~~O~~STP Procedure Approval

Reviewing the Common Performance Indicator, ~~#4~~ Technical Quality of Licensing Actions - SA-104

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Expiration Date:

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NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact. ~~Copies of STP procedures will be distributed for information~~.

I. INTRODUCTION

This document describes the procedure for conducting reviews of NRC Regional ~~o~~Offices and Agreement States using the Common Performance Indicator ~~#4~~, 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 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 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 ~~d~~Decommissioning ~~m~~Management ~~p~~Plan (SDMP) ~~sites~~ 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. ~~The evaluation of t~~Technical quality includes not only the review of the application and completed actions, but also an examination of any ~~actions~~ renewals that have been pending for more than a year ~~significant amount of time. A delay on some actions~~ because the failure to act on such requests may have health and safety implications.

IV. ROLES AND RESPONSIBILITIES

A. Team Leader~~.~~:

~~The team leader for the Regional or State review will d~~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~~.~~:

~~The principal reviewer is responsible for s~~Select~~ing~~s licenses to be reviewed, review~~ing~~s relevant documentation, conduct~~ing~~s staff discussions, and maintain~~ing~~s a summary of all licenses reviewed.

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 materials licensing actions issued by the Region or Agreement State in the period since the last review.

2. This procedure excludes non-Atomic Energy Act ~~licensees~~ 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 conducted as non-common performance indicators for Agreement State programs. This procedure is not intended to apply to ~~these~~ 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 ~~Directive's Glossary defines~~ 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 ~~potential~~ candidates for review. Reviews of license terminations, bankruptcies, and complex decommissioning will be treated as a subset of this common performance indicator.

3. Depending upon the size of the Regional or Agreement State program, the principal reviewer should select between 10-25 licensing actions 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~~, etc.~~) and industrial use licenses (e.g., radiography, irradiators, gauges, and measuring devices~~, etc.~~) should be ~~sought~~ 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 ~~one~~ bankruptcy. Licenses authorizing activities with ~~potential for~~ significant environmental impact potential, requiring an emergency plan, and requiring financial assurance should be included whenever possible. Complex decommissioning licensing activities should also be ~~sought~~ reviewed, if available. Termination of complex decommissioning sites formerly managed by the NRC under SDMP ~~sites for~~ and transferred to States whose Agreements became effective after August 26, 1999 should be reviewed, if applicable.

4. In accordance with STP 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 ~~this~~ 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.

~~7. No attempt should be made to evaluate Regional performance on a state-by-state basis for this indicator.~~

C. Review Guidelines.

1. The response generated by the Region or Agreement State to relevant questions in the IMPEP questionnaire should be used to focus the review.

2. For the Regions, both tallies and lists of completed licensing actions can normally be obtained from the Licens~~ing~~e ~~Management~~ Tracking System (L~~M~~TS). This information can be obtained prior to the Regional visit from the Office of Nuclear Material Safety and Safeguards' (NMSS) Division of Industrial and Medical Nuclear Safety. 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 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 ~~noted~~ documented, discussed with the team leader and communicated to the Agreement State;

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

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;

~~5~~6. Any pre-licensing visits completed for complex and major licensing actions;

~~6~~7. Procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program;

~~7~~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);

~~8~~9. Appropriate use of signature authority;

~~9~~10. Consideration of the present compliance status of ~~the~~ licensees ~~in the~~during reviews of licensing actions;

~~10~~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.).

~~11~~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.

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

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

2. The license number;

3. The license reviewer's initials;

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

5. The date the licensing action was issued;

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

7. The amendment number.

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

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

VI. APPENDIX

A. IMPEP License File Reviewer Guidance.

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.

~~3~~4. ~~O~~STP Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

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

APPENDIX A

IMPEP LICENSE FILE REVIEWER GUIDANCE

A/S OR REGION: _____

FILE NO.: _____

LICENSEE: _____

LOCATION: _____

LICENSE TYPE: _____

DATE OF ACTION: _____

LICENSE NO.: _____

AMENDMENT NO.: _____

TYPE OF LICENSING ACTION: NEW ☐
RENEWAL ☐
AMENDMENT ☐
TERMINATION ☐

LICENSE REVIEWER: _____

NO.	COMMENTS FOR REPORT

QUESTIONS FOR REVIEWERS

SUPERVISORY REVIEW BY: _____ DATE: _____

IMPEP REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____

_____ ON: _____

TIE-DOWN DOCUMENT DESCRIPTION (LETTER, TELCON, FAX, E-MAIL, ETC.)	DATE	O.K.	OR 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 ~~SECURITY REQUIREMENT~~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 ☐		