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FSME Procedure Approval

Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions - SA-104

Issue Date:

Review Date:

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NOTE
Any changes to the procedure will be the responsibility of the FSME Procedure Contact. Copies of the FSME procedures are available through the NRC website.

	Procedure Title: ***Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*** **Procedure Number: SA-104**	**Page: 1 of 8** **Issue Date:**

I. INTRODUCTION

This document describes the procedure for conducting reviews of U.S. Nuclear Regulatory Commission (NRC) Regional and Agreement State radioactive materials programs using the common performance indicator, Technical Quality of Licensing Actions in accordance with NRC Management Directive (MD) 5.6*, Integrated Materials Performance Evaluation Program (IMPEP)*~~]~~.

II. OBJECTIVE~~S~~S

A. To verify that licens~~e~~ing action reviews are thorough, complete, consistent, and of acceptable technical quality with health and safety issues properly addressed.

B. To ensure that decisions regarding the issuance, denial, amendment, termination, or renewal of radioactive materials licenses are made in a technically sound fashion and in a manner consistent with approved NRC or Agreement State policies, procedures and guidance.

C. To verify that essential elements of license applications have been submitted and that these elements meet current NRC or Agreement State regulatory guidance for describing the isotopes and quantities used, qualifications of ~~personnel who will use~~ authorized~~material~~ users, facilities~~ and~~, equipment, locations of use, operating and emergency procedures and any other requirements necessary to ensure an adequate basis for the licensing action, e.g. financial assurance, increased controls~~and operating and emergency procedures~~, etc.~~ sufficient to establish the basis for licensing actions~~.

D. To confirm that license reviewers, if applicable, have the proper signature authority for the cases they review independently.

E. To determine that license tie-down conditions are usually stated clearly and are inspectable.

F. To verify that deficiency letters clearly state regulatory positions and are used at the proper time.

G. To confirm that reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.

H. To verify that applicable guidance documents are available to reviewers and are followed.

~~I. To determine the status of complex decommissioning sites formerly managed by the NRC under the Site Decommissioning Management Plan (SDMP) and transferred to States whose Agreements became effective after August 26, 1999.~~

III. BACKGROUND

This performance indicator evaluates the technical quality of the licensing program on the basis of an in-depth, on-site review of a representative cross-section of licensing actions (new applications, amendments, renewals, terminations, etc.), decommissioning actions, bankruptcies, and notifications. The evaluation of ~~T~~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.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader:

Determines which team member(s) is assigned lead review responsibility for this performance indicator.

B. Principal Reviewer:

1. ~~1. SS~~Selects licens~~es~~ing actions to be reviewed, reviews relevant documentation, conducts staff discussions, and maintains a summary of all licens~~es~~ing actions reviewed.

2. ~~The principal reviewer should m~~Meet~~s~~ the appropriate requirements as specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.

3. Informs the team leader of their findings throughout the review.

4. Completes their portion of the IMPEP report for th~~is~~e performance indicator(s) reviewed.

5. Attends the IMPEP Management Review Board meeting for the review and is prepared to discuss their findings, if necessary (this can be done either in-person or via teleconference).~~-~~

V. GUIDANCE

A. Scope

1. This procedure applies only to review (for adequacy, accuracy, completeness, clarity, specificity, and consistency) of the technical quality of completed radioactive materials licensing actions issued by the NRC Region or Agreement State in the period since the last IMPEP review.

2. This procedure excludes non-Atomic Energy Act licenses and reviews issued by NRC Headquarters personnel.

3. This procedure does not apply to the technical quality of licensing action reviews ~~of~~conducted for~~While it is also necessary to evaluate~~ the non-common indicators, i.e. ~~an Agreement State's~~ sealed source and device evaluation program, uranium recovery program, and low-level radioactive waste program. ~~,~~ (~~those reviews are conducted as non-common performance indicators for Agreement State programs. This procedure is not intended to apply to those reviews.~~See the specific SA procedure for the applicable non-common indicator review).

B. Evaluation Procedures

1. The principal reviewer should refer to Part III, *Evaluation Criteria*, of MD 5.6 for specific evaluation criteria. The definition of the term "Materials Licensing Action" can be found in the Directive's Glossary.

2. Depending on the size of the NRC Regional or Agreement State radioactive materials program, the principal reviewer should select approximately10-25 licensing actions of various types for review~~.~~:

   a. All licensing actions performed since the last review are candidates for review.

   b. Reviews of license terminations, bankruptcies, and complex decommissioning will be treated as a subset of this common performance indicator.

   c. Licensing casework should be selected to represent a cross-section of the program's workload. The cross-section should be based on types of licenses, types of licensing actions, and license reviewers. The principal reviewer should perform a "judgmental" sample of the program's licensing casework based upon safety significance. The use of "judgmental" sampling, rather than "random" sampling, maximizes the efficiency of the review of casework. By focusing on safety significant licensing actions, the reviewer has a greater probability of identifying programmatic weaknesses that would have the greatest impact on public health and safety.

   d. The reviewer should select a mix of licensing actions to include medical and academic use ~~s~~ (e.g., universities, community hospitals, gamma stereotactic radiosurgery units, physicians, and broad scope facilities) and industrial use ~~licenses~~ (e.g., radiography, irradiators, and manufacturers/distributors) for review.

e. If possible, the selected licenses should include at least two licensing actions for new licenses, three major program amendments (including one denial), three license renewals, and one license termination or bankruptcy.

f. Licens~~es~~ing actions authorizing possession of radioactive material in quantities exhibiting potential for significant environmental impact, requiring an emergency plan, and/or requiring financial assurance should be included whenever possible.

g. ~~In addition to the guidance found in TI 002, "*Integration of the IC's into IMPEP*", I~~Licens~~es~~ing actions authorizing possession of "Risk-Significant Radioactive Material" requiring implementation of Increased Controls and/or Security Requirements, should be properly identified and evaluated using current NRC policies/guidance ~~the criteria specified in Appendix C.6 to NUREG-1556, Vol. 20 and the "Guide for Applying the License Condition for the Orders for Increased Controls and Fingerprinting" (ML 080070152)~~or equivalent Agreement State policies, procedures and guidance.

h. Licenses should be evaluated to ensure that they contain legally binding requirements or license conditions, as necessary; and that these requirements/conditions were incorporated in a timely manner, e.g. for new license applicants or existing licensees requesting to possess radioactive materials in quantities of concern requiring Increased Controls, these requirements/conditions should have been in place by June~~-~~ 2, 2006, or by the first day that the licensee possessed materials exceeding these quantities, whichever is later.

~~h~~i. Applications for new licenses and certain amendment and renewal requests are being evaluated using the criteria for Pre-licensing screening specified in Appendix C of NUREG-1556, Vol. 20 or equivalent Agreement State policies, procedures and guidance.

~~i~~j. Licensing documents (both incoming and outgoing) containing sensitive ~~and/or safeguards~~ information are appropriately marked, stored, transported and viewed in accordance with current NRC regulations, policies and guidance or equivalent Agreement State policies, procedures and guidance.~~ guidance.~~

~~g. Complex decommissioning licensing activities should be reviewed, if applicable, including activities associated with the decommissioning of complex sites formerly managed by the NRC under SDMP and~~

~~transferred to States whose Agreements became effective after August 26, 1999.~~

~~h~~j~~k~~. No attempt should be made to evaluate an NRC Region's performance on a State-by-State basis for this indicator.

~~ik~~l. ~~To evaluate~~For guidance on evaluating the technical quality of individual licensing actions, the principal reviewer should refer to the program-specific guidance in NRC's NUREG-1556, *Consolidated Guidance About Materials Licenses*, Vols. 1-2~~0~~1 and other current NRC policies/guidance, as applicable. The NUREG-1556 series provides guidance to license applicants and reviewers to help ensure the quality of license applications and reviews. The principal reviewer should be aware that an Agreement State's licensing practices may vary from those described in the NUREG-1556 series.

~~3. In accordance with FSME Procedure SA-1000, *Implementation of the Grants Program for Funding Assistance for Formerly Licensed Sites in Agreement States*, the reviewer should include a sampling of Agreement State actions implemented through the Grant Program, if applicable.~~

~~4~~3. If the initial review indicates a systematic weakness in the technical quality in a specific licensing action on the part of one reviewer, or problems with respect to one or more type(s) of licensing action(s), additional ~~similar license~~ files for licensing actions of a similar nature should be obtained and reviewed, in order to determine the magnitude of the programmatic weakness and its root cause. If previous reviews indicate a programmatic weakness in a particular area, additional casework in that area should be reviewed to assure that the weakness has been addressed.

~~5~~4. If the evaluation of approximately 10-25 licensing actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.

~~6~~5. Licensing actions pending completion for unusually long periods of time (e.g., amendments not completed for periods greater than six months or renewals not completed for periods over one year), should be identified specifically, in order to determine whether or not there have been any safety-significant impacts on each licensee's program.

C. Review Guidelines

1. The response ~~generated~~provided by the NRC Region or Agreement State radioactive materials program to relevant questions in the IMPEP questionnaire should be used to focus the review.

2. For the NRC Regions, both tallies and lists of completed licensing actions can normally be obtained from the License Tracking System (LTS) or current system in use at the time. This information can be obtained prior to the on-site review from the Office of Federal and State Materials and Environmental Management Programs (FSME). ~~Once the appropriate license files are selected, a call to the Region can be made to have the licenses pulled and ready for review at the time of the visit~~The Region should be contacted to make arrangements for the reviewing of electronic files, if paper docket files no longer exist.~~.~~

3. For Agreement States, the principal reviewer, in coordination with the team leader, should consider the quantitative and qualitative responses to the questionnaire as well as general knowledge about the nature and scope of the specific program under review in determining the licens~~e~~ing action files to be reviewed on-site.

D. Review Details

To determine the technical quality of licensing actions, the principal reviewer should evaluate the following:

1. Technical correctness with regard to license conditions, issu~~e~~ance and expiration dates, and nomenclature in distribution licenses;

2. License ~~A~~applications (e.g. new, amendment, renewal, termination, etc.) are properly completed and signed by an authorized official;

3. Any significant errors, omissions, deficiencies or missing information in licensing action files (i.e., documents, letters, file ~~notes,~~notes and telephone conversations). Licenses should be properly supported by information in the file. Any significant deficiencies related to health and safety should be documented, discussed with the team leader and communicated to ~~the p~~Program ~~being evaluated~~management (See Item V.F. of this procedure);

4. Licensees meeting the criteria to implement increased controls have been identified and the additional security requirements have been implemented~~.;are subject to increased controls. A system is in place to readily identify new licensees that should be subject to increased controls. For new applicants for a license or for existing licensees seeking possession of radioactive materials in quantities of concern, 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.~~

~~4~~5. Improper and/or illegal license authorizations. Any variances/exceptions to standards should receive management approval and not undermine health and safety;

~~5~~6. Appropriate financial assurance instruments are in place for licenses authorizing possession of radionuclides, quantities, or a combination thereof that meet the criteria for financial assurance requirements;

~~6~~7. ~~Any p~~Pre-licensing ~~visits~~visits completed for ~~for~~ new applicants and complex/ ~~and~~ major licensing actions, as applicable;

~~7~~8. Procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflect~~s~~ the current scope of the licensed program;

~~8~~9. Licensing guides, checklists, and policy memoranda are used and are consistent with current NRC ~~practice~~ or equivalent Agreement State practice.~~(For the Regions, the emphasis should be on proper implementation of same).~~ The reviewer should ensure that the radioactive materials licensing program is promptly incorporating ~~N~~new standards and guidance ~~that have been generated by the NRC or the State since last renewal/amendment have been incorporated~~ into their licensing process (See NUREG-1556, *Consolidated Guidance About Materials Licenses*, Vol. 1-2~~0~~1, for NRC-generated licensing guidance)~~. For example, the licensing process was modified to provide the mechanism for the reviewer and cognizant supervisor to request an evaluation of a potential security risk (see NUREG-1556, Volume 20, Appendix C, that provides the Checklist and refers to Implementation Guidance)~~;

~~9~~10. Appropriate use of signature authority;

~~10~~11. Consideration of the present compliance status of licensees during reviews of licensing actions;

~~11~~12. Use of standard license conditions to expedite and provide uniformity to the licensing process, whenever practicable;

~~12~~13. Verification of legally binding requirements, such as license conditions, implemented by Agreement States in place of promulgated regulations; and

~~13~~14. Implementation of licensing initiatives. In particular, the reviewer should identify these initiatives for a performance-based review (i.e., radiography certification, general licensing programs, etc.).

E. Review Information Summary

1. At a minimum, the summary maintained by the principal reviewer will include:

   a. The licensee's name, city, and state;

   b. The license number;

   c. The license reviewer's initials;

   d. The type of licensing action (e.g., new, amendment, renewal, or termination, etc.);

   e. The date the licensing action was issued;

   f. The type of licensed operation (e.g., program code ~~or~~, license category, etc.); and

   g. The amendment number.

2. Appendix A, Licensing Casework Review Summary Sheet, provides a template for recording the necessary information that should be maintained by the principal reviewer. The principal reviewer should not feel obligated to use Appendix A, but may find it as a useful means of recording the necessary information.

3. Due to the NRC policies on sensitive information, not all the information maintained in the reviewer's summary will appear in the list of licensing casework review in the report's appendix. Please contact the IMPEP Project Manager for the current guidance and format on the report's licensing casework appendix.

4. Comments in regard to licensing casework that will appear in the report's appendix should be factual, concise, and concentrate on casework deficiencies and their root cause(s).

F. Discussion of Findings with the Region or Agreement State.

The reviewer should follow the guidance given in FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussing technical findings with reviewers, supervisors, and management.

VI. APPENDI~~X~~CES

A. Licensing Casework Review Summary Sheet
B. Frequently Asked Questions

VII. REFERENCES

1. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

2. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members.*

3. NUREG-1556, *Consolidated Guidance About Materials Licenses*, Vol. 1-2~~0~~1.

4. FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP).*

~~5. FSME Procedure SA-1000, *Implementation of the Grants Program for Funding Assistance for Formerly Licensed Sites in Agreement States.*~~

VIII. ADAMS REFERENCE DOCUMENTS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into the NRC~~'~~s Agencywide Document Access Management System (ADAMS) are listed below.

No.	Date	Document Title/Description	Accession Number
1	5/7/04	STP-04-034, Opportunity to Comment on Draft Revisions to STP Procedure SA-104	ML041320486
2	5/7/04	Draft STP Procedure SA-104	ML041320524
3	10/20/04	Summary of Comments on SA-104	ML051830136
4	3/8/05	STP-05-018, Final STP Procedure SA-104	ML050680544
5	3/9/05	STP Procedure SA-104	ML051830527
6	2/22/07	STP-07-018, Opportunity to Comment on Draft Revisions to FSME Procedure SA-104	ML070540530
7	2/22/07	Draft FSME Procedure SA-104	ML070570164
8	5/14/07	FSME Procedure SA-104	ML071400002

9	10/28/10	FSME-10-091, Opportunity to Comment on Draft Revision to FSME Procedure SA-104	ML102770128

APPENDIX A
LICENSING CASEWORK REVIEW SUMMARY SHEET

A/S OR REGION: _____

FILE NO.: _____ TYPE OF LICENSING ACTION: ☐ NEW
LICENSEE: ☐ RENEWAL
_____ ☐ AMENDMENT
LOCATION: ☐ TERMINATION
_____
LICENSE TYPE: LICENSE REVIEWER:_____
_____
DATE OF ACTION: _____
LICENSE NO.:
AMENDMENT NO

NO	COMMENTS FOR REPORT

QUESTIONS FOR REVIEWERS

SUPERVISORY REVIEW BY:_____ DATE:_____

IMPEP REVIEW BY:_____ DATE:_____

FINDINGS DISCUSSED WITH: _____ DATE: _____

Appendix B

Frequently Asked Questions

Q: I'm supposed to confirm that license reviewers have the proper signature authority for the cases that they review independently. What if the Agreement State only allows supervisors or certain levels of management to sign licenses?

A: We are aware that not all radioactive materials programs permit their technical reviewers to sign radioactive materials licenses. In these cases, the principal reviewer for this indicator should ensure that the license reviewer has met his/her respective program's qualifications to independently review the types of licenses under review. There is no requirement that a license reviewer must have signature authority. The policy of signing licenses is dependent upon the program's legal requirements and administrative procedures.

Q: Why don't we evaluate the quantitative aspect of a licensing program? The program's licensing actions that I'm reviewing are of high technical quality, but there is a significant backlog of licensing actions.

A: We do evaluate the quantitative aspect of a licensing program, just not as formally as the quantitative aspect of an inspection program. It is important to note if there is a significant backlog of licensing actions and to determine whether or not there are any potential health and safety impacts. In most cases, a significant backlog of licensing actions is indicative of a staffing issue and would be fully evaluated under the common performance indicator, Technical Staffing and Training.

Q: I'm reviewing an Agreement State's performance in regard to licensing and it is apparent that they are not following the guidance in NUREG-1556. Is that okay?

A: NRC's NUREG-1556 is, in fact, guidance. Agreement States are welcome to use the guidance provided in NUREG-1556, but it is also acceptable for an Agreement State to develop their own licensing guidance. We typically do not evaluate an Agreement State's policies and procedures after the initial approval of the Agreement. IMPEP is performance-based and a review team's findings are based on actual performance. If the review team identifies potential weaknesses with an Agreement State's licensing program, the review team is expected to determine the root cause of the weakness, which may include assessing the adequacy of the program's licensing procedures. The key is that health and safety issues are properly addressed during all license reviews.

Q: What is the expectation for reviewing a State's procedure for protecting and controlling documents containing sensitive information?

A: Current guidance (see RCPD-11-005) instructs the reviewer to verify and document that NRC Regional and Agreement State radioactive materials programs are protecting sensitive information in a manner consistent with Increased Control-6 (IC-6). Increased Control (IC)-6 is not a prescriptive requirement. Instead of providing detailed instructions for the control of sensitive information, it allows licensees to develop, maintain, and implement their own policies and procedures for protecting sensitive information. IC-6

also provides a list of items that are to be included in the procedures, such as identification and marking of sensitive information.

Having a program consistent with IC-6 and the guidance referenced above allows each Agreement State program the opportunity to develop, maintain and implement its own policies and procedures in a manner consistent with its applicable State laws and policies on the protection and release of sensitive information. Policies and procedures developed by Agreement States should address, at a minimum, the means for identifying, marking, properly handling, controlling access to, transmitting, and storing documents that contain sensitive information.