

SUMMARY OF COMMENTS ON SA-104, "Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions"

I. Sent to the Agreement States for Comment: October 28, 2010 (FSME-10-091)

Comments/Dated: Organization of Agreement States--12/22/10 (e-mail)
State of North Carolina –12/01/10 (e-mail)
State of Virginia—12/10/10 (e-mail)
State of Nebraska—12/14/10 (letter)

Organization of Agreement States (OAS):

Comment 1:

Given that two states, Nebraska and Kansas, have raised issues on their IMPEPs regarding marking, storage and transportation of sensitive information, OAS would like to request that NRC provide better definition to the Agreement States as to what aspects of handling sensitive information are considered "program elements". Issues that have been raised to date:

- Some reviewers cite RIS-2005-031 which is intended for licensees to follow, not Agreement States.
- Some reviewers cite TI-002 which states that Agreement States are expected to protect sensitive information in a likewise manner to Increased Control 6. IC 6 is not applicable as Agreement States do not typically have the security plans and detailed information for their licensees in their files. Information gathered on inspection regarding Increased Controls is typically segregated and secured. Licensee information, such as their security plan, is reviewed on inspection.
- Agreement States must adhere to their own State open records laws. Some states can protect sensitive information under their own statutory authority but others may need to rely on federal law.
- Determining whether a document is sensitive information is somewhat of a judgment call. Facility diagrams, for example, should be restricted as sensitive information. However, there are a variety of opinions on whether radioactive material licenses should be classified as sensitive information. Better definition and consensus should be reached on these issues.

Response:

We agree with some items of this comment. As OAS stated, this issue was raised at both the Kansas and Nebraska Integrated Materials Performance Evaluation Program (IMPEP) reviews and Management Review Board (MRB) meetings. In addition, review teams are advised to take into account each State's laws on protecting and withholding documents containing sensitive information. On December 22, 2005, NRC issued Regulatory Issue Summary (RIS) 2005-31,

“Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Materials.” (ML053480073). The intent of RIS 2005-31 is to provide NRC licensees with guidance that they are encouraged to follow when handling or submitting documents to NRC that contain security-related sensitive information that could be useful, or reasonably be expected to be useful, to a terrorist in a potential attack, other than classified or safeguards information. The guidance in RIS 2005-31 was provided to NRC licensees and was not specifically addressed to Agreement States; however it was sent to all Agreement States via listserver.

On March 28, 2006, the NRC issued Temporary Instruction (TI)-002, “Integration of Increased Controls into the Integrated Materials Performance Evaluation Program” (ML060900564). This document describes the process used by the NRC to evaluate the implementation of Increased Controls (IC) through IMPEP. Section V.C.1.c. of TI-002 instructs the reviewer to verify and document that the Agreement State or NRC Region is protecting sensitive information in a manner consistent with Increased Control-6 (IC-6). A State’s laws or policies (such as certain “open records” type Acts) may ultimately authorize or require the release of some records or documents considered sensitive but the records or documents should still be protected from disclosure that might be inadvertent or unauthorized. Consistent with each State’s laws or policies, such records or documents may also be redacted to remove sensitive information prior to being released. The purpose of identifying, marking, properly handling, controlling access to, transmitting, and storing documents that contain sensitive or security-related information, consistent with IC-6, is to protect it from inadvertent or unauthorized release.

After the first year of evaluating Agreement State and NRC Regional programs with respect to the Increased Controls, the TI was reviewed and revised to reflect NRC organizational changes and to incorporate any lessons learned. On June 13, 2007, Agreement States and NRC Regional offices were provided with the opportunity to comment on the proposed revisions to TI-002 (ML071500402). The proposed revisions did not substantially change Section V.C.1.c. Comments on the proposed revisions were received by NRC but the procedure was not finalized or reissued. However, IMPEP teams were instructed to use this draft revision of TI-002 during the conduct of IMPEP reviews and to provide feedback on the use of the draft revision to the IMPEP Project Manager.

Recently, staff in the Office of Federal and State Materials and Environmental Management Programs (FSME) has been asked to incorporate the content of TI-002 into the existing FSME procedures related to the conduct of IMPEP reviews. As the FSME procedures are revised, they will be provided to Agreement State and NRC Regional programs for review and comment. When this process is complete, TI-002 will be rescinded. Until that process is complete, IMPEP review teams will continue to use the draft revision of TI-002. NRC staff has also issued a letter, RCPD-11-005, addressing these concerns. We will incorporate any changes that may be applicable to this procedure at a future date, if necessary. No changes were made to the procedure in response to this comment.

Comment 2:

Safeguards information is actually “modified safeguards information” and is rarely handled in Agreement State offices. If it does arrive, it typically comes to either the Radiation Control Program Director or the State Liaison Officer. These individuals safely store, do not share and typically destroy this information as soon as practical. The distinction between “modified

safeguards information” and “sensitive information” needs to be clear-both to the IMPEP reviewers and the management review board. We support making this distinction clear in this procedure and specifying the different approaches or standards that apply.

Response:

We agree with this comment. The procedure was revised to omit information regarding the review of safeguards information as this would not be part of a routine IMPEP review.

State of North Carolina:

No comments

State of Virginia:

Comment:

In Section V.B.2, Virginia recommends that where it says “or equivalent State procedure(s)” it state “or equivalent State policies, procedures or guidance”.

Response:

We agree with this comment. The procedure was revised accordingly.

State of Nebraska:

Comment 1:

Section II, Objectives: The removal of the “s” at the end of the word “Objectives” is inconsistent with the formatting of other recently revised FSME procedures in the series.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 2:

Section IV.A. The following sentence should be added to the roles and responsibilities of the Team Leader “is familiar with the practices that are considered by the NRC to be essential program components and are a matter of Agreement State compatibility from other licensing practices that may vary from those described in NRC guidance documents”. See Comment #5.

Response:

We appreciate, but disagree with this comment. IMPEP team leaders are not always qualified as authorized reviewers for every indicator and as such, rely on the qualified reviewer assigned to the performance indicator to be the one who is familiar with the practices that are considered by NRC to be essential program components for compatibility. No changes were made to the procedure in response to this comment.

Comment 3:

Section IV. Part B.5. One of the periods at the end of the sentence should be deleted.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 4:

Section V. Part B.2, Item g. The stricken text does not appear in the final version of SA 104 dated 5/14/2007. The only changes that should be addressed in this document are those related to the previous final version of the procedure not a draft that was never issued. The proposed Item g should be deleted. The marking of sensitive information is addressed in Item j and the evaluation of licensing actions is addressed in Item l.

Response:

We agree with the first sentence of this comment and have corrected the error. On the second point of this comment, we disagree that the proposed Item g. be deleted as it is addressing both the proper identification of those licenses containing risk significant radioactive materials, and the evaluation of these licenses against current guidance, regulation, etc. Item j. addresses the marking, storing, transporting and viewing of these documents, and Item l. addresses the evaluation of the overall technical quality of licensing actions other than the Increased Controls requirements. No changes were made to the procedure in response to this portion of the comment.

Comment 5:

Section V, Part B.2., Item i. The proposed Item i should be deleted for several reasons. The evaluation of the technical quality of licensing actions is already addressed in Item l. Additionally, Item l. correctly points out that "The principle reviewer should be aware that an Agreement State's licensing practices may vary from those described in the NUREG-1556 series". This concept is missing from the proposed text of this Item.

Response:

We appreciate, but disagree with this comment. Item i. is meant to address the pre-licensing guidance specifically (see NRC Region III's Comment/Response #1). No changes were made to the procedure in response to this comment.

Comment 6:

Section V. Part B.2. Item j. This item should be divided into several paragraphs. One paragraph should address the marking, storage and transportation of safeguards information in accordance with NRC regulations, policies and guidance. This paragraph would apply to both NRC staff and Agreement State staff. The second paragraph should address how NRC Regional Staff should handle other sensitive information in accordance with NRC regulations, policies and guidance. The final paragraph should address Agreement State staff handling of

sensitive information. Agreement States have different laws than the NRC governing the marking and release of documents. The NRC should refrain from implying in this document that equivalence with an NRC guidance documents is required for Agreement States unless specifically identified as an essential program element. However, Agreement States should have procedures in place to ensure compliance with their state law(s) on the marking and release of documents. It should be noted that, to date, there have been no FSME or RCPD letters to Agreement States identifying the marking and release of sensitive documents as an essential component of the licensing program.

Response:

See Responses to OAS Comments 1 and 2 above.

Comment 7:

Section V. B.2. Item I. The proposed new text should not be added. If other NRC policy/guidance is to be used to assist in the evaluation, it should be identified in this item and in Section VII. References. It is objectionable to tie the evaluation of performance to a standard that is not named.

Response:

We appreciate, but disagree with this comment. Since regulations, policies and guidance are constantly changing, we are using a generic statement in the place of specific document listings. This is consistent with our style for FSME procedures. However, all documents that were referred to in the procedure can be found in the "References" section. No changes were made to the procedure in response to this comment.

Comment 8:

Section V. B.4. The following should be added after the existing sentence "The number of licensing actions reviewed should also be commensurate with the program size if no programmatic weaknesses are identified."

Response:

We agree with the general intent of this comment; however, we still feel that there is a need to specify minimum and maximum criteria. No changes were made to the procedure in response to this comment.

Comment 9:

Section V. C.2. One of the periods at the end should be deleted.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 10:

Section V. D.4. To be consistent with the rest of the Part, a semicolon is needed at the end of the paragraph.

Response:

We agree with this comment. The procedure was revised accordingly

Comment 11:

Section V. D.9. The first sentence should be amended to read “Licensing guides, checklists and policy memoranda are used consistent with current NRC or Agreement State practice.” As noted above, Agreement State practices may vary from those described in NRC guidance documents.

Response:

We agree with this comment. The procedure was revised to incorporate this and another related comment (See NRC DILR Comment/Response #10 below).

II. Sent to the NRC Offices for Comment: October 29, 2010

Comments/Dated: Region I – 11/26/10 (e-mail)
Region III – 11/10/10 (e-mail)
Region IV - 11/15/10 (e-mail)
DILR/FSME – 11/24/10
OGC – 11/23/10 (e-mail)

Region I:

No comments

Region III:

Comment 1:

Section V.B.2.i. This section, which provides guidance to the principal IMPEP reviewer, no longer highlights the need to verify that pre-licensing visits were performed of new licensees. Instead, it now tells the reviewer to ensure that current NRC or State policies/guidance is used for new license applications. We believe that specifically mentioning “pre-licensing visits” will help the reviewer to key in on that area, as opposed to this more generic approach.

Response:

We agree with the comment. The procedure was revised accordingly.

Comment 2:

Section V.D.4. Regarding the sentence "...increased controls should be in place by the first day that actual possession quantities are at or above the established limits of concern, whichever is later." We suggest that the word "should" be changed to "must" or "shall" and that the unneeded "whichever is later" clause be removed from the sentence.

Response:

We agree with this comment. The procedure was revised accordingly.

Region IV:

Comment 1:

Update D.7. to include the pre-licensing guidance for new applicants.

Response:

We agree with this comment. The procedure was revised accordingly.

**Office of Federal and State Materials and Environmental Programs/
Division of Intergovernmental Liaison and Rulemaking (FSME/DILR)**

Comment 1:

On page 1, section 1, paragraph 1, lines 4-5, delete the "[]" and insert the phrase "In accordance with" between "Actions" and "NRC". This revision is suggested to clearly reference the authority of the applicable Management Directive.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 2:

On page 1, section II, subsection A, line 1, delete the word "action". This revision is suggested for grammatical correctness.

Response:

We disagree with this comment. The term "action" is consistent with licensing practice and other FSME procedures. No changes were made to the procedure in response to this comment.

Comment 3:

On page 1, section II, subsection C, lines 3-5, after "quantities used", delete the current wording and insert the following: "qualifications of users, facilities, equipment, locations of use, and any

other requirements necessary to ensure an adequate basis for the licensing action, e.g. financial assurance, and operating and emergency procedures.” This revision is suggested to clarify that licensing requirements vary based upon the complexity of the license. For example, not all licenses are required to have financial assurance arrangements.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 4:

On page 2, section IV, subsection B, paragraph 5, line 1, insert the phrase, “and is prepared to discuss their findings, if necessary”. This revision is suggested to ensure that the reviewer is knowledgeable of his/her role and the purpose during the Management Review Board meeting.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 5:

On page 2, section V, subsection A, paragraph 1, line 1, insert the word “usually” between “procedure” and “applies”. This revision is suggested for clarification purposes.

Response:

We appreciate, but disagree with this comment. Inserting the word “usually” may cause confusion if not explained further, and is also outside the scope of this procedure. No changes were made to the procedure in response to this comment.

Comment 6:

On page 2, section V, subsection A, paragraph 1, line 4, insert the following sentence at the end of the paragraph “It may be necessary to review licenses beyond the last IMPEP review period in order to follow up on special regulatory issues, e.g. to respond to Congressional requests, allegations, or verification of newly applied requirements such as additional security control measures.” This revision is suggested so that cognizant persons are aware that there maybe special circumstances that will warrant review of licenses beyond the last IMPEP review period.

Response:

We appreciate, but disagree with this comment. Special circumstances requiring an expanded review beyond the routine 4 year period is considered on a case-by-case basis and outside the scope of the routine procedure. Special instructions to the team would be given at that time. The comment will be considered for future revisions to this procedure or others if it appears that additional guidance is needed for these exceptions to the procedure. No changes were made to the procedure in response to this comment.

Comment 7:

On page 5, section V, subsection C, paragraph 2, line 7, delete the word “viewing” and insert “reviewing”. This revision is suggested for clarification purposes.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 8:

On page 5, section V, subsection C, paragraph 2, line 8, delete the extra “.” at the end of the sentence. This revision is suggested for grammatical correctness.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 9:

On page 6, section V, subsection D, paragraph 4, lines 1-2, delete the first sentence and insert the following, “Licenses meeting the increased control criteria have been identified and the additional security requirements have been implemented.” This revision is suggested for clarification purposes.

Response:

We agree with this comment. The procedure was revised to incorporate this comment and other rewording consistent with the revised IMC 2800 and other FSME procedures.

Comment 10:

On page 7, section V, subsection D, paragraph 9, line 1, insert the phrase “and are” between “used” and “consistent”. This revision is suggested for grammatical correctness.

Response:

We agree with this comment. The procedure was revised accordingly.

Comment 11:

On page 7, section V, subsection D, paragraph 9, line 2, delete the phrase “current NRC practice” and insert “current acceptable health and safety practices.” This revision is suggested because not all Agreement States follow the NRC licensing practices described in NUREG-1556, and have developed their own licensing guidance. This suggested revision would also ensure consistency with “Q&A” No. 3, in Appendix B of the subject procedure—SA-104.

Response:

We appreciate, but disagree with this comment. NRC policy is based on current health and safety practices, and any procedures used by the States must be equivalent to NRC and thereby based on current acceptable health and safety practice. No changes were made to the procedure in response to this comment.

Comment 12:

On page 7, section V, subsection D, paragraph 9, lines 3-7, delete the sentence that begins with "New standards" and insert the following sentence: "The reviewer should ensure that the radioactive materials licensing program is promptly incorporating new standards and guidance into their licensing process. (See NUREG-1556, *Consolidated Guidance About Materials Licenses*, Vol. 1-21 for the NRC generated guidance.)" This revision is suggested for grammatical correctness.

Response:

We agree with this comment. The procedure was revised accordingly.

Office of the General Counsel (OGC):

Comments:

OGC provided multiple minor edits to the procedure.

Response:

We agree with most of the edits. The procedure was revised in accordance with the agency's editorial style and consistent with other FSME procedures.