns or indicates repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations, and addressing the integrity of the products. (i)
- Not all registrations clearly summarize the product evaluation and not all provide license reviewers with adequate information to license possession and use of the product. (ii)
- Reviewers do not follow all appropriate guidance documents. (iii)
- The initial and concurrence reviews are not always performed by persons having adequate training. (iv)
- Completed registration certificates, and the status of obsolete registration certificates, are not always clear or are not always promptly transmitted to interested parties. (v)
- Not all product evaluations include an evaluation of proposed quality assurance and control programs. (vi)
- Commitments made by registrants in their applications, and referenced in the registration certificates, cannot be enforced for all registrations. (vii)

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G) (continued)

Technical Quality of the Product Evaluation Program (1) (continued)

Unsatisfactory (c)

- Review indicates that SS&D evaluations frequently fail to address important health and safety concerns or indicates chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality, adherence to existing guidance in product evaluations, and adequately addressing the integrity of the products. (i)
- Registrations often do not clearly summarize the product evaluation and do not provide license reviewers with adequate information to license possession and use of the product. (ii)
- Reviewers often do not follow appropriate guidance documents. (iii)
- The initial and concurrence reviews are often not performed by persons having adequate training. (iv)
- Completed registration certificates, and the status of obsolete registration certificates, are unclear and are not promptly transmitted to interested parties. (v)
- Product evaluations often do not include an evaluation of proposed quality assurance and control programs. (vi)
- Commitments made by registrants in their applications, and referenced in the registration certificates, often cannot be enforced. (vii)
- The review has identified potentially significant health and safety issues linked to a specific product evaluation. (viii)

Category N (d)

Not applicable.

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G) (continued)

Technical Staffing and Training (2)

Satisfactory (a)

The technical review and audit are performed by staff having proper training and qualifications.

Satisfactory with Recommendations for Improvement (b)

Some reviewers do not have the proper qualifications and training.

Unsatisfactory (c)

Technical review of the reviewer's evaluation is either not performed or not performed by management or staff having proper qualifications and training.

Category N (d)

Not applicable.

Evaluation of Defects and Incidents Regarding SS&Ds (3)

Satisfactory (a)

The SS&D evaluation program routinely evaluates the root causes of defects and incidents involving SS&D evaluations and takes appropriate actions, including modifications of SS&D sheets and notification of affected parties and other regulatory authorities.

Satisfactory With Recommendations for Improvement (b)

The SS&D evaluation program does not fully evaluate the root causes of all defects and incidents involving SS&D evaluations, or when performed, the programs do not always take appropriate actions, including notification of interested parties.

Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G) (continued)

Evaluation of Defects and Incidents Regarding SS&Ds (3) (continued)

Unsatisfactory (c)

The SS&D evaluation program does not ensure evaluation of the root causes of defects and incidents involving SS&D evaluations, or if performed, does not ensure appropriate actions are taken, including notification of interested parties.

Category N (d)

Not applicable.

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H)

Status of Low-Level Radioactive Waste Disposal Inspection (1)

Satisfactory (a)

- Low-level radioactive waste disposal licensees are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual, Chapter 2800. (i)
- Deviations from these schedules are normally coordinated between working staff and management. (ii)
- The inspection findings are communicated to licensees in a timely manner (30 calendar days as specified in NRC Inspection Manual, Chapter 0610-10). (iii)
- All nonoperational phase inspections are conducted at the State's prescribed frequency. (iv)

Satisfactory With Recommendations for Improvement (b)

- The licensee is inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequency by more than 25 percent. (i)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Status of Low-Level Radioactive Waste Disposal Inspection (1) (continued)

- All nonoperational phase inspections are conducted at intervals that exceed the State frequencies by more than 25 percent. (ii)
- Some of the inspection findings are delayed, or not communicated to licensees within 30 days. (iii)

Unsatisfactory (c)

- The licensee is inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequency by more than 100 percent. (i)
- Nonoperational phase inspections are conducted at intervals that exceed the State frequencies by more than 100 percent. (ii)
- Inspection findings are frequently delayed. (iii)

Category N (d)

Not applicable.

Technical Quality of Inspections (2)

Satisfactory (a)

- Review team member accompanying inspectors combined with an onsite review of completed inspection files indicate inspection findings are usually well-founded and well-documented throughout the assessment period. (i)
- A review of inspector field notes or completed reports, as appropriate, indicates that most inspections are complete and reviewed promptly by supervisors or management. (ii)
- Procedures are in place and normally used to help identify root causes and poor licensee performance. (iii)
- In most instances, followup inspections address previously identified open items and/or past violations. (iv)

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Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Technical Quality of Inspections Satisfactory (2) (continued)

- Inspection findings generally lead to appropriate and prompt regulatory action. (v)
- Supervisors accompany nearly all inspectors on an annual basis. (vi)

Satisfactory With Recommendations for Improvement (b)

- Review indicates that low-level radioactive waste disposal inspections do not fully address potentially important health and safety concerns or it indicates periodic problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality, and consistency. (i)
- Review indicates that findings in inspection reports and inspection files are, on occasion, not well-founded or well-documented. (ii)
- The review does not demonstrate an appropriate level of management review. (iii)
- Accompaniments of inspectors by supervisors are performed non systematically. (iv)
- Followup actions to inspection findings are often not timely. (v)

Unsatisfactory (c)

- Review indicates that inspections (including construction phase and closure/monitoring phase) frequently fail to address potentially important health and safety concerns or it indicates chronic problems exist with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency. (i)
- Accompaniments of inspectors are infrequently performed. (ii)
- Followup actions to inspection findings are often not timely and appropriate. (iii)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Technical Quality of Inspections Satisfactory (2) (continued)

Category N (d)

Not applicable.

Technical Staffing and Training (3)

Satisfactory (a)

- Review indicates that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate a low-level radioactive waste disposal facility. (i)
- The management has developed and implemented a training program for staff. (ii)
- Staffing trends that could have an adverse impact on the quality of the program are tracked, analyzed, and addressed. (iii)

Satisfactory With Recommendations for Improvement (b)

- There is some staff turnover that could adversely impact the low-level radioactive waste disposal program. (i)
- Some vacant positions are not readily filled. (ii)
- There is some evidence of lack of management attention or action to deal with staffing problems. (iii)
- Some of the licensing and inspection personnel in the low-level radioactive waste disposal program are not making prompt progress in completing all of the training and qualification requirements. (iv)
- The training and qualification standards include areas that could be improved. (v)
- Some of the new staff is hired with little education or experience in physical and/or life sciences; materials licensing and inspection; civil or mechanical engineering; geology, hydrology and other earth sciences; and environmental science. (vi)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Technical Staffing and Training (3) (continued)

Unsatisfactory (c)

- There is significant staff turnover relative to the size of the program. (i)
- Most vacant positions are not filled for extended periods. (ii)
- There is little evidence of management attention or actions to deal with staffing problems. (iii)
- Most of the licensing and inspection personnel are not making prompt progress in completing all of the training and qualification requirements. (iv)
- New staff members are hired without having education or experience in physical and/or life sciences; materials licensing and inspection; civil or mechanical engineering; geology, hydrology and other earth sciences; and environmental science. (v)

Category N (d)

Not applicable.

Technical Quality of Licensing Actions (4)

Satisfactory (a)

- Prelicensing interactions with the applicant are occurring on a regular basis. (i)
- Special license tie-down conditions are usually stated clearly and are inspectable. (ii)
- Deficiency letters clearly state regulatory positions and are used at the proper time. (iii)
- Reviews of amendments and renewal applications demonstrate thorough analysis of a licensee's inspection and enforcement history, if applicable. (iv)
- Applicable guidance documents are available to reviewers in most cases, and are generally followed. (v)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Technical Quality of Licensing Actions (4) (continued)

- Public hearings in accordance to the State administrative laws have occurred. (vi)
- Review of certain technical aspects of the low-level radioactive waste license files indicates that aspect of the license review is generally thorough, complete, consistent, and of acceptable technical quality. (vii)
- Health and safety issues are properly addressed. (viii)
- An evaluation of the license review process indicates that the process is thorough and consistent. (ix)

Satisfactory With Recommendations for Improvement (b)

- Review indicates that some technical aspects of licensing do not fully address health and safety concerns or indicates problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance in licensing actions. (i)
- Some aspects of the public hearings are not consistent with State administrative law or do not address some aspects of the licensing of a low-level radioactive waste disposal facility. (ii)

Unsatisfactory (c)

- Review indicates that technical aspects of the licensing actions frequently fail to address important health and safety concerns or indicates chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance in licensing actions. (i)
- Public hearings are not consistent with State administrative law or fail to address aspects of the licensing of a low-level radioactive waste disposal facility. (ii)

Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) (continued)

Technical Quality of Licensing Actions (4) (continued)

Category N (d)

Not applicable.

Response to Incidents and Allegations (5)

Satisfactory (a)

Meets "Satisfactory" performance for common performance indicator criteria, Section (E)(1) of this part, as applied to the response to incidents and allegations sub-element for the low-level radioactive waste disposal program.

Satisfactory With Recommendations for Improvement (b)

Meets "Satisfactory With Recommendations for Improvement" performance for common performance indicator criteria, Section (E)(2) of this part, as applied to the response to incidents and allegations sub-element for the low-level radioactive waste disposal program.

Unsatisfactory (c)

Meets "Unsatisfactory" performance for common performance indicator criteria, Section (E)(3) of this part, as applied to the response to incidents and allegations sub-element for the low-level radioactive waste disposal program.

Category N (d)

Not applicable.

Non-Common Performance Indicator 4—Uranium Recovery Program (I)

Status of Uranium Recovery Inspection Program (1)

Satisfactory (a)

- Uranium recovery licensees are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual, Chapters 2801 and 2600. (i)
- Deviations are generally the result of decisions that consider the risk of licensee operation, past licensee performance, and the need to temporarily defer the inspection(s) to address more urgent or more critical priorities. (ii)
- There is a plan to reschedule any missed or deferred inspections or a basis established for not rescheduling. (iii)
- Inspection findings are communicated to licensees at the exit briefings and confirmed formally in writing in a timely manner (30 calendar days as specified in NRC Inspection Manual, Chapter 0610-10). (iv)

Satisfactory With Recommendations for Improvement (b)

- The licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2801, frequencies for conventional uranium mills or the NRC Inspection Manual, Chapter 2600, frequencies for insitu leach facilities by more than 25 percent. (i)
- Some of the inspection findings are delayed, or not communicated to licensees within 30 days. (ii)

Unsatisfactory (c)

- The licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2801, frequencies for conventional uranium mills or NRC Inspection Manual, Chapter 2600, frequencies for insitu leach facilities by more than 100 percent. (i)
- Inspections findings are frequently delayed. (ii)

Category N (d)

Not applicable.

Approved: September 12, 1995
(Revised: November 5, 1999)

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Technical Quality of Inspections (2)

Satisfactory (a)

- Review team members accompanying inspectors combined with an onsite review of a representative cross-section of completed inspection files indicate inspection findings are usually well-founded and well-documented throughout the assessment period. (i)
- Licensing history and status are incorporated into the inspection program as demonstrated through accompaniments and procedures in place. (ii)
- A review of inspector field notes or completed reports indicates that most inspections are complete and reviewed promptly by supervisors or management. (iii)
- Procedures are in place and normally used to help identify root causes and poor licensee performance. (iv)
- In most instances, followup inspections address previously identified open items and/or past violations. (v)
- Inspection findings generally lead to appropriate and prompt regulatory action. (iv)
- Supervisors accompany nearly all inspectors on an annual basis. (vii)

Satisfactory With Recommendations for Improvement (b)

- Review indicates that uranium recovery inspections occasionally do not address potentially important health, safety, and environmental concerns or it indicates periodic problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality, and consistency. (i)
- Review indicates that findings in inspection reports and inspection files are, on occasion, not well-founded or well-documented, and the review does not demonstrate an appropriate level of management review. (ii)

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Technical Quality of Inspections (2) (continued)

- Accompaniment of inspectors by supervisors is performed non-systematically. (iii)
- Followup actions to inspection findings are often not timely. (iv)

Unsatisfactory (c)

- Review indicates that uranium recovery inspections frequently fail to address potentially important health, safety, and environmental concerns or it indicates chronic problems exist with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency. (i)
- Accompaniments of inspectors are infrequently performed. (ii)
- Followup actions to inspection findings are often not timely and appropriate. (iii)

Category N (d)

Not applicable.

Technical Staffing and Training (3)

Satisfactory (a)

- Review indicates that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate uranium recovery facilities. (i)
- The management has developed and implemented a training program for staff. (ii)
- Staffing trends that could have an adverse impact on the quality of the program are tracked, analyzed, and addressed. (iii)

Approved: September 12, 1995
(Revised: November 5, 1999)

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Technical Staffing and Training (3) (continued)

Satisfactory With Recommendations for Improvement (b)

- There is some staff turnover, which adversely impacts the uranium recovery program. (i)
- Some vacant positions, necessary for continued program effectiveness, are not readily filled. (ii)
- There is some evidence of lack of management attention or action to deal with staffing problems. (iii)
- Some of the uranium recovery licensing and inspection personnel are not making prompt progress in completing all of the training and qualification requirements. (iv)
- The training and qualification standards include areas that could be improved. (v)
- Some of the new staff are hired with little education or experience in physical and/or life sciences; materials licensing and inspection; civil or mechanical engineering; geology, hydrology and other earth sciences; and environmental science. (vi)

Unsatisfactory (c)

- There is significant staff turnover relative to the size of the program. (i)
- Most vacant positions are not filled for extended periods. (ii)
- There is little evidence of management attention or action to deal with staffing problems. (iii)
- Training program is not in place. (iv)
- Most of the licensing and inspection personnel are not making prompt progress in completing all of the training and qualification requirements. (v)

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Technical Staffing and Training (3) (continued)

- New staff members are hired without having education or experience in physical and/or life sciences; materials licensing and inspection; civil or mechanical engineering; geology, hydrology and other earth sciences; and environmental science. (vi)

Category N (d)

Not applicable.

Technical Quality of Licensing Actions (4)

Satisfactory (a)

- Review of completed licenses and a representative sample of licensing files indicates that license reviews are generally thorough, complete, consistent, and of acceptable technical quality. (i)
- Health, safety, and environmental issues are properly addressed. (ii)
- License reviewers almost always have the proper signature authority for the cases they review. (iii)
- Special license tie-down conditions are usually stated clearly and are inspectable. (iv)
- Deficiency letters clearly state regulatory positions and are used at the proper time. (v)
- Reviews of renewal applications demonstrate thorough analysis of a licensee's inspection and enforcement history. (vi)
- Applicable guidance documents are available to reviewers in most cases, and are generally followed. (vii)

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Technical Quality of Licensing Actions (4) (continued)

Satisfactory With Recommendations for Improvement (b)

Review indicates that some licensing actions do not fully address health, safety, and environmental concerns or indicates repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality and adherence to existing guidance in licensing actions.

Unsatisfactory (c)

Review indicates that licensing actions frequently fail to address important health, safety, and environmental concerns or indicates chronic problems with respect to thoroughness, completeness, consistency, clarity, technical quality and adherence to existing guidance in licensing actions.

Category N (d)

Not applicable.

Response to Incidents and Allegations (5)

Satisfactory (a)

Meets "Satisfactory" performance for common performance indicator criteria, Section (E)(1) of this part, as applied to the response to incidents and allegations sub-element for the uranium recovery program.

Satisfactory With Recommendations for Improvement (b)

Meets "Satisfactory with Recommendations for Improvement" performance for common performance indicator criteria, Section (E)(2) of this part, as applied to the response to incidents and allegations sub-element for the uranium recovery program.

Non-Common Performance Indicator 4—Uranium Recovery Program (I) (continued)

Response to Incidents and Allegations (5) (continued)

Unsatisfactory (c)

Meets "Unsatisfactory" performance for common performance indicator criteria, Section (E)(3) of this part, as applied to the response to incidents and allegations sub-element for the uranium recovery program.

Category N (d)

Not applicable.

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J)

Status of Fuel Cycle Inspection Program (1)

Satisfactory (a)

- Licensee facilities are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual, Chapter 2600, with appropriate documented adjustments to reflect licensee performance and the inherent risk of licensee operations. (i)
  - The schedules for facility inspections are appropriately updated and maintained in the fuel cycle master inspection plan. (*a*)
  - The inspections scheduled for each facility are consistent with the requirements of NRC Inspection Manual, Chapter 2600, with appropriate adjustments. (*b*)
  - There are few differences between the inspections planned and scheduled for the current fiscal year, and the inspection program currently intended for each facility for the fiscal year. (*c*)
  - Changes in the fuel cycle master inspection plan are documented when they occur and generally are the result of joint decisions between management and staff in the regions and headquarters. (*d*)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Status of Fuel Cycle Inspection Program (1) (continued)

- Changes in the region's inspection program for each facility are well-documented and primarily based on the inherent risks of licensee operation, past licensee performance, and the need to address more urgent or more critical priorities or deal with unforeseen resource limitations. (*e*)

- There is evidence that regional management periodically ascertains the status of the inspection program and, when necessary, acts swiftly to resolve problems affecting performance. Management is confident that the existing inspection schedule adequately reflects the region's stated objectives for each facility's inspection program. Management also is aware of the comparison between planned inspections and actual performance of inspections, and is confident that the objectives for each facility's inspection program are being met. (ii)

- There is clear evidence of an ongoing process to reschedule any missed or deferred inspections, and to optimize the ability to meet the stated objectives. (iii)

- The scheduling and performance of inspections optimizes the utilization of inspection resources so that inspectors are permitted sufficient time to prepare for and document inspections. The percentage of time inspectors spend on routine inspections, reactive inspections, preparation and documentation, and other programmatic activities, is close to that originally planned in accordance with stated objectives. Significant departures from what was originally planned, and the reasons for their occurrence, are documented as they become apparent. (iv)

- Inspection findings are communicated to licensees in a timely manner (normally within 30 calendar days, or 45 days for team inspections, as specified in NRC Inspection Manual, Chapter 0610-10, unless there are legitimate documented reasons for delays). (v)

- The region adequately maintains documentation of licensee performance in support of the licensee performance review program. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Status of Fuel Cycle Inspection Program (1) (continued)

Satisfactory With Recommendations for Improvement (b)

- Licensees are inspected at greater intervals than specified in NRC Inspection Manual, Chapter 2600, absent timely written documentation of the intention to do so. (i)
  - Objectives for the inspection of some of the region's facilities are not documented in an inspection plan for each facility, or they are not in sufficient detail to adequately express the inspection requirements for each facility in terms of licensee performance or inherent facility risk. (*a*)
  - The inspections scheduled in the fuel cycle master inspection plan for a facility do not correspond to the objectives previously documented for the facility's inspection program, and the reasons for the discrepancies have not been documented adequately. (*b*)
  - The inspections scheduled in the fuel cycle master inspection plan for one or more facilities do not reflect the requirements contained in NRC Inspection Manual, Chapter 2600, and no timely documentation exists to justify the discrepancies. (*c*)
- Reliable documentation regarding the conduct of the region's inspection program cannot be readily produced, and the region cannot confirm within a reasonable time that the inspection program meets the requirements of NRC Inspection Manual, Chapter 2600, or the objectives previously documented for each facility's inspection program. (ii)
- Regional management is slow to react to problems affecting performance of planned inspections, with the result that the inspections contained in the fuel cycle master inspection program no longer correspond to the inspection direction needed to focus on changes in licensee performance. (iii)
- Some inspectors are under-utilized or over-utilized for routine inspections to the extent that their onsite inspection hours do not correspond to the region's stated objectives for utilization of inspection resources, with no adequate documentation to justify the discrepancies. (iv)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Status of Fuel Cycle Inspection Program (1) (continued)

- Some of the inspection findings are delayed, or not communicated to licensees within 30 days (45 days for team inspections), without adequate documentation of justification or legitimate reasons for such delays or deletions (as in the case of pending escalated enforcement). (v)
- Documentation in support of the observations required to be formulated for the licensee performance review program do not exist, or are not easily located. (vi)

Unsatisfactory (c)

- Licensees are inspected at intervals that frequently exceed the NRC Inspection Manual, Chapter 2600, frequencies, irrespective of licensee performance or facility risk, without adequate documentation or justification for such departures. (i)
- Objectives for each facility's inspection program have not been documented, or do not adequately consider NRC Inspection Manual, Chapter 2600, requirements, licensee performance, or the inherent risk of licensee operations. (ii)
- Management cannot readily demonstrate that the existing regional fuel cycle inspection schedule, in combination with the recent history of completed inspections, support the inspection objectives described in the inspection programs for each facility. (iii)
- Inspections of licensees or communications of the inspection findings are frequently delayed, without adequate documentation or justification. (iv)
- The region does not adequately maintain documentation necessary to document licensee performance in support of the licensee performance review program. (v)
- Observations provided to support the licensee performance review program cannot be supported by existing documentation. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Status of Fuel Cycle Inspection Program (1) (continued)

Category N (d)

Special conditions exist that provide adequate justification for withholding a rating. For example, an unforeseen event or emergency with significant health and safety consequences may have required a temporary diversion of resources from the core inspection program. However, these programmatic adjustments are well-founded and properly coordinated with NMSS management.

Technical Quality of Inspections (2)

Satisfactory (a)

- An onsite review of a representative cross-section of completed inspection files indicates inspection findings are usually well-founded and well-documented throughout the assessment period. (i)
- A review of completed inspection reports indicates that most inspections are complete, consistent with the requirements of NRC Inspection Manual, Chapter 0610, and reviewed promptly by supervisors or management. (ii)
- Inspection efforts focus on the safety or safeguards significance of licensee performance, while maintaining alertness to possible trends and patterns of poor licensee performance. Plant operations addressed and performance areas emphasized correspond closely to the objectives documented for the region's inspection program for the facility. (iii)
- In most instances, followup inspections address previously identified open items and/or past violations. (iv)
- Inspection findings generally lead to prompt and appropriate regulatory action. (v)
- All inspections are conducted or led by qualified NRC inspectors. Contractors and inspector trainees, augmenting inspections, are provided proper guidance by the inspection leader during onsite inspections, resulting in good integration of the efforts of these personnel with those of the other qualified inspectors. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Quality of Inspections (2) (continued)

- Supervisors accompany all inspectors on at least an annual basis, with greater emphasis on the less-experienced inspectors. (vii)

Satisfactory With Recommendations for Improvement (b)

- Review indicates that findings in inspection reports and inspection files are, on occasion, not well-founded or well-documented, or the review demonstrates an inappropriate level of management review. (i)
- Review indicates that some inspections do not address potentially important health and safety concerns, or indicates recurring problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality, or consistency, relative to the requirements specified in NRC Inspection Manual, Chapter 0610. (ii)
- Inspection efforts do not always focus on the safety or safeguards significance of licensee performance. Inspection reports do not attempt to address possible trends or patterns of poor licensee performance. Plant operations addressed and performance areas emphasized do not always correspond closely to the objectives documented in the region's inspection program for the facility. (iii)
- An instance occurs in which a contractor or inspector trainee, augmenting an inspection, is not provided proper guidance by the inspection leader during an onsite inspection, resulting in inappropriate activity by the contractor that is not immediately corrected when discovered. (iv)
- Supervisors do not systematically accompany all inspectors to ensure at least annual frequency, but the more recently hired, inexperienced inspectors are accompanied at least annually. (v)
- Followup actions to inspection findings often are not timely, or not appropriate. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Quality of Inspections (2) (continued)

Unsatisfactory (c)

- Review indicates that inspections frequently fail to address potentially important health and safety concerns, or indicates that chronic problems exist with respect to completeness, adherence to procedures, management review, thoroughness, technical quality and consistency, relative to the requirements specified in NRC Inspection Manual, Chapter 0610. (i)
- Inspection efforts typically do not focus on the safety or safeguards significance of licensee performance. Inspection reports do not attempt to address possible trends or patterns of poor licensee performance. Plant operations addressed and performance areas of emphasis typically bear little correspondence to the objectives documented in the region's inspection program for the facility, or such documentation does not exist. (ii)
- More than one instance occurs in which a contractor, augmenting an inspection, is not provided proper guidance by the inspection leader during an onsite inspection, resulting in inappropriate activity by the contractor that is not immediately corrected when discovered. (iii)
- An inspection is conducted solely by an individual who is not a qualified NRC inspector, or is led by an individual who is not a qualified NRC inspector. (iv)
- Supervisors infrequently accompany inspectors, and accompaniments that are performed fail to involve the more recently hired, less experienced inspectors. (v)
- Followup actions to inspection findings are often not timely or appropriate. (vi)

Category N (d)

Not applicable.

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Staffing and Training (3)

Satisfactory (a)

Review indicates implementation of a well-conceived and balanced staffing strategy throughout the assessment period, and demonstrates the qualifications of the technical staff. This is indicated by the presence of most of the following features:

- Prompt management attention and review to recognize staffing or training problems (e.g., high rates of attrition, positions being vacant for extended periods, lack of adequate training opportunities), and to develop appropriate corrective action plans. (i)
- Qualification criteria for hiring new technical staff have been established and are being followed. Staff would normally be expected to have bachelor's degrees or equivalent training in the physical and/or life sciences. Senior personnel should have additional training and experience beyond their original area of specialization to reflect the broader area of responsibility in their organization. (ii)
- Inspectors are trained and qualified in a reasonable time period, despite difficulties that may be encountered in the availability of training opportunities provided by NRC, or of alternative outside training opportunities determined by the Division of Fuel Cycle Safety and Safeguards (FCSS) to meet requirements specified in NRC Inspection Manual, Chapter 1246. Training plans and schedules for qualification are established, maintained, and personally reviewed by the inspector and management. (iii)[3]
- Management ensures that inspectors avail themselves of opportunities for required training infrequently provided by NRC, or identifies to FCSS alternative outside training opportunities that can be determined by FCSS to meet NRC Inspection Manual, Chapter 1246, requirements, resulting in trainees reaching qualification without undue delays. (iv)

[3]For the regions, this means there has been and continues to be, a clear effort to adhere to the requirements and conditions specified in NRC Inspection Manual, Chapter 1246, and the applicable qualifications journals, or to receive equivalent training elsewhere.

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Staffing and Training (3) (continued)

- Management commitment to training is clearly evident. (v)
- Inspectors are provided cross-training opportunities to develop skills necessary to substitute for or assist other inspectors in functional areas outside their normal assignments. (vi)
- Inspectors are current with regard to required retraining and refresher training. (vii)
- Records are kept to track of how training requirements are satisfied for those requiring training, to provide reminders of when refresher training is due, and to provide reliable and accurate statistics on the status of the training program. (viii)

Satisfactory With Recommendations for Improvement (b)

- Some unanticipated staff turnover has occurred, that could adversely affect the ability of remaining staff to conduct the inspection program, and management has not taken immediate steps to adjust inspection planning accordingly, or begin the process of replacement. (i)
- Some vacant positions have not been readily filled. (ii)
- Some evidence of management attention or actions to deal with staffing problems that may have arisen, but problem still persists. (iii)
- Some of the inspection personnel are not making reasonable progress in completing the training (or retraining) and qualification requirements, despite allowing for difficulties in arranging for NRC Inspection Manual, Chapter 1246, required courses infrequently provided by NRC. (iv)
- Management permits several instances to occur, in which inspectors do not avail themselves of opportunities for required training infrequently provided by NRC, resulting in extensions of the time needed for trainees to reach qualification. (v)
- The region's training and qualification standards do not completely correspond to functional requirements for inspections. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Staffing and Training (3) (continued)

- Minor difficulties arise when attempting to accurately determine the status of training, retraining, and refresher training requirements and accomplishments for those requiring such training. (vii)

- Some of those requiring retraining or refresher training are not current. There is an effort to track and schedule the required training, but there is no documentation to explain why the necessary training has not been provided. (viii)

Unsatisfactory (c)

Review determines the presence of chronic or acute problems related to some of the following conditions, which cause concerns about their likely impacts on other sub-elements of this performance indicator:

- Significant unanticipated staff turnover relative to the size of the program, the causes of which cannot all be attributed to normal attrition. (i)

- Many vacant positions remain unfilled for extended periods. (ii)

- Little evidence is exhibited of management attention or actions to deal with staffing problems found to exist. (iii)

- Many of the inspection personnel have not met their schedules for qualification, or met refresher training requirements, falling short of written plans and schedules to do so. (iv)

- Some opportunities for taking NRC Inspection Manual, Chapter 1246, required training courses infrequently provided by NRC, or alternative outside training opportunities identified by FCSS as meeting such requirements, were not attended by inspectors needing such courses for qualification, contributing to failure of inspector trainees to meet established schedules for qualification. (v)

- New staff members are hired without having adequate scientific or technical backgrounds. (vi)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Technical Staffing and Training (3) (continued)

- Management is unable to determine within a reasonable time the status of training, retraining, and refresher training for those requiring such training. (vii)
- Inadequate or no tracking or scheduling for those requiring retraining or refresher training. (viii)
- Newly hired inspector trainees are not provided sufficient onsite training experience, or they are not provided proper guidance by inspection leaders or supervisors while directly contributing to inspections. (ix)
- Management consistently withdraws inspection personnel from required training activities to participate in other activities, with the result that established schedules for qualification of inspection personnel are not met. (x)

Category N (d)

Special conditions exist that provide justification for withholding a rating. For example, there has been a substantial management effort to deal with staffing problems, or the mission of the organization has changed too rapidly for training programs to adjust. NMSS has been kept informed of the situation, and discernable recent progress is evident.

Response to Incidents and Allegations (4)

Satisfactory (a)

- Incident response and allegation procedures are in place. (i)
- Incident response and allegation procedures are appropriately followed in nearly all cases. Actions taken are well-coordinated with headquarters, as appropriate, and timely in most instances. Level of effort investigating incidents is usually commensurate with potential health and safety significance of incident. (ii)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Response to Incidents and Allegations (4) (continued)

- Corrective (enforcement or other) actions are adequately identified to licensees promptly, and appropriate followup measures are taken, in coordination with headquarters, as appropriate, to ensure prompt compliance and protection of public health and safety. (iii)

- Followup inspections are scheduled, if necessary, and completed within a reasonable time. Notifications to NMSS, IRO, and others, as appropriate, are usually provided in a timely fashion. (iv)

- Preparations for the region's portion of the response to major incidents are appropriate to the types of incidents that may occur at the region's facilities. Sufficient documentation exists to identify individuals with required skills and experience to be summoned to respond in an emergency, and potential regional participants have been trained to respond to worst-case-scenario incidents. (v)

- Procedures are in place to periodically check for completeness of materials needed for emergency response and to occasionally update these materials when circumstances change (e.g., staff turnover, completion of training requirements by staff who would respond, change in processes conducted at facilities, or addition or deletion of a facility). (vi)

- The region's portion of self-assessment activities following a drill or actual event are comprehensive in recognizing problems that arose during the subject activity. Recommendations for improvement arising in self-assessment studies are tracked to ensure further study or implementation. (vii)

- Inspection activity conducted as follow up to receipt of allegations is technically sound and successful in determining the safety implications of the allegations, as appropriate. (viii)

Satisfactory With Recommendations for Improvement (b)

- The regional portions of incident response and allegation procedures are in place, but occasionally are not adhered to in detail. (i)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Response to Incidents and Allegations (4) (continued)

- Resolution of potential public health and safety issues is marginal, with problems in coordination, or timeliness. (ii)

- Preparations for the regional portions of emergency response lag behind changes in circumstances (as described above). Some lapses in training, background, or experience needed to deal with identified types of incidents requiring response, or some types of incidents have been analyzed at the region's facilities but are not recognized in the region's portion of emergency response plans. (iii)

- The region's portion of self-assessment activities following a drill or actual event are shallow in some areas, in not recognizing or further analyzing problems that arose during the subject activity. Some recommendations for improvement in self-assessment studies are not tracked to ensure further study or implementation. (iv)

- The regional portion of inspection activity conducted as follow up to receipt of allegations fails to completely address the safety implications of the allegations. (v)

Unsatisfactory (c)

- Review indicates frequent examples of the regional portion of response to incidents or allegations to be incomplete, inappropriate, poorly coordinated, or not timely. As a result, the identified potential health and safety problems persist. (i)

- Through regional direction, excessive effort is allocated to the investigation of relatively minor safety issues to the detriment of addressing more significant ones. (ii)

- The region has failed to adequately prepare for significant incidents that could occur at its facilities, despite existing documentation or analyses that indicate those incidents could occur. (iii)

- Inspection activity is not conducted as a follow up to receipt of an allegation, though there was a clear need to investigate the safety implications of the allegations. (iv)

Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) (continued)

Response to Incidents and Allegations (4) (continued)

Category N (d)

Not applicable.

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K)

Quality of SDMP Decommissioning Reviews (1)

Satisfactory (a)

Nearly all decommissioning plans are reviewed and the reviews are documented in accordance with NRC Inspection Manual, Chapter 2605.

Satisfactory With Recommendations for Improvement (b)

Most decommissioning plans are reviewed and the reviews are documented in accordance with NRC Inspection Manual, Chapter 2605.

Unsatisfactory (c)

Decommissioning plans are not being consistently reviewed or documented in accordance with NRC Inspection Manual, Chapter 2605.

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more evaluation criteria.

Financial Assurance for Decommissioning (2)

Satisfactory (a)

- For nearly all sites, financial assurance is provided for the estimated costs for an independent, third party to perform decommissioning with the objective of releasing the site. (i)

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

Financial Assurance for Decommissioning (2) (continued)

- For sites where financial assurance has not been provided, alternative arrangements have been approved by the applicable regulators. (ii)
- Financial assurance mechanisms are reviewed and maintained to ensure that they are executable and provide sufficient funding for decommissioning in the event that the licensee liquidates or is otherwise unable to pay for decommissioning. (iii)

Satisfactory With Recommendations for Improvement (b)

- For most sites, financial assurance is provided for the estimated costs for an independent, third party to perform decommissioning with the objective of releasing the site. (i)
- For most sites where financial assurance has not been provided, alternative arrangements have been approved by the applicable regulators. (ii)
- For most sites, financial assurance mechanisms are reviewed and maintained to ensure that they are executable and provide sufficient funding for decommissioning in the event that the licensee liquidates or is otherwise unable to pay for decommissioning. (iii)

Unsatisfactory (c)

- Financial assurance is not consistently provided for the estimated costs for an independent, third party to perform decommissioning with the objective of releasing the site. (i)
- For sites where financial assurance has not been provided, alternative arrangements have not been always approved by the applicable regulators. (ii)
- Financial assurance mechanisms are not being consistently reviewed and maintained to ensure that they would be executable and provide sufficient funding for decommissioning in the event that the licensee liquidates or is otherwise unable to pay for decommissioning. (iii)

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Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

Financial Assurance for Decommissioning (2) (continued)

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more evaluation criteria.

Termination Radiological Surveys (3)

Satisfactory (a)

- For nearly all SDMP sites, sufficient radiological surveys are being performed before license termination and site release, as outlined in NRC Inspection Manual, Chapter 2605, to ensure that residual radioactivity levels comply with release criteria. (i)
- Licensee survey results are routinely validated through a closeout inspection or confirmatory survey, as outlined in NRC Inspection Manual, Chapter 2605, given the extent and significance of any residual contamination. (ii)

Satisfactory With Recommendations for Improvement (b)

- For most SDMP sites, sufficient radiological surveys are being performed before license termination and site release, as outlined in NRC Inspection Manual, Chapter 2605, to ensure that residual radioactivity levels comply with release criteria. (i)
- License survey results are usually validated through a closeout inspection or confirmatory survey, as outlined in NRC Inspection Manual, Chapter 2605, given the extent and significance of any residual contamination. (ii)

Unsatisfactory (c)

Sufficient radiological surveys are not consistently being performed before license termination and site release, as outlined in NRC Inspection Manual, Chapter 2605, to ensure that residual radioactivity levels comply with release criteria. Also, survey results are not normally validated through a closeout inspection or confirmatory survey, given the extent and significance of any residual contamination, as outlined in NRC Inspection Manual, Chapter 2605.

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

Termination Radiological Surveys (3) (continued)

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more evaluation criteria.

Inspections (4)

Satisfactory (a)

- At nearly all SDMP sites, inspections are carried out in accordance with established frequencies. (i)
- SDMP sites are inspected at least once during decommissioning, and at all significant milestones in the decommissioning process, in addition to the closeout inspection before license termination. (ii)
- Inspections are documented and carried out in accordance with NRC Inspection Procedures 87104 and 88104. (iii)

Satisfactory With Recommendations for Improvement (b)

- At most SDMP sites, inspections are carried out in accordance with established frequencies. (i)
- SDMP sites are inspected at least once during decommissioning and at most significant milestones, in addition to the closeout inspection before license termination. (ii)
- At most SDMP sites, inspections are documented and carried out in accordance with NRC Inspection Procedures 87104 and 88104. (iii)

Unsatisfactory (c)

- Inspections are not consistently being carried out in accordance with established frequencies. (i)
- SDMP sites are not inspected at least once during decommissioning or at significant milestones, in addition to the closeout inspection before license termination. (ii)
- Inspections are not consistently being documented and carried out in accordance with NRC Inspection Procedures 87104 and 88104. (iii)

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Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

Inspections (4) (continued)

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more evaluation criteria.

Staff Qualifications (5)

Satisfactory (a)

- Qualifications for license reviewers and inspectors are established and reviewed annually. (i)
- Nearly all staff members are qualified to perform licensing reviews and inspections related to decommissioning through training and documented work experience. (ii)
- Nonqualified staff are subject to the direct supervision of qualified managers; this supervision is evidenced by concurrence on inspection reports and licensing documentation. (iii)

Satisfactory With Recommendations for Improvement (b)

- Qualifications for license reviewers and inspectors are established and reviewed every 2 to 3 years. (i)
- Most staff members are qualified to perform licensing reviews and inspections related to decommissioning through training and documented work experience. (ii)
- Nonqualified staff are usually subject to the direct supervision of qualified managers; this supervision is evidenced by concurrence on inspection reports and licensing documentation. (iii)

Unsatisfactory (c)

- Qualifications for license reviewers and inspectors are not established or if established, these qualifications are not reviewed. (i)
- The majority of staff is not qualified to perform licensing reviews and inspections related to decommissioning through training and documented work experience. (ii)

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

Staff Qualifications (5) (continued)

- Nonqualified staff are not typically subject to direct supervision of qualified managers. (iii)

Category N (d)

- Special conditions exist that provide justification for withholding a rating for one or more of the evaluation criteria.

SDMP Milestones (6)

Satisfactory (a)

- At nearly all SDMP sites, the decommissioning milestones summarized in the SDMP are being met or delays are identified and a mechanism is in place to ensure that any appropriate corrective actions are taken. (i)
- Policy issues affecting decommissioning of SDMP sites are being identified. (ii)
- Staff is updating the SDMP database in a timely manner. (iii)

Satisfactory With Recommendations for Improvement (b)

- For most SDMP sites, the decommissioning milestones summarized in the SDMP are being met or delays are identified and a mechanism is in place to ensure that any appropriate corrective actions are taken. (i)
- Staff routinely identify policy issues affecting the decommissioning of SDMP sites in a timely manner. (ii)
- Staff are updating the SDMP database for most sites in a timely manner. (iii)

Unsatisfactory (c)

- The decommissioning milestones summarized in the SDMP are not routinely being met or delays are not being identified and a mechanism is not in place to ensure that any appropriate corrective actions are taken. (i)

Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) (continued)

SDMP Milestones (6) (continued)

- Policy issues affecting the decommissioning of SDMP sites are not typically being identified in a timely manner. (ii)
- Staff are not routinely updating the SDMP database in a timely manner. (iii)

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more evaluation criteria.

Part IV
Programmatic Assessment

General (A)

A management review board (MRB) will make the overall assessment of each NRC region's or Agreement State's program, on the basis of the proposed final report and recommendations prepared by the team that conducted the review of that region or State, including any unique circumstances. The overall assessment will include a consideration of information provided by the region or State at the MRB meeting. In addition to a recommended overall finding, the proposed final report will contain the team's recommendations for each common indicator and each applicable non-common indicator for both Agreement States and NRC regions. (1)

The MRB will consist of a group of senior NRC managers, or their designees, to include—(2)

- Deputy Executive Director for Materials, Research and State Programs, as Chair (a)
- Director, Office of Nuclear Material Safety and Safeguards (b)
- Director, Office of State Programs (c)
- General Counsel (d)

The Organization of Agreement States also will be invited to specify a representative to serve as a member of each MRB, as a nonvoting Agreement State liaison. In this capacity, the State representative will receive applicable documentation and engage in all MRB discussions. The Agreement State liaison does not have voting authority, since this function is reserved solely to NRC. The Agreement State liaison representative is expected to provide an Agreement State perspective on any matter that is voted on by the MRB. (3)

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General (A) (continued)

For an NRC region, the MRB will assess only the adequacy of the program to protect public health and safety. For an Agreement State program review, the MRB will assess both adequacy and compatibility. (4)

Adequacy Findings for Agreement State Programs (B)

Finding 1—Adequate To Protect Public Health and Safety (1)

- If the MRB finds that a State program is satisfactory for all performance indicators, the State's program will be found adequate to protect public health and safety. (a)

- If the MRB finds that a State program is satisfactory with recommendations for improvement for one or two performance indicators and satisfactory for all remaining performance indicators, the MRB should consider whether the State's program is adequate or adequate but needs improvement. (b)

Finding 2—Adequate But Needs Improvement (2)

- If the MRB finds that a State program is satisfactory with recommendations for improvement for one or two performance indicators and satisfactory for all remaining performance indicators, the MRB should consider whether the State's program is adequate or adequate but needs improvement. (a)

- If the MRB finds that a State program protects public health and safety but is satisfactory with recommendations for improvement for three or more performance indicators and satisfactory for the remaining performance indicators, the MRB should give strong consideration to finding the State's program adequate but needs improvement. (b)

- If the MRB finds that a State program protects public health and safety but is unsatisfactory for one or more performance indicators and satisfactory or satisfactory with recommendations for improvement for the remaining performance indicators, the MRB should give strong consideration to finding the State's program adequate but needs improvement. (c)

Adequacy Findings for Agreement State Programs (B) (continued)

Finding 2—Adequate But Needs Improvement (2) (continued)

- In cases in which previous recommendations associated with indicator findings of adequate but needs improvement have not been completed for a significant period of time beyond the originally scheduled date, the MRB also may find that the program is adequate but needs improvement. (d)

Finding 3—Inadequate To Protect Public Health and Safety (3)

If the MRB finds that a State program is not capable of reasonably ensuring public health and safety for any reason, the MRB will find that the State's program is inadequate to protect public health and safety.

Compatibility Findings for Agreement State Programs (C)

Finding 1—Compatible (1)

If the MRB determines that a State program does not create conflicts, gaps, or disruptive duplication in the collective national effort to regulate materials under the Atomic Energy Act, the program will be found compatible.

Finding 2—Not Compatible (2)

If the MRB determines that a State program creates unnecessary gaps, conflicts, or disruptive duplication in the collective national effort to regulate materials under the Atomic Energy Act, the program will be found not compatible.

Adequacy Findings for NRC Regional Programs (D)

The MRB adequacy findings for regional programs will be the same as those listed above for Agreement States.

Guidance for MRB Determinations for Agreement State Programs (E)

For most Agreement State reviews, no action other than issuance of the final IMPEP report is needed. For those infrequent reviews where additional action is needed, the following alternatives should be considered.

Heightened Oversight (1)

When one or more of the common and non-common performance indicators are found unsatisfactory and are of such safety significance that assurance of the program's ability to protect the public health may be degraded, heightened oversight by the NRC will be considered by the MRB. When strong commitments to improve their program have been made by the Agreement State at the department director management level, the MRB will consider heightened oversight, if the MRB believes the actions by the Agreement State will result in necessary program improvements and the State is capable of implementing those commitments. Heightened oversight could include requests for an Agreement State program improvement plan, periodic Agreement State progress reports, periodic NRC/Agreement State conference calls, and a followup review by the IMPEP team.

Probation (2)

The MRB will consider probation for an Agreement State using the Office of State Programs (OSP) Procedure SA-113, "Placing an Agreement State on Probation," as a reference. Probation is appropriate for MRB consideration when the finding for an Agreement State is adequate but needs improvement or not compatible and any of the following circumstances occur: (a)

- When one or more of the common and non-common performance indicators are found unsatisfactory and are of such safety significance that assurance of the program's ability to protect the public health may be degraded, heightened oversight by the NRC is required, and heightened oversight without a formal declaration of probation may not result in necessary program improvements (i)

Guidance for MRB Determinations for Agreement State Programs (E) (continued)

Probation (2) (continued)

- When previously identified programmatic deficiencies have gone uncorrected for a significant period of time beyond which the corrective actions had been originally scheduled for completion and the NRC is not confident of the State's ability to correct such deficiencies in an expeditious and effective manner without heightened oversight and a formal probation declaration by the NRC (ii)

- When a program has repeatedly been late in adopting required compatibility elements and only heightened oversight by NRC, together with a formal declaration of probation, would yield improvements (iii)

The following are examples of Agreement State program deficiencies for which the MRB would consider probation for an Agreement State. This list is not all inclusive and other Agreement State program deficiencies may require consideration. (b)

- Repeated failure to identify design deficiencies in followup analysis of events or incidents involving sealed sources and devices (i)

- Inability to retain skilled staff resulting in increased backlog in inspections and deficiencies in the technical quality of inspection and licensing programs (ii)

- Inability or difficulty in adopting regulations that could result in significant impacts across State boundaries or allow licensees to be subject to less stringent requirements than the NRC requirements determined to be necessary to satisfy compatibility criteria (iii)

Suspension (3)

The MRB will consider if suspension of an agreement is required to protect public health and safety, or if the State has not complied with one or more of the requirements of Section 274 of the Atomic Energy Act, in accordance with OSP Procedure SA-114 "Suspension of a Section 274b Agreement," when any of the following circumstances occur: (a)

Guidance for MRB Determinations for Agreement State Programs (E) (continued)

Suspension (3) (continued)

- In cases in which the MRB finds that program deficiencies related to either adequacy or compatibility are the kind that require NRC action, the MRB will recommend to the Commission to suspend all or part of its agreement with the State. (i)

- In cases in which the State radiation control program has not complied with one or more requirements of the Atomic Energy Act (i.e., the State program is not compatible with the NRC program and the State has refused or is unable to address those areas previously identified as compatibility concerns) and the noncompatibility is disruptive to the national program conducted by NRC and Agreement States for the regulation of material under the Atomic Energy Act. (ii)

Suspension, rather than termination, will be the preferred option in those cases where the MRB believes that the State has provided evidence that the program deficiencies are temporary and that the State is committed to implementing program improvements. (b)

Termination (4)

The MRB will consider termination for an Agreement State in accordance with OSP Procedure SA-115, "Termination of a Section 274b Agreement," when any of the following circumstances occur: (a)

- The State radiation control program is found to be inadequate to protect public health and safety and no compensating program has been implemented. (i)

- The State has been on probation for a period of time during which it failed to respond to NRC concerns regarding the State's ability to carry out a program to protect public health and safety. (ii)

- The State radiation control program is not compatible with the NRC program and the State has refused, or is unable, to address those areas previously identified as compatibility concerns and the noncompatibility is significantly disruptive to the national program

Guidance for MRB Determinations for Agreement State Programs (E) (continued)

Termination (4) (continued)

among NRC and Agreement States for the regulation of material under the Atomic Energy Act. (iii)

The following are examples of situations in which the MRB will consider recommending initiating formal procedures to terminate an agreement. This list is not all inclusive and other situations may require consideration. (b)

- Significant loss of staff, which includes number of staff or those with critical skills coupled with a State's inability to hire appropriate replacements (i)
- Continual problems that manifest in the State's inability to perform adequate inspections or issue appropriate licenses (ii)
- Inability to adopt compatible program elements over a significant period of time (years) and nationally disruptive regulatory program conflicts, gaps, or duplication exist (iii)
- Continued probationary or suspension status for a State program beyond the period originally envisioned (iv)

Guidance for MRB Determinations for NRC Regional Programs (F)

If significant adequacy-related concerns are identified in a regional materials program by an IMPEP review, the same criteria for an Agreement State determination should be used by the MRB (i.e., that a program is inadequate to protect public health and safety or adequate but needs improvement). Program probation, suspension, and termination are not applicable to regional programs. NRC must implement immediate action to correct regional program deficiencies that are similar to those that would warrant probation, suspension, or termination actions for an Agreement State. A significant weakness that could affect public health and safety or program deficiencies will be addressed by adjustment of priorities and redirection of resources.

Glossary

It is necessary to note that some Agreement States or NRC regions may not define these terms identically. In such cases, the review team will highlight any differences in its review, but draw its conclusions and make its assessments based on the definitions used by that State or region at the time of the review.

Allegation. A declaration, statement, or assertion of impropriety or inadequacy associated with regulated activities, the validity of which has not been established. This term includes all concerns identified by sources such as the media, individuals, or organizations, and technical audit efforts from Federal, State, or local government offices regarding activities at a licensee's site. Excluded from this definition are matters being handled by more formal processes such as 10 CFR 2.206 petitions, hearing boards, appeal boards, and so forth.

Fuel Cycle Inspections. The definition of "Inspections" in 10 CFR 170.3 should be used to determine what constitutes a fuel cycle inspection. The term includes both routinely scheduled and reactive inspections.

Incident. An event or condition that has the possibility of affecting public health and safety such as described in 10 CFR 20.2201 through 20.2204, 30.50, 34.25, 34.30, 35.33, 36.83, 39.77, 40.60, 70.50, 71.97, or the equivalent State regulations.

Materials Inspection. The definitions in 10 CFR 170.3, and in NRC Inspection Manual, Chapter 2800, Sections 03.03 and 07.01, should be used to determine what constitutes an inspection. In addition, Agreement State hand-delivery of new licenses may constitute initial inspections. The term includes both routinely scheduled and reactive inspections.

Materials Licensing Action. Reviews of applications for new byproduct materials licenses, license amendments, renewals, and license terminations.

Glossary (continued)

Overdue Inspections. Currently, NRC defines this term based on guidance in NRC Inspection Manual, Chapter 2800, especially Sections 04.03 (a), and 05.01 through 05.04. Many States use different definitions. For purposes of this directive, a materials license will be considered overdue for inspection in the following cases:

- A new licensee that possesses licensed material has not been inspected within 6 full months of receipt of licensed material, within 6 months of beginning licensed activities, or within 12 months of license issuance, whichever comes first.
- An existing core license is more than 25 percent beyond the interval defined in NRC Inspection Manual, Chapter 2800, Enclosure 1. An existing non-core license is more than 1 year beyond the interval. (An inspection will not be considered overdue if the inspection frequency has been extended in accordance with NRC Inspection Manual, Chapter 2800, Section 05.01, based on good licensee performance.)
- Overdue inspections will not be determined on the basis of any inspection frequencies established by States or regions that are more stringent than those contained in NRC Inspection Manual, Chapter 2800. The frequencies provided in NRC Inspection Manual, Chapter 2800, will generally be used as the yardstick for determining if an inspection is overdue.

QUESTION 4. Have the questions of national policy referred to in the 1962 *Federal Register* notice been resolved? Please provide copies of any documents that support a statement of resolution.

ANSWER.

Almost 40 years of implementation in this area of regulation has demonstrated to the NRC that the jurisdictional framework set out in 10 CFR §150.15 is appropriate for addressing the issues involved. To this extent, we believe that questions concerning NRC's role in the licensing of these activities have been resolved.

QUESTION 5. In 1969, the term "general public" was deleted from 10 CFR 150.15. The rewritten section prohibited transfer of byproduct material to "all other persons exempted" from an NRC license. Did this change reduce or expand the number of persons and/or products covered by the prohibition? Please explain and provide supporting documentation.

ANSWER.

In promulgating §150.15(a)(6) in 1962 (27 FR 1351, February 14, 1962), the Atomic Energy Commission indicated that it was not implementing a "blanket reservation" of authority over the transfer of manufactured products. The Commission stated that "control of the manufacture and transfer of industrial type devices, such as thickness gauges, would be exercised by the Agreement States." [27 FR 1351] The Commission retained control over the transfer of products designed for distribution to the general public. However, in 1969 (34 FR 6517, April 16, 1969), the Commission amended the provision to redefine the category of products covered by §150.15(a)(6) "in view of the increasing difficulty in determining whether or not such products are intended for use by the general public ...." In order to effect this change, the Commission revised the language in §150.15(a)(6) to specify that the reservation of NRC authority applies to transfers of products whose "subsequent possession, use, ... by all other persons are exempted from licensing ...." To the extent to which some products were not considered to be "intended for use by the general public" prior to the rule change, the amendment no doubt expanded the number of products covered by the rule.

QUESTION 6. Byproduct material is defined by statute as "radioactive material (except special nuclear material) that is a byproduct of the process of producing or utilizing special nuclear material." (42 U.S.C. 2014(e).) Under 10 CFR 30.71, technetium-99 is listed as a byproduct material. Since January 1, 1999, has the NRC removed technetium-99 from the byproduct material list? If the answer is in the affirmative, please provide supporting documentation.

ANSWER.

No, technetium-99 has not been removed from the list. Technetium-99 is a byproduct material as defined in NRC's regulations, and is included in 10 CFR 30.71, Schedule B. Therefore, NRC and Agreement States regulate technetium-99.

QUESTION 7. The Department of Energy has 6,000 tons of nickel barrier from its gaseous diffusion plant in Oak Ridge, Tennessee, which contains technetium-99. This contaminated material resulted from the uranium enrichment process undertaken at this plant. Is the technetium a "byproduct of the process of producing or utilizing special nuclear material"? If not, please describe what it is and provide any documentation supporting a different definition.

ANSWER.

Yes, the technetium-99 is a byproduct of the process of producing or utilizing special nuclear material. Therefore, technetium meets the definition of byproduct material in the AEA and 10 CFR 30.4: "... material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material." As you are aware, DOE is for the most part self-regulated, and thus, in most cases, NRC does not have authority over DOE activities.

QUESTION 8. MSC intends to melt the nickel barrier, remove some, but not all, of the technetium-99, and sell the resulting product to whomever wishes to purchase it. Is this nickel a product containing byproduct material as defined by 42 U.S.C. 2014(c) and 10 CFR 30.71?

ANSWER.

The nickel resulting from the MSC process will no doubt contain trace concentrations of byproduct material. However, the nickel ingots are not "products" as the term is used in 10 CFR 30.18(c) (10 CFR 30.18 references 10 CFR 30.71) and 10 CFR 150.15(a)(6). As discussed in the response to Question 3, the term "products" in these references applies to products containing byproduct material which was intentionally introduced into the product to utilize the radioactive, physical, or chemical properties of the byproduct material. The term does not apply to material released for unrestricted use which contains very low levels of radioactive material.

QUESTION 9. In its contract with BNFL, the Department of Energy has described the contaminated nickel as "process equipment" that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. *(See* East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain why recycling and release as scrap metal does not constitute the "transfer" of a product containing byproduct material to exempt persons does not require a license from the NRC under Part 30.3. Please provide supporting documentation.

ANSWER.

As discussed in the response to Question 3, NRC differentiates between commercial distribution of products containing radioactive material which has been intentionally introduced to the products, and release of materials for unrestricted use which happen to contain very low levels of radioactive material. The release of material for unrestricted use is not considered by NRC to be a transfer under 10 CFR 30.3, and either NRC or an Agreement State can authorize licensees to release materials for unrestricted use. As a point of clarification, MSC is not an NRC-licensed facility; rather, it is licensed only by the State of Tennessee.

QUESTION 10. Is it the NRC's understanding that the nickel contaminated with technetium-99 which will be released by MSC into interstate commerce without any restrictions on use may find its way into a host of consumer products, such as tableware, orthodontic braces, caps for baby food jars, cans used for food and beverages, automobiles, intrauterine devices, hip replacement devices, and all other products that incorporate steel and/or of various types?

ANSWER.

Material that is released for unrestricted use can be used for any purpose or in any product including those listed. The criteria approved by Tennessee for authorizing such releases will ensure that the public health would be protected, regardless of use. NRC staff independently calculated potential dose consequences from release of nickel at the levels approved by Tennessee. Our dose analysis is conservative and shows the doses to be comparable to those calculated by MSC, although our analysis considered different pathways, assumptions and exposure groups.

QUESTION 11. As of January 1, 1999, by regulation (published in 10 CFR 150.1 *et seq.*), the NRC has prohibited agreement states from exempting persons from the Commission's licensing and regulatory requirements in 10 CFR Parts 30-40 who carry out the following activity: "The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter." (10 CFR 150.15.) That prohibition is repeated in 10 CFR 30.3. Has there been any regulatory revision of this prohibition since January 1, 1999? Please provide copies of any such revisions.

ANSWER.

No, there have been no revisions to these regulations containing this prohibition (10 CFR 30.3 and 150.15) since January 1, 1999.

QUESTION 12. Article III of the agreement between the NRC and the State of Tennessee incorporates the prohibition cited in 10 CFR 150.15 and 10 CFR 30.3 as a limitation on the State's authority. Has there been any revision of Article III that now allows the State of Tennessee to exempt persons from the Commission's licensing and regulatory requirements under Parts 30 and 40 who are undertaking the activities listed in 10 CFR 150.15? Please provide copies of any such revisions.

ANSWER.

No, there have been no revisions to Article III.

QUESTION 13. The MSC nickel containing the byproduct material appears to be one or more of the following: "equipment, device, commodity, or other product containing source material or byproduct material." (10 CFR 150.15.) Please describe which of the above categories are applicable to the MSC nickel. If it is the NRC's position that none applies, please explain and provide supporting documentation.

ANSWER.

As discussed in the response to Question 3, none of the categories listed in 10 CFR 150.15(a)(6) apply to the MSC nickel. The categories in 10 CFR 150.15 apply to products containing source or byproduct material where the material has been intentionally introduced in order to use its radioactive, physical, or chemical properties. Section 150.15(a)(6) does not apply to material released for unrestricted use which happens to contain very low levels of radioactive material.

QUESTION 14. Under its license amendment, the State of Tennessee has permitted MSC to transfer "possession or control" of metal containing technetium-99 to anyone who wishes to purchase or otherwise use it. Are those persons "exempt from the licensing and regulatory requirements of the Commission under Parts 30 ... of this chapter"? If they are, under what authority does Tennessee issue such a license? If the answer is in the negative, please explain and provide documentation.

ANSWER.

Yes, recipients of the metal containing technetium-99 would be exempt from licensing and regulatory requirements. As discussed in the response to Question 3, such transfers are not within the scope of the authority reserved to NRC in 10 CFR 150.15(a)(6), because MSC has not intentionally introduced the technetium-99 into the metal to take advantage of its properties. Agreement States can, and do routinely, grant authorizations for release of material containing very low levels of radioactive material for unrestricted use.

QUESTION 15. The transfer of byproduct material by NRC licensees to exempt persons is prohibited in 10 CFR 150.15 and 10 CFR 30.3 without certain licenses from the NRC itself. Is it the NRC's position that the sale or transfer of byproduct material by MSC to exempt persons is not covered by these regulations? If so, please explain and provide supporting documentation.

ANSWER.

Yes, as discussed in the response to Question 3, NRC's position is that, for byproduct material, 10 CFR 150.15 applies to transfers of material containing byproduct material which has been intentionally introduced in order to use its radioactive, physical, or chemical properties. It does not apply to authorizations to release material containing very low levels of radioactive material for unrestricted use. Therefore, the release of the material is not a transfer under 10 CFR 30.3.

QUESTION 16.(A). (continued)

QUESTION 16. NRC regulations in 10 CFR 30.14 (c) and (d) requires that anyone introducing any concentration of byproduct material into a "product or material" must have a "specific license issued by an agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction." Persons who put the material in a product "knowing or having reason to know" it will be transferred to exempt persons have a specific prohibition. This appears to cover both MSC and any subsequent purchaser of the MSC nickel who plans to incorporate it into another product or commodity, such as a carload of nickel scrap or steel or nickel products. How does the NRC or the State of Tennessee plan to determine that each one of these processors and manufacturers has a "specific license" to incorporate this material into their products? Please explain and provide supporting documentation.

ANSWER.

The NRC does not consider the MSC license to involve the introduction of byproduct material into a product. As explained in more detail in the response to Question 3, this is because MSC is not intentionally introducing byproduct material into the products to be used for its radioactive, physical, or chemical properties. 10 CFR 30.14(c) and (d) do not apply to the MSC nickel.

MSC will release material which contains very low levels of radioactive material for unrestricted use. Once the material is released for unrestricted use, there are no restrictions on how it is processed or transferred by subsequent recipients of the material. Therefore, it is not necessary for NRC or Tennessee to determine whether recipients of the metal are licensed.

QUESTION 17. 10 CFR 30.14 further limits the introduction of byproduct material in less than exempt concentrations into both industrial and consumer products to those applications in which the byproduct material is used for its radioactive purposes. This can only be done by a holder of an NRC or agreement state license. The byproduct material released by MSC will be inserted into many products by numerous persons. Will it be released only for applications in which it will be used for its radioactive purposes by licensees with "express authorization" in their license to do so? If not, please explain why these regulations do not apply and provide supporting documentation.

ANSWER.

No, the material will not be required to be released only to licensees. As discussed in the response to Questions 3 and 16, this case does not involve introduction of byproduct material into a product to be used for its radioactive, physical or chemical properties. Therefore, 10 CFR 30.14 does not apply. The material may be released for unrestricted use to unlicensed persons.

QUESTION 18. The specific license requirements for the introduction of byproduct material into a product or material - even in exempt concentrations - and the transfer of ownership or possession to an exempt person are governed by 10 CFR 32.11. These requirements are numerous and specifically provide that the material not be incorporated into any product designed for application to a human being. Are these regulations applicable to persons obtaining byproduct material from MSC? If they are not applicable to persons who obtain byproduct material from MSC, please explain why and provide documentation.

ANSWER.

No, 10 CFR 32.11 does not apply to persons receiving material which has been released by MSC for unrestricted use. As discussed in the responses to Questions 16 and 17, the radioactive material is already in the metal, and is not being intentionally introduced by MSC.

QUESTION 19. 10 CFR 32.11 specifically prohibits the introduction of byproduct material into other products that are designed "for application to a human being." Some of the potential uses for the nickel containing byproduct material are earrings, orthodontic braces, hip replacement devices and intra-uterine devices. Are these products designed for application to a human being? If not, please explain why not and provide supporting documentation.

ANSWER.

Yes, these devices are products designed for application to a human being. However, as discussed in the response to Question 16, NRC does not consider MSC to be introducing byproduct material into the products in order to use the material's radioactive, physical, or chemical properties (also see response to Question 8). Therefore, the restrictions in 10 CFR 32.11 do not apply to recipients of material which has been released for unrestricted use by MSC.

QUESTION 20. 10 CFR 32.18 establishes the requirements for obtaining a license to release byproduct material in exempt quantities for commercial distribution to a person without a license. Does MSC's license amendment allow it to release byproduct material in exempt quantities for commercial distribution to a person without a license? If the answer is in the affirmative, please explain and provide supporting documentation.

ANSWER.

No, MSC's license does not allow it to release byproduct material in exempt quantities for commercial distribution. As discussed in the responses to Questions 3, 8, and 9, NRC does not consider the unrestricted release of material containing very low levels of radioactive material to be a commercial distribution under 10 CFR 32.18, because the byproduct material has not been intentionally introduced for use of its radioactive, physical or chemical properties.

QUESTION 21. According to 10 CFR 32.18, prior to transfer from a licensee to a person exempt from licensing, the byproduct material must be in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources or similar substances, be identified as radioactive and to be used for its radioactive properties, cannot be incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

(a) Will the MSC nickel containing byproduct material be in one of the above forms? If so, state which one and provide documentation of that form.

ANSWER.

After the decontamination process takes place, the MSC nickel will have undergone processing which results in some separation of chemical elements, thereby producing processed chemical elements. The process is described in the license amendment request submitted by MSC to Tennessee Department of Environment and Conservation (TDEC). Note, however, that the premise of this question appears to be that the MSC amendment permits a transfer of an otherwise licensable byproduct material to a person exempt from licensing. Contrary to this premise, the MSC amendment does not authorize a transfer to a person exempt from licensing, but rather permits the release for unrestricted use of material containing very low levels of radioactive material.

(b) Will the MSC byproduct material be identified as radioactive? If the answer is in the affirmative, please provide documentation of the labeling requirements or other methods of identification. If the answer is in the negative, please explain why this material is not required to be identified as radioactive and provide supporting documentation.

ANSWER.

No, the MSC license submitted in response to Question 2 authorizes the release of the material for unrestricted use because the concentration of radioactive material present in or on the material being released is so small that it is no longer necessary to subject the material to regulatory control (e.g., further licensing, registration, labeling, or notification) for purposes of protection of the public health and safety. TDEC would not exert, or expect the licensee to exert, any additional specific requirements or controls on the material. This is consistent with NRC's regulatory approach.

(c) Will the MSC byproduct material be used for its radioactive properties? If the answer is in the affirmative, please provide documentation of that use. If the answer is in the negative, please explain why this material is not required to be used for its radioactive properties and provide supporting documentation.

ANSWER.

No, in this case, there is no intent to introduce byproduct material intentionally into a product to take advantage of its properties (e.g., in the operation or use of the product itself, such as use of tritium in self luminous watches, the use of americium-241 in smoke detectors, and the use of carbon-14 in ulcer diagnostic pills). The very low levels of radioactive material are residual and remain with the nickel as a trace contaminant that does not have a significant effect on public health and safety. Moreover, NRC is unaware of any potential use of the MSC nickel that would involve the use of the properties of the trace amounts of radioactive material that it may contain. Accordingly, Tennessee has not required a license because the use of byproduct material in the end product will not be used for its radioactive, physical or chemical properties.

(d) Will the MSC byproduct material be incorporated into a commodity intended for commercial distribution? If the answer is in the negative, please explain and provide supporting documentation.

ANSWER.

Depending on its end use, some or all of the material resulting from MSC's operation may eventually be incorporated into a commodity intended for commercial distribution. However, as discussed in more detail in other responses, the material released by MSC does not fall into the types of products covered by 10 CFR 32.18 and does not constitute a commercial distribution under 10 CFR 32.18.

QUESTION 22. Under 10 CFR 32.18-.19, the applicant must submit, and the NRC approve, prototype labels and brochures for each container of byproduct material which include the following statements: (a) the material is exempt from licensing; (b) the label will bear these specific words: "Radioactive Material -- Not for Human Use -- Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (c) set forth appropriate additional radiation safety precautions and instructions about handling, use, storage, and disposal of the radioactive material.

Does the MSC license amendment permitting release of the DOE nickel contaminated with byproduct material mandate any of these labeling requirements? Please explain your response and provide supporting documentation.

ANSWER.

No. As discussed in the responses to Questions 9 and 20 and the responses referenced therein, the release of material containing very low levels of radioactive material does not constitute commercial distribution of a product or commodity under 10 CFR 32.18. Therefore, the labeling requirements do not apply.

QUESTION 23. As described in the MSC license amendment, does the 6,000 tons of nickel containing byproduct material to be transferred by MSC contain in total more or less than the exempt quantity of technetium listed in 10 CFR 30.71? Please explain and provide supporting documentation.

ANSWER.

The total quantity of technetium released in the entire 6000 tons of nickel would exceed an exempt quantity. The MSC license amendment authorizes release of nickel which contains an average of 3 becquerels (81 picocuries) per gram. Therefore, using the average concentration, the 6,000 metric tons of nickel could contain up to 480,000 microcuries of technetium, which exceeds the exempt quantity of 10 microcuries.

The exempt quantity limits listed in 10 CFR 30.71 are irrelevant in this case, however, because, as stated previously, the material released by MSC does not fall into the types of consumer products covered by 10 CFR 32.18 and does not constitute a commercial distribution under 10 CFR 32.18 for persons exempt pursuant to 30.18.

QUESTION 24. 10 CFR 32.19 requires that no more than 10 individual packages containing exempt quantities of byproduct material shall be contained in an outer package or sold or transferred in a single transaction to an exempt person. Does MSC's license to transfer byproduct material contain that restriction? If not, please explain and provide supporting documentation.

ANSWER.

No, the MSC license does not contain such a restriction. As discussed in the responses to Questions 9 and 20, 10 CFR 32.19 does not apply to the release for unrestricted use of material containing very low levels of radioactive material.

QUESTION 25: Is NRC Regulatory Guide 1.86 -- which the NRC is using to release surface-contaminated metal from decommissioned nuclear power plants - a regulation under the Administrative Procedure Act? What force of law does it have? Please explain and provide supporting documentation.

ANSWER.

Regulatory Guide (RG) 1.86, "Termination of Operating Licenses for Nuclear Reactors," is not a regulation promulgated pursuant to the Administrative Procedure Act (APA). Regulatory Guides are issued to; (1) describe and make available to the public methods acceptable to the NRC staff for implementing the Commission's regulations, (2) delineate techniques used by the staff in evaluating specific problems or postulated accidents, or, (3) provide guidance to applicants, licensees, and regulatory staff. Because Regulatory Guides are issued as guidance and not as regulations, they do not have the force of law. It is noted, however, that a Regulatory Guide does carry the force of law when the licensee has committed to adhere to the Regulatory Guide, and the commitment is included, in whole or in part, in the license of an NRC or Agreement State licensee, or the Regulatory Guide is incorporated in the regulations of an Agreement State Radiation Control program.

QUESTION 26: Regulatory Guide 1.86 cites no statutory or regulatory authority for its implementation, but in its recent issue paper, the NRC stated that Regulatory Guide 1.86 was compliant with the case-by-case reviews for alternative disposal provided for under the Part 20 regulations. (See 64 Fed. Reg. 35090, 35092, 35095, June 30, 1999.) In the AEA and in the NRC's implementing regulations, "disposal" is defined as "isolation" of a radioactive waste. *(See e.g.,* 42 U.S.C. 2021h; 10 CFR 61.2; 62.2; and 110.2.)

Please explain under what authority the NRC classified the unrestricted release of byproduct material into interstate commerce as "disposal" providing "isolation" of radioactive waste under the above-cited statute and regulations. Provide supporting documentation.

ANSWER.

With the exception of 20.2002 and 20.2003 disposals, NRC does not generally consider releases of solid material to be "disposals" authorized under Part 20 or Part 61. However, as recognized by the issues paper published by NRC in June 1999 (64 FR 35090), the releases of solid material authorized under NRC's current practice resemble those disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control. Part 20 does not contain a definition for the term "disposal." While the term "disposal" is defined as involving the isolation of material in the context of licensing requirements for low-level waste disposal facilities licensed under Part 61 and export licensing under Part 110, the general radiation protection standards in Part 20 do not limit the acceptable means of

disposition of material to the concept of isolation. For example, Part 20 allows transfer of material to an authorized (licensed) recipient (§20.2001(a)(1)); release of material as an effluent (§20.2001(a)(3)); and decay in storage with transfer for disposal of material according to its non-radiological properties (§20.2001(a)(2)). In many of these cases, the material disposed of is not subject to any further or continuing regulatory control.

NRC currently addresses the release of solid materials in several contexts. In the reactor context, licensees typically follow a policy that was established by Office of Inspection and Enforcement Circular 81-07 and Information Notice 85-92 (attached). Under this approach, reactor licensees must survey equipment and material before its release. If the surveys indicate the presence of AEA material above natural background levels, then no release may occur. Of course, the fact that no radioactive material above background is detected does not mean that none is present; there are limitations on detection capability. Although NRC imposes no specific approval process for this procedure, the licensees' actions must be generally consistent with the requirements of Part 20 (see e.g., Subpart F of Part 20 (§20.1501)). Once a licensee has conducted appropriate surveys and has not detected AEA material above natural background levels, the solid material in question does not have to be treated as waste under the requirements of Part 20. This approach is consistent with NRC's general authority to regulate material under the AEA as well as the provisions of Part 20. However, this practice has occasionally created problems in the past when new detectors with greater sensitivity are used and low levels of radioactivity are detected in previously released material.

In the non-reactor materials license context, NRC usually authorizes the release of solid material through specific license conditions. One set of criteria that is used to evaluate solid materials before they are released is contained in Regulatory Guide 1.86, entitled "Termination of Operating Licenses for Nuclear Reactors." A similar guidance document is Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both documents contain a table of surface contamination criteria which may be applied by licensees for use in demonstrating that solid material with surface contamination can be safely released with no further regulatory control. These surface contamination criteria are generally incorporated into license conditions and provide acceptable criteria for demonstrating that solid materials with surface contamination can be safely released with no further regulatory control. Although RG 1.86 was originally developed for nuclear power plant licensees, the surface contamination criteria have been used in other contexts for all types of licensees for many years. Of course, by setting out maximum allowable limits for surface contamination, RG 1.86 implicitly reflects the fact that materials with surface contamination below those limits may be released without adverse effects on the public health and safety.

In the case of volumetrically contaminated materials, the NRC has not provided guidance like that found in RG 1.86 for surface contamination. Instead, the NRC has treated these situations on an individual basis, typically by seeking to assure, by an evaluation of doses associated with the proposed release of the material, that the maximum doses are a small percentage of the Part 20 limit for members of the public. In a few instances, licensees have used the specific process set out in §20.2002 to seek approval for the unrestricted release of material. The release of material using the §20.2002 process is consistent with other disposition provisions in

Part 20 that allow for the unrestricted release of material (e.g., §20.2003 and §20.2005). Thus, the standard practice over the years has been to allow the release of material with slight levels of volumetric contamination based on a case-by-case evaluation. In all instances, NRC has sought to assure that the release is protective of public health and safety.

Two examples of case-specific releases with volumetric contamination are 5,000 tons of calcium fluoride with a low enriched uranium activity of about 3 picocuries per gram and 175,280 pounds of calcium fluoride with a natural uranium activity of about 7 picocuries per gram. There would be little or no impact to workers or members of the public from these cases. To put these releases in perspective, EPA encourages the recycling of coal ash, with a natural uranium activity level that may be an order of magnitude or more higher. Fertilizers also contain naturally occurring radioactive material at these or higher levels.

As discussed in the issues paper on this subject, NRC's existing approach to these matters although protective of public health and safety, does not provide a consistent, overall framework to address the case-by-case disposition of solid material in the possession of NRC licensees. The NRC has used the public dose limits in Part 20 (§20.1301) to establish concentration values in Table 2 of Appendix B of Part 20 for radioactivity in gaseous and liquid effluents or discharges that may be released from a nuclear facility to the environment. However, unlike the regulations applicable to gaseous and liquid releases from a licensed nuclear facility, there are currently no generally applicable standards in Part 20 governing releases of solid materials by licensees. NRC is currently exploring the need for a standard in this area. At this time, however, NRC generally addresses the release of solid material on a case-by-case basis using license conditions and existing regulatory guidance. In each case, material may be released

from a licensed operation with the understanding and specific acknowledgment that the material may contain very low levels of radioactive material, but that the concentration of radioactive material is so small that its control through licensing for the protection of public health and safety is no longer necessary. This case-by-case approach is consistent with the Commission's general authority under the AEA to regulate material either through the issuance of specific license conditions or through the promulgation of generally applicable rules (see, e.g., §161b and §81 of the AEA of 1954, as amended). See SEC v. Chenery, 332 U.S. 194, 203 (1947).

The Commission has recently conducted workshops to seek public input on the need for a consistent and generally applicable standard. Until such a standard is promulgated, NRC will continue to follow a case-by-case approach on these issues and will continue to ensure that any action taken by licensees is protective of public health and safety.

Attachments: Office of Inspection and Enforcement
Circular 81-07 and Information Notice 85-92

Q-26

SSINS: 6830
Accession No.:
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IEC 81-07

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

May 14, 1981

IE Circular No. 81-07: CONTROL OF RADIOACTIVELY CONTAMINATED MATERIAL

Description of Circumstances:

Information Notice No. 80-22 described events at nuclear power reactor facilities regarding the release of radioactive contamination to unrestricted areas by trash disposal and sale of scrap material. These releases to unrestricted areas were caused in each case by a breakdown of the contamination control program including inadequate survey techniques, untrained personnel performing surveys, and inappropriate material release limits.

The problems that were described in IE Information Notice No. 80-22 can be corrected by implementing an effective contamination control program through appropriate administrative controls and survey techniques. However, the recurring problems associated with minute levels of contamination have indicated that specific guidance is needed by NRC nuclear power reactor licensees for evaluating potential radioactive contamination and determining appropriate methods of control. This circular provides guidance on the control of radioactive contamination. Because of the limitations of the technical analysis supporting this guidance, this circular is applicable only to nuclear power reactor facilities.

Discussion:

During routine operations, items (e.g., tools and equipment) and materials (e.g., scrap material, paper products, and trash) have the potential of becoming slightly contaminated. Analytical capabilities are available to distinguish very low levels of radioactive contamination from the natural background levels of radioactivity. However, these capabilities are often very elaborate, costly, and time consuming making their use impractical (and unnecessary) for routine operations. Therefore, guidance is needed to establish operational detection levels below which the probability of any remaining, undetected contamination is negligible and can be disregarded when considering the practicality of detecting and controlling such potential contamination and the associated negligible radiation doses to the public. In other words, guidance is needed which will provide reasonable assurance that contaminated materials are properly controlled and disposed of while at the same time providing a practical method for the uncontrolled release of materials from the restricted area. These levels and detection capabilities must be set considering these factors: 1) the practicality of conducting a contamination survey, 2) the potential of leaving minute levels of contamination undetected; and, 3) the potential radiation doses to individuals of the public resulting from potential release of any undetected, uncontrolled contamination.

Studies performed by Sommers[1] have concluded that for discrete particle low-level contamination, about 5000 dpm of beta activity is the minimum level of activity that can be routinely detected under a surface contamination control program using direct survey methods. The indirect method of contamination monitoring (smear survey) provides a method of evaluating removable (loose, surface) contamination at levels below which can be detected by the direct survey method. For smears of a 100cm^2 area (a de facto industry standard), the corresponding detection capability with a thin window detector and a fixed sample geometry is on the order of 1000 dpm (i.e., 1000 dpm/100 cm^2). Therefore, taking into consideration the practicality of conducting surface contamination surveys; contamination control limits should not be set below 5000 dpm/100 cm^2 total and 1000 dpm/ 100 cm^2 removable. The ability to detect minute, discrete particle contamination depends on the activity level, background, instrument time constant, and survey scan speed. A copy of Sommers studies is attached which provides useful guidance on establishing a contamination survey program.

Based on the studies of residual radioactivity limits for decommissioning (NUREG-0613[2] and NUREG-0707[3]), it can be concluded that surfaces uniformly contaminated at levels of 5000 dpm/ 100cm^2 (beta-gamma activity from nuclear power reactors) would result in potential doses that total less than 5 mrem/yr. Therefore, it can be concluded that for the potentially undetected contamination of discrete items and materials at levels below 5000 dpm/100cm^2, the potential dose to any individual will be significantly less than 5mrem/yr even if the accumulation of numerous items contaminated at this level is considered.

Guidance:

Items and material should not be removed from the restricted area until they have been surveyed or evaluated for potential radioactive contamination by a qualified* individual. Personal effects (e.g., notebooks and flash lights) which are hand carried need not be subjected to the qualified individual survey or evaluation, but these items should be subjected to the same survey requirements as the individual possessing the items. Contaminated or radioactive items and materials must be controlled, contained, handled, used, and transferred in accordance with applicable regulations.

The contamination monitoring using portable survey instruments or laboratory measurements should be performed with instrumentation and techniques (survey scanning speed, counting times, background radiation levels) necessary to detect 5000 dpm/100 cm^2 total and 1000 dpm/100 cm^2 removable beta/gamma contamination. Instruments should be calibrated with radiation sources having consistent energy spectrum and instrument response with the radionuclides being measured. If alpha contamination is suspected appropriate surveys and/or laboratory measurements capable of detecting 100 dpm/100 cm^2 fixed and 20 dpm/100 cm^2 removable alpha activity should be performed.

*A qualified individual is defined as a person meeting the radiation protection technician qualifications of Regulatory Guide 1.8, Rev. 1, which endorses ANSI N18.1, 1971.

In evaluating the radioactivity on inaccessible surfaces (e.g., pipes, drain lines, and duct work), measurements at other appropriate access points may be used for evaluating contamination provided the contamination levels at the accessible locations can be demonstrated to be representative of the potential contamination at the inaccessible surfaces. Otherwise, the material should not be released for unrestricted use.

Draft ANSI Standard 13.12[4] provides useful guidance for evaluating radioactive contamination and should be considered when establishing a contamination control and radiation survey program.

No written response to this circular is required. If you have any questions regarding this matter, please contact this office.

REFERENCES

[1]Sommers, J. F., "Sensitivity of Portable Beta-Gamma Survey Instruments," Nuclear Safety, Volume 16, No. 4, July-August 1975.

[2]U.S. Nuclear Regulatory Commission, "Residual Radioactivity Limits for Decommissioning, Draft Report," Office of Standards Development, USNRC NUREG-0613, October 1979.

[3]U.S. Nuclear Regulatory Commission, "A Methodology for Calculating Residual Radioactivity Levels Following Decommissioning," USNRC NUREG-0707, October 1980.

[4]Draft ANSI Standard 13.12, "Control of Radioactive Surface Contamination on Materials, Equipment, and Facilities to be Released for Uncontrolled Use," American National Standards Institute, Inc., New York, NY, August 1978.

Attachments:
1. Reference 1 (Sommers Study)
2. Recently issued IE Circulars

Control and Instrumentation

Edited by E. W. Hagen

Sensitivity of Portable Beta–Gamma Survey Instruments

By J. F. Sommers*

Abstract: *Development of a new generation of portable radiation survey instruments and application of the "as low as practicable" (ALAP) philosophy have presented a problem of compliance with guides for radioactive contamination control. Isolated, low-level, discrete-particle beta-gamma contamination is being detected with the new instruments. To determine the limits of practicability requires, in turn, the determination of the limits of detection of these surface contaminants. The data and calculations included in this article indicate the source detection frequencies that can be expected using the new generation of survey instruments. The author concludes that, in low-population groups of discrete particles, about 5000 dis/min of beta activity per particle is the minimum level of activity per particle which is applicable for confident compliance with surface contamination-control guides. Lower control levels are possible with additional development of instruments or through high-cost changes in radiation survey and contamination-control methods. Additional analyses are required for assessment of the hazard caused by widely dispersed discrete-particle contaminants.*

The common, historical way to classify surface radioactive contamination has developed into standard definitions, limits, and control guides which, in some instances, are difficult, if not impossible, to apply.

In general, the definition of "removable" radioactive contamination must be inferred from guides[1] and regulations[2] on the significance of the quantity of radioactive materials removed. "Fixed" contamination, although not as uniquely defined, is, by inference, the radioactive contaminants that remain on a surface after the surface has been checked and found to have less than some defined removable contamination level. There are many minor variations of these definitions, but these will suffice to outline a major problem that applied health physicists have to verify compliance with radioactive surface contamination limits and guides.

In recent years the lowering of limits and the emphasis on as low as practicable[3] (ALAP) hazard control has encouraged commercial development of more sensitive survey instruments, the big improvement being detectors with thin windows. Peripheral features, such as audible alarms with adjustable set points, external speakers (instead of earphones), and selectable meter time constants, are common. However, the strong commercial competition to supply this type of instrumentation, the extreme competition for funds that could be used to improve radiation protection equipment, and the health physicists' reluctance or inability to provide adequate specifica-

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tions have left something to be desired in quality and overall performance of many of the instruments.

Although present beta–gamma contamination-control practices are more rigorous than in the past, there is still less than complete control of low-activity low-density particulate sources within the operating areas. In a typical situation the highest density of these particles, outside of contamination-control zones, may be on the order of one detectable particle per 10^2 to 10^3 ft^2. The particles are removable beta–gamma activity, but because of the large areas involved, the multiple types of surfaces on which they are deposited, and the low area density of the particles, they are not subject to detection with any sensible frequency using the smear or wipe technique. Thus survey instruments must be used to detect and measure the activity of the removable particles.

The particles tend to be trapped and concentrated on certain types of surfaces, such as mopheads and acrylic fiber rugs. From these deposits it has been determined that the specific activities of most of the particles range from about 2×10^3 to 2×10^4 dis/min. In order to determine why the particles escape detection and control within the operating areas, experimenters devised a rigorous test to determine the expected frequency of detection of the particles using standard survey methods. The results of these experiments have shown that the main hope for improvement lies in the development of more sensitive survey instruments and portal monitors and the development and application of contamination-control methods similar to those used in facilities where the much more hazardous alpha-emitting materials are handled.

THEORY

The ability of a count-rate meter to provide reliable information for detection of small-diameter sources during surveys for radioactive contaminants depends upon a number of factors. These factors, for any given type and energy of radiation sources, are the specific activity of the sources, the influence of background radiation, the instrument time constant, the source–detector geometry, and the relative source–detector velocities. When an alarm set point is used to indicate the presence of radioactive sources, investigation shows that the sensitivity of the instrument is increased by setting the alarm set point as low as possible without causing alarms due to the fluctuations of background; the response of the count-rate meter is modified from the equilibrium count rate when source residence time under the detector is on the same order of magnitude of or less than the time constant of the meter; the count rate of the instrument increases as the source–window distance decreases; and the response of the count-rate meter increases as the source residence time under the detector window increases.

On the basis of the approximate Gaussian distribution of a count rate around the true average count rate, an alarm set point A has a probability p of being reached and causing an alarm due to an average background count rate B during a counting interval T that can be expressed as

$$A = (1 - e^{-T/\tau})(B + k|T^{-1/2} B^{1/2}|) \qquad (1)$$

where τ is the time constant of the count-rate meter and k is a constant that uniquely defines the probability of alarm.[4] The term $1 - e^{-T/\tau}$ (the fraction of equilibrium count rate obtained during T) is limited by design considerations of count-rate meters to the accuracy of the meter output. Most instruments have 1% (of full-scale reading) or larger accuracy limits. For this reason the value of $0.99 = 1 - e^{-T/\tau}$ has been assigned for this study. Knowing the value of τ allows solution for T, and the solution is used in the second term of Eq. 1. This solution can be thought of as the practical, constant, integrating interval observed by the count-rate meter.

The approximate response of an instrument to small-diameter sources can be calculated by defining standard survey conditions and relating them to the response characteristics of the instrument. For these calculations the velocity vector v of a flat circular window of the detector is assumed to be parallel to the surface being surveyed, and the velocity is held constant. The sources passing under the window of the detector bisect the circular projection of the window on the surface. The beta-counting efficiency of the instrument is assumed to be positive and constant when a source resides in the circular projection of the window on the surface; otherwise, the efficiency for counting the source is zero. This latter assumption may cause significant perturbations of experimental data from calculated data when source–window distances are larger than 2.5 cm. Gamma-counting efficiencies, the same order of magnitude as the beta-counting efficiencies, may also cause significant perturbation of experimental results, depending on the detector shielding configuration and effectiveness. The ideal source residence time t is assumed to be equal to the window diameter d divided by the velocity vector v. Under field conditions, t will usually be less than the ideal value

because the source velocity vector will hardly ever exactly bisect the circular window projection on the surface being surveyed.

Using the ideal survey conditions and an average background count rate B, a source with a net equilibrium count rate S will cause a count rate as large as, or larger than, A, with a probability P_i that is uniquely defined by the constant K_i when the source residence time under the window is t and the time-dependent meter response term is $1 - e^{-t/\tau}$. The count rate A can then be expressed as

$$A \leq (1 - e^{-t/\tau})\,(B + S + K_i|t^{-1/2}(B + S)^{1/2}|) \quad (2)$$

By substitution of the alarm set-point count rate A from Eq. 1 into Eq. 2 and rearrangement, the source strength is found to be

$$S \geq \left(\frac{1 - e^{-T/\tau}}{1 - e^{-t/\tau}}\right)(B + k|T^{-1/2}\,B^{1/2}|) - (B + K_i|t^{-1/2}(B + S)^{1/2}|) \quad (3)$$

Analysis of Eq. 3 shows that P_i is the probability, or time-dependent frequency, that S will cause an alarm when K_i is positive, and $(1 - P_i)$ is the probability that the alarm will be actuated when K_i is negative. Solutions for S can be obtained using selected values of K_i, B, τ, t, and T.

METHODS

In order to determine expected alarm-actuation frequencies during standard contamination surveys, experimenters established the following conditions. These conditions would also allow an experimental check of the calculated alarm-actuation probabilities that occur when the source strength, background, instrument time constants, and source residence time are changed.

Commercially available (two manufacturers) portable survey instruments were used as models for the calculations and experiments. Selectable time constants of 0.0159 and 0.159 min were calculated from the manufacturers' quoted time-response characteristics: "90% of the equilibrium count rates in 2.2 or 22 seconds." Survey velocities between 2.4 and 15 cm/sec were selected for analysis, velocities that cause the source residence times under the 5-cm-diameter detector windows to range from 0.33 to 2.1 sec. Cesium-137 sources having small diameter and low backscatter were used experimentally for verification of calculated data; these sources are counted with an efficiency of 0.1 count per beta at ½ in. from the center of 1.7 mg/cm², 5-cm-diameter windows of "pancake"-type semishielded Geiger-Mueller tubes. Extrapolation of the data to other beta emitters is a practical exercise; i.e., from Evans,[5] beta transmission factors through 3.0 mg/cm² (air plus window) were calculated and shown to be greater than 72% for betas with energy spectra having maximum-energy betas (E_{max}) greater than 0.2 MeV. Thus ^{137}Cs betas, with a mean $E_{max} \cong 0.58$ MeV, provide a beta-counting efficiency from the thin-window detectors which is typical of beta emitters with E_{max} greater than 0.2 MeV. Also, background and source size data are presented in counts per minute, so that changes in beta energies of sources and/or source–window distances can be normalized, using observed counting efficiencies, to the calculated data presented in this article.

With some manipulation of Eq. 3, a computer program was used to obtain an iterative set of solutions for S that are accurate to within 1% of the true values. The alarm set points were determined using Eq. 1. Selections of background count rates, relative detector–source velocities, and the instrument time constant were arbitrary but within the ranges chosen for investigation. Values of K_i were chosen to provide known probabilities of alarm actuation.

An extensive set of experimental data was obtained by moving calibrated sources past the detector windows at measured velocities and source–window distances to check the validity of the calculations. The same experimental setup to determine source detection frequencies was used with the audio (speaker) output of the survey meters. The use of audio output during contamination surveys is a well-known practice and will not be described further.

When the experimental and calculated source detection frequencies were compared, it became apparent that the time constants of the commercial survey instruments were not equal to specified values. Variations were noted between instruments of one model and between the different alarm set points on the other model. By measuring the buildup of the indicated count rates to 90% of equilibrium, we were able to determine the actual time constant on the instruments for any particular alarm set point.

The experimental data were obtained on an instrument that exhibited the advertised time constants. However, the poor (time-dependent response) performance of these instruments as a group has caused us to abandon the alarm set-point method for source detection under field conditions.

RESULTS

Alarm set points vs. background count rate were calculated from Eq. 1. These are illustarted in Fig. 1 for time constants of 0.0159 and 0.159 min. The k value selected, 4.89, uniquely defines the probability of an alarm being caused by a constant average background as 5×10^{-7} min^{-1}.

Figure 2 shows that the short-time-constant set point is more sensitive for source detection, even though the long-time-constant set point is the lowest. The relative difference between the two becomes less as the source residence time increases.

Figure 3 illustrates the improved sensitivity to be expected as the source residence time increases (detector velocity decreases). The set point is obtained from Eq. 1 or Fig. 1. Note that with a source residence time of 1 sec (5 cm/sec), it takes 5000 betas/min (500 counts/min) at a background of 60 counts/min to cause an alarm 90% of the time. As a practical illustration, if an individual surveys himself at 10 cm/sec, it will take about 3 min for him to survey half the surface area of his body, and the particles he discovers with a 90% confidence level will have a beta-emission rate of about 9000 per minute (900 counts/min).

Figure 4 illustrates the benefit of selecting low-background areas to perform contamination surveys. As indicated by Eq. 1, the alarm set point has to be changed each time the background changes, and, if the time constant is not dependable (known), the set point may not be correct. Changing background count rates are a common occurrence in our operations, and our inability to make time-constant determinations in the field has caused us to abandon the alarm set-point method for contamination surveys.

Figure 5 shows that the calculational method of determining source detection frequencies using the alarm set point is valid in comparison with experimental data. Both the time constant and the alarm set point were verified on the instrument used. In practice, there would be some ambiguity in the setting of the alarm owing to the crude alarm set-point dial furnished on this model instrument.

Figure 6 compares calculated alarm-actuation frequencies with experimental data on audio-output source detection frequencies at an average background of 120 counts/min and a relative surface–window velocity of 15 cm/sec. Using the speaker output method, smaller sources are detected with the same frequency that is obtained using the alarm set-point method. The improvement is about a factor of 3.

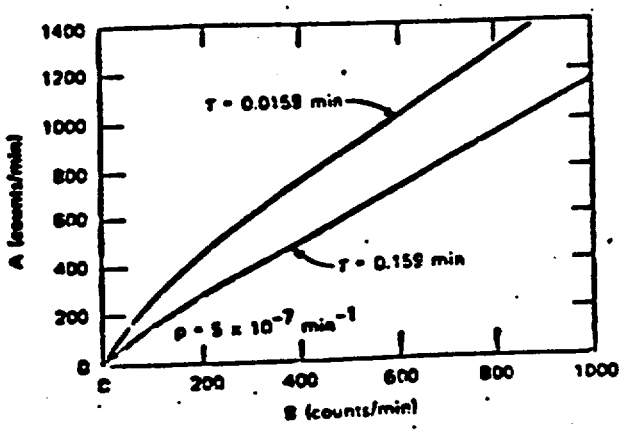

Fig. 1 Effect of background on the optimum alarm set point.

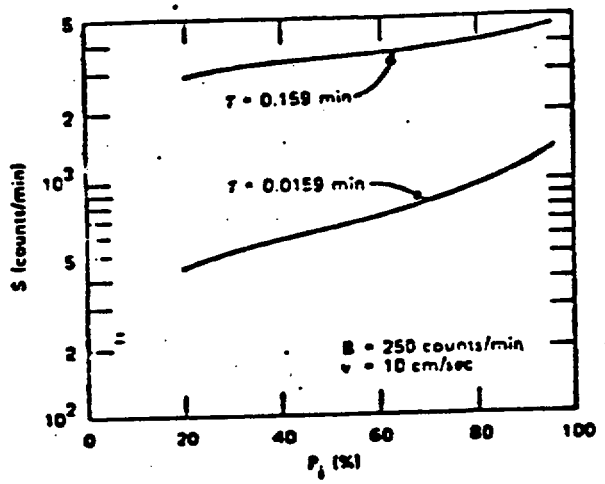

Fig. 2 Effect of instrument time constant on source detection frequency.

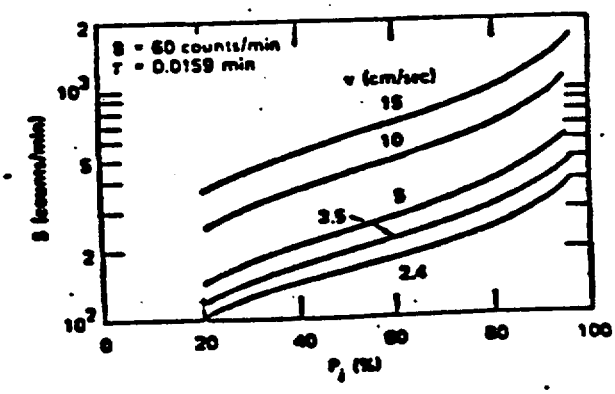

Fig. 3 Effect of probe velocity on source detection frequency.

Figure 7 shows a similar comparison using a detector velocity of 3.5 cm/sec. Here, the difference in detection frequencies narrows, and the alarm set-point method becomes better than the audio detection method for the larger sources at this low survey velocity.

Figure 8 compares experimental audio-output data for three different survey velocities at 120 counts/min background. The difference in source detection frequencies is surprisingly small when compared with the alarm-actuation method. This is explained by the adaptability of the human audio response; i.e., the effective time constant (human) adapts, within bounds, to the source size that can be detected with a given survey velocity and background count rate. Note that at 500 counts/min (5000 betas/min), the source detection frequencies appear to converge at about 80%. The results shown are averages of over 100 observations per datum point from two or more experienced surveyors. The largest variations in the data occurred between individuals; i.e., the largest variables were caused by the physical and psychological conditioning

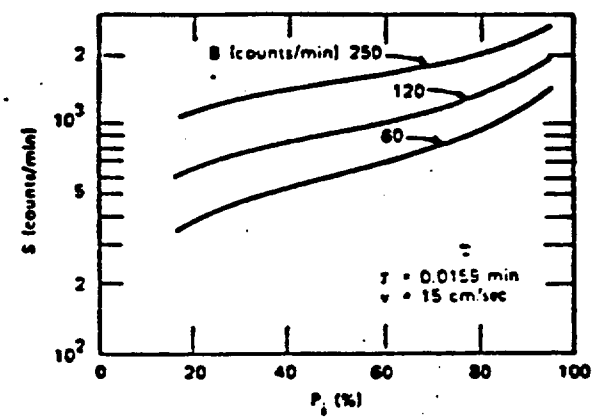

Fig. 4 Effect of background on source alarm-actuation frequency.

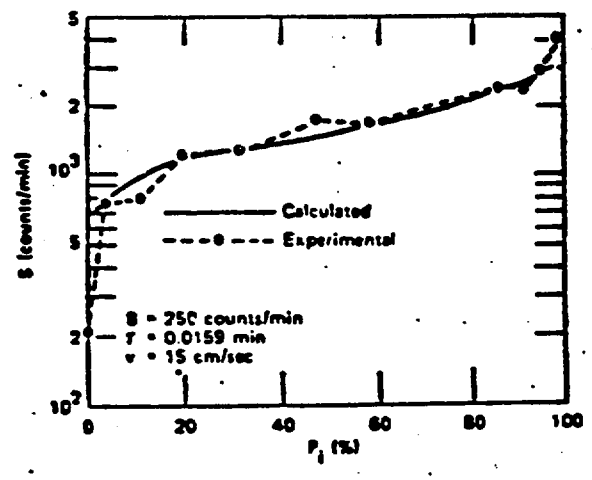

Fig. 5 Comparison of experimental and calculated data on source detection frequencies.

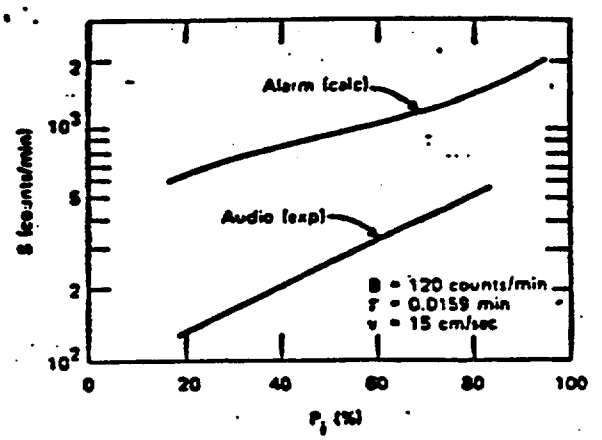

Fig. 6 Comparison of source detection frequencies using alarm set-point and audio detection methods.

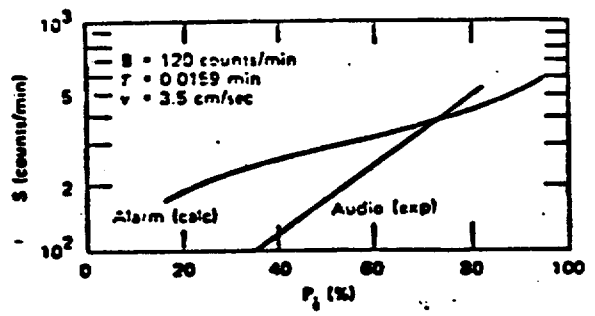

Fig. 7 Comparison of source detection frequencies using alarm and audio detection methods.

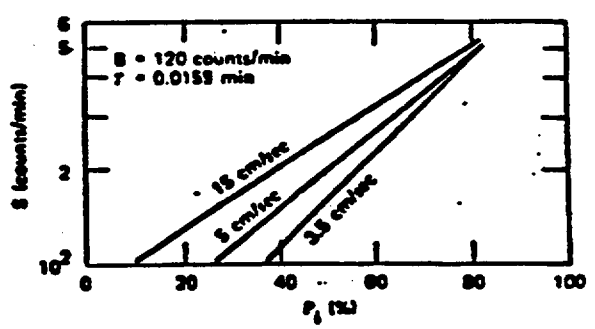

Fig. 8 Comparison of audio source detection frequencies and velocities.

of the surveyors. The lower detection frequencies have been ignored because of the statistical deviations that occurred. The time consumed to obtain reliable data at the higher detection frequencies was considerable, and, as our interest is in setting high-confidence-level control criteria, it was considered not practicable to obtain good, small source, detection-frequency statistics.

DISCUSSION AND CONCLUSIONS

A method has been shown whereby detection frequencies of small-diameter radioactive sources can be calculated for portable survey instruments that have known time constants and alarm set points. Source detection frequencies are strongly dependent upon (1) source strength, (2) survey velocities, (3) background activity, (4) detector sensitivity, and (5) the time constant of the survey meter. With activity of a large-area uniform surface, the survey velocity and the time constant of the survey meter are immaterial (within reasonable bounds). The calculations show that, even under the most rigorous conditions (survey velocities <2.5 cm/sec), small-diameter sources emitting 3000 betas/min can only be detected in low-background areas with a confidence of about 90% using the alarm set-point method. At more sensible survey velocities of 10 to 15 cm/sec, it takes sources emitting 10,000 to 15,000 betas/min to provide the same detection frequency using the alarm set-point detection method.

At the higher probe velocities investigated, source detection frequencies are larger using the audio output rather than the alarm set-point method. With small-diameter sources emitting 5000 betas/min, source detection frequency at 120 counts/min background is about 80% using the speaker output, regardless of the survey velocities between 3.5 to 15 cm/sec. With 3000 beta/min sources, the speaker detection frequency, using the slowest survey velocity (3.5 cm/sec), is only about 65%. At this velocity the alarm set-point method is as good as or better than the audio method with sources larger than 3500 betas/min. Although most of the experimental data were obtained at only one background level (120 counts/min), it is apparent that it is not practical to set contamination-control limits on discrete particles of beta–gamma activity much below 5000 betas/min if we are to have confidence in our ability to detect discrete-particle sources before they escape the contamination-control areas.

These results then pose several problems. Are the particles of beta–gamma activity that escape detection, and thus control, a health hazard of consequence? Krebs[6] and Healy[7] have presented arguments on the relative hazards of discrete-particle and small-area sources in relation to more diffuse sources. However, the data used involved higher specific activity than that of the particles we have been observing. Healy has published[8] a comprehensive resuspension hazards analysis for diffuse contaminants which is difficult to apply to the low-density particle population we observe. Good hazards analyses are needed on the resuspension of discrete particles in the size range under discussion. Development of portable instruments for surveying large areas with a practical expenditure of time and effort appears possible, but it will take time and money to design, develop, and make them commercially available. In the meantime, the advisory, standards, and regulation agencies need to look at the control guides and limits to assure that the conservatism applied using the ALAP philosophy is, in fact, *practicable* for compliance with the equipment and methods available to the industry. For this particular problem (low-density discrete particles of removable beta–gamma activity), I suggest that removable contamination be defined in two categories, "uniform" and "dispersed," and then resuspension factors applied that have some reality in the calculation of exposure hazards. This is the only way at this time that the industry has any hope for practicable compliance with contamination-control limits.

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1. Administrative Guide for Packaging and Transporting Radioactive Materials, ANSI-N14.10.1-1973, p. 7, American National Standards Institute, New York.
2. Department of Transportation, Hazardous Materials Regulations of the Department of Transportation, *Code of Federal Regulations*, Title 49, 173.397, effective Sept. 13, 1973.
3. Concluding Statement of the AEC Regulatory Staff in the "As Low As Practicable" Hearing, *Nucl. Safety*, 15(4): 443-452 (July–August 1974).
4. A. A. Jarrett, Statistical Methods Used in the Measurement of Radioactivity (Some Useful Graphs), USAEC Report AECU-262, 1946.
5. R. D. Evans, *The Atomic Nucleus*, pp. 627-628, McGraw-Hill Book Company, Inc., New York, 1955.
6. J. S. Krebs, The Response of Mammalian Skin to Irradiation with Particles of Reactor Debris, Report USNRDL-TR-67-118, U. S. Naval Radiological Defense Laboratory, September 1967.
7. J. W. Healy, A Proposed Interim Standard for Plutonium in Soils, USAEC Report LA-5483-MS, Appendix C, Los Alamos Scientific Laboratory, January 1974.
8. J. W. Healy, Surface Contamination: Decision Levels, USAEC Report LA-4558-MS, Los Alamos Scientific Laboratory, September 1971.

Attachment 2
IEC 81-07
May 14, 1981

RECENTLY ISSUED IE CIRCULARS

Circular No.	Subject	Date of Issue	Issued to
81-06	Potential Deficiency Affecting Certain Foxboro 20 to 50 Milliampere Transmitters	4/14/81	All power reactor facilities with an OL or CP
81-05	Self-Aligning Rod End Bushings for Pipe Supports	3/31/81	All power reactor facilities with an OL or CP
81-04	The Role of Shift Technical Advisors and Importance of Reporting Operational Events	4/30/81	All power reactor facilities with an OL or CP
81-03	Inoperable Seismic Monitoring Instrumentation	3/2/81	All power reactor facilities with an OL or CP
81-02	Performance of NRC-Licensed Individuals While on Duty	2/9/81	All power reactor facilities (research & test) with an OL or CP
81-01	Design Problems Involving Indicating Pushbutton Switches Manufactured by Honeywell Incorporated	1/23/81	All power reactor facilities with an OL or CP
80-25	Case Histories of Radiography Events	12/5/80	All radiography licensees
80-24	AECL Teletherapy Unit Malfunction	12/2/80	All teletherapy licensees
80-23	Potential Defects in Beloit Power Systems Emergency Generators	10/31/80	All power reactor facilities with OL or a CP
80-22	Confirmation of Employee Qualifications	10/2/80	All holders of a power reactor OL or CP architect-engineering companies and nuclear steam system suppliers

OL = Operating Licenses
CP = Construction Permit

SSIN No.: 6835
IN 85-92

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, D.C. 20555

December 2, 1985

IE INFORMATION NOTICE NO. 85-92: SURVEYS OF WASTES BEFORE DISPOSAL FROM NUCLEAR REACTOR FACILITIES

Addressees:

All production and utilization facilities, including nuclear power reactors and research and test reactors, holding an operating license (OL) or construction permit (CP).

Purpose:

The purpose of this information notice is to supplement the guidance of IE Circular 81-07 as it applies to surveys of solid waste materials before disposal from nuclear reactor facilities. It is expected that recipients will review the information for applicability to their facilities. However, this information notice does not constitute NRC requirements; therefore, no specific action or licensee response is required.

Description of Circumstance:

Some questions have arisen concerning appropriate methods of surveying solid waste materials for surface contamination before releasing them as nonradioactive (i.e., as wastes that do not contain NRC-licensed material).

Discussion:

The need to minimize the volume of radioactive waste generated and shipped to commercial waste burial sites is recognized by the NRC and industry. Some nuclear power plants have initiated programs to segregate waste generated in radiologically controlled areas. Such programs can contribute to the reduction in volume of radioactive waste; however, care should be taken to ensure that no licensed radioactive material is released contrary to the provisions of 10 CFR Section 20.301. In practice, no radioactive (licensed) material means no detectable radioactive material.

In 1981, IE Circular 81-07 was issued by the NRC. That circular provided guidance on the control of radioactively contaminated material and identified the extent to which licensees should survey for contamination. It did not establish release limits. The criteria in the circular that addressed surface contamination levels were based on the best information available at the time and were related to the detection capability of portable survey instruments

equipped with thin-window "pancake" Geiger-Mueller (G.M.) probes, which respond primarily to beta radiation. Monitoring of aggregated, packaged material was not addressed. In 1981, there was no major emphasis on segregating waste from designated contamination areas. As a consequence, large volumes of monitored wastes were not being released for unrestricted disposal. However, because of recent emphasis on minimizing the volume of radioactive waste, current practices at many nuclear power facilities result in large volumes of segregated, monitored wastes, containing large total surface areas, being released as "clean" waste.

When scanning surfaces with a hand-held pancake probe, there is a chance that some contamination will not be detected. (See the papers by Sommers,[1] for example.) There is the chance also that the total surface area will not be scanned completely. Thus, when numerous items of "clean" material (e.g., paper and plastic items) are combined, the accumulation of small amounts of contamination that have escaped detection with the pancake probe may be detected using a detector that is sensitive to gamma radiation (e.g., by using a sensitive scintillation detector in a low-background area). Such measurements of packaged clean waste before disposal can reduce the likelihood that contaminated waste will be disposed of as clean waste, then found to be contaminated after disposal. (Some operators of sanitary landfills have begun to survey incoming waste for radioactivity using scintillation survey meters which in some cases are supplemented by portable gamma-ray spectrometers.[2])

In order to preclude the unintentional release of radioactive materials, a good monitoring program like would include the following:

1. Careful surveys, using methods (equipment and techniques) for detecting very low levels of radioactivity, are made of materials that may be contaminated and that are to be disposed of as clean waste. These survey methods should provide licensees with reasonable assurance that licensed material is not being released from their control.

2. Surveys conducted with portable survey instruments using pancake G.M. probes are generally more appropriate for small items and small areas because of the loss of detection sensitivity created by moving the probe and the difficulties in completely scanning large areas. This does not preclude their use for larger items and areas, if supplemented by other survey equipment or techniques.

3. Final measurements of each package (e.g., bag or drum) of aggregated wastes are performed to ensure that there has not been an accumulation of licensed material resulting from a buildup of multiple, nondetectable quantities (e.g., final measurements using sensitive scintillation detectors in low-background areas).

The foregoing does not constitute NRC requirements; therefore, no specific action or written response is required by this information notice. If you have any questions about this matter, please contact the Regional Administrator of the appropriate NRC regional office or this office.

Edward L. Jordan, Director
Division of Emergency Preparedness
and Engineering Response
Office of Inspection and Enforcement

Technical Contacts: John D. Buchanan, IE
(301) 492-9657

LeMoine J. Cunningham, IE
(301) 492-9664

Attachments:
1. References
2. List of Recently Issued IE Information Notices

REFERENCES

[1] Sommers, J. F., (a) "Sensitivity of Portable Beta-Gamma Survey Instruments," Nuclear Safety 16 (No. 4), 452-457, July - August 1975, (b) "Sensitivity of GM and Ion-Chamber Beta-Gamma Survey Instruments," Health Physics 28 (No. 6), pp. 775-761, June 1975.

[2] Anonymous, "LA Nuclear Medicine Community Improves Radiation Monitoring at Landfills, " J. Nuclear Medicine 26 (#4), 336-337, April 1985.

QUESTION 27: Is the MSC facility an NRC licensee undergoing decommissioning?

ANSWER.

No. The MSC facility is licensed by the State of Tennessee, an Agreement State and, based on information provided by Tennessee, is an active licensee. MSC is not an NRC licensee undergoing decommissioning.

QUESTION 28: In 1986, the Congress ordered the NRC to "identify methods of the disposal of low-level radioactive waste other than shallow land burial, and establish and publish technical guidance regarding licensing" of those facilities. Technical requirements for those methods are outlined in the statute. They include "site suitability, site design, facility operation, disposal site closure, and environmental monitoring as necessary to meet the performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility." (42 U.S.C. 2021 h.) (Emphasis added.)

Please explain how the unrestricted release of byproduct material into interstate commerce as an alternative method of disposal meets the "performance objectives established by the Commission for a licensed low-level radioactive waste disposal facility" and provide supporting documentation.

ANSWER.

As discussed in the cover letter and the response to Question 26, NRC does not generally consider releases of very low levels of byproduct material to be "disposals." Therefore, such releases are not subject to, or required to meet, the performance objectives for a licensed low-level radioactive waste disposal facility.

QUESTION 29: The resulting NRC report on alternative methods of disposal was published in December 1986. Entitled "Licensing of Alternative Methods of Disposal of Low-Level Radioactive Waste"(NUREG- 1241), the study began by stating that all "siting, design, operations, closure, and the monitoring criteria" of Subpart D (Technical Requirements for Land Disposal Facilities) of 10 CFR 61 (Licensing Requirements for Land Disposal of Radioactive Waste) should apply. Subpart D limits off-site releases of radioactive material to those which is released "to the general environment in ground water, surface water, air, soil, plants, or animals." (*See* 10 CFR 61.41.)

Please explain how the unrestricted release of byproduct material into interstate commerce is an alternative method of disposal limiting off-site release of radioactive material to those contained "in ground water, surface water, air, soil, plants, or animals." Provide supporting documentation.

ANSWER.

As discussed in the cover letter and responses to Questions 26 and 28, NRC generally does not consider releases of byproduct material to be "disposals" authorized under 10 CFR Part 61. Therefore, the technical requirements in Subpart D of this Part do not apply. In addition, as recognized by the issues paper on the release of solid materials published by NRC (64 FR 35090, June 30, 1999), the release of solid material authorized under NRC's current practice

resembles disposition methods specifically listed in Part 20 that allow for the unrestricted release of material from a licensee's control (e.g., §20.2003 and §20.2005).

QUESTION 30: 10 CFR 20.2002 allows the NRC only to license alternative forms of "waste disposal." Please explain how unrestricted release qualifies as an alternative form of waste disposal, based on definition in the statute, regulations and NRC report cited in the previous questions. Provide supporting documentation.

ANSWER.

In a few instances licensees have used the specific process set out in §20.2002 to seek approval for the disposition of material in a manner not specifically enumerated elsewhere in Part 20. The disposition of material under the §20.2002 process through release is consistent with other disposition provisions in Part 20 that allow for the unrestricted release of material (e.g., §20.2005). Because 10 CFR Part 20.2002 (or compatible regulations of Agreement States) allows for the disposal of licensed material by means other than those specifically identified elsewhere in Subpart K of Part 20, the specific elements of disposal pursuant to 10 CFR Part 61, or one of the approved methods in 20.2001, do not apply, and compliance with the requirements of Part 61 is not necessary.

QUESTION 31: The 1986 alternate method report reported on five types: below-ground vaults, above-ground vaults, earth-mounded concrete bunkers, mined cavities and augured holes and specifically refers to Subpart D, 10 CFR 61. Please explain how unrestricted release of byproduct material into interstate commerce compares with the criteria applied to these listed alternate methods of disposal and provide supporting documentation.

ANSWER.

The 1986 alternate method report discusses five types of facility design that could be used to demonstrate compliance with the technical requirements in Subpart D of Part 61. These technical requirements are intended to ensure permanent isolation of waste that is required to be disposed of under the provisions of 10 CFR Part 61. As discussed in the response to Question 26, the unrestricted release of solid material containing very low levels of radioactive material is not a disposal under the provisions of 10 CFR Part 61. Therefore, technical requirements in Subpart D of Part 61 do not apply.

QUESTION 32. 10 CFR Part 20 covers all persons licensed by the Commission to "receive, possess, use, transfer, or dispose of byproduct ... material ... under Parts 30 through 35." (10 CFR 20.1002.) Is there any other section in Part 20 that exempts MSC from the requirements of Parts 30-35? If the answer is in the affirmative, please explain and provide supporting documentation.

ANSWER.

There are no sections or provisions in 10 CFR Part 20 that would specifically exempt NRC licensees from the specific licensing requirements of Parts 30-35. In this case, Tennessee has approved the release pursuant to its licensing authority. As a Tennessee (Agreement State) licensee, MSC is not subject to the requirements of 10 CFR Part 20, which applies to NRC licensees, but rather to the requirements in Tennessee regulations that are comparable with the requirements in 10 CFR Part 20.

QUESTION 33. 10 CFR 20.1302 allows for some radioactive material from the normal operations of a licensee to be released in gaseous and liquid effluents. At the boundary of the licencee's restricted area, these releases must meet certain standards. Effluent is most commonly defined as "waste material (as smoke, liquid industrial refuse, or sewage) discharged into the environment especially when serving as a pollutant." Does the NRC or the State of Tennessee have a different definition of "effluent" that would include products or commodities sold into interstate commerce? Please explain and provide supporting documentation.

ANSWER.

The NRC does not have in 10 CFR Part 20 a specific definition for the word "effluent." Similarly, Tennessee does not have a specific definition of "effluent" in its Part 20 equivalent rule. NRC does not believe "effluents" would include products or commodities sold into interstate commerce.

Nevertheless, the NRC views release of solid materials containing very low levels of radioactivity for unrestricted use as similar to releases of radioactivity to the air or water. In each case, material with very low levels of radioactivity may be released from a licensee's operation because the concentration of radioactive material present is so small that it is no longer necessary to subject the material to regulatory control for purposes of protection of the public health and safety. In other words, if the material meets acceptable radiological criteria for release, whether it is in gaseous, liquid or solid form, it would not be subject to any further

licensing control and would be acceptable for unrestricted use. Similarly, for each of these forms of material, monitoring would occur prior to release to ensure that the release criteria are met. A similar regulatory framework for release was codified as part of the license termination rule, issued July 21, 1997, which set forth criteria in 10 CFR 20.1402.

QUESTION 34. In its recent issues paper, the NRC stated that although Part 20 provided for the release of air and liquid effluents from licensees' operations, it was "inconsistent" because it did not have a standard for a release of solid material, presumably as an effluent.

Please explain how 6,000 tons of nickel to be sold into interstate commerce can be defined as a solid "effluent" emanating from a licensee's normal operations and released for natural dispersion at the boundary of the licensee's restricted area similar to the gaseous and liquid effluents. Provide supporting documentation.

ANSWER.

The NRC views release of solid materials containing very low levels of radioactivity for unrestricted use as similar in basis and process to releases of radioactivity to the air or water. In each case, material with very low levels of radioactivity may be released from a licensee's operation because the concentration of radioactive material present is so small that it is no longer necessary to subject the material to regulatory control for the purposes of protection of the public health and safety.

QUESTION 35. In the same issues paper, the NRC stated that Part 20 does not have a provision for the release of solid material. This does not appear to be accurate, as 10 CFR 20.2003 allows for the disposal by release of "licensed material" into sewerage if it is "readily soluble" in water.

Please state whether this provision allows solid material to be released under certain conditions and provide supporting documentation.

ANSWER.

The provisions in 10 CFR 20.2003 are limited to allowing discharges under certain conditions, i.e., it permits a licensee to discharge licensed material into sanitary sewerage if the material is readily soluble in water (or if it is readily dispersible biological material), and if the amount and type of material meets the conditions indicated in 20.2003(a)(2), (3), and (4). For example, a researcher may pour liquid waste containing residual radioactivity down a laboratory drain provided that Part 20 limits are not exceeded.

The issues paper does note (at 64 FR 35091) that there are some NRC regulations in 10 CFR Part 20 covering the release of certain materials and lists a few of those regulations as examples. However, the issues paper also notes that there are no current overall criteria in Part 20 governing control of solid materials, and that, therefore, NRC is currently considering reexamining its approach for control of these materials in order to provide a more consistent regulatory framework.

QUESTION 36. Please explain how, under Part 20, MSC would release its solid byproduct material at the boundary of its restricted area and how it will carry out the other provisions requiring monitoring of those releases for persons "continuously present" at the boundary of the licensee's restricted area. Provide supporting documentation.

ANSWER.

Prior to any release of solid material, a licensee, such as MSC, would conduct a radiation survey of that material within the restricted area before the material leaves the licensee's control to ensure that radioactivity concentration levels in, or on, the material meet acceptable criteria as required by the regulatory agency for unrestricted use. After surveys confirm that radioactivity levels meet these criteria, the material would be authorized for release for unrestricted use.

The radiation surveys would be similar to those required for air and liquid releases in that they would demonstrate that the material meets criteria for release. However, the surveys would not include monitoring for persons who might be continuously present at the boundary of the licensee's restricted area, because the maximum exposure for solid materials would more likely be persons away from the site who process, handle, or use the material, rather than a person at the site boundary.

QUESTION 37: In its contract with BNFL, the Department of Energy has described the contaminated nickel as "process equipment" that may be recycled and released as scrap metal by MSC, an NRC-licensed facility. (*See* East Tennessee Technology Part (ETTP) Three-Building Decontamination and Decommissioning (D&D) and Recycle Project Contract, August 25, 1997, Attachment A, pp. 23, 33-34.) Please explain how recycling and release as scrap metal qualifies as the disposal of waste. Provide supporting documentation.

ANSWER.

As discussed in the response to Question 26, NRC does not generally consider releases of solid material for unrestricted use to be "disposals." For such releases, regulatory guidance on permissible releases, such as the surface contamination limits in Regulatory Guide 1.86, ensure that any subsequent use of the material will provide reasonable assurance of protection of the public health and safety with no further need for regulatory control. Also, as discussed in the responses to Questions 9 and 27, MSC is not licensed by NRC but is licensed by Tennessee, an Agreement State.

QUESTION 38: Since 1992, has the NRC promulgated through the regulatory process under the Administrative Procedure Act an unrestricted release standard for solid material of any type that contains byproduct material in any form? If the answer is in the affirmative, please provide supporting documentation.

ANSWER.

In July 1997, NRC promulgated its final rule establishing radiological criteria for license termination (10 CFR Part 20, Subpart E). This rule codified radiological criteria for the unrestricted and restricted release of land and structures or buildings with residual levels of radioactive contamination upon license termination. This rulemaking set standards that are generally consistent with criteria applied by NRC for many years prior to the rulemaking at individual sites though the licensing process. These criteria do not apply to uranium and thorium recovery facilities already subject to Appendix A of 10 CFR Part 40. (See 62 FR 39058, July 21, 1997).

Provisions for the release of land and structures or buildings at uranium recovery facilities were amended in April 1999 (10 CFR Part 40, Appendix A, Criterion 6(6)). (See 64 FR 17506, April 12, 1999.)

None of these rulemakings bear directly on the MSC licensing action.

QUESTION 39: Based on the above response, has the NRC established a legally binding release standard for solid material of any type containing byproduct material in any other process? Please explain and provide supporting documentation.

ANSWER.

The rule changes referred to in the response to Question 38 were promulgated in accordance with the requirements of the Administrative Procedure Act and are therefore legally binding. Please see our response to Question 26 for information on current practices relating to the release of solid material.

QUESTION 40: If there are such release standards, under what statutory and/or regulatory authority did the NRC issue them?

ANSWER.

The approach discussed in response to Question 39 is consistent with the Commission's general authority under the AEA to regulate matters under its jurisdiction through the issuance of specific license conditions or through the promulgation of generally applicable rules. (See, e.g., §161b and §81 of the AEA of 1954, as amended).

QUESTION 41. Section 274(j)(1) of the Atomic Energy Act allows the Commission to terminate or suspend all or part of its agreement with a state if it finds that the state's program is not compliant with the statute. Section 274 (g) requires that radiation standards be "coordinated and compatible." (*See* 42 U.S.C. 2021 (g) and (j)(1).) In September of 1997, the NRC adopted its "Statement of Principles and Policy for the Agreement State Program Policy Statement on Adequacy and Compatibility of Agreement State Programs." It was published in the *Federal Register* after extensive public comment. (*See* 62 Fed. Reg. 46517, Sept. 3, 1997.)

Specifically, compatibility is defined in the policy as "program elements necessary to meet a larger nationwide interest in radiation protection generally limited to areas of regulation involving radiation protection standards and activities with significant transboundary implications." (*See* "The Commission Policy," Subsection III (B).) State radiation control programs are compatible only when they do "not create conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis." (*See* "Compatibility," Subsection III (E).) State standards for release limits "should be essentially identical to those of the Commission, unless Federal statutes provide the State authority to adopt different standards." (*See* "Basic Radiation Protection Standards," Subsection III (E)(A).)

Several years ago the NRC attempted to establish a level of byproduct contamination "below regulatory concern" that would allow the release of solid byproduct material. In 1992, Congress ordered the NRC to halt that rulemaking. In June of this year, the NRC published in the *Federal Register* an issue paper on the release of solid materials at licensed facilities. In that paper, the Commission states that it has no specific regulatory requirements regarding release of solid material," and that it wants "to establish a regulatory framework more consistent with existing NRC requirements on air and liquid releases."

(a) Are those accurate statements as of this date?

ANSWER.

Yes. We note that, in 1992, Congress revoked two NRC policy statements concerning material "below regulatory concern"; no NRC rulemaking action had been initiated.

(b) How does the State of Tennessee have an "essentially identical" standard to one promulgated by the NRC for the release of solid material containing byproduct material when there is no standard? Please explain and provide supporting documentation.

ANSWER.

The action taken by Tennessee does not establish a "basic radiation protection standard" that is generally applicable to all licensees. Rather, Tennessee has authorized one of its licensees to release solid material containing specific concentrations of particular radionuclides through a license condition. This is consistent with case-by-case reviews and use of license conditions to address licensee requests for release of solid material, as discussed in responses to earlier questions. (See response to Question 26.) The action taken by Tennessee is consistent with case-by-case actions taken by NRC and other Agreement States for the release of solid material containing very low levels of radioactive material.

NRC has not established a "basic radiation protection standard" for the release of solid material. In cases where NRC has established a basic radiation protection standard or regulation, and made a determination of the extent to which the Agreement State program must be compatible with that standard or regulation, States are expected to adopt and implement the standard in accordance with the compatibility level assignment. In those circumstances where NRC has not established a specific standard, States have flexibility to establish their own requirement, or to develop and apply a criterion or limit applicable to a specific case, provided the States continue to provide reasonable assurance of protection of public health and safety and their activities are, in a broad sense, compatible with the Commission's program. (See Policy Statements at 62 FR 46525, September 3, 1997 and Management Directive 5.9 (attached)).

Attachment: Management Directive 5.9