



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE [STATE] AGREEMENT STATE [OR NRC REGION] PROGRAM

DATE - DATE, YEAR

DRAFT REPORT

[GENERAL NOTES]:

- **Numbers: spell out numbers from one through nine; use numerals for a single number of 10 or more; and if the number 10 or more is in the the same sentence with a lower number, use numerals for all.**
- **Do not start sentence with acronym, even if it's been used and defined previously;**
- **Limit statements to facts affecting performance, not hearsay or assumptions;**

Enclosure

- **Avoid using qualifiers, e.g. “generally”, “mostly” or “the majority of”; use specific numbers instead (e.g. 10 of the 15 reviewed, 90 percent, etc)**
- **provide enough detail especially when performance-based issues are found, for the next team to review thoroughly;**
- **make Recommendations for issues involving specific problems within the indicator, not for issues that are basically required by the indicator(s)**

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the {STATE/REGION} Agreement State Program. The review was conducted during the period of [Month date-date, YEAR], by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of [NAME].

Based on the results of this review, [STATE's] performance was found [satisfactory/satisfactory, but needs improvement/unsatisfactory,] for the/all indicator(s) [LIST INDICATORS], and [satisfactory/satisfactory, but needs improvement/unsatisfactory] for the (LIST INDICTORS) performance indicator(s) reviewed. (INSERT OTHER NOTABLE FINDINGS: e.g. "The finding for the Compatibility Requirements indicator remains unchanged from the previous IMPEP review. / Progress has been made on the indicator (NAME), but the State has not yet addressed a number of outstanding NRC comments regarding earlier regulation packages/ Two regulation amendments were overdue for adoption by the State, etc.). [INSERT OTHER NOTABLE FINDINGS, e.g. Team recommends Monitoring, Heightened Oversight, etc.]

The review team did not make any recommendations OR made (number) recommendations regarding program performance by the State regarding (LIST BRIEF DESCRIPTION OF RECOMMENDATIONS) and determined that the recommendation(s) from the (YEAR) IMPEP review, regarding (regulation adoption/document security markings/development and implementation of a formal training program/ETC.), should be [closed/kept open/modified].

Accordingly, the review team recommends that the (STATE) Agreement State Program is adequate/adequate, but needs improvement/inadequate) to protect public health and safety and is [compatible/not compatible] with NRC's program. The review team recommends that the next IMPEP review take place in approximately (number) years [and that a periodic meeting be held in...yrs—(ADD THIS STATEMENT ONLY IF THE FREQUENCY OF THE PERIODIC MEETING IS BEING REDUCED or EXTENDED)].

1.0 INTRODUCTION

This report presents the results of the review of the (STATE/NRC REGION) Agreement State Program. The review was conducted during the period of [MONTH DATE-DATE, YEAR], by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of [NAME]. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of (DATE) to (DATE), were discussed with [STATE/NRC REGION] managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The [STATE/NRC REGION] Agreement State Program is administered by the [EXAMPLE: Bureau of Radiation Control (the Bureau), which is located within the Division of Environmental Health (the Division). The Division is part of the Department of Health (the Department). Organization charts for the Department and the Bureau are included as Appendix B.]

At the time of the review, the [STATE] Agreement State Program regulated [NUMBER] specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of [STATE].

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the [Bureau/Program/Division, etc.] on [Date]. The [Bureau] provided its response to the questionnaire on [date]. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number MLxxxxxxx.

The review team's general approach for conduct of this review consisted of (1) examination of the [Bureau]'s response to the questionnaire, (2) review of applicable [STATE] statutes and regulations, (3) analysis of quantitative information from the [Bureau]'s database, (4) technical review of selected regulatory actions, (5) field accompaniments of [number] inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the [STATE] Agreement State Program's performance.

IF PREVIOUS REPORT HAD RECOMMENDATIONS, INCLUDE THIS SENTENCE:

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews.

OR-

There were no recommendations made during the previous review.

Results of the current review of the common performance indicators are presented in Section [No. 2.0 OR 3.0 DEPENDING ON INCLUSION OF PREVIOUS SENTENCE]. Section [3.0 or 4.0] details the results of the review of the applicable non-common performance indicators, and Section [4.0 OR 5.0] summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on [DATE], the review team made (NUMBER) recommendation(s) regarding the [STATE] Agreement State Program's performance. The status of the recommendation(s) is/are as follows:

LIST PREVIOUS RECOMMENDATIONS AND BRIEF EXPLANATION AS TO WHY THE RECOMMENDATION SHOULD BE CLOSED/MODIFIED/KEPT OPEN

EXAMPLES:

The review team recommends that the State evaluate the effectiveness of their existing procedures and policies for marking and handling sensitive information and modify the existing procedures or policies, if needed, to ensure that documents containing sensitive information are appropriately marked in a consistent manner. (Section 3.3 of the 2007 IMPEP Report)

Status: The State implemented a procedure to ensure that all outgoing documents containing sensitive information are appropriately marked. Internal documents were already being appropriately marked prior to the IMPEP review in 2007. The limitation on this procedure is that, in accordance with the State's Sunshine Law, only security-related information pertaining to physical security systems (e.g., alarm systems, room diagrams) can be withheld from the public. The review team confirmed that license and inspection documents were marked appropriately, in accordance with the limitations noted above. This recommendation is closed.

The review team recommends that the State take additional actions, such as increasing salary and/or benefits, to stabilize staffing and ensure successful program implementation. (Section 3.1 of the 2009 IMPEP report)

Status: In an effort to address the high staff turnover rate experienced by the Program in recent years, management increased starting salaries and introduced flexible work hours, resulting in a better work-life balance. They have also modified management of the Program to give the staff more ownership of the process. Staff members are now part of the decision making process, are involved in the development of processes and procedures, and are involved in workload distribution. Overall management has responded in a positive manner to the issues facing the Program. This recommendation is closed.

The review team recommends that the State update its existing procedures and develop new procedures, if necessary, to institutionalize the policies and practices of the Agreement State program and to serve as a knowledge management tool. (Section 3.1 of the 2009 IMPEP report)

Status: The Program reviewed existing procedures to ensure they were current and accurately reflected any changes to the manner in which they conduct business. This review found that several of their existing procedures needed to be updated. The Program also noted that due to recent NRC operational changes, additional procedures needed to be developed to meet these changes. In response, the staff updated existing procedures and developed new procedures where needed. They then provided staff training on the procedures to ensure they had a common understanding. This recommendation is closed.

The review team recommends that the State evaluate current and future staffing needs and business processes to develop and implement a strategy that improves the effectiveness and efficiency of the Program and ensures its continued adequacy and compatibility. (Section 3.2)

Status: The review team found that during the time period covered by this review, the staffing issue and business process development had been addressed as evidenced by the improvement in the status of inspections. The program has created and utilized a database of license activities. From this database, the program can track inspection frequencies, which allowed the program to improve their inspection efficiency. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Considerations central to the evaluation of this indicator include the Bureau's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Bureau's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Bureau is managed by the [DESCRIBE ORGANIZATIONAL STRUCTURE]. The Radioactive Materials Program is responsible for [materials inspection, licensing and compliance activities, emergency response activities, etc.].

At the time of the review, there were [Number.] technical staff members with various degrees of involvement in the radioactive materials program, totaling approximately [Number] full-time equivalents (FTE). [No OR NUMBER] positions were vacant at the time of this review. **IF THE PROGRAM HAS EXPERIENCED SIGNIFICANT TURNOVER, ADDRESS THE FOLLOWING: NO. OF STAFF WHO LEFT, WERE THEY REPLACED?, HOW LONG WERE THE POSITIONS VACANT, EXPERIENCE LEVEL OF THOSE WHO LEFT AND THOSE WHO REPLACED THEM AND REASON(S) FOR LEAVING.** The review team determined that staffing levels were adequate for the Agreement State program.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs." Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Bureau's training program is adequate to carry out its regulatory duties and noted that [STATE] management supports the Bureau training program.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC REGION]'s performance with respect to the indicator, Technical Staffing and Training, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Bureau's questionnaire response relative to this indicator, data gathered from the Bureau's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that [STATE]'s inspection frequencies for all types of radioactive material licenses are [at least as frequent as, more frequent as], similar license types listed in IMC 2800, "Materials Inspection Program." [NUMBER] of the [NUMBER] license categories established by the Bureau were assigned inspection priority codes that prescribe a more frequent inspection schedule than those established in IMC 2800 for similar license types.

The Bureau conducted [number] Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. [NUMBER] of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800 (indicate range of how long overdue). In addition, the Bureau performed [no.] initial inspections during the review period, [no.] of which [number] were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The initial inspections were conducted late due to [EXPLAIN: e.g. database entry errors, lack of resources,

etc.]. The Bureau [EXPLAIN HOW/WHY/WHAT actions were taken to correct, e.g. provided additional training to personnel, diverted resources from another section to perform inspections, concentrated efforts on performing overdue inspections, etc.]. Overall, the review team calculated that the Bureau performed [no.] percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. A sampling of [no.] inspection reports indicated that [no.] of the inspection findings were communicated to the licensees beyond the Bureau's goal of 30 days after the inspection. [IF A LARGE MAJORITY IS DELAYED, DETAIL WHY/HOW ESPECIALLY IF IT RESULTS IN THE INDICATOR FINDING OF SAT, NEEDS IMPROVEMENT OR UNSAT]

During the review period, the Bureau granted [no.] reciprocity permits, [no.] of which were candidate licensees based upon the criteria in IMC 1220. The review team determined that the Bureau [met and/or exceeded/ did not meet] the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC REGION]'s performance with respect to the indicator, Status of Materials Inspection Program, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for [no.] radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by [no.] Bureau inspectors and covered inspections of various license types: [LIST TYPES: e.g. medical broad scope, medical institutions-therapy including (e.g. high dose rate remote afterloader, unsealed radioiodine therapy, permanent or temporary implant brachytherapy etc), , radionuclide production (cyclotron),, medical-diagnostic, portable gauges, industrial radiography, veterinary use, panoramic and self-shielded irradiators, gamma knife, nuclear pharmacy, mobile nuclear medicine, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls), etc]. Appendix C lists the inspection casework files reviewed, [with case-specific comments], as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Bureau are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then [reviewed and signed by the Regional Manager/senior reviewer/etc.]. Supervisory

accompaniments were conducted annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Bureau issues to the licensee, either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, which details the results of the inspection. When the Bureau issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days. All findings are reviewed by the [Program Manager/Inspection Coordinator/etc.].

The review team noted that the Bureau has an adequate supply of survey instruments to support its inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, was observed to be available. The Bureau also has portable multi-channel analyzers located in offices across the State. Instruments are calibrated at least annually, or as needed, by [NAME] with National Institute of Standards and Technology traceable sources. The Bureau uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of [no.] Bureau inspectors were conducted by [no.] IMPEP team members during the week(s) of [date]. The inspectors were accompanied during health and safety inspections of [LIST: source manufacturing, industrial radiography, nuclear pharmacy, irradiator, medical therapy including high dose rate remote afterloader/gamma knife/ unsealed radioiodine therapy/permanent implant brachytherapy, etc., and medical diagnostic licenses/ETC.]. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC REGION]'s performance with respect to the indicator, Technical Quality of Inspections, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for [no.] specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included [LIST: [no.] new licenses, [no.] renewals, [no.] decommissioning or termination actions, and [no.] amendments. Files reviewed included a cross-section of license types, including: broadscope, medical diagnostic and therapy including (LIST all that apply: high dose rate remote afterloader, unsealed radioiodine therapy, temporary/permanent implant brachytherapy, etc.) gamma knife, industrial radiography, research and development, nuclear pharmacy, gauges, manufacturers, panoramic and self-shielded irradiators. The casework sample represented work from [number] license reviewers. A list of the licensing casework evaluated [with case-specific comments] is provided in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Bureau's licensing guides and/or NRC NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

All license evaluators have signature authority for licensing actions. The [Program Manager/Director/ Licensing Manager] performs a technical and supervisory review on all licensing actions before issuance to the licensee. Licenses are issued for a [no.]-year period under a timely renewal system.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Branch licensing procedures and/or NUREG-1556 guidance documents, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Program performs pre-licensing checks of all new applicants. The Bureau's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Bureau's licensing practices and methodology for identifying those licenses that required Increased Controls and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Bureau's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive

information related to the Increased Controls. The review team noted that the Program controls access to all of their licensing and inspection files via password protection and key-card entry. Files that contained sensitive information were further secured in locked file cabinets.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC REGION]'s performance with respect to the indicator, Technical Quality of Licensing Actions, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for [STATE] in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for [no.] radioactive materials incidents. A list of the incident casework examined, [with case-specific comments], may be found in Appendix E. The review team also evaluated the Bureau's response to [no.] allegations involving radioactive materials, including [no.] allegations referred to the State by the NRC during the review period.

The incidents selected for review included the following categories: [LIST: lost/stolen radioactive material, potential overexposure, medical event, damaged equipment, leaking source, etc.]. The review team determined that the Bureau's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Bureau dispatched inspectors for on-site investigations in [no.] of the cases reviewed and took suitable enforcement and follow-up actions. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner.

The review team examined the Program's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the [Incident Response Coordinator/PROGRAM MANAGER/ETC.] determine the appropriate level of initial response.

The review team identified [no.] radioactive material incidents in NMED for [STATE] during the review period, of which [no.] required reporting. [No.] non-reportable incidents in NMED for [STATE] were reviewed for reportability and found to be correctly categorized as non-reportable by the Bureau. The review team selected [no.] radioactive material incidents for evaluation. These incidents included the following types of events: [LIST: lost/stolen radioactive material; potential overexposure; medical event; damaged equipment; leaking source, etc.]. The Program's responses to the incidents were found to be complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the potential health and safety significance of the event. Inspectors were dispatched for onsite investigations when appropriate. Enforcement and/or other regulatory actions were taken as

appropriate. The Program reported events to the NRC in a prompt manner. The actions taken in response to incidents were documented and filed, and the data were submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for [no.] allegations, including [no.] that NRC referred to the State during the review period. The review team concluded that the Program took prompt and appropriate actions in response to concerns raised. The review team noted that the Program documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Program notified the concerned individuals of the conclusion of their investigations. The review team determined that the Program adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC REGION]'s performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with [STATE] does not relinquish regulatory authority for a [sealed source and device evaluation/low level radioactive waste disposal and/or uranium recovery program]; therefore, only the first [no.] non-common performance indicators applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

[STATE] became an Agreement State on [DATE]. The current effective statutory authority is contained in the [LIST REGULATORY AUTHORITY/REGULATIONS], of the [STATE] Statutes. The Department is designated as the State's radiation control agency. The Bureau implements the radiation control program.

The review team noted that no legislation affecting the radiation control program was passed during the review period. [OR EXPLAIN ANY CHANGES TO STATE LEGISLATION THAT AFFECTED PROGRAM]

4.1.2 Program Elements Required for Compatibility

[DESCRIBE STATE'S RULEMAKING PROCESS; SEE EXAMPLES BELOW or REFER TO PREVIOUS IMPEP REPORT]

EXAMPLE:

The [STATE] regulations governing radiation protection requirements are located in

Chapter XXX of the [STATE] Administrative Code and apply to all ionizing radiation. [STATE] requires a license for possession and use of all radioactive material. [STATE] also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The Bureau's rulemaking process is governed by the Administrative Procedure Act in Title X, Chapter 120, of the [STATE] Statutes. The administrative process for regulation adoption is provided in Chapter 1S-1 of the {Code}. With the changes described above now in effect, the State's administrative rulemaking process takes approximately 12 months from drafting to finalizing a rule. [Name of committee] reviews and approves all rulemaking efforts. After the Bureau drafts a proposed regulation, they must publish a notice in the [STATE] Administrative Weekly offering to hold public workshops about the proposed regulations. After the workshops (if held), the Bureau publishes a notice in the XXX of proposed rulemaking and offers the opportunity for a public hearing on the proposed rules. Concurrently, the Bureau must prepare and send an initial rule review file to the Joint Administrative Procedures Committee, which is a legislative committee that oversees rulemaking by all State agencies. If there are no objections or changes needed, the Bureau prepares the final regulation and files it with the [STATE] Secretary of State. The final rule must be filed within 90 days of the notice of the proposed rule. While not all rules require legislative ratification, those that do will not become effective until ratified by the [STATE] Legislature.

EXAMPLE:

[STATE]'s regulations for the control of radiation are contained in [Name of Regulations], "Regulations for the Control of Ionizing Radiation" and apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation. [Name/number of regulation], "Disposal of Controlled Hazardous Substances - Radioactive Hazardous Substances," contains statutes that govern the management of radioactive hazardous substances and addresses low-level radioactive waste issues. [STATE] requires a license for the receipt, possession, use, ownership, or transfer of all radioactive material, including byproduct, source, certain quantities of special nuclear material, accelerator-produced radionuclides, and naturally-occurring materials, such as radium. [STATE] also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes six months to a year from the development stage to the final approval by the Secretary of the Environment, after which the rule becomes effective in 10 days. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Secretary of the Environment.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt the regulations of another agency by reference and also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. Changes or revisions to regulations are incorporated into [REGULATION] by means of supplements. During the review period, four supplements to [Name/number of regs] were issued that addressed regulatory changes related to the radioactive materials program

The review team evaluated [STATE]'s response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

[REVIEW CURRENT SRS SHEET FOR STATE ON FSME WEBSITE AT: <http://nrc-stp.ornl.gov/rulemaking.html> AND COMPLETE AS APPLICABLE]

During the review period, [STATE] submitted [no.] final regulation amendments, [no.] proposed regulation amendment and [no.] legally binding license condition to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. [Number or No] of the amendments were overdue for State adoption at the time of submission. The NRC's compatibility review resulted in [no.] comments, which will need to be addressed by the State in upcoming rulemaking activities. The following five amendments were submitted overdue during this review period:

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State adoption on October 24, 2005.
- "Medical Use of Byproduct Material – Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that was due for Agreement State adoption on April 29, 2008.
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005) that was due for Agreement State adoption on March 27, 2009.
- "National Source Tracking System – Serialization Requirements," 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685) that was due for Agreement State adoption on February 6, 2007.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043) that was due for Agreement State adoption on January 3, 2011.

According to the Bureau's Environmental Health Program Consultant, who is responsible for oversight of rulemaking and associated activities, the Bureau is reviewing the NRC comments on the final regulation amendments submitted during this review period and plans to address the comments in upcoming rulemaking.

At the time of this review, the following two amendments were overdue:

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that was due for Agreement State adoption by December 17, 2010.

- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 amendment (72 FR 55864), that was due for Agreement State adoption by November 30, 2010.

The Bureau is currently drafting proposed regulations for these two amendments and plans to submit them to NRC for review by [date]. The review team noted that the State had made significant process in the promulgation of regulations since the last IMPEP review, but still faced challenges in negotiating the arduous State regulatory process.

A complete list of regulation amendments can be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE]'s performance with respect to the indicator, Compatibility Requirements, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Bureau's performance regarding the Sealed Source and Device (SS&D) Evaluation Program. These subelements were (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the State SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The team also evaluated SS&D staff training records; certain reported incidents involving products authorized in [STATE] SS&D registrations, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1. Technical Staffing and Training

SS&D evaluation responsibilities are distributed between two reviewers, with one additional reviewer in training. Another individual who evaluated most of the SS&D registries in the current reporting period is no longer with the Bureau.

The Bureau has a documented qualification program for SS&D reviewers as a subsection of its overall Licensing Evaluator Qualification Procedures. The Bureau is in the process of developing a structured in-house training program, but due to the infrequent SS&D application or amendment requests, the Bureau is focusing its resources on developing structured training programs for more frequent regulatory actions. In the interim, the Bureau will use on-the-job training for new reviewers with oversight from the two qualified senior SS&D reviewers.

The Bureau currently has three qualified reviewers, although one individual has not performed any SS&D evaluations. All three individuals have completed the NRC SS&D Workshop. The new reviewer in training will be trained in-house with oversight from the senior SS&D reviewers. As part of their on-the-job training, the Bureau will use a double concurrence approach, where

the two active senior reviewers will both perform technical and concurrence reviews for any new application or amendment request.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Bureau processed six SS&D actions. Five of the actions were amendments, with one new application. There were no inactivations of SS&D registrations or emerging technology evaluations processed during the review period. The review team evaluated all six actions processed during the review period. The casework selected for review was representative of two qualified reviewers (one of whom is no longer with the Bureau) and one reviewer in-training. A listing of the SS&D certificates evaluated by the review team, with case-specific comments, may be found in Appendix F.

The review team identified that one of the SS&D registries issued was not signed by two qualified individuals. The concurrence reviewer for the new SS&D had not completed the in-house SS&D training program and is not considered a qualified reviewer. The Bureau has an internal policy that two qualified individuals review the SS&D application and a third individual in-training may also review the SS&D application. The concurrence signature for the SS&D registry was signed by the individual in-training. Therefore, the SS&D registration was not signed by two qualified reviewers. The Bureau performed evaluations based on sound conservative assumptions to ensure public health and safety was adequately protected. Good health physics practices were implemented throughout this review.

In assessing the Bureau's SS&D evaluation activities, the review team examined information contained in the questionnaire response and interviewed program staff and managers. The review team confirmed that the Bureau follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556 Series Guidance, applicable and pertinent American National Standards Institute (ANSI) standards and Military Standards, ISO-9001 and [STATE] regulations, statutes, policies and procedures. The review team verified these documents were available and used appropriately in performing SS&D reviews.

Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that product evaluations were complete and adequately addressed the integrity of the products during use and in the event of accidents.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED, the review team examined four incidents involving SS&D registered products during the review period. The review team examined all events that occurred in [STATE] that involved equipment or source failures within the period, as well as any events that occurred nationally involving sources/devices registered by the Bureau. The review team determined that the State analyzed the events, reviewed the issues, and followed up on the incidents. None of the events involving sources/devices manufactured or distributed by a licensee with a SS&D registered in [STATE] were related to manufacturing or design of the product.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE/NRC OFFICE]'s performance with respect to the indicator, Sealed Source and Device Evaluation

Program, be found satisfactory.

4.3 Low-level Radioactive Waste Disposal Program

IF NOT APPLICABLE:

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Although the [STATE] Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in [STATE]. Accordingly, the review team did not review this indicator.

IF APPLICABLE:

4.3 Low-level Radioactive Waste Disposal Program

In reviewing this indicator, the review team used five subelements to evaluate the [STATE]'s performance regarding the low-level radioactive waste (LLRW) disposal program. These subelements were (1) Technical Staffing and Training, (2) Status of Low-level Radioactive Waste Disposal Inspection, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

The regulatory responsibility for LLRW disposal resides with the [STATE OFFICE/DIVISION/ETC.]. Since the [YEAR OF LAST] IMPEP review, the [STATE]'s Radioactive Material Licensing team has issued two Technical Notices of Deficiencies in response to XYZ facility (XYZ) license application and the initial radioactive materials license to receive, handle, process, store, and dispose of LLRW at a site near[CITY, STATE]. The [STATE] Legislature established the process and timelines for receiving license applications and their review, ending with the issuance of a disposal site license after two rounds of interrogatories.

4.3.1 Technical Staffing and Training

The LLRW program team currently has [number] full-time and/or part-time staff members with a staffing effort of [number] FTE. The FTE total includes support by the Uranium Technical Assessment program. Staff supporting the LLRW program include: the Division Director, Radioactive Materials Licensing Manager, Health Physicists, engineers, geologists, and an administrative assistant.

[Number, if applicable] primary contractors were also utilized for technical support during the review period. Contractors provided assistance in health physics, nuclear engineering, hydrogeology, geology, geotechnical engineering, financial assurance, ecology, land/mineral rights, law, and civil engineering.

The review team examined the training records of the staff and found them up to date and complete. The review team determined that the current staff has the right balance of technical expertise and is adequate to maintain the quality and performance of the LLRW program. Through interviews with the professional staff and program managers, combined with an evaluation of training and experience, the review team concluded that the [STATE] staff is qualified to carry out regulatory duties for licensing and inspecting of the LLRW site.

4.3.2 Status of Low-level Radioactive Waste Disposal Inspection Program

The review team focused on three factors while reviewing this indicator. These include the inspection frequency, overdue inspections or any deviations from the schedule and timely dispatch of inspection findings to the licensee. The review team's evaluation was based on the Division's questionnaire response relative to this indicator, examination of inspection casework, and interviews with management and staff.

The review team evaluated the number of inspection modules completed during the review period. The inspection modules completed annually ranged from 82 to 100 percent. The review team evaluated the completed modules and determined that critical modules, which involved health, safety and security, such as radiation safety, dosimetry, security, and site access/postings, were completed annually. Though not all modules were completed on an annual basis the review team considered the Division's practice of having health physics inspectors at the XYZ disposal facility nearly weekly and concluded that adequate oversight of facility operations and the Radiation Safety Program was occurring.

The review team determined that the inspection findings for the LLRW disposal program were typically communicated by formal correspondence to the licensee within 30 days following the inspection.

4.3.3 Technical Quality of Inspections

The review team assessed the quality of LLRW disposal program inspections by evaluating inspector performance during the accompaniments and reviewing inspection field notes, completed reports, inspection procedures and the staff's follow-up to previous inspection findings, as well as regulatory actions taken and annual supervisory accompaniments.

On [date], two review team members accompanied two inspectors at the [Name] facility, as indicated in Appendix C. The inspectors were well prepared and thorough during their limited review of the LLRW disposal site. Under the LLRW license, site security, pre-operational environmental monitoring, and facility posting were observed. Inspectors conducted proper entrance and exit interviews with licensee managers and safety staff. Inspectors also conducted interviews with non-supervisory site personnel during the course of the inspection to ascertain perspective on licensee commitment to safety and training. During the accompaniments, the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspections were adequate to assess the safety and radiological hazards at the LLRW disposal facility.

Based on an evaluation of [number] inspection files, the review team determined that the inspection reports were thorough, complete, consistent, and had sufficient documentation to ensure that licensee's performances with respect to health, safety and security were acceptable. The findings were well-founded, supported by regulations and were appropriately documented. Based on interviews and review of documentation, the review team concluded that the inspectors reviewed the previous inspection report and discussed past inspection findings with other inspectors and the Low Level Waste/Uranium Mills Section Manager, in preparation for an inspection. Inspectors either followed-up on previous inspection findings during the subsequent inspection or dispositioned the findings as escalated enforcement actions.

4.3.4 Technical Quality of Licensing Actions

The team reviewed a selection of licensing actions that had been completed during the review period including (list type of actions performed). A listing of the licensing casework reviewed [with case-specific comments] can be found in Appendix D.

The review team determined that the examined licensing actions were thorough, complete, consistent, and of acceptable technical quality. The license conditions, including the tie-down conditions, were stated clearly and backed by information contained in the file and enforceable. The review team found that health and safety issues were generally properly addressed as part of the licensing action.

EXAMPLE:

The Division used independent analyses and actively solicited public comments during the licensing process through public hearings. The Division hired a technical consultant to address certain complex technical issues to verify the licensee's analysis for license renewal. The Board approved a new rule on April 14, 2010, that required XYZ facility to conduct a performance assessment before disposing of concentrated depleted uranium. The review team noted that the Division engaged in extensive public outreach on (date) regarding the performance assessment for the disposal of large quantities of concentrated depleted uranium. The Division indicated that information from these discussions was taken into consideration as the final performance assessment was developed. The licensee's performance assessment was delivered to the Division on June 1, 2011, and is currently under review by the Division.

The review team examined the financial surety proposed for the facility. Per license condition, discrete financial surety amounts for several categories (e.g., decommissioning, closure, and post-closure) are stated. The review team determined that the [STATE] adequately addressed the financial surety component of the license.

The review team concluded that the [STATE]'s licensing process was thorough, complete, consistent, and of acceptable quality.

4.3.5 Technical Quality of Incident and Allegation Activities

The review team found that the [STATE] had procedures in place for handling incidents and allegations. The procedures for handling incidents include information on what constitutes an incident, appropriate documentation of the incident, reference to NRC abnormal occurrence criteria, and incident tracking. The procedures for handling allegations include information on protecting the identity of the alleged, documentation of the allegation, and allegation tracking.

During the review period, there were no incidents or allegations pertaining to the LLRW program.

OR

During the review period, the State addressed one reportable incident involving LLRW disposal program activities. The review team determined that the Division took prompt and appropriate action. The review team noted that all documentation related to the investigation of the incident was complete and appropriately maintained in a separate file.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE]'s performance with respect to the indicator, Low-level Radioactive Waste Disposal Program, be found [satisfactory, satisfactory, but needs improvement, unsatisfactory].

4.4 Uranium Recovery Program

In reviewing this indicator, the review team used five subelements to evaluate the State's performance regarding the uranium recovery program. These subelements were (1) Technical Staffing and Training, (2) Status of Uranium Recovery Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

EXAMPLE

The [STATE] uranium recovery program has undergone inter-agency jurisdictional changes since the 2005 IMPEP review. In 2005, the Department had jurisdiction for the licensing, inspection, and enforcement actions for the above ground processes at licensed sites, including the review of the design, construction, operation, record keeping, maintenance, decommissioning, decontamination, and surface reclamation. The [STATE] had jurisdiction on the permitting, inspection, and enforcement actions for wells permitted by the underground injection control (UIC) program, including wellhead assemblies and groundwater monitoring

requirements. Both agencies were responsible for the review, permitting, licensing, inspection, and enforcement activities for fluid holding ponds.

At the time of this IMPEP review, the [STATE] uranium recovery program consists of three conventional mill licenses (three sites currently under decommissioning and currently undergoing groundwater assessments), five in-site recovery licenses (two licensees in decommissioning status, one licensee in “standby” status, one licensee in active production, and one licensee newly approved but not in operation), three in-situ recovery applications for new facilities, and one “reclamation” licensee to administer cleanup of vicinity properties abutting an in-situ recovery licensee that had been revoked by the Department.

4.4.1 Technical Staffing and Training

In reviewing this subelement, the review team considered staffing level, technical qualifications of the staff, staff training, and staff turnover.

The duties and responsibilities for the [STATE] uranium recovery program are assigned to staff within the Radioactive Materials Division. Division staff members are responsible for licensing actions associated with source material licenses and for permitting of the injection wells, requirements for exempt aquifers, and groundwater restoration. Program staff members are responsible for routine inspections of facilities that have a uranium recovery program license.

The Division staffing level is currently at 30 persons with various degrees of involvement in the uranium recovery program. Staffing levels have remained consistent throughout the IMPEP review period. The staff has expertise in various technical disciplines including health physics, geology, hydrology, and engineering. A majority of the staff has a professional registration and/or an advanced degree.

The review team examined staff training records as well as interviewed various staff members regarding training efforts. Training for the staff is hampered somewhat by the agency-wide restriction on out-of-state travel. This restriction is mitigated by staff attending NRC-sponsored classes and the [STATE] providing in-house training by outside experts.

The review team determined that the staffing levels, staff qualifications, and training levels for the uranium recovery program are adequate.

4.4.2 Status of Uranium Recovery Inspection Program

In reviewing this subelement, the review team evaluated the inspection frequency for uranium recovery licensees and the timeliness of inspection finding communications to the licensees. The review team's evaluation is based on [STATE]'s response to the questionnaire relative to this indicator, the uranium recovery inspection schedule, selected inspection casework files, and interviews with inspection staff and managers.

During the review period, the [STATE] performed 48 license inspections at 7 active licenses: 3 conventional mills in decommissioning, 2 in-situ recovery licenses in decommissioning, 1 active

but non-production in-situ recovery license, and 1 active in-situ recovery license. Inspections were performed in accordance with IMC 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program," requirements.

The review team concluded that there were no overdue inspections in the Uranium Mills program. A listing of the inspection casework reviewed can be found in Appendix C.

The review team determined that all inspection reports and inspection findings reports were issued within 30 days of the inspections. The supervisor reviewed all inspection reports. Appropriate follow-up actions were conducted when items of noncompliance were identified.

4.4.3 Technical Quality of Inspections

In reviewing this subelement, the review team examined inspection reports for five inspections conducted by the [STATE] during the review period and accompanied inspectors on inspections at two licensed facilities. The cases selected for review represented a range of uranium recovery licensing activities in different stages of operation. The review team interviewed inspectors and managers to assess the adequacy of their preparation for the inspections, guidance and/or protocols for inspection procedures, the depth and content of the actual inspections, and the appropriateness of inspection findings. The uranium recovery program inspection files evaluated by the review team are listed in Appendix C.

The inspector accompaniments and casework reviews confirmed that [STATE] inspections were thorough, included operational and record reviews, and violations were communicated by the inspector to the licensee during the inspection and exit interviews. The inspectors focused on interviews with licensee personnel to ensure that the work force was adequately trained and knowledgeable of the existing safety procedures, that the procedures were being followed, and that worker and public health and safety were properly monitored.

The review team found that the inspection reports provided appropriate depth of coverage, addressed license conditions and the regulations, and demonstrated that the inspector pursued corrective actions for items of noncompliance that were identified. Inspection files contained photographs documenting both general facility features and items of interest or concerns.

4.4.4 Technical Quality of Licensing Actions

For this subelement, the review team examined files and associated documentation related to licensing of in-situ and conventional mill facilities, license amendment files, and other licensing documentation. Appendix D lists the licensing files reviewed.

For the conventional mills, the licensing actions during the review period consisted of license renewal, annual financial assurance updates, compliance monitoring, and post-decommissioning monitoring for groundwater compliance. For in-situ recovery facilities, the licensing actions during the review period consisted of reviews of new applications, license renewals, license amendments, annual financial updates, decommissioning plans, and project area authorizations.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with [STATE] procedures, State regulations, and good health physics practices.

4.4.5 Technical Quality of Incident and Allegation Activities

For this subelement, the review team examined files and associated documentation related to incident and allegation activities, response timeliness, and inspection reports, and interviewed the inspection personnel involved with incident and allegation activities.

The review team evaluated the [STATE]'s response to two incidents and three allegations (complaints) regarding the uranium recovery program. A listing of the incident casework examined can be found in Appendix E.

The State's investigations were thorough and results of the allegation investigations were discussed with the originating complainant. Appropriate enforcement actions were taken given the scope of the violations noted. The review team discussed with [STATE] staff the importance of documentation of all investigations. The [STATE] is developing a database designed for agency-wide tracking of incidents, complaints, and enforcement actions.

Based on the IMPEP evaluation criteria, the review team recommends that [STATE]'s performance with respect to the indicator, Uranium Recovery Program, be found [satisfactory, satisfactory, but needs improvement or unsatisfactory].

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, [STATE]'s performance was found satisfactory for [number out of number reviewed] of performance indicators reviewed and/or satisfactory, but needs improvement, for the indicator(s), [list indicators], and/or unsatisfactory for the performance indicator(s) [list indicators] reviewed. The review team did not make any recommendations OR made (number) recommendations regarding program performance by the State and determined that the recommendation(s) from the [YEAR] IMPEP review should be closed/kept open/modified.

Accordingly, the review team recommends that the [STATE] Agreement State Program be found [adequate or not adequate] to protect public health and safety and [compatible or not compatible] with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately [xx] years. (NOTE: if you are recommending to increase/decrease the frequency of the periodic meeting from the normal 2 year interval, state that also)

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

RECOMMENDATIONS

1.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	[STATE] Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
NAME, Region/STATE	INDICATOR(S)
NAME, Region/STATE	INDICATOR(S)
NAME, Region/STATE	INDICATOR(S)
NAME, Region/STATE	INDICATOR(S)

APPENDIX B

[STATE] ORGANIZATION CHARTS

ADAMS ACCESSION NO.: MLXXXXXX

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1	
Licensee:	License No.:
Inspection Type: [Initial/Routine and Un/announced]	Priority:
Inspection Date: xx/xx/xx	Inspector(s):

File No.: 2	
Licensee:	License No.:
Inspection Type:	Priority:
Inspection Date:	Inspector:

File No.: 3	
Licensee:	License No.:
Inspection Type:	Priority:
Inspection Date:	Inspector:

Comment: ONLY LIST DEFICIENCIES THAT WERE MENTIONED IN BODY OF REPORT.

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	
Licensee:	License No.:
Inspection Type: [Initial/Routine and Un/announced]	Priority:
Inspection Date: xx/xx/xx	Inspector:

Accompaniment No.: 2	
Licensee:	License No.:
Inspection Type:	Priority:
Inspection Date: xx/xx/xx	Inspector(s):

Comment: ONLY LIST DEFICIENCIES THAT WERE MENTIONED IN BODY OF REPORT.

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee:
Type of Action: New/Amendment/Renewal/Termination
Date Issued: xx/xx/xx

License No.:
Amendment No.:
License Reviewer:

File No.: 2
Licensee:
Type of Action:
Date Issued:

License No.:
Amendment No.:
License Reviewer:

File No.: 3
Licensee:
Type of Action:
Date Issued:

License No.:
Amendment No.:
License Reviewer:

Comment: ONLY LIST DEFICIENCIES THAT WERE MENTIONED IN BODY OF REPORT.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee:

Date of Incident: xx/xx/xx

Investigation Date: xx/xx/xx

License No.:

NMED No.:

Type of Incident: Medical Event/ Lost/Stolen RAM

Type of Investigation: Site

File No.: 2

Licensee: /

Date of Incident: xx/xx/xx

Investigation Date: xx/xx/xx

License No.:

NMED No.:

Type of Incident:
Type of Investigation:

Comment: ONLY LIST ANY DEFICIENCIES THAT WERE MENTIONED IN BODY OF REPORT.

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.:
Applicant Name:
Date Issued: xx/xx/xx

SS&D Type:
Type of Action:
SS&D Reviewer(s):

Comments:

File No.: 2
Registry No.:
Applicant Name:
Date Issued: xx/xx/xx

SS&D Type:
Type of Action:
SS&D Reviewer:

ATTACHMENT

[date] letter from [Name]
[STATE]'s Response to the Draft Report
ADAMS Accession No.: MLXXXXXX