

April 29, 2011

MEMORANDUM TO: Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Scott Moore, Acting Director
Office of Federal and State Materials
and Environmental Management Programs

Art Howell, Deputy Regional Administrator
Region IV

FROM: Lisa Dimmick, Health Physicist */RA/*
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF THE NEW JERSEY AGREEMENT
STATE PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the New Jersey Agreement State Program. The review was conducted by an interoffice team during the period of February 28 – March 4, 2011. The review team issued a draft report to the State on March 23, 2011, for factual comment. New Jersey responded to the findings and conclusions of the review by email dated April 19, 2011, from Patricia Gardner, Chief, Bureau of Environmental Radiation. New Jersey's response letter and the associated comment resolution document can be found in ADAMS (ML111100390) and are attached to the proposed final report.

The review team is recommending that New Jersey's performance be found "satisfactory" for four performance indicators and "satisfactory, but needs improvement" for two performance indicators reviewed. Overall, the review team is recommending that the New Jersey Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team is recommending that the next IMPEP review of the New Jersey Agreement State Program take place in approximately 4 years.

MRB Members

-2-

The MRB meeting to consider the New Jersey report is scheduled for **Monday, May 9, 2011, from 1:00 p.m. to 3:00 p.m. (EST), in Two White Flint North, Room 2-B5**. In accordance with Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact me at 301-415-0694.

Enclosures:
As stated

cc w/encl: Irene Kropp, Deputy Commissioner
New Jersey Department of Environmental Protection

Robert Gallagher, Massachusetts
Organization of Agreement States
Liaison to the MRB

MRB Members

-2-

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE NEW JERSEY AGREEMENT STATE PROGRAM

FEBRUARY 28-MARCH 4, 2011

PROPOSED FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the initial IMPEP review of the New Jersey Agreement State Program. The review was conducted during the period of February 28 – March 4, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio.

Based on the results of this review, the review team found New Jersey's performance to be satisfactory, but needs improvement for two performance indicators, Status of the Materials Inspection Program and Technical Quality of Licensing Actions; and, found New Jersey's performance to be satisfactory for all other indicators reviewed. The review team made two recommendations regarding the performance of the State. The review team recommends that the State consistently implement their licensing procedures and NRC's pre-licensing guidance, as well as other administrative licensing procedures found in the NUREG-1556 series; and, that the State provide additional training to staff members and supervisors regarding technical review of licensing actions for uses and technologies that were transferred from the NRC to the Bureau's jurisdiction.

Overall, the review team recommends that the New Jersey Agreement State Program be found adequate to protect public health and safety and compatible with 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 4 years.

New Jersey Proposed Final Report

1.0 INTRODUCTION

This report presents the results of the review of the New Jersey Agreement State Program. The review was conducted during the period of February 28 – March 4, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New Mexico. This was the initial review of the program since the Agreement was signed in September 2009. 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 September 30, 2009, to March 4, 2011, were discussed with New Jersey 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 New Jersey Agreement State Program is administered by the Bureau of Environmental Radiation (the Bureau), in the Division of Environmental Safety and Health (the Division). The Division is part of the New Jersey Department of Environmental Protection. Organizational charts for the Department, the Division, and the Bureau are included as Appendix B.

At the time of the review, the New Jersey Agreement State Program regulated approximately 620 specific licenses authorizing byproduct, source, and certain special nuclear 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 the NRC and the State of New Jersey.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on October 22, 2010. The Bureau provided its response to the questionnaire via email on February 11, 2011. A publicly available version of the questionnaire response can be found in NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML110450005.

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 New Jersey statutes and regulations; (3) analysis of quantitative information from the Bureau’s databases; (4) technical review of selected regulatory actions; (5) field accompaniments of five 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 New Jersey Agreement State Program’s performance.

Results of the review for the common performance indicators are presented in Section 2.0. Section 3.0 details the results of the review of the applicable non-common performance indicators, and Section 4.0 summarizes the review team’s findings and recommendations. The review team’s recommendations are comments that relate directly to Bureau performance by the State. A response is requested from the State to all recommendations in the final report.

New Jersey Proposed Final Report

2.0 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.

2.1 Technical Staffing and Training

Issues 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 any workload backlogs.

The New Jersey Agreement State Program is composed of a Manager, four supervisors, seven technical staff and three administrative support staff. Supervisors and technical staff members have at least a bachelor's degree in a physical or life science and several years of professional experience in radiation protection. Supervisors and technical staff conduct inspections, perform licensing actions, and respond to incidents and allegations based on individual qualifications. Supervisors and technical staff also perform emergency response duties as necessary. Based on information provided by the Bureau, the review team estimated that the Bureau expends approximately 12.5 full-time equivalents (FTE), including administrative support, to administer the Agreement State program. During the review period, no supervisors or technical staff left or joined the Bureau. At the time of the review, the Bureau had no vacancies in 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) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The Bureau uses on-the-job training, such as inspector accompaniments, to supplement formal coursework. Staff members are typically assigned increasingly complex duties as they progress through the qualification process. Staff members are authorized to perform regulatory duties independently after demonstrating competency. In the State's application to become an Agreement State, the State committed to using qualification journals for each of its staff members. The review team found that the technical staff members have been maintaining their individual qualification journals as they complete training classes and licensing and inspection tasks. Technical staff members and supervisors also complete individual training plans for each calendar year based on their individual and program needs. The team noted one training issue, specific to the technical review of licensing actions, which is described in Section 2.4, "Technical Quality of Licensing Actions".

The review team noted that Bureau managers encourage and support training opportunities, based on program needs. The review team concluded that the Bureau's staffing and training is adequate to carry out its regulatory duties.

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Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

2.2 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 issuance 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 Bureau managers and staff members.

The review team verified that the Bureau's inspection priorities were the same as those found in NRC's IMC 2800, "Materials Inspection Program." Over the review period, the Bureau performed 81 Priority 1, 2, and 3 inspections, of which six had been performed overdue (i.e. greater than 25% of the assigned inspection frequency). These ranged from 6 months past the due date to 11 months past the due date. None were overdue at the time of the review. Initial inspections are to be conducted within 12 months of license issuance. The review team noted that during the review period four initial inspections had become due, one of these inspections had been performed and three were still overdue (from one to five months) at the time of the review. Overall, the review team calculated that the Bureau performed 12 percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness in issuing inspection findings. The Bureau is required to follow the New Jersey Department of Environmental Protection's (NJDEP) policy which requires all NJDEP programs to issue inspection findings to licensees within 90 days of the final date of the inspection. While this policy differs from NRC's requirement of issuing findings within 30 days, the Bureau typically issues inspection findings within 30 days of final completion and often within 1-2 weeks if no findings were identified. The review team found that the majority of inspection findings were issued within NRC's identified 30-day goal.

During the review period the Bureau received 47 reciprocity requests, of which 31 were candidates for inspection based on the criteria in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Bureau met the 20 percent requirement found in IMC 1220.

The Bureau had 34 licensees that were subject to the Increased Controls at the time of the review. The initial Increased Control (IC) inspections were completed by the NRC prior to this review period. The review team noted that follow-up IC inspections as well as National Source Tracking System (NSTS) verifications were being conducted during routine inspections of these licensees.

Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory, but needs improvement.

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2.3 Technical Quality of Inspections

The review team evaluated 20 inspection reports that included enforcement documentation and letters to licensees, and interviewed inspectors who were responsible for radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by eight current inspectors and covered a wide variety of inspection types involving initial, routine, and special inspections. The casework included inspections of various types of programs including: academic, research and development, medical institution-written directive required, high dose-rate remote after-loaders, nuclear pharmacies, PET production facilities, brachytherapy sealed source treatments including Sr-90 eye applicator and permanent seed implants used for prostate treatments, gamma stereotactic radiosurgery, self-shielded irradiator, and industrial radiography. Appendix C lists the inspection casework files reviewed.

Based on the evaluation of casework, the review team determined that inspection reports were thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performance with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews. The review team also evaluated the Bureau's handling and storing of sensitive documents. The review team determined that documents containing sensitive and security-related information were appropriately protected, and maintained in a manner to limit access. The review team found that outgoing correspondence containing sensitive information (licenses, inspection reports, etc.) was appropriately marked.

The Bureau has a policy to accompany all staff performing radioactive materials inspections on an annual basis. The review team verified that all qualified inspectors had been accompanied prior to the review. Inspectors are accompanied by supervisors. Supervisors who perform inspections accompany each other.

The review team noted that the Bureau maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency conditions. Each basic kit contains three survey instruments for performing surveys under various radiological conditions. Each kit is assigned to an individual staff member who is also responsible for ensuring it is properly calibrated. The Bureau has a contract with a Pennsylvania calibration lab for calibration services.

The Section receives laboratory and sample analysis support from the State laboratory located in Trenton. The State laboratory has a wide array of analytical equipment and is capable of detailed radiochemistry analysis. The Bureau also has a total of 13 gamma spectroscopy units for on-the-spot radiological determinations should the need arise.

The review team accompanied five of the Bureau's inspectors in February 2011. The inspectors conducted inspections at two medical brachytherapy licensees and at a Type-A broad scope academic licensee. The inspector accompaniments are listed in Appendix C. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors focused their efforts

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beginning with the most risk significant activities. The inspectors conducted interviews with appropriate personnel, observed licensed operations and appropriately pursued issues noted, conducted confirmatory measurements, and utilized good health physics practices. The inspectors also held entrance and detailed exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

2.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 18 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, proper signatures, and marking of licenses as *Official Use Only-Security Related Information* when appropriate.

The licensing casework was selected to provide a representative sample of licensing actions completed during the initial review period. Licensing actions selected for evaluation included 5 new licenses, 2 renewals, 3 decommissioning or termination actions, 7 amendments, and 1 financial assurance action. Files reviewed included a cross-section of license types, including: medical diagnosis and therapy, gamma stereotactic radiosurgery, research and development, nuclear pharmacy, cyclotron production, gauges, industrial radiography, and self-shielded irradiators. The casework sample represented work from nine of the ten license reviewers. A listing of the licensing casework reviewed is provided in Appendix D.

On September 30, 2009, NRC transferred 542 specific licenses to New Jersey's jurisdiction. The Bureau merged the NRC licenses with existing Bureau licenses for naturally occurring and accelerator-produced radioactive materials. As a result, the Bureau had 620 licenses at the time of the review. The majority of the license amendments completed by the Bureau during the review period consisted of merging NRC licenses into New Jersey licenses, and reformatting all of the NRC licenses into the Bureau's license template. The Bureau completed approximately 32 new licenses, 63 license renewals, and 42 termination licensing actions during the review period. All licensing actions are initially entered into the Bureau's computer tracking system called the New Jersey Environmental Management System (NJEMS), a database system used by all programs in the New Jersey Department of Environmental Protection to centrally locate information regarding licenses, inspections, enforcement actions, and incidents. In addition to tracking licensing actions, NJEMS is used to generate licensing documents in a standardized format. License reviewers use standardized sets of conditions specific to the type of licensed program to ensure consistency in licenses. Each licensing action is reviewed and signed by a Bureau supervisor.

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Overall, the review team concluded that licensing actions were adequate to protect public health and safety; however, based on the evaluation of casework, the review team noted repeated examples of issues with thoroughness and adherence to existing licensing procedures and guidance. Issues with the technical quality of some reviews were also noted. Specific examples included in part, the addition of a complex, new technology to a license without a thorough technical review; inconsistent implementation of the Bureau's licensing procedures; and inconsistent implementation of the licensing guidance in the NRC NUREG-1556 series. Supervisory reviews did not identify the technical or administrative issues identified by the review team. Documentation of licensing actions was often split between the paper license file and NJEMS, and in some cases it appeared that records of deficiency calls or e-mails to licensees were not retained.

The Bureau's procedures require use of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. The team identified that these procedures were not applied consistently. To determine the extent of condition, Bureau staff then reviewed 20 new licenses and determined that the pre-licensing guidance was either not followed or not fully followed for more than half of these. Bureau staff quickly reviewed these license files with the review team, and it appeared that each of the licensees either had a previous Agreement State or NRC license, had a current State registration for other operations within the scope of its licensed activities, and/or State personnel visited the licensee's site to deliver the new license. Following discussion with the review team, the Bureau took immediate action to review all new licenses issued from September 30, 2009 through March 4, 2011 to complete or verify completion of the pre-licensing checklist and place copies in NJEMS and license files; print out e-mails, notes, and phone logs used to make decisions about license issuance and place copies in the license file; and confirm that any pre-licensing visit is documented in NJEMS and the license file. If completion of the pre-licensing process identified that a license was inappropriately issued, the Bureau planned to immediately address this. The review team recommends that the Bureau consistently implement their licensing procedures, and NRC's pre-licensing guidance, as well as other administrative licensing procedures found in the NUREG-1556 series.

The review team discussed licensing training received by Bureau staff prior to initial implementation of the Agreement. The Bureau Manager stated that in March of 2009 the Bureau hosted the licensing course and the majority of the technical staff had attended the course. The review team also noted that a team of Bureau staff had traveled to the NRC Region I office for one day to look at the space requirements for docket files and to review the administrative aspects of the licensing program. Additionally, one Bureau staff member spent a week in the Region I office observing the licensing process and reviewed NRC's Licensing Tracking System (LTS) as it relates to the administrative licensing process. The IMPEP review team then discussed the licensing deficiencies noted with the Bureau Manager and in part, suggested additional technical licensing training for the staff as an adjunct to any licensing training already received. The Bureau Manager acknowledged that the issues noted regarding licensing would likely be improved with additional technical training. The review team recommends that the Bureau provide additional training to staff members and supervisors regarding technical review of licensing actions for uses and technologies that were transferred from the NRC to the Bureau's jurisdiction.

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The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the Bureau uses license conditions for Increased Controls and Fingerprinting, as appropriate. Requirements for National Source Tracking System are included in the State's regulations. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. 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 found that files containing increased controls licenses are kept in a locked room and the licenses and corresponding cover letters were marked as containing sensitive information.

The Bureau had initiated the process to address maximum possession limits on radioactive materials licenses as requested by RCPD-10-007 letter dated June 21, 2010. The Bureau had identified the licenses affected and had sent letters to the respective licensees requesting information for the maximum possession limit authorization.

Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

2.5 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 New Jersey in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 4 reported radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Bureau's response to 3 allegations involving radioactive materials. The NRC did not refer any allegations to the Bureau during the review period.

When notified of an incident or an allegation, the Bureau Manager and staff discuss the initial response and the need for an on-site investigation, based on the safety significance. If the incident meets 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 Bureau notifies the NRC Headquarters Operations Center and enters the information into NMED in a prompt manner.

The incidents selected for review included personnel and equipment contamination, lost and/or stolen radioactive material, and damaged equipment. The review team determined that the Bureau's responses to incidents were thorough, complete, and comprehensive in all instances. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance of the event. When no immediate threat was present and the Bureau determined that the licensee had qualified, competent individuals investigating the incident, the Bureau generally responded telephonically with an on-site follow-up inspection at a later date when appropriate.

In evaluating the effectiveness of the Bureau's response to allegations, the review team evaluated the casework for 3 allegations. The review team concluded that the Bureau took

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prompt and appropriate action in response to concerns raised. The review team noted that the Bureau thoroughly documented the investigation and retained all necessary documentation to appropriately close the allegation. The Bureau notified the allexer of the conclusion of the investigation. The review team determined that the Bureau adequately protected the identity of allexers.

Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

3.0 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 the State of New Jersey does not relinquish authority to regulate a sealed source and device evaluation program, a low-level radioactive waste disposal program, or a uranium recovery program, so only the first non-common performance indicator was applicable to this review.

3.1 Compatibility Requirements

3.1.1 Legislation

New Jersey became an Agreement State on September 30, 2009. Legislative authority to create the Bureau and enter into an Agreement with NRC is granted in the Radiation Protection Act (N.J.S.A 26:2D-1), the Administrative Procedures Act (N.J.S.A. 52:14B-1 et seq.), and the Atlantic Interstate Low-Level Radioactive Waste Compact Implementation Act.

The State's rulemaking process automatically adopts NRC requirements by reference with the exception of Subpart E of 10 CFR Part 20. When NRC amends requirements, the amendments are automatically incorporated into New Jersey's rules without further proposal or publication. However, because New Jersey specifically substitutes some New Jersey titles, addresses and language, there are times when the State may be required to amend its rules to make administrative changes which are then sent to NRC for review. These administrative changes do not alter the substantive portions of the regulation.

New Jersey regulations are subject to sunset review and recently came due for review in 2010. A one year extension was granted and the State is currently working to complete the review. Once approved, the next sunset review will take place in 2015.

3.1.2 Program Elements Required for Compatibility

New Jersey's regulations for control of radiation are located in the New Jersey Administrative Code, Title 7, Chapter 28, and apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation. New Jersey requires a license for the receipt, possession, use, transfer, ownership, or acquisition, of radioactive material. New Jersey also requires the registration of ionizing radiation machine facilities.

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The review team evaluated the Bureau's response to the questionnaire, 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.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of this review, New Jersey had no overdue regulations and has completed all outstanding regulation changes through the last NRC final rulemaking which was issued in 2009.

The State adopts most NRC regulations by reference and uses legally binding requirements such as license conditions when necessary. New Jersey regulations that are adopted by reference indicate a "pointer" to the appropriate NRC regulations, so that if the NRC modifies a regulation, the change is automatic for the State's regulations. If the NRC develops a new regulation section, such as the upcoming 10 CFR Part 37 security requirements rule, or updates regulations that the State does not adopt by reference, the State must create a new section in their regulations or update their regulations accordingly. The State's regulatory process typically takes approximately two years to complete, which includes time for public comment.

Based on the IMPEP evaluation criteria, the review team recommends that New Jersey's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.0 SUMMARY

As noted in Sections 2.0 and 3.0 above, the review team found New Jersey's performance to be satisfactory, but needs improvement for two performance indicators: Status of the Materials Inspection Program and Technical Quality of Licensing Actions. The review team found New Jersey's performance to be satisfactory for all other indicators reviewed. The review team made two recommendations regarding the performance of the State. Overall, the review team recommends that the New Jersey Agreement State Program be found adequate to protect public health and safety and compatible with 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 4 years.

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

1. The review team recommends that the Bureau consistently implement their licensing procedures and NRC's pre-licensing guidance, as well as other administrative licensing procedures found in the NUREG-1556 series. (Section 2.4)
2. The review team recommends that the Bureau provide additional training to staff members and supervisors regarding technical review of licensing actions for uses and technologies that were transferred from the NRC to the Bureau's jurisdiction. (Section 2.4)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	New Jersey Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Randy Erickson, Region IV	Team Leader Technical Quality of Inspections Compatibility Requirements Inspector Accompaniments
Donna Janda, Region I	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Sandra Gabriel, Region I	Technical Quality of Licensing Actions
Santiago Rodriguez, New Mexico	Status of Materials Inspection Program

APPENDIX B

NEW JERSEY ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML110450003

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1 Licensee: Janx Integrity Group Inspection Type: Routine, Unannounced Inspection Date: 1/27/10	License No.: 507152 Priority: 1 Inspectors: CB
File No.: 2 Licensee: Certified Testing Labs Inspection Type: Special, Unannounced Inspection Date: 10/7-8/10	License No.: 507161 Priority: 1 Inspector: CB
File No.: 3 Licensee: Branch Radiographic Labs, Inc. Inspection Type: Special, Unannounced Inspection Date: 6/4/10 and 6/29/10	License No.: 507051 Priority: 1 Inspectors: CB
File No.: 4 Licensee: Jersey Shore Medical Center Inspection Type: Routine, Unannounced Inspection Date: 7/14/09	License No.: 331191 Priority: 2 Inspector: JM
File No.: 5 Licensee: IBA Molecular North America, Inc. Inspection Type: Routine, Unannounced Inspection Date: 12/21/10	License No.: 439619 Priority: 2 Inspector: DZ, CB
File No.: 6 Licensee: Mountainside Hospital Inspection Type: Routine, Unannounced Inspection Date: 12/7/10	License No.: 332177 Priority: 2 Inspector: NS, RP
File No.: 7 Licensee: Newark Beth Israel Medical Center Inspection Type: Special, Unannounced Inspection Date: 12/1-2/10	License No.: 455336 Priority: 2 Inspector: JT, JM
File No.: 8 Licensee: Memorial Sloan Kettering Cancer Center Inspection Type: Routine, Unannounced Inspection Date: 11/9/10	License No.: 332593 Priority: 2 Inspectors: ET, RP

File No.: 9

Licensee: Somerset Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 11/1/10

License No.: 450635
Priority: 2
Inspector: ET, RP

File No.: 10

Licensee: Ocean Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 10/14/10

License No.: 457842
Priority: 2
Inspector: JT

File No.: 11

Licensee: Petnet Solutions, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 10/13/10 and 11/17/10

License No.: 459066
Priority: 2
Inspectors: DZ, CB

File No.: 12

Licensee: Riverview Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 10/6/10

License No.: 297846
Priority: 2
Inspector: JT

File No.: 13

Licensee: Robert Wood Johnson University Hospital
Inspection Type: Special, Announced
Inspection Dates: 6/16/10

License No.: 450729
Priority: 2
Inspectors: JM, BC, RP

File No.: 14

Licensee: Centrastate Health Care System, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 5/3/10

License No.: 444567
Priority: 2
Inspectors: NS, JM

File No.: 15

Licensee: Monmouth Medical Center
Inspection Type: Special, Announced
Inspection Date: 3/10/10

License No.: 332041
Priority: 2
Inspectors: JM

File No.: 16

Licensee: JFK Medical Center
Inspection Type: Special, Unannounced
Inspection Date: 2/17/10

License No.: 441325
Priority: 2
Inspector: JM, RP, JT

File No.: 17

Licensee: Robert Wood Johnson Medical Center @ Rahway
Inspection Type: Routine, Unannounced
Inspection Date: 11/24/10

License No.: 425392
Priority: 3
Inspectors: NS, RP

File No.: 18

Licensee: Johnson & Johnson Pharmaceutical R&D
Inspection Type: Routine, Unannounced
Inspection Date: 10/21/10

License No.: 507685
Priority: 3
Inspector: CB, JT

File No.: 19

Licensee: Chilton Memorial Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 8/24/10

License No.: 332052
Priority: 3
Inspector: RP

File No.: 20

Licensee: Trinitas Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 2/14-15/11

License No.: 540-137-1
Priority: 2
Inspectors: RP, JM

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Trinitas Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 2/14-15/11

License No.: 332163
Priority: 2
Inspector: RP, JM

Accompaniment No.: 2

Licensee: Rutgers, The State University of New Jersey
Inspection Type: Routine, Unannounced
Inspection Date: 2/16-17/11

License No.: 29-05218-28
Priority: 3
Inspector: BC, CB

Accompaniment No.: 3

Licensee: Kennedy Health System
Inspection Type: Routine, Unannounced
Inspection Date: 2/18/11

License No.: 454375
Priority: 2
Inspector: JT

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Central New Jersey Blood Center

Type of Action: Amendment

Date Issued: 11/17/09

License No.: 508156

Amendment No.: 090001

License Reviewer: CB

File No.: 2

Licensee: Central New Jersey Blood Center

Type of Action: Amendment

Date Issued: 9/22/10

License No: 508156

Amendment No.: 100001

License Reviewer: BC

File No.: 3

Licensee: Monmouth Medical Center

Type of Action: Amendment

Date Issued: 2/7/11

License No.: 332041

Amendment No.: 100004

License Reviewer: JM

Comment:

- 1) Reviewer did not address technical issues such as licensee commitments that were inappropriate for the requested device or inconsistent with current regulations.
- 2) Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.

File No.: 4

Licensee: Consultants in Cardiology

Type of Action: Renewal

Date Issued: 2/24/10

License No.: 448385

Amendment No.: 100001

License Reviewer: ET

Comment:

Technical review was not performed in accordance with NUREG-1556 guidance.

File No.: 5

Licensee: Duffield Associates Inc.

Type of Action: New

Date Issued: 3/7/10

License No.: 518330

Amendment No.: 100001

License Reviewer: AW

Comment:

Pre-licensing review was not performed in accordance with RCPD-08-020.

File No.: 6
Licensee: EMSL Analytical Inc.
Type of Action: New
Date Issued: 11/30/10

License No.: 535776
Amendment No.: 100001
License Reviewer: JG and CB

Comment:

License did not include decay-in-storage license condition.

File No.: 7
Licensee: URS Corporation
Type of Action: Amendment
Date Issued: 2/22/11

License No.: 507141
Amendment No.: 110001
License Reviewer: JT

File No.: 8
Licensee: Branch Radiographic Laboratories, Inc.
Type of Action: Amendment
Date Issued: 3/9/10

License No.: 507051
Amendment No.: 100001
License Reviewer: AW

File No.: 9
Licensee: IBA Molecular North America Inc.
Type of Action: Amendment
Date Issued: 9/21/10

License No.: 452369
Amendment No.: 100002
License Reviewer: AW

File No.: 10
Licensee: IBA Molecular North America Inc.
Types of Action: Amendment
Date Issued: 12/28/10

License No.: 439619
Amendment Nos.: 100001
License Reviewer: CB

File No.: 11
Licensee: The Heart Specialists Group LLC
Types of Action: New
Date Issued: 2/24/10

License No.: 514223
Amendment No.: 090001
License Reviewer: NS

Comment:

- 1) Pre-licensing review was not performed in accordance with RCPD-08-020.
- 2) Technical review was not performed in accordance with NUREG-1556 guidance.

File No.: 12
Licensee: Integral PET Associates
Type of Action: New
Date Issued: 1/31/11

License No.: 526648
Amendment No.: 110001
License Reviewer: NS

Comment:

Technical review was not performed in accordance with NUREG-1556 guidance.

File No.: 13

Licensee: Hackensack University Medical Center of Westwood

Type of Action: New

Date Issued: 11/17/10

License No.: 542561

Amendment No.: 100001

License Reviewer: NS, RP

Comment:

- 1) Pre-licensing review was not performed in accordance with RCPD-08-020.
- 2) Technical review was not performed in accordance with NUREG-1556 guidance.

File No.: 14

Licensee: Roxbury Open MRI & Surgical Center

Type of Action: Termination

Date Issued: 1/20/11

License No.: 436770

Amendment No.: N/A

License Reviewer: JG

File No.: 15

Licensee: Ligand Pharmaceuticals

Type of Action: Termination

Date Issued: 2/10/11

License No.: 507506

Amendment No.: N/A

License Reviewer: JG

File No.: 16

Licensee: Wyeth Pharmaceuticals Inc. DBA Wyeth Research

Type of Action: Termination

Date Issued: 1/21/11

License No.: 330948

Amendment No.: N/A

License Reviewer: JG

File No.: 17

Licensee: Xenobiotics Laboratories, Inc.

Type of Action: Financial Assurance

Date Issued: 8/18/10

License No.: 507356

Amendment No.: N/A

License Reviewer: DZ

File No.: 18

Licensee: Hopewell Radiology Group (Jamesburg Facility)

Type of Action: Renewal

Date Issued: 11/29/10

License No.: 453815

Amendment No.: 100003

License Reviewer: ET

Comment:

Technical review was not performed in accordance with NUREG-1556 guidance.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Cardinal Health Nuclear Pharmacy
Date of Incident: 3/11/10
Investigation Date: 3/11/10, 5/25/10

License No.: 440735
NMED Log No.: 100128
Type of Incident: Contamination Event
Type of Investigation: Telephone, Site

File No.: 2

Licensee: Bed, Bath and Beyond
Date of Incident: 10/1/09
Investigation Date: 4/12/210

License No.: General
NMED Log No.: 100229
Type of Incident: Damaged Equipment
Type of Investigation: Telephone

Comment:

The general licensee identified the damaged exit sign on 3/14/10 and reported it to the Bureau on 4/12/10.

File No.: 3

Licensee: SOR Testing Laboratories
Date of Incident: 10/8/10
Investigation Date: 10/9/10

License No.: 507162
NMED Log No.: 100505
Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 4

Licensee: Bed, Bath and Beyond
Date of Incident: 8/26/10
Investigation Date: 9/17/10

License No.: General
NMED Log No.: 100535
Type of Incident: Lost RAM
Type of Investigation: Telephone

ATTACHMENT

April 19, 2011 Email from Patricia Gardner
New Jersey's Response to the Draft Report
ADAMS Accession No.: ML111100390

**Agenda for Management Review Board Meeting
May 9, 2011, 1:00 p.m. – 3:00 p.m. (EDT), TWFN-2-B5**

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives and other participants.
3. Consideration of the New Jersey IMPEP Report.
 - A. Presentation of Findings Regarding New Jersey's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from New Jersey representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees: Michael Weber, DEDMRT
Bradley Jones, OGC
Scott Moore, FSME
Robert Lewis, FSME
Art Howell, Region IV
Bob Gallagher, MA
Patricia Gardner, NJ
Lisa Dimmick, FSME
Randy Erickson, Region IV

Donna Janda, RI
Sandra Gabriel, RI
Santiago Rodrigues, NM
Terrence Reis, FSME
Duncan White, FSME
Karen Meyer, FSME
Michelle Beardsley, FSME
Kathryn Brock, OEDO