



## Office of Nuclear Material Safety and Safeguards Procedure Approval

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

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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 procedure for conducting reviews of Agreement State and U.S. Nuclear Regulatory Commission (NRC) radiation control programs (Program) 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 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 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.

## **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, 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.

#### **IV. ROLES AND RESPONSIBILITIES**

##### **A. Team Leader:**

In coordination with the IMPEP Program Manager, determines which team member(s) is assigned lead review responsibility for this performance indicator.

##### **B. Principal Reviewer:**

1. Meets the appropriate requirements as specified in State Agreement (SA)-111, *“Formal Qualifications for IMPEP Team Members and Team Leaders.”*
2. Selects licensing actions to be reviewed, reviews relevant documentation, conducts staff discussions, and maintains a summary of all licensing actions reviewed.
3. Informs the Team Leader of their findings throughout the review.
4. Completes their portion of the IMPEP report for the 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, Skype, video conference, 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 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 applies to the technical quality of licensing action reviews conducted for the non-common performance indicators, i.e. uranium recovery program, and low-level radioactive waste 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 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. 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. Depending on the size of the NRC or Agreement State radioactive materials program, the Principal Reviewer should select approximately 10-25 licensing actions of various types for review. For NRC and applicable Agreement State 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 weaknesses that would have the greatest impact on public health and safety.

- 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 or license conditions, as necessary; and that these requirements/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 contained in the Program’s licensing procedure, to ensure that they have been 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.
- k. The “Team Member Materials” tab in the IMPEP toolbox (<https://scp.nrc.gov/impeptools.html>) 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*, Vols. 1-21 and other current NRC policies/guidance (e.g., medical uses licensing toolbox and regulatory issue summaries), as applicable, or compatible Agreement State procedure.

3. 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.
4. If the evaluation of approximately 10-25 licensing actions does not reveal any programmatic weaknesses, no additional casework needs to be reviewed.
5. 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 over 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.
6. Appendix C of this procedure contains examples to assist the reviewer in identifying less than satisfactory programs.

**C. Review Guidelines**

1. The response provided by the NRC or Agreement State radiation control 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 can be obtained from the WBL system. This information is typically obtained prior to the on-site review from the regional office as a response to the IMPEP questionnaire. However, it can also be obtained, upon request, from the Division of Materials Safety, Security, State, and Tribal Programs (MSST) in the Office of Nuclear Material Safety and Safeguards (NMSS) in coordination with the IMPEP Program manager and Team Leader. The NRC should be contacted to make arrangements for the reviewing of electronic files by an Agreement State team 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 distribution 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 (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 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/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/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*, Vol. 1-21, for NRC-generated licensing guidance);
10. Appropriate use of signature authority;
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, 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, license category, etc.); and
  - g. The amendment number.
2. Appendix A of this procedure, 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 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.
4. 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).

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

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. In terms of general guidance for the IMPEP review team, a finding of "satisfactory" should be considered when none or only a few or small number of the cases or areas reviewed involve performance issues/deficiencies (e.g., inspection, licensing, staffing, etc.) ; an "unsatisfactory" finding should be considered when a majority or a large number of cases or areas reviewed involve performance issues/deficiencies, especially if they are chronic, programmatic, and/or of high-risk significance; and a finding of "satisfactory, but needs improvement" should be considered when more than a few or a small number of the cases or areas reviewed involve performance issues/deficiencies in high-risk-significant regulatory areas, but not to such an extent that the finding would be considered unsatisfactory. Specific guidance and examples pertaining to each finding can be found in the applicable NMSS SA procedures for each indicator.
3. If the IMPEP review team identifies performance issues/deficiencies that lead to programmatic weaknesses, 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. Section II.A.3 of NMSS procedure SA-100 contains criteria regarding the development of recommendations by the IMPEP team.

**VI. APPENDICES**

- A. Licensing Casework Review Summary Sheet
- B. Frequently Asked Questions
- C. Examples of Less than Satisfactory Findings of Program Performance

**VI. REFERENCES**

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*, Vol. 1-21.

## **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.

<b>No.</b>	<b>Date</b>	<b>Document Title/Description</b>	<b>Accession Number</b>
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

## Appendix A

### LICENSING CASEWORK REVIEW SUMMARY SHEET

AS / NRC \_\_\_\_\_

Supervisory Review by: \_\_\_\_\_ Date: \_\_\_\_\_

File No. _____	Type of Licensing Action
Licensee _____	<input type="checkbox"/> New
License No. _____	<input type="checkbox"/> Renewal
Location _____	<input type="checkbox"/> Amendment
License Type _____	<input type="checkbox"/> Termination
Date of Action _____	<input type="checkbox"/> Bankruptcy
Amendment No. _____	<input type="checkbox"/> Denial
License Reviewer _____	<input type="checkbox"/> Part 37 Req.
Peer Reviewer _____	<input type="checkbox"/> Financial Assurance
Signed by individual with signature authority <input type="checkbox"/> yes <input type="checkbox"/> no	

No	Comment for Report

Questions for Reviewer

IMPEP Review by: \_\_\_\_\_ Date: \_\_\_\_\_

Findings Discussed with: \_\_\_\_\_ Date: \_\_\_\_\_

## **Appendix B**

### **FREQUENTLY ASKED QUESTIONS**

- Q1: 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?
- A1: We are aware that not all radioactive control 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.
- Q2: 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.
- A2: 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, the reviewer would determine whether or not there are any potential health and safety and/or security 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.
- Q3: 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?
- A3: 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 that contain the essential objectives of NUREG-1556. 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 team's findings are based on actual performance. However, if the team identifies potential weaknesses with an Agreement State's licensing program, the 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, safety, and security issues are properly addressed during all license reviews.
- Q4: What is the expectation for reviewing a State's procedure for protecting and controlling documents containing sensitive information?
- A4: 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.

## Appendix C

### EXAMPLES OF LESS THAN SATISFACTORY FINDINGS OF PROGRAM'S PERFORMANCE

The effectiveness of a program is assessed through the evaluation of the criteria listed in Section III, Evaluation Criteria, of MD 5.6. These criteria are NOT intended to be exhaustive but provide a starting point for the IMPEP review team to evaluate this indicator. The review team should also take into consideration other relevant mitigating factors that may have an impact on the program's performance under this performance indicator. The review team should consider a less than satisfactory finding when the identified performance issue(s) is/are programmatic in nature, and not isolated to one aspect, case, individual, etc. as applicable.

This list is not all inclusive and will be maintained and updated in the IMPEP Toolbox on the state communications portal at <https://scp.nrc.gov>.

The following are examples of review findings that resulted (or could result) in a program being found **"satisfactory, but needs improvement"** for this indicator:

1. Licensing actions reviewed contain typos, missing license conditions, missing tie down conditions, incorrect issuance date, lacking signature, demonstrating a lack of thoroughness, completeness, and technical quality.
2. In granting authorization for users/radiation safety officer/medical physicist of radioactive materials, supporting documentation of proper training, experience, and preceptor attestation was not verified. As a result, authorized users were added to the license incorrectly. This has a cross jurisdictional impact on health and safety because the authorized user can use the license as proof of qualifications and be added to other licenses without further review.
3. A license was terminated with insufficient information from the licensee to support the request. This resulted in the release of a facility which did not meet regulatory requirements or continued possession of material after termination.
4. The Program's deficiency letter did not clearly state the regulatory requirement, and the licensee's response was not adequate, however, the license amendment was issued. The team member determined that a security concern was not addressed as a result of the issuance of the license amendment which resulted in a violation being cited during the licensee's inspection.
5. License reviewers are not consistently following the Pre-Licensing Guidance (PLG). The team determined that a pre-licensing site visit was not conducted for all new applications of unknown entities. Failure to consistently implement the PLG may result in health, safety, and security implications.
6. License reviewers did not follow the Risk Significant Radioactive Materials (RSRM) Checklist and one reviewer failed to perform an on-site security review for a radiography application. The lack of an on-site security review posed a potential security threat of Category 2 material.

The following are examples of review findings that resulted (or could result) in a program being found “**unsatisfactory**” for this indicator:

1. Most licensing actions reviewed contain typos, missing license conditions, missing tie down conditions, incorrect issuance date, lacking signature, demonstrating a lack of thoroughness, completeness, and technical quality.
2. Granting authorization to authorized users/radiation safety officer/medical physicist of radioactive materials without supporting documentation of training and experience and the team determines this to be a programmatic issue.
3. Consistent failure to properly address aggregation of sealed sources and identify these licensees as security licensees or insert a license condition restricting the ability to contain all the sources in an aggregated quantity. This poses a serious potential of a security threat.
4. Deficiency letters requesting additional information are not clearly stated and/or fail to address health, safety, and security issues. This can result in incomplete licensing actions and hinder the regulators ability to enforce prudent safety or security practices. For example, the lack of a commitment from a licensee to perform inventory, leak test, exposure evaluations, and other aspects of the radiation safety program can result in health, safety, and security implications.
5. License reviewers are not following the NUREG-1556 series, Pre-Licensing Guidance and/or Risk Significant Radioactive Materials Checklist when performing license reviews. This resulted in an applicant obtaining a license under false pretense.
6. License reviewers do not verify inspection and enforcement history for renewals and in one instance; the team identified a licensee that had a documented history of poor performance that could lead to loss of risk-significant radioactive material.
7. License review of a termination request failed to obtain sufficient information from the licensee that resulted in release of an area and/or facility which does not meet regulatory requirements or allowed the licensee to continue to possession radioactive material after license termination.