

SUMMARY OF COMMENTS ON REVISION TO MANAGEMENT DIRECTIVE 5.6,
INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

I. Sent to the Agreement States for Comment: September 25, 2003 (STP-03-073)

Comments Dated: Ohio, October 10, 2003 (email)
Illinois, November 18, 2003 (letter)

Response to/Resolution of Comments:

Ohio

Comment 1:

Ohio agrees with the proposed changes to Management Directive 5.6, Integrated Materials Performance Evaluation Program as presented in STP-03-073, dated September 25, 2003.

Response:

No response is necessary.

Illinois

Comment 1:

The 2002 Staff report apparently included a recommendation that the criteria for SS&D reviewers include, "NRC Incident and Investigation and Root Cause Analysis Course." In response, the course is listed as one of the minimum qualifying criteria for staff authorized to sign registration certificates in the Non-Common Performance Indicator 2-Sealed Source and Device Evaluation Program on page 9-10 of MD 5.6. Only one member of our staff, who no longer performs SS&D reviews, has completed the course. It is an informative course, but not essential for someone to perform an SS&D review; therefore, we strongly object to it being included as a minimum criteria to qualify someone to sign a registration certificate. We are very fortunate as our current staff have all completed the other listed training, and each has over a decade of experience in SS&D reviews. Currently, Gibb Vinson and myself are the only staff that perform concurrent reviews and neither of us has had the opportunity to complete the root cause analysis course. I have signed registration certificates for over 20 years and Gibb approximately a decade, we have both lectured on sealed source and device evaluations over the years, we both serve on SS&D Working Groups, etc. and to suddenly find ourselves unqualified is more than a bit disturbing. When did this course become so critical to performing an SS&D review? We would consider trying to take the course but we note from your website that one is not even scheduled for FY 2004 (it is on the list but no date or place has yet been determined). In addition, last year's tuition for the course ranged from \$1534 to \$1638 depending on the location with an additional approx. \$1000 minimum travel expense. This constitutes a significant financial requirement on state programs that are already facing severe budgetary constraints.

Including this course as a requirement to obtain a “Satisfactory” rating allows for a strict interpretation of the criteria by an IMPEP evaluator that could result in our program, and we suspect many other state programs, being deemed “unsatisfactory. Please list this course as recommended training, but not as one of the minimum qualifications criteria;

Response:

We appreciate Illinois’ comment and note that NRC has not yet issued final IMC 1246 guidance for Sealed Source and Device qualifications for NRC staff. It is our understanding that the proposed IMC 1246 guidance for NRC reviewers does not include the “NRC Incident and Investigation and Root Cause Analysis Course” as a minimum requirement. We believe that this course is appropriate as a recommended course also; however, since NRC has not issued the guidance for this area, we believe it is not appropriate to include this course as either a required or recommended course in the Handbook. We will delete this course as a minimum qualifying criterion for SS&D staff.

Comment 2:

The Division strongly objects to the addition on page 33 of MD 5.6 concerning Common Performance Indicator 2—Status of Materials Inspection Program. This section states that for a “Satisfactory, But Needs Improvement” finding, “Many of the inspection findings are delayed or not communicated to licensees within 30 days.” Even more disturbing is the addition of, “Inspection findings are delayed, or not communicated to licensees within 30 days” as the criterion for a program to be found “Unsatisfactory.” We have commented many times on this issue, and contend that our “goal ” is to send written communication to our licensees within 30 days after an inspection. For the most part this is not a problem but we also contend that there is no evidence that sending the written communication later than 30 days after an inspection has any health and safety significance. Findings are communicated to every licensee during the exit briefing for each inspection. Written communication is normally sent prior to 30 days; however, if the inspection is complex and requires additional investigation, if the inspection staff is sent on training, incident investigations, etc., the written communication may be sent later than the 30 day goal period. With budget problems and fewer people to perform more duties, the 30 day period will likely be exceeded even more in the future by State Programs as well as NRC Regions. What are the health and safety consequences of such a situation? Nothing that would warrant a finding of “Satisfactory, But Needs Improvement” or “Unsatisfactory.” Criteria for these findings must be directly related to health and safety and indicative of the adequacy of a program and not just an arbitrary administrative period of time that would be nice to achieve. Please do not include the 30 day period in your Findings criteria as it will simply provide an opportunity for someone to misapply and misinterpret during an IMPEP review and result in a contentious debate with little or no significance.

Response:

We appreciate Illinois’ viewpoint; however, this is not a new addition or requirement under the “Satisfactory, But Needs Improvement” finding. A bullet was added for the “Unsatisfactory” finding to provide consistency with the comparable bullets under other findings for this indicator. (Note, see revision to this bullet based on NMSS comment 4). The staff disagrees with Illinois that there is no evidence that sending written communication later than 30 days has any health and safety significance. We believe that safety issues could go unresolved with only the verbal exit briefing. We are not aware of any IMPEP reviews where this criteria has been misapplied or misinterpreted during the past IMPEP reviews. NRC staff will revisit this criteria if issues are

identified during the IMPEP reviews. There will be no change to the Handbook based on this comment.

II. Sent to the NRC Offices for Comment: September 25, 2003

Comments Dated: Region II, October 3, 2003 (email)
OCG, October 10, 2003 (mark-up)
NMSS, October 21, 2003 (email)
Region III, October 24, 2003 (email)
Region I, October 28, 2003 (memorandum)
Region IV, November 5, 2003 (email)
IG, November 10, 2003 (memorandum)

Region II

Comment 1:

This is in response to your memorandum dated September 25, 2003, requesting comment on a draft revision of MD 5.6 regarding IMPEPs. Because of the recent consolidation of the materials program in Region I and the fuel facility inspection program in Region II, we only reviewed the draft as it relates to fuel facilities. We only have two minor comments and one comment for integration of the fuel facility review.

Integration - This revision might be the appropriate vehicle to establish an evaluation of the fuel facility inspection program in an integrated manner, reviewing at the same time and with the same team the entire fuel facility inspection program, including the Region II program, the NMSS inspections of nuclear criticality safety, and NSIRs inspections of material control and accountability.

Response

We appreciate the comment; however, the expansion of IMPEP to headquarters functions was identified previously in the IMPEP Lessons Learned Working Group (see Region I Comment 4 response) and was not the subject of this revision. Your comment will be forwarded and discussed with NMSS and NSIR regarding future revisions for headquarters and the Regions. There will be no change to the Handbook at this time based on this comment.

Comment 2:

Minor Comments - We suggest that where the MD references IMC 2600, that it rather refer to the "appropriate 2600 series IMCs" since fuel facility inspection now includes 2600 and several IMCs in the 2600 series. Also, under indicator 5, we suggest that any reference to IMC 610 be to 610 in total rather than by section since the sections might change as the IMC is revised.

Response:

We agree with the comment to delete the reference to specific sections within an IMC. Throughout the entire handbook, the specific section under IMC 0610 and other IMCs will be deleted. We appreciate the suggestion that appropriate 2600 series IMCs would encompass additional IMCs as they are issued. However, the style of the Management Directive is to

include as a reference any document listed in the Management Directive or Handbook. No additional text with specific references to other ICM 2600 series was recommended in this revision of the Management Directive or Handbook. No additional changes to the Handbook will be made based on this aspect of the comment.

OGC

Comment 1:

Editorial Comment: Part II, page 3, Section A(1), last sentence. The word “does” should be “do.”

Response:

We disagree with this comment. There will be no change to the Handbook based on this comment.

Comment 2:

Editorial Comment: Glossary, Definition of Concurrence Review, seventh line, remove the “,” after source.

Response:

We agree with this comment and will revise the Handbook accordingly.

NMSS

Comment 1:

Page 3, 3rd Paragraph. Change to: "Certain non-reactor functions that continue to be completed from NRC **Headquarters or Region II**, such as fuel cycle licensing, ***fuel cycle inspections***...

Response:

We agree with this comment and will revise the Handbook accordingly.

Comment 2:

Page 10, 2nd Bullet. According to the OHR's website, H-309 is now the five-day Health Physics in Radiation Accidents Course, which is probably not the course you intended to reference here. We understand that H-309 may have been discontinued. If so, change to: "Formal Health Physics courses or equivalent health physics background.

[Note, Our course description for H-305 in the SS&D training journal follows: Provides an intensive radiation protection training program consisting of lectures, and preferably tours, workshops, and lab exercises to provide an understanding of atomic and nuclear physics, radiation biology, radiation detection principles, monitoring methods and equivalent calibration, external and internal dosimetry, uses of radiation and radiation protection, radionuclide pathways and environmental monitoring and radiation protection in emergencies.]

Response:

The course number was listed incorrectly in the proposed revision to Handbook 5.6. It will be changed to H-109. It should be noted that H-109 has not been discontinued but will only be available as an external course.

Comment 3:

Page 21, 3rd Paragraph. Change second sentence to read as follows: "Chapter 2600-04.02 provides the ~~responsible headquarters and regional offices~~ flexibility to adjust...."

Response:

We agree with this comment and will revise the Handbook accordingly. In addition, as noted in the response to Region II's comment 2, we will delete "-04.02".

Comment 4:

Page 33, 4th Bullet. Add the word "most" to the beginning of the second bullet under the Unsatisfactory heading. This is to provide more consistency with comparable items elsewhere in the Handbook.

Response:

We agree with this comment and will revise the Handbook accordingly.

Comment 5:

Page 51, 3rd Bullet. Same change as page 33. Add the word "most".

Response:

We agree with this comment and will revise the Handbook accordingly.

Region III

Comment 1:

All references to the performance of initial inspections should be consistent with the revised Inspection Manual Chapter 2800 which states that initial inspections of new licensees should be announced and completed within 12 months of the date the new license is issued.

Response:

We agree and the text on page 33 for the first and third bullets will be revised to indicate that licensees should be inspected within 12 months. We disagree that the language should be changed to indicate that the inspections should be announced. We believe that States should have the option to perform either announced or unannounced inspections. No change to the Handbook will be made based on this aspect of the comment.

Also, the definition of "overdue core inspections" in the Glossary has been revised with the elimination of the term "core" licensee from the revised IMC 2800 as follows:

Overdue Core Inspections. NRC no longer defines the term "core" licensees in NRC Inspection Manual, Chapter 2800. Many States use different definitions. For purposes of this management directive, a core licensee will be defined as

new licensees and licensees in Priorities 1, 2, and 3. A core license will be considered overdue for inspection in the following cases:

- A new licensee that has not been inspected within 12 months of license issuance.
- An existing Priority 1, 2 or 3 license is more than 25 percent beyond the interval defined in NRC Inspection Manual, Chapter 2800. (An inspection will not be considered overdue if the inspection frequency has been extended in accordance with NRC Inspection Manual, Chapter 2800, on the basis of good licensee performance.)

Region I

Comment 1:

Directive 5.6, References: The following references should be included in MD 5.6 due to their applicability to the IMPEP process:

- A. STP Procedure SA-100 "Implementation of the Integrated Materials Performance Evaluation Program"
- B. STP Procedure SA-106 "Management Review Board"
- C. STP Procedure SA-116 "Periodic Meetings with Agreement States between IMPEP Reviews"
- D. STP Procedure SA-119 "Follow-up IMPEP Reviews",
- E. MD 5.10 "Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members"

Response:

We appreciate the comment that the additional procedures are applicable to the IMPEP process. The style and format for NRC Management Directives is to list as a reference any document that is used in the text of the Management Directive or Handbook. With the exception of SA-116, the above-mentioned documents are not used in the text of Management Directive 5.6. No change to the Handbook will be made based on this comment. However, with the inclusion of SA-116 in the text of the Handbook (see IG comment 1 response), SA-116 will be included in the list of references.

Comment 2:

Handbook, Part II, General: The discussion of performance indicators should clearly state that for non-common performance indicators which have subelements, only **one** rating is provided for the entire indicator. Although past experience has shown that reviewers of non-common indicators with subelements have or have been directed to provide a rating for each subelement, the MD should provide clear guidance on how to determine the overall recommendation for the indicator.

Response:

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. For the non-common performance indicators that contain subelements, a single finding for the overall performance of the non-common performance indicator will be made by the review team. If the review team finds that a State's performance is satisfactory for all subelements evaluated for the non-common performance indicator, the State's performance for this indicator should be found satisfactory. If the review team finds that a State's performance is satisfactory but needs improvement for one or two subelements within the non-common performance indicator and is satisfactory for all remaining subelements, the review team should consider whether the State's performance is satisfactory or is satisfactory but needs improvement for this indicator. If the review team finds that a State's performance is unsatisfactory for one or two subelements within the non-common performance indicator, the review team should consider whether the State's performance is unsatisfactory or is satisfactory but needs improvement for this indicator.

Comment 3:

Handbook, Part II, Non-Common Performance Indicator 2 - Sealed Source and Device Evaluation Program: Two courses are listed as "G109". The current name of the course with this number is "Licensing Practices and Procedures Course". The listing "Licensing and Inspection Course" appears to be an error.

Response:

We agree with the comment that an error occurred. The second course will be revised to be the Inspection Procedure Course - "G-108."

Comment 4:

Handbook, Part II, Non-Common Performance Indicator 6 - Site Decommissioning Management Plan: The subelements for this indicator are subject to a very narrow aspect of the overall Regional program and do not follow the format or content of the common performance indicators or the non-common indicators which review the SS&D, LLRW, or uranium recovery programs. In addition, the financial assurance for decommissioning subelement is applied to materials licensing actions which are routinely reviewed for Agreement States under the common performance indicator "Technical Quality of Licensing Actions". The subelements for this indicator should be changed to follow the five basic performance indicators as used with the remainder of evaluated program areas.

Response:

We appreciate the concerns that the non-common performance indicator site decommissioning management plan is very narrowly focused and does not follow the format or content. This was also identified in the April 2002 IMPEP Lessons Learned Working Group as follows:

Recommendation 1-6: The Working Group recommends that the non-common performance indicator criteria in Management Directive 5.6 be revised to be more consistent and performance-based.

Your comment will be forwarded and discussed with NMSS for future revisions to this non-common performance indicator. There will be no change to the Management Directive at this time based on this comment.

Comment 5:

Handbook, Part III, Status of Materials Inspection Program: Category N correctly indicates that special conditions may arise that warrant the withholding of a rating. An additional example should be added to address the circumstances found during follow-up IMPEP reviews in which the Program has not inspected sufficient numbers of core or initial licenses to warrant a rating reflective of the program performance.

Response:

We appreciate the recommendation to add an additional example to the Category N description but do not agree that a program that has not inspected a sufficient number of core or initial licensees during a followup does not warrant a rating. We believe that the information regarding the rating should be gathered and presented. The experience has been that either a State has eliminated the backlog and can be found satisfactory in this category or there has been no change and the finding from the original IMPEP has not changed. There will be no change to the Handbook based on this comment.

Comment 6:

Handbook, Part IV, Adequacy Findings for Agreement State Programs: The term "satisfactory with recommendations for improvement" is used four times in this section. It should be replaced with "satisfactory, but needs improvement".

Response:

We agree with this comment and will revise the Handbook accordingly.

Comment 7:

General comment from memorandum: One recent enhancement to the IMPEP process was the use of heightened oversight and monitoring for State programs that have performance problems identified during an IMPEP review or periodic management meeting. Although this revision addresses the use of heightened oversight as a further action in Part IV of the Handbook, it does not address the use of monitoring of a State program. It is our understanding that the monitoring of an Agreement State program will be addressed in the next revision of MD 5.6. The inclusion of this tool would be an important addition to MD 5.6.

Response:

We agree with this comment and will revise Part IV, Section E(1), to include text on monitoring from SA-122 as follows:

Monitoring (1)

When weaknesses in a program result in, or could result in, less than fully satisfactory performance for one or more performance indicators, monitoring by

NRC will be considered by the MRB in accordance with STP Procedure SA-122, "Heightened Oversight and Monitoring." Monitoring is an informal process that allows the NRC to maintain an increased level of communication with an Agreement State program.

Region IV

Comment 1:

We believe that the criteria for performing routine and initial inspections should be revisited. In the current criteria, the performance of initial and routine inspections are included in a single calculation and weighted equally. Based on the current environment of national security, we believe that the timely performance of initial inspections is more important than the timely performance of routine inspections. The initial inspection serves two purposes: 1) it allows the Program to assess a licensee's radiation safety program soon after receiving material in order to redirect activities if necessary, and 2) it allows the Program to know if they have a valid licensee.

We recommend that criteria for the performance of initial inspections be established separately from criteria for performance of routine inspections.

Response:

We appreciate the comment that the criteria for the performance of initial inspections be established separately from the criteria for performance of routine inspections. We believe that Region IV has raised a valid concern; however, a change in this criteria would need to be shared and reviewed with all stakeholders. With the maturing of the national security requirements for both NRC and Agreement State, we will explore changes with in this area with the States/Regions, including a possibility of a changed criteria. The criteria could be initially applied in a similar fashion as Temporary Instructions (TIs) used by NRC to field test changes to IMCs. There will be no change to the Handbook at this time based on this comment.

IG

Comment 1:

Our one comment is related to the Office of State and Tribal Programs procedure SA-116, Periodic Meetings with Agreement States Between IMPEP Reviews (currently in draft revision). This procedure provides the guidelines for conducting periodic or mid-cycle meetings with Agreement States between scheduled IMPEP reviews. These periodic meetings have evolved to where they are effectively gathering important performance information. This is due to an increased focus on identifying performance issues early. Current periodic meeting practices include:(1) increased scope of discussion that allows a better sharing of information between the NRC and the States; (2) briefing the Management Review Board on the meeting's results with active participation from State staff; (3) identification of Program weaknesses (e.g., staffing shortage, inspection backlogs) and implementation of corrective measures in a timely manner. These interim meetings are essentially an adjunct to the IMPEP reviews, yet the two are separate in NRC guidance. MD 5.6 does not mention SA-116 and vice-versa. It would be more effective for NRC to integrate the two processes into a consolidated whole to reflect NRC's complete process of evaluating Agreement State programs.

Response

We appreciate the comment that the periodic meetings have evolved to where they are gathering performance information for the Management Review Board and that MD 5.6 does not contain any reference to SA-116. We also agree the two processes are being more closely integrated. STP has several procedures that deal with various aspects of the IMPEP to enable staff to have documents that are effective and easy to use on specific subjects, such as references in Handbook 5.6 to procedures on probation, suspension, and termination. We have included a reference to periodic meetings in MD 5.6 and the Handbook. "Periodic Meetings with Agreement States Between IMPEP Reviews" will be listed in the references in MD 5.6. We will also revise the Handbook, Part IV, Section A(1) as follows:

A management review board (MRB) will make the overall assessment of each NRC region's or Agreement State's program. Information considered by the MRB includes the proposed final report, recommendations prepared by the team that conducted the review of that region or State, information from periodic meetings in accordance with Office of State and Tribal Programs (STP) Procedure SA-116, "Periodic Meetings With Agreement States Between IMPEP Reviews," and any unique circumstances. The overall assessment will also 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. The MRB may also direct that a program be placed on monitoring, heightened oversight, or that the next IMPEP review or periodic meeting be scheduled earlier.(1)