

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 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 risk 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 risk 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 31 (Sections (B)(31)(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<sup>1</sup> 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. (iiiiv)
- 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.) (vi)

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. (viii)

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

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<sup>1</sup>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.

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.

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 ~~interested parties~~ 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.