



## Office of Nuclear Material Safety and Safeguards Procedure Approval

### *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions State Agreements (SA) Procedure SA-104*

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*Director, NMSS/MSST* **Kevin Williams** Digitally signed by Kevin Williams Date: 2020.09.15 12:50:51 -04'00'

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David Crowley  
*Chair, Organization of Agreement States*  Date: 9/15/2020

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**NOTE**

**Any changes to the procedure will be the responsibility of the NMSS Procedure Contact. Copies of the procedures are available through the NRC website at <https://scp.nrc.gov>.**

## **I. INTRODUCTION**

This document describes the process for conducting reviews of Agreement State and U.S. Nuclear Regulatory Commission (NRC) radiation control programs (Programs) as specified in NRC Management Directive (MD) 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*.

## **II. OBJECTIVES**

- A. To verify that licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security 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 authorized users, facilities, equipment, locations of use, operating and emergency procedures and any other requirements necessary to ensure an adequate basis for the licensing action (e.g. pre-licensing guidance, risk significant radioactive material checklist, enhanced security requirements, financial assurance, etc.)
- 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 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.

## **II. 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 (e.g., new applications, amendments, renewals, terminations, etc.), decommissioning actions, bankruptcies, financial assurance, and notifications. The evaluation of 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, safety, and security implications.

### **III. ROLES AND RESPONSIBILITIES**

- A. IMPEP Review Team Leader (Team Leader)
  - 1. In coordination with the IMPEP Program Manager, the Team Leader determines which team member(s) is assigned lead review responsibility for this performance indicator.
  - 2. Communicates the team's findings to Program Management and ensures the team's findings are in alignment with MD 5.6.
- B. Principal Reviewer
  - 1. Selects licensing actions to be reviewed, reviews relevant documentation, conducts staff discussions, and maintains a summary of all licensing actions reviewed.
  - 2. Informs the Team Leader of their findings throughout the on-site review.
  - 3. Presents the team's findings to the Program at the staff exit.
  - 4. Completes their portion of the IMPEP report for the Technical Quality of Licensing Actions performance indicator 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 remotely).

### **IV. GUIDANCE**

- A. Scope
  - 1. This procedure applies only to review of the technical quality of completed radioactive materials licensing actions issued by the regulatory program in the period since the last IMPEP review.
  - 2. This procedure excludes non-Atomic Energy Act licenses.
  - 3. Section V.D, "Review Details" of this procedure also applies to the technical quality of licensing action reviews conducted for the non-common performance indicators, uranium recovery program, and low-level radioactive waste disposal program. See the specific SA procedure for the applicable non-common indicator for additional criteria that should be considered during the review.
  - 4. This procedure does not apply to the non-common performance indicator, Sealed Source and Device (SS&D) evaluation program. NMSS Procedure SA-108, *Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program*, describes the criteria that should be used to evaluate the SS&D program.

B. Selection of Casework

1. Depending on the size of the Program, the Principal Reviewer should select approximately 10-25 licensing actions of various types for review. For applicable Agreement State and NRC programs, the reviewer can use the Web-Based Licensing (WBL) system to review case files.
  - a. All licensing actions performed since the last review are candidates for review.
  - b. The reviewer should select a mix of licensing actions to include new licenses, major program amendments and renewals.
  - c. Reviews of license terminations, bankruptcies, financial assurance, and complex decommissioning will be treated as a subset of this common performance indicator.
  - d. 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 performance issues that would have the greatest impact on public health, safety, and security of radioactive materials.
  - e. The reviewer should select a mix of licensing actions to include medical and academic use (e.g., universities, community hospitals, gamma stereotactic radiosurgery units, physicians, and broad scope facilities) and industrial use (e.g., radiography, irradiators, service and manufacturers/distributors) for review.
  - f. Licensing 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. Licensing actions authorizing possession of Category 1 or Category 2 quantities of radioactive materials requiring implementation of the physical protection of the radioactive material, should be properly identified and evaluated using current NRC policies/guidance or equivalent Agreement State policies, procedures and guidance.
  - h. Licenses should be evaluated to ensure that they contain legally binding requirements, such as, license conditions, as necessary; and that these requirements and conditions were incorporated in a timely manner. The reviewer should examine any license conditions other than those that restate the regulations or are standard license conditions sent to the NRC for a compatibility review.

- i. Applications for new licenses and transfer of control (e.g., change of ownership) are being evaluated using the applicable pre-licensing guidance or equivalent Agreement State policies, procedures and guidance.
  - j. Licensing documents (both incoming and outgoing) containing sensitive 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. Agreement State programs should 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. Regulatory Issue Summaries 2005-31, Revision 1, "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 Material" provides the screening criteria used by the NRC to identify and protect security-related information in documents generated or received by the NRC.
  - k. The "Team Member Materials" tab in the IMPEP toolbox on the state communication portal web site. This tab contains links to the relevant guidance described below, that should be used during the evaluation of this indicator. 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*, Volumes 1-21 and other current NRC policies and guidance (e.g., medical uses licensee toolkit, information notices, and regulatory issue summaries), as applicable, or compatible Agreement State procedure.
2. Licensing actions pending completion for unusually long periods of time (e.g., amendments not completed for periods greater than 6 months or renewals not completed for periods greater than 1 year), should be identified specifically, in order to determine whether or not there have been any safety-significant impacts on the licensee's program. In most cases, a significant backlog of licensing actions is indicative of a staffing issue and should be communicated to the reviewer assigned to the common performance indicator, Technical Staffing and Training.

**C. Review Guidelines**

1. The response provided by the Program to relevant questions in the IMPEP questionnaire should be used to focus the review. The Principal Reviewer, in coordination with the Team Leader, should consider the quantitative and qualitative responses to the questionnaire and/or Web-Based Licensing System output in determining the licensing action files to be reviewed on-site.
2. For the NRC, both tallies and lists of completed licensing actions will be obtained from the WBL system. This information will be available to the

IMPEP team prior to the on-site review as part of the response to the IMPEP questionnaire. The Principal Reviewer, in coordination with the Team Leader, must select the licensing actions that will be reviewed prior to the on-site review, in order for the NRC to have the files available for the review. The Principal Reviewer may request additional files, as needed, through the Team Leader or designated NRC staff member.

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, issuance and expiration dates, and nomenclature in specific licenses;
2. License 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 (e.g., 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 or security should be documented, discussed with the Team Leader and communicated to Program management (See Item V.F. of this procedure);
4. Licensees meeting the criteria to implement increased security requirements have been identified and the additional security requirements have been implemented;
5. Improper and/or illegal license authorizations. Any variances or exceptions to standards should receive management approval and not undermine health and safety or security;
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 and are reviewed at the proper frequency;
7. Pre-licensing site visits completed for new applicants and complex or major licensing actions, as applicable;
8. Procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflect the current scope of the licensed program;
9. Licensing guides, checklists, and policy memoranda are used and are consistent with current NRC or equivalent Agreement State practice. 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*, Volumes 1-21, for NRC-generated licensing guidance). Agreement States may use the guidance provided in NUREG-1556, but it is also acceptable for an Agreement State to develop their own licensing guidance that contain the essential objectives of NUREG-1556. IMPEP is performance-

based and a team's findings are based on actual performance. However, if the team identifies potential performance issues with an Agreement State's licensing program, the team is expected to determine the root cause of the issue(s), which may include assessing the adequacy of the program's licensing procedures;

10. Appropriate use of signature authority. In instances where the license reviewer does not have signature authority, the Principal Reviewer for this indicator should ensure that the license reviewer has met the respective program's qualifications to independently review the types of licenses under review. The policy of signing licenses is dependent upon the program's legal requirements and administrative procedures;
11. Consideration of the present compliance status of licensees during reviews of licensing actions;
12. Use of standard license conditions to expedite and provide uniformity to the licensing process, whenever practicable;
13. Verification of legally binding requirements, such as license conditions, implemented by Agreement States in place of promulgated regulations; and
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).

**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, license category, etc.); and
  - g. The amendment number.
2. A Licensing Casework Review Summary Sheet can be found in the IMPEP Toolbox on the state communications portal web site. The 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 the summary sheet but may find it as a useful means of recording the necessary information.

3. The licensing casework may be incorporated into the IMPEP report as an appendix, when the team is recommending a finding of satisfactory, but needs improvement for this indicator. The licensing casework must be incorporated into the report when the team is recommending a finding of unsatisfactory for this indicator. 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).
4. 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 Program Manager for the current guidance and format on the report's licensing casework appendix. The reviewer should not retain or remove any documents containing sensitive material from the Program's facility.

F. Evaluation Process

1. The Principal Reviewer should refer to MD 5.6, Section III, *Evaluation Criteria*, for specific evaluation criteria. The definition of the term "Materials Licensing Action" can be found in the Directive's Glossary. As noted in MD 5.6, the criteria for a satisfactory program is as follows:
  - a. Evaluation of licensing casework indicates that licensing actions are thorough, complete, consistent, and of acceptable technical quality.
  - b. Licensing actions adequately address health, safety, and security issues; including cases involving risk-significant activities that have the potential to result in an overexposure, loss of risk-significant radioactive materials, or unintended/unauthorized use of radioactive material.
  - c. License reviewers have the proper signature authority for the cases they review independently.
  - d. License tie-downs and other conditions are stated clearly, enforceable, and appropriate for the type of license.
  - e. Deficiency letters and emails clearly state regulatory positions and are used at the proper time.
  - f. Reviews of renewal applications demonstrate thorough analysis of a licensee's inspection and enforcement history.
  - g. Reviewers are following the criteria specified in the NUREG-1556 series, as applicable or compatible Agreement State procedures.
2. If the initial review indicates a performance weakness in the technical quality limited to 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 files for licensing actions of a similar nature should be obtained and reviewed to determine whether this is a programmatic weakness. The reviewer should seek to determine the extent of condition of the issue, and the root cause(s). 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.

3. If the evaluation of approximately 10-25 licensing actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.  
Note: Number of licensing actions reviewed is dependent on the size of the program.

Note: Examples of Less than Satisfactory Findings of Program Performance can be found in the IMPEP Toolbox on the state communication portal web site. These examples may assist the reviewer in identifying less than fully satisfactory findings of a Program's performance.

G. Discussion of Findings with the Radiation Control Program.

1. The reviewer should follow the guidance given in NMSS Procedure SA-100, *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*, for discussing technical findings with reviewers, supervisors, and management.
2. If the IMPEP review team identifies programmatic performance issues, the IMPEP review team should seek to identify the root cause(s) of the issues, which can be used as the basis for developing recommendations for corrective actions. The NMSS procedure SA-100 contains criteria regarding the development of recommendations by the IMPEP team.

## VI. REFERENCES

IMPEP Toolbox (containing the "Licensing Casework Review Summary Sheet" and "Examples of Less than Satisfactory Findings of Program Performance") available at <https://scp.nrc.gov/impeptools.html>

Management Directives (MD) available at <https://scp.nrc.gov>

NMSS SA Procedures available at <https://scp.nrc.gov>

NUREG-1556, Consolidated Guidance About Materials Licenses, Volumes 1-21, available at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

Regulatory Issue Summaries available at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/>

## 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
10	4/13/12	FSME Procedure SA-104	ML120750384
11	12/18/19	SA Procedure SA-104	ML19351E407
12	09/10/20	Resolution of Comments	ML20258A063
13	09/15/20	NMSS Final Procedure SA-104	ML20255A207