FSME Procedure Approval

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

Issue Date:

Review Date:

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NOTE

These procedures were formerly issued by the Office of State and Tribal Programs (STP). Any changes to the procedure will be the responsibility of the FSME Procedure Contact as of October 1, 2006. Copies of FSME procedures will be available through the NRC website.

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

I. INTRODUCTION

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

II. OBJECTIVES

A. To verify that license 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 guidance.

C. To verify that essential elements of license applications have been submitted and that these elements meet current regulatory guidance for describing the isotopes and quantities used, qualifications of personnel who will use material, facilities and equipment, financial assurance, and operating and emergency procedures 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, decommissioning actions, bankruptcies, and notifications. 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. ~~The principal reviewer should meet the appropriate requirements as specified in MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*.~~

B. Principal Reviewer:

1. Selects licenses to be reviewed, reviews relevant documentation, conducts staff discussions, and maintains a summary of all licenses reviewed.

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

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. While it is also necessary to evaluate an Agreement State's sealed source and device evaluation program, uranium recovery program, and low-level radioactive waste program, those reviews ~~will be~~are conducted as non-common performance indicators for Agreement State programs. This procedure is not intended to apply to those reviews.

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. All Regional or Agreement State materials licensing actions since the last performance review are candidates for review. Reviews of license terminations, bankruptcies, and complex decommissioning will be treated as a subset of this common performance indicator.~~

~~3~~2. Depending ~~up~~on the size of the NRC Regional or Agreement State radioactive materials program, the principal reviewer should select ~~between~~ 10-25 licensing actions of various types for review. ~~Whenever possible, the selected licenses should represent a cross-section of the Agreement State's or Region's workload, including as many different license reviewers and license categories as practical. No attempt should be made to evaluate Regional performance on a State-by-State basis for this indicator. A mix of medical and academic uses (e.g., universities, community hospitals, teletherapy licenses, physicians, and broad scope facilities) and industrial use licenses (e.g., radiography, irradiators, gauges, and measuring devices) should be selected for review. Whenever possible, the selected licenses should include at least two new licenses, at least three major program amendments (including one denial), at least three license renewals, and at least one license termination or bankruptcy. Licenses authorizing activities with significant environmental impact potential, requiring an emergency plan, and requiring financial assurance should be included whenever possible. Complex decommissioning licensing activities should also be reviewed, if available. Termination of complex decommissioning sites formerly managed by the NRC under SDMP and transferred to States whose Agreements became effective after August 26, 1999 should be reviewed, if applicable.~~

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 medical and academic uses (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 new licenses, three major program amendments (including one denial), three license renewals, and one license termination or bankruptcy.

f. Licenses 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. 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. No attempt should be made to evaluate an NRC Region's performance on a State-by-State basis for this indicator.

i. To evaluate 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. 1-20. 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~~4~~. In accordance with ~~STP~~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~~5~~. If the initial review indicates a systematic weakness on the part of one reviewer~~,~~ or problems with respect to one or more type(s) of licensing action(s), additional similar license files 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~~6~~. If the evaluation of ~~the~~ 10-25 licensing actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.

6~~7~~. 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 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). This information can be obtained prior to the ~~Regional visit~~on-site review from the Office of ~~Nuclear Material Safety and Safeguards' (NMSS) Division of~~

~~Industrial and Medical Nuclear Safety~~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.

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 license files to be reviewed on-site.

D. Review Details~~:~~

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

1. Technical correctness with regard to license conditions, issue and expiration dates, and nomenclature in distribution licenses;

2. Applications 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, 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 ~~Agreement State~~program being evaluated;

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

5. 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. Any pre-licensing visits completed for complex and major licensing actions;

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

8. Licensing guides, checklists, and policy memoranda consistent with current NRC practice (For the Regions,~~.~~ the emphasis should be on proper implementation of same). New standards and guidance that have been generated by the NRC or the State since last renewal/amendment have been incorporated into the licensing process (See NUREG-1556, *Consolidated Guidance About Materials Licenses*, Vol. 1-20, 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. Appropriate use of signature authority;

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

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

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

13. 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.).

14. ~~Appendix A, IMPEP License File Reviewer Guidance, was developed to assist in reviewing certain completed licensing actions. However, the principal reviewer should not feel compelled to address every item in the guidance or to use the guidance for each type of licensing action selected for review.~~

E. Review Information Summary~~:~~

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

   ~~1~~a. The licensee's name, city, and state;

   ~~2~~b. The license number;

   ~~3~~c. The license reviewer's initials;

~~4~~d. The type of licensing action (e.g., new, amendment, renewal, or termination);

~~5~~e. The date the licensing action was issued;

~~6~~f. The type of licensed operation (e.g., program code or license category);

~~7~~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 ~~STP~~FSME Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussing technical findings with reviewers, supervisors, and management.

VI. APPENDIXES

A. ~~IMPEP~~ License~~e~~ing ~~File Reviewer Guidance~~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. 1-20.

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

5. ~~STP~~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

APPENDIX A

~~IMPEP LICENSE~~ING ~~FILE REVIEWER GUIDANCE~~CASEWORK REVIEW SUMMARY SHEET

A/S OR REGION: _____

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

NO.	COMMENTS FOR REPORT

	QUESTIONS FOR REVIEWERS

SUPERVISORY REVIEW BY: _____ DATE: _____

IMPEP REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____ DATE: _____

~~TIE-DOWN DOCUMENT DESCRIPTION (LETTER, TELCON, FAX, E-MAIL, ETC.)~~	~~DATE~~	~~O.K.~~	~~COMMENTS~~
~~1. APPLICATION~~			
~~2. DEFICIENCY LETTER RESPONSE~~			
~~3.~~			
~~4.~~			
~~5.~~			
~~6.~~			
~~7.~~			
~~8.~~			
~~9.~~			
~~10.~~			

~~ITEM~~	~~O.K.~~	~~COMMENTS OR QUESTIONS~~
~~APPLICATION DEFICIENCIES IDENTIFIED BY REVIEWER:~~		
~~CORPORATE OFFICER SIGNATURE, DATE~~		
~~ISOTOPE, FORM, QUANTITY, AUTHORIZED USE~~		
~~PLACES OF USE (INCLUDING TEMP JOB SITE, FIELD, ETC)~~		
~~DESCRIPTION OF FACILITY (HOODS, SHIELDING, ETC.)~~		
~~ID & DUTIES OF AUTHORIZED USERS, RSO, RSC~~		
~~USER QUALIFICATIONS, TRAINING, SUPERVISION~~		
~~INSTRUMENTS & CALIBRATION~~		
~~SS&D IDENTIFICATION; LEAK TEST PROCEDURES; USES & ENVIRONMENTAL CONDITIONS ACCORDING TO SS&D SHEETS~~		
~~SERVICE PROCEDURES (DOSE CALIBRATOR TESTS, IR, ETC.)~~		
~~PERSONNEL MONITORING, BIOASSAYS~~		
~~OPERATING PROCEDURES~~		
~~EMERGENCY PROCEDURES OR PLAN~~		
~~SECURITY, POSTING REQUIREMENTS~~		
~~PROCUREMENT, RECEIPT PROCEDURES~~		
~~INVENTORY, RECORDKEEPING REQUIREMENTS~~		
~~TRANSPORTATION OF RAM~~		
~~WASTE DISPOSAL (INCINERATION, COMPACTING, ETC.)~~		
~~EFFLUENT RELEASE & RECORDS~~		

~~SPECIAL AUTHORIZATION~~		
~~MONITORING AND SURVEY PROGRAM~~		
~~INTERNAL AUDITS~~		
~~FINANCIAL ASSURANCE -IF NEEDED~~		
~~QA/QC/QM~~		
~~ALARA, ACTION LEVELS~~		
~~**ITEM**~~	~~**O.K.**~~	~~**COMMENTS OR QUESTIONS**~~
~~LICENSE FILE~~		
~~FILE ORDERLY; COMPLETE WITH APPLICATION, DEFICIENCY LETTERS, ALL AMENDMENTS, ETC.~~		
~~TELCONS, CHECKLISTS INCLUDED~~		
~~PEER REVIEW DOCUMENTED~~		
~~LICENSING PROCESS~~		
~~DEFICIENCIES CLEARLY STATED IN LETTER~~		
~~APPLICANT RESPONSE ADEQUATE OR FOLLOWED-UP~~		
~~PRE-LICENSING VISIT CONDUCTED AND DOCUMENTED~~		
~~LICENSEE'S COMPLIANCE HISTORY CONSIDERED~~		
~~SUPERVISORY REVIEW CORRECTED ALL PROBLEMS~~		
~~LICENSE~~		
~~LICENSE CORRECTLY LISTS MATERIALS TO BE POSSESSED AND AUTHORIZED USE~~		
~~NORMAL CONDITIONS FOR LICENSE TYPE INCLUDED~~		
~~SPECIAL OR MODIFIED CONDITIONS PROPER~~		
~~TIE-DOWN CONDITION COMPLETE~~		
~~REGULATIONS CITED~~		
~~EXPIRATION DATE CORRECT~~		
~~SIGNATURE LINE, DATE O.K.~~		

~~**TERMINATED LICENSES**~~

~~**ITEM**~~	~~**O.K.**~~	~~**COMMENTS OR QUESTIONS**~~
~~APPLICATION FOR TERMINATION~~		
~~ACCEPTABLE METHOD OF RAM DISPOSAL~~ ~~TRANSFER TO ANOTHER STATE LICENSEE ☐~~ ~~TRANSFER TO OUT-OF-STATE LICENSEE ☐~~ ~~RETURN TO MANUFACTURER ☐~~ ~~SHIPMENT TO BURIAL SITE OR OTHER ☐~~		
~~SUPPORTING DOCUMENTS~~		

~~SS&D LEAK TESTS~~		
~~CURRENT COPY OF RECIPIENT'S LICENSE~~		
~~LICENSEE'S CLOSE-OUT SURVEY~~ ~~MAKE, MODEL, S/N OF INSTRUMENT~~ ☐ ~~DATES OF SURVEY AND CALIBRATION~~ ☐ ~~IDENTIFICATION OF PERSON MAKING SURVEY~~ ☐ ~~ALL READINGS, INCLUDING BACKGROUND~~ ☐		
~~VERIFICATION OF RECEIPT BY RECIPIENT FOR TRANSFER~~		
~~STATE'S ACTIONS~~		
~~LICENSEE'S STATEMENTS VERIFIED~~		
~~NEW JURISDICTIONAL AGENCY NOTIFIED~~		
~~NECESSARY ACTION TAKEN PROMPTLY TO PREVENT ABANDONMENT OF RAM~~		
~~TERMINATION INSPECTION CONDUCTED AND PROPERLY DOCUMENTED IF REQUIRED~~		
~~REVIEW OF RECEIPTS~~		
~~TRANSFER AND/OR DISPOSAL RECORDS~~		
~~VERIFICATION OF TRANSFER AND DISPOSAL~~		
~~FACILITY SURVEY DOCUMENTATION~~ ~~MAKE, MODEL, S/N OF INSTRUMENT~~ ☐ ~~DATES OF SURVEY AND CALIBRATION~~ ☐ ~~IDENTIFICATION OF PERSON MAKING SURVEY~~ ☐ ~~ALL READINGS, INCLUDING BACKGROUND~~ ☐		

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 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.