

(STP-04-034, May 2004, Program, SA-104)

May 7, 2004

ALL AGREEMENT STATES, MINNESOTA, PENNSYLVANIA

**OPPORTUNITY TO COMMENT ON DRAFT REVISION TO STP PROCEDURE SA-104,
“REVIEWING THE COMMON PERFORMANCE INDICATOR, TECHNICAL QUALITY OF
LICENSING ACTIONS” (STP- 04- 034)**

Enclosed for your review and comment* is the draft revision to Office of State and Tribal Programs (STP) Procedure SA-104, “Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions.” This procedure describes the process to be used by Integrated Material Performance Evaluation Program (IMPEP) teams for conducting reviews of NRC and Agreement State materials licensing programs during IMPEP reviews. Changes are in redline/strikeout format. We would appreciate receiving your **comments within 30 days** from the date of this letter.

Thank you for your attention to this matter. If you have any questions regarding this correspondence, please contact me on 301-415-2325 or the individual named below.

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Enclosures:
As stated

* This information request has been approved by OMB 3150-0029, expiration 06/30/04. The estimated burden per response to comply with this voluntary collection is approximately 6 hours. Forward any comments regarding the burden estimate to the Information and Records Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0029), Office of Management and Budget, Washington, DC 20503. If a document does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information.



OSTP Procedure Approval

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

Issue Date:

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.



Procedure Title:

Reviewing *the* Common Performance Indicator #4, Technical Quality of Licensing Actions

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I. INTRODUCTION

This document describes the procedure for conducting reviews of NRC Regional 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, 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 site decommissioning management plan (SDMP) sites 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 **Agreement** State review will determine 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 selecting licenses to be reviewed, reviewing relevant documentation, conducting staff discussions, and maintaining 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. 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 should be included whenever possible. Complex decommissioning licensing activities should also be ~~sought~~ **reviewed if available.** Termination of SDMP sites for States whose Agreements became effective after August 26, 1999 should be reviewed.
4. **In accordance with STP Procedure SA-1000, *Implementation of the Grants Program for Funding Assistance for Formerly Licensed Sites in Agreement States*, the review of licensing actions should include any Agreement State activities implemented through the Grant Program.**
45. 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, 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 case work **in that area** should be reviewed to assure **this that the** weakness has been addressed.

56. If the evaluation of the 10-25 licensing actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.
67. 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.
78. 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 Licensing Management System (LMS). 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. Any pre-licensing visits completed for complex and major licensing actions;
6. Procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program;
7. 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. Appropriate use of signature authority;
9. Consideration of the present compliance status of ~~the~~ licensees **in the** **during reviews of** licensing actions;
10. Use of standard license conditions to expedite and provide uniformity to the licensing process, whenever practicable;
- 11. 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~~**12.** 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 OSTP 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.
34. OSTP 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.*

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 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 <input type="checkbox"/> TRANSFER TO OUT-OF-STATE LICENSEE <input type="checkbox"/> RETURN TO MANUFACTURER <input type="checkbox"/> SHIPMENT TO BURIAL SITE OR OTHER <input type="checkbox"/>		
SUPPORTING DOCUMENTS		
SS&D LEAK TESTS		
CURRENT COPY OF RECIPIENT'S LICENSE		
LICENSEE'S CLOSE-OUT SURVEY MAKE, MODEL, S/N OF INSTRUMENT <input type="checkbox"/> DATES OF SURVEY AND CALIBRATION <input type="checkbox"/> IDENTIFICATION OF PERSON MAKING SURVEY <input type="checkbox"/> ALL READINGS, INCLUDING BACKGROUND <input type="checkbox"/>		
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		

<p>REVIEW OF RECEIPTS</p>		
<p>TRANSFER AND/OR DISPOSAL RECORDS</p>		
<p>VERIFICATION OF TRANSFER AND DISPOSAL</p>		
<p>FACILITY SURVEY DOCUMENTATION</p> <ul style="list-style-type: none"> MAKE, MODEL, S/N OF INSTRUMENT <input type="checkbox"/> DATES OF SURVEY AND CALIBRATION <input type="checkbox"/> IDENTIFICATION OF PERSON MAKING SURVEY <input type="checkbox"/> ALL READINGS, INCLUDING BACKGROUND <input type="checkbox"/> 		