(STP-03-073, September 2003, Program, MD 5.6)

September 25, 2003

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA,

REVISION TO MANAGEMENT DIRECTIVE 5.6, INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (STP-03- 073)

Enclosed for your review and comment is a draft revision to NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." The revision incorporates recommendations from the 2000 Sealed Source and Device (SS&D) Working Group report, February 2002 NRC staff's response to the SS&D working group report, April 2002 IMPEP Lessons Learned Working Group report, directions from the Management Review Board and additional enhancements identified since April 2002 based on the iterative process employed in IMPEP to factor in experience, comments, and suggestions. Also enclosed for your information in reviewing MD 5.6 is the document *Staff Resolution of Changes to Management Directive (MD) 5.6 Based on Integrated Materials Performance Evaluation Program (IMPEP) Lessons Learned Working Group and Sealed Source and Devices (SS&D) Working Group Recommendations*, dated July 23, 2003.

We would appreciate receiving your comments* within 45 days of receiving this letter.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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/RA/

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Enclosure:
As stated

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TN: DT-03-XX

To:	NRC Management Directives Custodians
Subject:	Transmittal of Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)"
Purpose:	Directive and Handbook 5.6 are being revised to incorporate recommendations from two working group reports; directions from the Management Review Board; additional enhancements identified since 2002; and to provide updated revisions based on the Office of State and Tribal Programs name change.
Office and Division of Origin:	Office of State and Tribal Programs
Contact:	Kathleen N. Schneider, 301-415-2320
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Integrated Materials Performance Evaluation Program (IMPEP)

Directive 5.6

Contents

Policy 1
Objectives 1
Organizational Responsibilities and Delegations of Authority 2
Deputy Executive Director for Materials, Research and State Programs (DEDMRS) 2
Directors, Office of Nuclear Material Safety and Safeguards (NMSS), and Office of State and Tribal Programs (STP) 2
General Counsel 3
Regional Administrators 3
Applicability 3
Handbook 3
References 4

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 and Tribal 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 decisionmaking process and indicate areas in which NRC and the Agreement States should dedicate more resources or management attention. (023)

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)

Directors, Office of Nuclear Material Safety and Safeguards (NMSS), and Office of State and Tribal Programs (STP)
(032)

- Implement the IMPEP within NMSS and STP. 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)
- Prepare final reports for each region and State for consideration by the MRB and signature by the DEDMRS. (d)
- Participate on MRBs. (e)

Organizational Responsibilities and Delegations of Authority
(5.6-03) (continued)

Directors, Office of Nuclear Material Safety and Safeguards (NMSS), and Office of State and Tribal Programs (STP)
(032) (continued)

- Coordinate with Agreement States to provide appropriate representatives for IMPEP reviews and MRB meetings. (f)

General Counsel
(033)

Participates on MRBs.

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.

Handbook
(5.6-05)

Handbook 5.6 describes the performance indicators that will be used, the performance standards against which these indicators

Handbook

(5.6-05) (continued)

will be evaluated, and the frequency and process sequence to be employed. The Glossary in the handbook also defines the most commonly used key terminology.

References

(5.6-06)

Code of Federal Regulations, Title 10, "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."

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."

References

(5.6-06) (continued)

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 and Tribal Programs Procedures—

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-122, "Heightened Oversight and Monitoring."

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

SA-201, "Reviewing State Regulations."

SA-300, "Reporting Material Events."

Integrated Materials Performance Evaluation Program (IMPEP)

Handbook 5.6

Contents

Part I

Evaluation 1
- Evaluation Frequency (A) 1
- Evaluation Process Sequence (B) 1

Part II

Performance Indicators 3
- General (A) 3
- Common Performance Indicators (B) 4
  - Common Performance Indicator 1—Technical Staffing and Training (1) 4
  - Common Performance Indicator 2—Status of Materials Inspection Program (2) 5
  - Common Performance Indicator 3—Technical Quality of Inspections (3) 6
  - Common Performance Indicator 4—Technical Quality of Licensing Actions (4) 7
  - Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (5) 7
- Non-Common Performance Indicators (C) 8
  - Non-Common Performance Indicator 1—Compatibility Requirements (1) 8
  - Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (2) 9
  - Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (3) 12
  - Non-Common Performance Indicator 4—Uranium Recovery Program (4) 16
  - Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (5) 18
  - Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (6) 26

Contents (continued)

Part III

Evaluation Criteria 29
Common Performance Indicator 1—Technical Staffing and Training (A) . . 29
Satisfactory (1) 29
Satisfactory, But Needs Improvement (2) 30
Unsatisfactory (3) 31
Category N (4) 32
Common Performance Indicator 2—Status of Materials Inspection Program (B) 32
Satisfactory (1) 32
Satisfactory, But Needs Improvement (2) 33
Unsatisfactory (3) 33
Category N (4) 33
Common Performance Indicator 3—Technical Quality of Inspections (C) . 34
Satisfactory (1) 34
Satisfactory, But Needs Improvement (2) 34
Unsatisfactory (3) 35
Category N (4) 35
Common Performance Indicator 4—Technical Quality of Licensing Actions (D) 35
Satisfactory (1) 35
Satisfactory, But Needs Improvement (2) 36
Unsatisfactory (3) 36
Category N (4) 37
Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (E) 37
Satisfactory (1) 37
Satisfactory, But Needs Improvement (2) 38
Unsatisfactory (3) 38
Category N (4) 38
Non-Common Performance Indicator 1—Compatibility Requirements (F) 38
Satisfactory (1) 38
Satisfactory, But Needs Improvement (2) 40

Contents (continued)

Part III (continued)

Unsatisfactory (3) 40
Category N (4) 41
Non-Common Performance Indicator 2—Sealed Source and Device Evaluation Program (G) 42
Technical Staffing and Training (1) 42
Technical Quality of the Product Evaluation Program (2) 43
Evaluation of Defects and Incidents Regarding SS&Ds (3) 46
Non-Common Performance Indicator 3—Low-Level Radioactive Waste Disposal Program (H) 47
Technical Staffing and Training (1) 47
Status of Low-Level Radioactive Waste Disposal Inspection (2) 50
Technical Quality of Inspections (3) 51
Technical Quality of Licensing Actions (4) 54
Technical Quality of Incident and Allegation Activities (5) 56
Non-Common Performance Indicator 4—Uranium Recovery Program (I) . 57
Technical Staffing and Training (1) 57
Status of Uranium Recovery Inspection Program (2) 59
Technical Quality of Inspections (3) 60
Technical Quality of Licensing Actions (4) 62
Technical Quality of Incident and Allegation Activities (5) 64
Non-Common Performance Indicator 5—Regional Fuel Cycle Inspection Program (J) 64
Technical Staffing and Training (1) 64
Status of Fuel Cycle Inspection Program (2) 69
Technical Quality of Inspections (3) 74
Technical Quality of Incident and Allegation Activities (4) 77
Non-Common Performance Indicator 6—Site Decommissioning Management Plan (SDMP) (K) 81
Staff Qualifications (1) 81
Quality of SDMP Decommissioning Reviews (2) 82
Financial Assurance for Decommissioning (3) 83
Termination Radiological Surveys (4) 84

Contents (continued)

Part III (continued)

Inspections (5) 86
SDMP Milestones (6) 87

Part IV

Programmatic Assessment 89
General (A) 89
Adequacy Findings for Agreement State Programs (B) 90
Finding 1—Adequate To Protect Public Health and Safety (1) 90
Finding 2—Adequate But Needs Improvement (2) 90
Finding 3—Inadequate To Protect Public Health and Safety (3) 91
Compatibility Findings for Agreement State Programs(C) 91
Finding 1—Compatible (1) 91
Finding 2—Not Compatible (2) 92
Adequacy Findings for NRC Regional Programs (D) 92
Guidance for MRB Determinations for Agreement State Programs (E) . . . 92
Heightened Oversight (1) 92
Probation (2) 93
Suspension (3) 94
Termination (4) 95
Guidance for MRB Determinations for NRC Regional Programs (F) 97

Glossary 98

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 and Tribal Programs (STP) in coordination with the regions and States. Approximately 8 to 10 reviews will be scheduled in most years. Under normal conditions, this schedule would allow evaluations of NRC regions 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 the most current information on the region or Agreement State. (5)

Evaluation Process Sequence (B) (continued)

- Assess a sample of inspections at different types of licensed facilities by accompanying inspectors before the onsite portion of the IMPEP. (6)

- Conduct the onsite portion of the IMPEP, using the criteria specified in this handbook and applicable performance review procedures. (7)

- Prepare a draft IMPEP report, with recommendation for overall performance evaluation, for the team leader'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 the proposed final report for consideration by the management review board (MRB). (11)

- Conduct the 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 Sections(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. The review should be performance based to evaluate whether the protection of public health and safety has been achieved. The outcome of the review should identify potential impacts on public health and safety and the root causes of performance that does not fully meet the criteria. (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

General (A) (continued)

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)

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

Common Performance Indicators (B)

Common Performance Indicator 1—Technical Staffing and Training (1)

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 turnover? (iii)
- What impact is it having on other performance indicators? (iv)

Common Performance Indicators (B) (continued)

Common Performance Indicator 1—Technical Staffing and Training (1) (continued)

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)

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 2—Status of Materials Inspection Program (2)

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory

Common Performance Indicators (B) (continued)

Common Performance Indicator 2—Status of Materials Inspection Program (2) (continued)

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 an NRC region's materials inspection program; reviews also should examine specific cases in detail when the inspection frequency has been significantly exceeded (i.e., by more than 50 percent). The terms "materials inspection" and "overdue core inspection" are defined in the Glossary of this handbook. (b)

Common Performance Indicator 3—Technical Quality of Inspections (3)

This performance indicator provides the qualitative balance to Performance Indicator 2 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 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 3—Technical Quality of Inspections (3) (continued)

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

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)

Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (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

Common Performance Indicators (B) (continued)

Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (5) (continued)

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—Compatibility Requirements (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 STP 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

Non-Common Performance Indicators (C) (continued)

Non-Common Performance Indicator 1—Compatibility Requirements (1) (continued)

requirement is not later than 3 years after the effective date of NRC's final rule. (c)

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 (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. Agreement States with authority for SS&D 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 this section) before performing evaluations. NUREG-1556, Volume 3, provides information on conducting SS&D reviews that may provide useful guidance for review teams. Three subelements will be evaluated to determine if the SS&D program is adequate.

- Technical Staffing and Training (a)

  Evaluation of SS&D review staffing and training should be conducted in the same manner and as part of the Common Performance Indicator 1 (Sections (B)(1)(a) and (b) of this part), except with a focus on training and experience commensurate with the conduct of the SS&D reviews. (i)

  The minimum qualifying criteria for SS&D staff authorized to sign registration certificates should be— (ii)

Non-Common Performance Indicators (C) (continued)

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

– BS/BA, or equivalent experience, in physical and/or life science or engineering (*a*)

– Five-week Applied Health Physics Course (H309) or equivalent health physics background (*b*)

– Licensing Practices and Procedures Course (G109) or equivalent training (*c*)

– Licensing and Inspection Course (G109) or equivalent training (*d*)

– One-week NRC course/workshop on SS&D review and evaluations (*e*)

– NRC Incident Investigation and Root Cause Analysis course or equivalent training (*f*)

Staff should have a minimum of 1 year of practical related experience and demonstrated ability to conduct adequate SS&D reviews, including being able to— (iii)

– Understand and interpret 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*)

Non-Common Performance Indicators (C) (continued)

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

- Understand and apply the appropriate regulations (*e*)
- Understand the conditions of use (*f*)
- Understand external dose rates, source activities, and nuclide chemical form (*g*)
- Understand and utilize basic knowledge of engineering materials and their properties (*h*)

• Technical Quality of the Product Evaluation Program (b)

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 to NRC, Agreement States, and others, as appropriate. (*b*)
- Vendors' quality assurance and control programs should be evaluated to ensure that products are built to the same specifications as those listed on the registration certificate. The commitments made in the registrant's application and

Non-Common Performance Indicators (C) (continued)

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

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)

- 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 incidents should be evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States, and others, as appropriate, should occur in a timely manner.

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

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

- Technical Staffing and Training (a)

  Evaluation of staffing and training should be conducted in the same manner and as part of the Common Performance Indicator 1 (Sections (B)(1)(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

Non-Common Performance Indicators (C) (continued)

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

complete review of a new application within 15 months, if practicable, in accordance with 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.

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

  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*)

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 (c)

  This subelement provides the qualitative balance to subelement b 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 subelement b 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 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

Non-Common Performance Indicators (C) (continued)

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

procedures, and institutional arrangements in a manner sufficient to establish a basis for licensing action. This program 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)

- Technical Quality of Incident and Allegation Activities (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)(5) of this part), unless the low-level radioactive waste program is organizationally separate from the materials program.

Non-Common Performance Indicators (C) (continued)

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

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

- Technical Staffing and Training (a)

  Evaluation of staffing and training should be conducted in the same manner and as part of Common Performance Indicator 1 (Sections (B)(1)(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.

- Status of the Uranium Recovery Inspection Program (b)

  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 in situ 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.

Non-Common Performance Indicators (C) (continued)

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

- Technical Quality of Inspections (c)

  This subelement provides the qualitative balance to subelement b 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 subelement 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.

- 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 program may be accomplished through the preparation and use of internal licensing guides, policy memoranda, or use of NRC equivalent guides to ensure

Non-Common Performance Indicators (C) (continued)

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

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)

- Technical Quality of Incident and Allegation Activities (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)(5) 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)

Four subelements, as appropriate, will be evaluated to determine if the performance of the regional fuel cycle inspection program is adequate.

- Technical Staffing and Training (a)

Non-Common Performance Indicators (C) (continued)

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

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. These requirements often result 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)

– Is the rate of turnover or the degree of understaffing symptomatic of a chronic problem, or is it merely a short-term phenomenon? (*a*)

– Why is turnover high? (*b*)

Non-Common Performance Indicators (C) (continued)

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

– 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 subelements? (*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 *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 poses 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)

- Status of Fuel Cycle Inspection Program (b)

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. 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 an 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

Non-Common Performance Indicators (C) (continued)

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

inspections can be conducted, 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)

Non-Common Performance Indicators (C) (continued)

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

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 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 step 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 (c)

  This subelement provides the qualitative balance to the subelement b above, which looks at the status of the inspection program on a quantitative basis. (i)

  Reviews of programs under this subelement focus on the scope, completeness, and technical accuracy of completed inspections and related documentation. The reviewer will

Non-Common Performance Indicators (C) (continued)

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

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 they are 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)

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 Quality of Incident and Allegation Activities (d)

Non-Common Performance Indicators (C) (continued)

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

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. These response activities 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)

Non-Common Performance Indicators (C) (continued)

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

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

- Staff Qualifications (a)

  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.

- Quality of SDMP Decommissioning Reviews (b)

  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 (c)

  Adequate financial assurance for the decommissioning of SDMP sites has been established in accordance with

Non-Common Performance Indicators (C) (continued)

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

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 (d)

  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.

- Inspections (e)

  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.

- SDMP Milestones (f)

Non-Common Performance Indicators (C) (continued)

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

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—Technical Staffing and Training (A)

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 performance 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)

Common Performance Indicator 1—Technical Staffing and Training (A) (continued)

Satisfactory (1) (continued)

- 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. 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. (e)

- Management commitment to training is clearly evident. (f)

Satisfactory, But Needs 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)

Common Performance Indicator 1—Technical Staffing and Training (A) (continued)

Satisfactory, But Needs Improvement (2) (continued)

- 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 the scientific or technical backgrounds that would equip them to receive technical training. (e)

Common Performance Indicator 1—Technical Staffing and Training (A) (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 STP has been kept informed of the situation, and discernable recent progress is evident.

Common Performance Indicator 2—Status of Materials Inspection Program (B)

Satisfactory (1)

- Core licensees (initial inspections of Priorities 1, 2, 3, 5, and 7 and all routine inspections of Priority 1, 2, or 3) 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)

- 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). (d)

Common Performance Indicator 2—Status of Materials Inspection Program (B) (continued)

Satisfactory, But Needs Improvement (2)

- More than 10 percent of the Priority 1, 2, or 3 licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. Initial inspections that are completed more than 6 months after receipt of licensed material or 12 months after license issuance (whichever comes first) are also included in the 10 percent calculation.(a)

- Many of the inspection findings are delayed or not communicated to licensees within 30 days. (b)

Unsatisfactory (3)

- More than 25 percent of the Priority 1, 2, or 3 licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. Initial inspections that are completed more than 6 months after receipt of licensed material or 12 months after license issuance (whichever comes first) are also included in the 25 percent calculation. (a)

- Inspection findings are delayed or not communicated to licensees within 30 days. (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 3—Technical Quality of Inspections (C)

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)

- 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, But Needs 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)

Common Performance Indicator 3—Technical Quality of Inspections (C) (continued)

Satisfactory, But Needs Improvement (2) (continued)

- Review does not demonstrate an appropriate level of management review. (c)
- Accompaniment of inspectors by supervisors is performed nonsystematically. (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)

Category N (4)

This category is not applicable.

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

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

Satisfactory (1) (continued)

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, But Needs 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.

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,

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

Unsatisfactory (3) (continued)

consistency, clarity, technical quality, and adherence to existing guidance in licensing actions.

Category N (4)

This category is not applicable.

Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (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, STP, Office of Nuclear Security and Incident Response (NSIR), and others, as appropriate, is usually performed in a timely fashion. (g)

Common Performance Indicator 5—Technical Quality of Incident and Allegation Activities (E) (continued)

Satisfactory, But Needs Improvement (2)

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

- 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, STP, NSIR, 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, STP, NSIR, and others, as appropriate, of incidents. (b)

Category N (4)

This category is not applicable.

Non-Common Performance Indicator 1—Compatibility Requirements (F)

Satisfactory (1)

- State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for

Non-Common Performance Indicator 1— Compatibility Requirements (F) (continued)

Satisfactory (1) (continued)

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)

- 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 legally 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 STP 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)

Non-Common Performance Indicator 1— Compatibility Requirements (F) (continued)

Satisfactory (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 of such designation by NRC. (h)

Satisfactory, But Needs Improvement (2)

- The State has adopted legally binding requirements, regulations, and other program elements in accordance with MD 5.9 and the current revisions of STP 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 more than 3 years after the effective date of NRC's final rule. (b)

- 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 after such designation by NRC. (c)

Unsatisfactory (3)

- The State no longer has statutes that authorize it to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. (a)

Non-Common Performance Indicator 1— Compatibility Requirements (F) (continued)

Unsatisfactory (3) (continued)

- The State is not authorized through its legal authority to license, inspect, or enforce legally binding requirements, such as regulations and licenses. (b)

- State statutes are in conflict with, or do not sufficiently reflect, the 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 legally binding requirements, regulations, and other program elements in accordance with MD 5.9 and the current revisions of STP 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 more (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 more (many months or years) than 6 months after such designation by NRC. (g)

Category N (4)

This category is not applicable.

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

Technical Staffing and Training (1)

Satisfactory (a)

The technical reviews are performed by staff with proper training and qualifications. (i)

Qualification criteria for reviewers are established, implemented, and documented. (ii)

Satisfactory, But Needs 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)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, cases in which an Agreement State may have currently sealed source and device (SS&D) evaluation authority but is not performing any SS&D reviews. In such cases, the program should commit in writing to having an SS&D evaluation program in place (as described in Section (C)(2) of Part II) before performing evaluations.

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

Technical Quality of the Product Evaluation Program (2)

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 under normal conditions of use and likely accident conditions. (i)

- Health and safety issues are properly addressed. (ii)

- Registrations clearly summarize the product evaluation and provide license reviewers with adequate information to license possession and use of the product. (iii)

- Deficiency letters clearly state regulatory positions and are used at the proper time. (iv)

- A concurrence review of each application and proposed certificate of registration is performed by a second qualified reviewer or supervisor, and the record indicated that the second reviewer concurs on the finding that the product is acceptable for licensing purposes. (v)

- Applicable guidance documents are followed, unless approval to use alternate procedures is obtained from management. (vi)

- Completed registration certificates, and the status of obsolete registration certificates, are clear and are promptly transmitted to NRC, Agreement States, and others, as appropriate. (vii)

- Reviewers ensure that registrants have developed and implemented adequate quality assurance and control programs. (viii)

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

Technical Quality of the Product Evaluation Program (2) (continued)

- There is a means for enforcing commitments made by registrants in their applications and referenced in the registration certificates by the program. (ix)

Satisfactory, But Needs 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 with adequate training. (iv)

- Completed registration certificates, and the status of obsolete registration certificates, are not always clear or are not always promptly transmitted to NRC, Agreement States, and others, as appropriate. (v)

- Not all product evaluations include an evaluation of proposed quality assurance and control programs. (vi)

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

Technical Quality of the Product Evaluation Program (2) (continued)

- Commitments made by registrants in their applications, and referenced in the registration certificates, cannot be enforced for all registrations. (vii)

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 with adequate training. (iv)

- Completed registration certificates, and the status of obsolete registration certificates, are unclear and are not promptly transmitted to NRC, Agreement States, and others, as appropriate. (v)

- Product evaluations often do not include an evaluation of proposed quality assurance and control programs. (vi)

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

Technical Quality of the Product Evaluation Program (2) (continued)

- 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)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, cases in which an Agreement State may have currently SS&D evaluation authority but is not performing any SS&D reviews. In such cases, the program should commit in writing to having an SS&D evaluation program in place (as described in Section (C)(2) of Part II) before performing evaluations.

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 NRC, Agreement States, and others, as appropriate.

Satisfactory, But Needs 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

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

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

actions, including notification of NRC, Agreement States, and others, as appropriate.

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 NRC, Agreement States, and others, as appropriate.

Category N (d)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, cases in which an Agreement State may have currently SS&D evaluation authority but is not performing any SS&D reviews. In such cases, the program should commit in writing to having an SS&D evaluation program in place (as described in Section (C)(2) of Part II) before performing evaluations.

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

Technical Staffing and Training (1)

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)

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

Technical Staffing and Training (1) (continued)

- 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, But Needs 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 (1) (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)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level radioactive disposal facility, it is expected to put in place a regulatory program as described in Section (C)(3) of Part II.

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

Status of Low-Level Radioactive Waste Disposal Inspection (2)

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, But Needs Improvement (b)

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

- 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)

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

Status of Low-Level Radioactive Waste Disposal Inspection (2) (continued)

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)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level radioactive disposal facility, it is expected to put in place a regulatory program as described in Section (C)(3) of Part II.

Technical Quality of Inspections (3)

Satisfactory (a)

- Review team members 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)

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

Technical Quality of Inspections (3) (continued)

- 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)

- Inspection findings generally lead to appropriate and prompt regulatory action. (v)

- Supervisors accompany nearly all inspectors on an annual basis. (vi)

Satisfactory, But Needs 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)

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

Technical Quality of Inspections (3) (continued)

- Accompaniments of inspectors by supervisors are performed nonsystematically. (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)

Category N (d)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level radioactive disposal facility, it is expected to put in place a regulatory program as described in Section (C)(3) of Part II.

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

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)
- Public hearings in accordance with 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)

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

Technical Quality of Licensing Actions (4) (continued)

Satisfactory, But Needs 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)

Category N (d)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level

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

Technical Quality of Licensing Actions (4) (continued)

radioactive disposal facility, it is expected to put in place a regulatory program as described in Section (C)(3) of Part II.

Technical Quality of Incident and Allegation Activities (5)

Satisfactory (a)

Meets "Satisfactory" performance for common performance indicator criteria, Section (E)(1) of this part, as applied to the technical quality of incident and allegation activities subelement for the low-level radioactive waste disposal program.

Satisfactory, But Needs Improvement (b)

Meets "Satisfactory, But Needs Improvement" performance for common performance indicator criteria, Section (E)(2) of this part, as applied to the technical quality of incident and allegation activities subelement 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 technical quality of incident and allegation activities subelement for the low-level radioactive waste disposal program.

Category N (d)

Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement; for example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a

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

Technical Quality of Incident and Allegation Activities (5) (continued)

host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level radioactive disposal facility, it is expected to put in place a regulatory program as described in Section (C)(3) of Part II.

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

Technical Staffing and Training (1)

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)

Satisfactory, But Needs 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)

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

Technical Staffing and Training (1) (continued)

- 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)

- 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)

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

Technical Staffing and Training (1) (continued)

Category N (d)

This category is not applicable.

Status of Uranium Recovery Inspection Program (2)

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, But Needs 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 in situ leach facilities by more than 25 percent. (i)

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

Status of Uranium Recovery Inspection Program (2) (continued)

- 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 in situ leach facilities by more than 100 percent. (i)

- Inspection findings are frequently delayed. (ii)

Category N (d)

This category is not applicable.

Technical Quality of Inspections (3)

Satisfactory (a)

- Review team members accompanying inspectors combined with 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)

- Licensing history and status are incorporated into the inspection program as demonstrated through accompaniments and procedures in place. (ii)

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

Technical Quality of Inspections (3) (continued)

- 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. (vi)

- Supervisors accompany nearly all inspectors on an annual basis. (vii)

Satisfactory, But Needs 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)

- Accompaniment of inspectors by supervisors is performed nonsystematically. (iii)

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

Technical Quality of Inspections (3) (continued)

- 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)

This category is 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)

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

Technical Quality of Licensing Actions (4) (continued)

- 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)

Satisfactory, But Needs 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)

This category is not applicable.

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

Technical Quality of Incident and Allegation Activities (5)

Satisfactory (a)

Meets "Satisfactory" performance for common performance indicator criteria, Section (E)(1) of this part, as applied to the technical quality of incident and allegation activities subelement for the uranium recovery program.

Satisfactory, But Needs Improvement (b)

Meets "Satisfactory, But Needs Improvement" performance for common performance indicator criteria, Section (E)(2) of this part, as applied to the technical quality of incident and allegation activities subelement for the uranium recovery program.

Unsatisfactory (c)

Meets "Unsatisfactory" performance for common performance indicator criteria, Section (E)(3) of this part, as applied to the technical quality of incident and allegation activities subelement for the uranium recovery program.

Category N (d)

This category is not applicable.

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

Technical Staffing and Training (1)

Satisfactory (a)

Review indicates implementation of a well-conceived and balanced staffing strategy throughout the assessment period and

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

Technical Staffing and Training (1) (continued)

demonstrates the qualifications of the technical staff. This balanced staffing strategy 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), NMSS, to meet requirements specified in NRC Inspection Manual, Chapter 1246. 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. Training plans and schedules for qualification are established, maintained, and personally reviewed by the inspector and management. (iii)

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

Technical Staffing and Training (1) (continued)

- 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)

- 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 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, But Needs 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 a problem still persists. (iii)

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

Technical Staffing and Training (1) (continued)

- 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 become qualified. (v)

- The region's training and qualification standards do not completely correspond to functional requirements for inspections. (vi)

- 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 subelements of this performance indicator:

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

Technical Staffing and Training (1) (continued)

- 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)

- 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

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

Technical Staffing and Training (1) (continued)

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.

Status of Fuel Cycle Inspection Program (2)

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*)

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

Status of Fuel Cycle Inspection Program (2) (continued)

– 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*)

– 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 optimize the utilization of inspection resources so that inspectors are

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

Status of Fuel Cycle Inspection Program (2) (continued)

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)

Satisfactory, But Needs 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

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

Status of Fuel Cycle Inspection Program (2) (continued)

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)

- 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)

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

Status of Fuel Cycle Inspection Program (2) (continued)

- Documentation in support of the observations required to be formulated for the licensee performance review program does not exist, or is 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 (2) (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 (3)

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)

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

Technical Quality of Inspections (3) (continued)

- 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)

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

Satisfactory, But Needs 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

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

Technical Quality of Inspections (3) (continued)

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 an 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)

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

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

Technical Quality of Inspections (3) (continued)

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)

This category is not applicable.

Technical Quality of Incident and Allegation Activities (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

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

Technical Quality of Incident and Allegation Activities (4) (continued)

with headquarters, as appropriate, and timely in most instances. The level of effort investigating incidents is usually commensurate with potential health and safety significance of the incident. (ii)

- 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, NSIR, 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 an actual event are comprehensive in recognizing

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

Technical Quality of Incident and Allegation Activities (4) (continued)

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 followup to receipt of allegations is technically sound and successful in determining the safety implications of the allegations, as appropriate. (viii)

Satisfactory, But Needs Improvement (b)

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

- 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 an 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)

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

Technical Quality of Incident and Allegation Activities (4) (continued)

- The regional portion of inspection activity conducted as followup 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 followup to receipt of an allegation, though there was a clear need to investigate the safety implications of the allegations. (iv)

Category N (d)

This category is not applicable.

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

Staff Qualifications (1)

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, But Needs 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)

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

Staff Qualifications (1) (continued)

- The majority of staff is not qualified to perform licensing reviews and inspections related to decommissioning through training and documented work experience. (ii)

- 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.

Quality of SDMP Decommissioning Reviews (2)

Satisfactory (a)

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

Satisfactory, But Needs 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.

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

Quality of SDMP Decommissioning Reviews (2) (continued)

Category N (d)

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

Financial Assurance for Decommissioning (3)

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)

- 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, But Needs 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)

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

Financial Assurance for Decommissioning (3) (continued)

- 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)

Category N (d)

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

Termination Radiological Surveys (4)

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

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

Termination Radiological Surveys (4) (continued)

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, But Needs 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 (4) (continued)

Category N (d)

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

Inspections (5)

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, But Needs 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)

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

Inspections (5) (continued)

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)

Category N (d)

Special conditions exist that provide justification for withholding a rating for one or more 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)

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

SDMP Milestones (6) (continued)

Satisfactory, But Needs 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)

- 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, including— (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 and Tribal 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

General (A) (continued)

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)

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

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

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

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)

- 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

Compatibility Findings for Agreement State Programs (C) (continued)

Finding 1—Compatible (1) (continued)

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 to be unsatisfactory, heightened oversight by the NRC will be considered by the MRB in accordance with Office of State and Tribal Programs (STP) Procedure SA-122, “Heightened Oversight and Monitoring.” When strong

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

Heightened Oversight (1) (continued)

commitments to improve its 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 STP 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)

- 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

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

Probation (2) (continued)

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

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

Suspension (3) (continued)

Energy Act, in accordance with STP Procedure SA-114 "Suspension of a Section 274b Agreement," when any of the following circumstances occur: (a)

- 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 in which 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 STP Procedure SA-115, "Termination of a Section 274b Agreement," when any of the following circumstances occur: (a)

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

Termination (4) (continued)

- 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 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)

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

Termination (4) (continued)

- 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 heightened oversight, 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.

Concurrence Review. A quality assurance review is an evaluation of the initial safety review and must be performed by a different qualified reviewer. It does not need to be performed to the same level of detail as the initial review. The depth of quality assurance review should be commensurate with the complexity of the application and the potential risks associated with the use of the source, or device. This review should ensure that the proposed product meets all applicable regulations and requirements and that appropriate health and safety concerns have been addressed and that the device will be safe under the proposed conditions of use and likely accident situations. The quality assurance review should also ensure that the registration certificate for the source or device is accurate and that it provides information essential for proper licensing of the product.

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.

Glossary (continued)

Incident. An event or condition that has the possibility of affecting public health and safety such as described in 10 CFR or equivalent regulations. Office of State and Tribal Programs Procedure SA-300, Reporting Material Events, includes a listing of NRC reporting requirements in Title 10.

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.

Overdue Core 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 management directive, a core 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 inspection will not be considered overdue if the inspection frequency has been extended in accordance with NRC Inspection Manual, Chapter 2800, Section 05.01, on the basis of good licensee performance.)

Glossary (continued)

- 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.

July 23, 2003

Staff Resolution of Changes to Management Directive (MD) 5.6
Based on Integrated Materials Performance Evaluation Program
(IMPEP) Lessons Learned Working Group and Sealed Source
and Devices (SS&D) Working Group Recommendations

Note: Staff has classified revisions into two categories, IMPEP or SS&D changes. IMPEP revisions are the results of recommendations from the April 2002 IMPEP Lessons Learned Working Group report, directions from the Management Review Board and additional enhancements identified since April 2002 based on the iterative process employed in IMPEP to factor in experience, comments, and suggestions. The SS&D changes are the result of the SS&D Working Group report (2000) and 2002 NRC staff's response to the SS&D working group report (2002 Staff report) issued February 2002.

Comment 1:
IMPEP: With the change of Office of State Programs (OSP) to Office of State and Tribal Programs (STP), all references to OSP should be revised throughout MD 5.6 and Handbook 5.6 to STP.

Response:
These corrections will be made.

Comment 2:
IMPEP: All footnotes that contain requirements or criteria should be moved into the text of Handbook 5.6.

Response:
The staff agrees and where appropriate, will note in this document those footnotes that will be moved into the text of the Handbook. These corrections will be made.

Changes to Management Directive 5.6

Comment 3:
IMPEP: In MD 5.6-032, the text should be revised to indicate that NMSS and STP Directors will no longer sign and issue draft reports but are responsible for preparing final reports for each region and State for consideration by the MRB and signature by the DEDMRS.

Response:
The present text in MD 5.6-032 states that NMSS and STP Directors will issue draft reports and prepare final reports for each region and State for consideration by the MRB and signature by the DEDMRS. Based on the present practice, the text of MD 5.6-032 will be revised as follows:

> ~~Issue draft reports and p~~Prepare final reports for each region and State for consideration by the MRB and signature by the DEDMRS. (d)

Changes to Handbook 5.6, Part I

Comment 4:
IMPEP: Section A should be revised to reflect the actual frequency of 8-10 reviews per year. The original projection of 10 to 12 reviews per year was based on performing Agreement State reviews every three years and Regional reviews every 2 years. Agreement States and Regional reviews are now performed every 4 years when there are no performance issues identified.

Response:
These revisions will be made.

Comment 5:
IMPEP: Section (B)(6) should be revised to clarify that inspector accompaniments should be conducted prior to the onsite portion of IMPEP.

Response:
This revision will be made.

Comment 6:
IMPEP: Section (B)(8) should be revised to indicate that the draft IMPEP report will be signed by the team leader.

Response:
This revision will be made.

Changes to Handbook 5.6, Part II

Comment 7:
SS&D: The 2002 Staff report proposes the following change fo Part II, Section (A):

> The IMPEP review should be risk informed and performance based to evaluate if the protection of public health and safety has been achieved. The outcome of the IMPEP should identify: (a)
>
> > • Any potential, or actual, danger to public health and the root causes of all problems.(i)

Response:
The IMPEP review process was created to assure that public health and safety are adequately protected from the hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. Common performance indicators were established to obtain comparable information in the evaluation of both types of programs. The staff agrees that a risk informed process is the basis for IMPEP file selections and staff accompaniments, and guidance to IMPEP reviewers should continue to reflect a risked informed selection for sampling during IMPEP reviews. (Note: From the IMPEP Working Group Action Plan, (Recommendation 1-2), the State and Tribal Program procedures are being revised to include additional guidance for file selections and additional training was given in the 2003 refresher IMPEP training course to assure that reviewers select the more significant actions undertaken from a risk standpoint for review.) The staff does not agree with the commentor's

proposed revision but believes that Section (A)(1) could be clarified by adding the following revision:

> The review should be performance based to evaluate if the protection of public health and safety has been achieved. The outcome of the review should identify potential impacts on public health and safety and the root causes of performance that does not fully meet the criteria.

It should be noted that although NRC is presently conducting its radioactive materials program on a risked informed basis, it is not a matter of compatibility that the Agreement States conduct their programs in a similar fashion.

Comment 8:
SS&D: The 2002 Staff report proposes the following changes to Section (A):

> The IMPEP process should be conducted in a cooperative and collegial environment with the intent of improving the program. It also should be performed consistently from one State to another, keeping in mind the following guidelines (b)
>
> > •NRC and Agreement States, independent authorities jointly responsible for implementing programs to protect public health and safety, should work together to review program effectiveness. (i)
> >
> > • IMPEP should be used as a resource to identify public health and safety issues, to share information, and to jointly work to craft potential improvements. (ii)
> >
> > • IMPEP team should work to resolve issues during the IMPEP review process, and prepare reports that accurately reflect how opportunities for improvement were discussed and implemented. (iii)

Response
The staff does not agree that these proposed revisions should be included in MD 5.6. We believe specific guidance as found in MD 5.6, SA-100 and the specific IMPEP guidance to be developed for SS&D reviewers should include information on conducting reviews in a cooperative and collegial environment. The need for communication during reviews was reemphasized in the 2003 IMPEP refresher training course. Also the existing language in MD 5.6 and Handbook, Section (A), Part II already addresses using the same criteria for States and regions where appropriate.

We agree that IMPEP reviews can be used as a resource to identify issues, but this is not the primary goal of the evaluation process nor is it unique to the SS&D program. As issues are identified by the IMPEP teams, NRC management, together with the Organization of Agreement States (OAS) has formed NRC/OAS working groups to address issues and jointly work on improvements. Additionally, the suggestion that the IMPEP report should contain narrative discussion of how “opportunities for improvement were discussed and implemented” has already been implemented in practice, but the Handbook is not the appropriate document for this guidance for reviewers. The present guidance to IMPEP reviewers is that any discussions with either the States or Regions on suggestions or opportunities for improvement be captured in the written

report. This was reemphasized during the 2003 refresher training course. These discussions are presently being captured in the reports and additional guidance will be included in the revision to SA-100 regarding documentation of discussions and suggestions.

No changes to Handbook 5.6, Part II based on these recommendations.

Comment 9:
IMPEP: Part II should be reorganized to list the Technical Staffing and Training performance indicator first for both the common performance indicator and the non common performance sub-elements as appropriate.

Response:
These revisions will be made for Part II, Section (B)(3), (C)(2)(b), (C)(3)(c), (C)(4)(c), (C)(5)(c) and (C)(6)(e).

Comment 10:
IMPEP: In Recommendation 1-5, the IMPEP Working Group recommended that "Legislation and Program Elements Required for Compatibility" should be renamed "Compatibility Requirements."

Response:
The staff agrees with this recommendation and the revision will be made in Section (A)(4) and (C)(1).

Comment 11:
IMPEP: In Recommendation 1-5, the IMPEP Working Group recommended that "Response to Incidents and Allegations" should be renamed "Technical Quality of Incident and Allegation Activities."

Response:
The staff agrees with this recommendation and the revisions will be made for both the common performance indicator and the corresponding non common performance sub-elements in Part II.

Comment 12:
IMPEP: In Section (C)(2), footnote 1 should be moved into the text since an Agreement State is still requested to commit in writing to having an SS&D evaluation program in place prior to conducting reviews if they are not performing reviews. [note: corresponding change will need to be made to Part III for the evaluation category N for SS&D programs and other noncommon performance indicators where the Agreement State has the authority, but has no active program at the present time]

Response:
This revision will be made.

Comment 13:
SS&D: In Section (C)(2), 2002 Staff report recommends the following revision:

> NRC publication NUREG-1556, Volume 3, provides useful comprehensive guidance on conducting SS&D reviews.

Response:
The staff agrees with this revision, but proposes the following editorial clarification to be consistent with the language found in MD 5.6:

> NUREG-1556, Volume 3, provides information on conducting SS&D reviews that may provide useful guidance for review teams.

Comment 14:
SS&D: The 2002 Staff report made the following recommendation to Section (C)(2)(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*)
> – Understand and utilize basic knowledge of engineering materials and their properties (*h*)

In addition, the 2002 Staff report recommended the following footnote for Part III, Section (G)(2)(a) for a satisfactory finding:

> FOOTNOTE: The NRC Inspection Manual does not specify qualification criteria for SS&D reviewers. Pending issuance of such criteria, the following criteria are recommended:
>
> 1. BS/BA in physical and/or life science or engineering; or equivalent
> 2. 5-week Applied Health Physics Course (H309) or equivalent health physics background
> 3. Licensing Practices and Procedures Course (G109) or equivalent
> 4. Licensing and Inspection Course (G108) or equivalent
> 5. One week NRC course/workshop on SS&D evaluations
> 6. NRC Incident Investigation and Root Cause Analysis Course
> 7. Minimum 1 year of practical related experience (e.g design, engineering, licensing and inspection)

Response:
Staff agrees with the recommendations, but consistent with the effort to place requirements within the text of the Handbook, we propose the footnote for Part III be placed in Part II as part of the description of the subelement consistent with style and format of Handbook 5.6.

> Evaluation of SS&D ~~review~~ staffing and training should be conducted in the same manner and as part of the Common Performance Indicator ~~3~~1 (Sections (B)(~~3~~1)(a) and (b) of this part), except with a focus on training and experience 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~~ The minimum qualifying criteria for SS&D staff authorized to sign registration certificates should be— (ii)
>
> – BS/BA, or equivalent experience, in physical and/or life science or engineering (*a)*
> – 5-week Applied Health Physics Course (H309) or equivalent health physics background (*b*)
> – Licensing Practices and Procedures Course (G109) or equivalent training (*c)*
> – Licensing and Inspection Course (G109) or equivalent training (*d)*
> – One week NRC course/workshop on SS&D review and evaluations (*e)*
> – NRC Incident Investigation and Root Cause Analysis course or equivalent training (*f)*
>
> Staff should have a minimum of 1 year of practical related experience and demonstrated ability to conduct adequate SS&D reviews including— (iii)
>
> – 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*)
> – Understand and utilize basic knowledge of engineering materials and their properties (*h*)

Comment 15:
IMPEP: In Technical Quality of the Product Evaluation Program, Section (C)(2)(b), the following clarification consistent with the rest of the Handbook should be made:

> 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~~ to NRC, Agreement States and others as appropriate. (*b*)

Response:
The staff agrees with this clarification and will revise the Handbook.

Comment 16:
IMPEP: In Evaluation of Defects and Incidents Regarding SS&Ds, Section (C)(2)(c), the following clarification consistent with the rest of the Handbook should be made:

> 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~~ incidents should be evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to NRC, Agreement States and others as appropriate should ~~take place~~ occur in a timely manner.

Response:
The staff agrees with this clarification and will revise the Handbook.

Changes to Handbook 5.6, Part III

Comment 17:
IMPEP: In Recommendation 1-5, the IMPEP Working Group recommended that "Satisfactory with Recommendation for Improvement" should be renamed "Satisfactory, but Needs Improvement".

Response:
The staff agrees with this recommendation and the revisions will be made for both the common performance indicator and the non common performance sub-elements.

Comment 18:
IMPEP: As noted in Part II, Part III should be reorganized to list the Technical Staffing and Training performance indicator first for both the common performance indicator and the non common performance sub-elements as appropriate.

Response:
These revisions will be made for Part III, Section (C), (G)(2), (H)(3), (I)(3), (J)(3) and (K)(5).

Comment 19:
IMPEP: The requirements in Footnote 1, in revised Section (A)(1)(e) should be contained within the text of Part III and not be in a footnote.

Response:
This revision will be made.

Comment 20:
IMPEP: Revise "Status of Materials Inspection Program" in Section (B) to indicate that core inspections are all initial inspections (Priorities 1, 2, 3, 5, and 7) and all routine inspections of Priority 1, 2, or 3 licensees. This change will comport with the clarifying changes to STP procedure, SA-101.

Response:
To clarify that initial inspections are core inspections, the following revisions will be made to "Status of Materials Inspection Program":

Satisfactory (1)

- Core licensees (~~those with inspection frequencies of 3 years or less~~ initial inspections of Priorities 1, 2, 3, 5, and 7 and all routine inspections of Priority 1, 2, or 3) are inspected at regular intervals in accordance with frequencies prescribed in NRC Inspection Manual, Chapter 2800. (a)

- ~~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)~~

Satisfactory, But Needs ~~With Recommendations for~~ Improvement (2)

- More than 10 percent of the Priority 1, 2, or 3 ~~core~~ licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. Initial inspections completed greater than 6 months after receipt of licensed material or 12 months after license issuance (whichever comes first) are also included in the 10 percent calculation. (a)

- ~~Inspections of new licensees are frequently not conducted within 6 months of license approval. (b)~~

Unsatisfactory (3)

- More than 25 percent of the Priority 1, 2, or 3 ~~core~~ licensees are inspected at intervals that exceed the NRC Inspection Manual, Chapter 2800, frequencies by more than 25 percent. Initial inspections are completed greater than 6 months after receipt of licensed material or 12 months after license issuance (whichever comes first) are also included in the 25 percent calculation. (a)

- Inspection findings are delayed, or not communicated to licensees within 30 days. ~~Inspections of new licensees are frequently delayed, as are the inspection findings~~. (b)

Comment 21:
IMPEP: In Recommendation 1-5, the IMPEP Working Group recommended that "Response to Incidents and Allegations" should be renamed "Technical Quality of Incident and Allegation Activities."

Response:
The staff agrees with this recommendation and the revisions will be made for both the common performance indicator and the corresponding non common performance sub-elements in Part III.

Comment 22:

IMPEP: With the reorganization of Incident Response Operations (IRO) into Nuclear Security and Incident Response (NSIR) revise references to IRO.

Response:
This revision will be made for Part III.

Comment 23:
IMPEP: In Recommendation 1-5, the IMPEP Working Group recommended that "Legislation and Program Elements Required for Compatibility" should be renamed "Compatibility Requirements."

Response:
The staff agrees with this recommendation and the revision will be made in Section (F), Part III.

Comment 24:
SS&D: The 2002 Staff report made the following recommendation to Section (G)(1)(a) including a footnote containing the information now found in the proposed revision to Part II, Section (C)(2)(a)(ii)

> The technical reviews ~~and audit~~ are performed by staff having proper training and qualifications. (i)
>
> Qualification criteria for reviewers are established, implemented and documented. (ii)

Response:
The staff agrees with the inclusion of these clarifications, however believes it is more appropriate to place the information in the proposed footnote in the text of Part II, Section (C)(2)(a)(ii). When final guidance is developed and placed in IMC 1246 for sealed source and device reviewers, the Handbook should be revised to reference IMC 1246 and the specifics removed from the text of the Handbook.

Comment 25:
SS&D: The 2002 Staff report recommended elimination of Section (G)(1)(d), (G)(2)(d) and (G)(3)(d), Category N.

Response:
Staff does not agree with this proposal. Staff believes that Category N should be revised as follows and used for those programs where Agreement States with authority for sealed source and device evaluation are not performing SS&D reviews. This is consistent with the approach to remove requirements from footnotes to the text of the Handbook and would clarify that with a commitment in writing to having an SS&D evaluation program in place (as described in Part II, Section (C)(2)) before performing evaluations.

> Category N (d)
>
> ~~Not applicable.~~ Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement. For example, cases

where an Agreement State may have currently sealed source and device evaluation authority but is not performing any SS&D reviews. In such cases, the program should commit in writing to having an SS&D evaluation program in place (as described in Section (C)(2) of part II) before performing evaluations.

Comment 26:
SS&D: The SS&D working group report (2000) proposed the following definition for concurrence review:

> A 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. A concurrence review is a quality assurance review of the evaluation generated by the initial reviewer. The concurrence review need not be to the same level of detail as the initial review (i.e., it is not necessary to review every page of the application). 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. The level of the review necessary should be based on the complexity of the application, potential risk, and reviewer discretion.

The 2002 Staff report recommended that definition of concurrence review be eliminated from the Handbook because of its prescriptive nature and proposed the following revisions. This was a significant issue that the NRC staff and the SS&D group disagreed on. NRC staff believes that their proposal give greater flexibility without compromising health and safety.

Response:
We believes that a definition of concurrence review will provide clarity to the document and proposes the following revisions based on the SS&D Working Group report. However, consistent with the efforts to place requirements within the text of the Handbook, we propose that the definition in the footnote be deleted and that the following definition be placed in the Glossary.

> **Concurrence Review.** A quality assurance review is an evaluation of the initial safety review and must be performed by a different qualified reviewer. It does not need to be performed to the same level of detail as the initial review. The depth of quality assurance review should be commensurate with the complexity of the application and the potential risks associated with the use of the source, or device. This review should assure that the proposed product meets all applicable regulations and requirements and that appropriate health and safety concerns have been addressed and that the device will be safe under the proposed conditions of use and likely accident situations. The quality assurance review should also assure that the registration certificate for the source or device is accurate and that it provides information essential for proper licensing the product.

The staff will revise Section (G)(2)(a) for a “satisfactory” finding to reflect the other recommended revisions of the 2002 Staff report.

- 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.~~ under normal conditions of use and likely accident conditions. (i)

- Health and safety issues are properly addressed. (ii)
- ~~All initial and concurrence reviews[1] are performed by persons having adequate training. (iii)~~
- Registrations ~~All registrations~~ clearly summarize the product evaluation and provide license reviewers with adequate information to license possession and use of the product. (iii~~iv~~)
- Deficiency letters clearly state regulatory positions and are used at the proper time. (iv)
- ~~An independent technical review~~ A concurrence review of ~~the~~ each application and proposed certificate of registration is performed by a second ~~individual and supports~~ qualified reviewer or supervisor, and the record indicated that the second reviewer concurs on 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.)~~ (v~~i~~)

Comment 27:

IMPEP: For Section (G)(2)(a)(vii), (G)(2)(b)(v) and (G)(2)(c)(v), the following revisions should made:

Satisfactory

- Completed registration certificates, and the status of obsolete registration certificates, are clear and are promptly transmitted to NRC, Agreement States and others as appropriate ~~interested parties~~. (vii~~i~~)

Satisfactory but needs improvement

- Completed registration certificates, and the status of obsolete registration certificates, are not always clear or are not always promptly transmitted to ~~interested parties~~ NRC, Agreement States and others as appropriate . (v)

Unsatisfactory

- Completed registration certificates, and the status of obsolete registration certificates, are unclear and are not promptly transmitted to ~~interested parties~~ NRC, Agreement States and others as appropriate . (v)

Response:

The staff agrees with these recommendations and the revisions will be made.

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[1]~~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.~~

Comment 28:
IMPEP: For Section (G)(3)(a), (G)(3)(b) and (G)(3)(c), the following revisions should made:

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 NRC, Agreement States and others as appropriate ~~affected parties and other regulatory authorities~~.

Satisfactory, But Needs ~~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~~ NRC, Agreement States and others as appropriate.

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~~ NRC, Agreement States and others as appropriate.

Response:
The staff agrees with these recommendations and the revisions will be made.

Comment 29:
SS&D: The 2000 SS&D working group recommended SS&D IMPEP reviewer qualifications be such that:

IMPEP training should focus on consistency, cooperation, collegiality, and risk informed and performance based evaluations; especially for team leaders.

SS&D IMPEP reviewers must have the following minimum qualifications:

- must be qualified SSD reviewers;
- have at least 2 years of SSD review experience within the past 5 years; and have taken IMPEP training.

Note: The 2002 Staff report stated refresher training was needed.

Response:
IMPEP training focuses on communication, consistency, cooperation in the IMPEP reviews which are risked-informed performance based evaluations of the Agreement States and regional program. A risk informed approach to case selection and inspector accompaniments is emphasized both in initial training and the biannual refresher IMPEP training courses conducted. The biannual refresher training was held in January 2003 with emphasis on these issues. Management Directive 5.10, Formal Qualifications for IMPEP Team Members, issued January 5, 1999 has as required professional experience the requirements as noted in the SS&D working

group comment.

No change based on this comment.

Comment 30:
IMPEP: In the Low-Level Radioactive Waste Disposal Program, Section (H), revise Category N to reflect actual practice of not evaluating low-level radioactive waste programs where there is no active program in a similar fashion to the change for the SS&D program as follows.

~~Not applicable.~~Special conditions exist that provide adequate justification for not conducting an evaluation and providing a rating for this subelement. For example, NRC has not required Agreement States to have a program for licensing a low-level radioactive disposal facility until such time as the State has been designated as a host State for such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a low level radioactive disposal facility, they are expected to put in place a regulatory program as described in Section (C)(3) of part II.

Response:
The staff agrees with these recommendations and the revisions will be made.

Changes to Handbook 5.6, Part IV

Comment 31:
IMPEP: Revise Section (E)(1) to include the reference to the new STP procedure 122, Heightened Oversight and based on IMPEP experience with heighten oversight, delete the phrase "...safety significance that assurance of the program's ability to protect the public health may be degraded..." in the first sentence.

Response:
The staff agrees with this recommendation and will make the following revision:

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 in accordance with Office of State and Tribal Programs (STP) Procedure SA-122, "Heightened Oversight and Monitoring".

Changes to Glossary

Comment 32:
IMPEP: Revise the definition of "incident" to include the references to the new regulations.

Response:
The staff agrees with this recommendation, but proposes removing the specific Title 10 reference and cross-referencing STP procedure SA-300 as follows:

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, 70.5, 71,97~~ or ~~the~~ equivalent regulations. Office of State and Tribal Programs Procedure SA-300, "Reporting Material Events" includes a listing of NRC reporting requirement in Title 10.

Comment 33:
IMPEP: Revise the definition of "Overdue Inspections" to clarify that IMPEP is evaluating core licenses as follows:

Overdue Core 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~~ core license will be considered overdue for inspection in the following cases:

- A new licensee that possesses licensed materials 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.)

Response:
The staff agrees with this recommendation and will make the revision.