June 23, 2005

MEMORANDUM TO: Martin J. Virgilio, Deputy Executive Director
for Materials, Research and State Compliance Programs

Paul H. Lohaus, Director
Office of State and Tribal Programs

Jack R. Strosnider, Director
Office of Nuclear Material Safety and Safeguards

Karen D. Cyr, General Counsel

/RA/

FROM: Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE ILLINOIS RADIATION CONTROL PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Illinois Radiation Control Program. The review of the Illinois program was conducted by an interoffice team during the period of April 4-8, 2005. The team issued a draft report to Illinois on May 5, 2005 for factual comment. Illinois responded to the findings and conclusions of the review by letter dated June 3, 2005, from Gary Wright, Assistant Director, Illinois Emergency Management Agency, Division of Nuclear Safety. The team prepared a resolution of comment document and it is attached to the IMPEP report.

The review team found Illinois performance to be satisfactory for seven of the performance indicators and unsatisfactory for one of the indicators reviewed, Compatibility Requirements. Accordingly, the review team recommends that the Illinois Agreement State program be found adequate to protect public health but not compatible with NRC's program.

The MRB meeting to consider the Illinois report is scheduled for **Tuesday, June 28, 2005, from 3:00 p.m. to 5:00 p.m., in One White Flint North, Room O-3B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 3).

If you have any questions prior to the meeting, please contact me at 301-415-2325 or John Zabko at 301-415-2308.

Attachments:
As stated

cc: Gary Wright, Assistant Director
Illinois Emergency Management Agency

Pearce O'Kelly, SC
OAS Liaison to the MRB

Paul Eastvold
Bureau of Radiation Safety
Illinois Emergency Management Agency

Management Review Board

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF ILLINOIS AGREEMENT STATE PROGRAM

April 4 - 8, 2005

PROPOSED FINAL REPORT

U.S. Nuclear Regulatory Commission

ATTACHMENT 1

1.0 INTRODUCTION

This report presents the results of the review of the Illinois Agreement State program. The review was conducted during the period of April 4-8, 2005, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 9, 2001 to April 8, 2005, were discussed with Illinois management on April 8, 2005.

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

In July 2003, the Illinois Department of Nuclear Safety (the Department) became a division of the Illinois Emergency Management Agency (the Agency). The Director for the Department was appointed the Assistant Director of the Agency and retained the management responsibility over activities that had been conducted by the Department. In March 2005, the Assistant Director became responsible for the five technical bureaus in the Agency: Bureau of Operations; Bureau of Disaster Assistance and Preparedness; Bureau of Nuclear Facility Safety; Bureau of Environmental Safety; and Bureau of Radiation Safety. The Illinois Agreement State program is administered by the Bureau of Radiation Safety (the Bureau), with support by other bureaus in the Agency, which is discussed in further detail later in the report. The Bureau has one field office located in West Chicago, Illinois.

Organization charts for the State of Illinois and the Agency are included as Appendix B. The Illinois Agreement program regulates approximately 742 specific licenses authorizing Agreement materials. The review focused on the 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 Illinois.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on November 29, 2004. A copy of the official letter and questionnaire can be found on NRC's Agency wide Document Access and Management System (ADAMS) using the Accession Number ML043350221. The State provided a response to the questionnaire on March 16, 2005. A copy of the State's questionnaire response can be found in ADAMS using the Accession Number ML051100389.

The review team's general approach for conduct of this review consisted of: (1) examination of Illinois' response to the questionnaire; (2) review of applicable Illinois' statutes and regulations; (3) analysis of quantitative information from the Bureau's licensing and inspection database; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of three Illinois inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Illinois Agreement State program's performance.

Section 2 discusses the State's actions in response to the previous IMPEP review recommendation and the team's conclusions regarding the closure of the recommendation. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendation. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN THE PREVIOUS REVIEW

During the previous IMPEP review which concluded on March 9, 2001, one recommendation was made and the results transmitted to Mr. Thomas W. Ortciger, Director, Illinois Department of Nuclear Safety on June 6, 2001. The review team's evaluation of the current status of the recommendation is as follows:

1. The review team recommends that the State adopt the regulations, or other legally binding requirements, which are overdue for adoption. (Section 4.1.2 of the 2001 report)

Current Status: The review team evaluated the status of the actions that the State has taken to address this recommendation since the 2001 IMPEP review. The team acknowledges that the State has drafted rules to meet the requirements of a number of the overdue amendments and submitted them to the Bureau's legal staff for review. At the time of the on-site portion of the IMPEP review, these draft rules had not yet been adopted as final rules by the State or sent to the NRC for review as required by STP procedure SA-201, *Review of State Regulatory Requirements.* The status of the regulations is discussed in further detail in Section 4.1 of this report. This recommendation remains open.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State 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

Issues central to the evaluation of this indicator include the Bureau's 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 Bureau management and staff, and considered any possible workload backlogs.

The Agency has assigned approximately 23 full time equivalent (FTE) total, including management and contractor support, to implement the Agreement State program and has adequate funds to support the program. This Section of the report will discuss the staffing and training for support of the materials program. Staffing and training for the Sealed Source and Device Evaluation Program are discussed in Section 4.2. Staffing and training for the Uranium Recovery Program are discussed in Section 4.4.

The Bureau has three Sections: the Radioactive Materials Section (the RAM Section), the Registration and Certification Section, and the Electronic Products Section. The RAM Section has two Units: the Materials Licensing Unit and the Inspection and Enforcement Unit. These two units are responsible for the routine licensing and inspection of 742 specific materials licensees with 12.7 budgeted FTE. The State's General License (GL) program is managed in the Registration and Certification Section with approximately 1 FTE. As a result of the reorganization in July 2003, the Low-Level Radioactive Waste and Site Decommissioning Section (the Decommissioning Section) was transferred to the Bureau of Environmental Safety within the Agency. However, the Decommissioning Section continues to provide technical support to the Bureau by managing the uranium recovery, financial assurance, and orphan source programs. They also provide decommissioning and license termination support. The Decommissioning Section has 3.6 FTE budgeted for this support. An internal policy memorandum describes the coordination of assignment and responsibility between the two bureaus.

The Bureau has an experienced staff and low staff turnover. The Bureau lost three staff members since the last IMPEP: one retired; one requested reassignment; and the Senior Project Manager for regulatory affairs was reassigned to the Bureau of Nuclear Facility Safety during the 2003 reorganization. The Radioactive Materials Section Head assumed the regulatory affairs responsibilities, but was deployed for military duty on October 1, 2004. The remaining two positions were filled expediently with staff from within the Agency.

The qualifications of the staff were determined from the questionnaire, training records, and interviews of personnel. The staff are well qualified through both education and experience. All staff have at least a Bachelor's degree in the sciences, or equivalent training and experience.

The Bureau has a documented training and qualification program for technical staff that is modeled after NRC's Manual Chapter (MC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Area." The Bureau uses a combination of self-study, formal training, and on-the-job experience to qualify both inspectors and license reviewers.

The Illinois Radiation Protection Advisory Council was created by the General Assembly in 1959. It is composed of seven members appointed by the Governor and two ex officio members. The members reflect a variety of backgrounds in the use of radiation sources. A Conflict of Interest Questionnaire form is filed and maintained on each member of the Council.

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

3.2 Status of Materials Inspection Program

The team focused on five factors in reviewing this indicator: inspection frequency and overdue inspections of Priority I, II, and III licensees; initial inspection of new licenses; timely dispatch of inspection findings to licensees; and the performance of reciprocity inspections. The review team's evaluation is based on the Bureau's response to the questionnaire relative to this indicator, data gathered independently from the Bureau's licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with managers and staff.

The review team's evaluation of the Bureau's inspection priorities verified that inspection frequencies for various types or groups of licenses are as frequent, or more frequent, than similar license types listed in the NRC Inspection Manual Chapter (MC) 2800. As examples, the Bureau requires more frequent inspection in the following license categories: Type A broad scope academic licenses are inspected on a one-year frequency compared with the NRC three-year frequency; nuclear laundry licenses on a two-year frequency compared with the NRC three year frequency; nuclear pharmacy licenses on a one-year frequency compared with the NRC two-year frequency; Type A broad scope research and development licenses on a one-year frequency compared with the NRC three-year frequency; and Type B and C broad scope academic licenses on a two-year frequency compared with the NRC five-year frequency.

The Bureau tracks all inspection activities in a database. The Bureau provided a list of all inspections conducted during the review period, including inspections of non-Agreement material and telephone contacts. The Bureau conducts approximately 400 inspections per year. The Bureau's database did not have the capabilities to provide status information for all inspections conducted during the review period. The review team obtained the information manually through examination of the review files.

In response to the questionnaire, the Bureau indicated that there were no inspections currently overdue by more than 25 percent of the NRC frequency. This information was verified during the examination of 104 inspection files during a time frame, May through June 2004, and the review of the monthly inspection reports provided to the team. None of the inspections were conducted overdue. Of the 104 inspection files reviewed, 25 were initial inspections. Initial inspections were scheduled and conducted within one-year of license issuance.

The timeliness of the issuance of inspection findings was evaluated by the team's review of inspection casework. In the majority of the cases, the response letters and inspection reports to the licensee regarding the inspection results were sent within 30 days of the inspection date.

Also as a result of the problems experienced in manipulating the data tracking system, the team was not able to apply the reciprocity inspection frequency criteria prescribed in NRC MC 1220, Appendix III. The team was unable to determine the amount of reciprocity licensees inspected each year based on the number of candidates for inspection. The Bureau's inspection data tracking system provided that 40 licensees had submitted requests for reciprocity during the review period. The review team verified that out of the 40 licensees, the Bureau inspected 26, which provides that 65 percent of the licensees were inspected over the review period. Although the team was unable to determine that at least 20 percent of the reciprocity candidates were inspected each year, the overall percentage of licensees inspected over the review period was determined to be an acceptable alternative.

The review team's difficult experience with the Bureau's data tracking system was discussed with managers and staff. The Bureau provided that the issues would be discussed with information technology staff and that steps would be taken to decrease the level of difficulty associated with manipulating and retrieving data from the tracking system. Notwithstanding the difficulty, the review team did not identify any licensees that were inspected overdue. The Bureau inspects their licensees at least as frequent, and often more frequently than NRC. The Bureau communicates inspection results to the licensees in a timely fashion, and inspects an acceptable number of reciprocity licensees.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed staff members for 20 radioactive materials inspections conducted during the review period. The casework included work performed by all of the Bureau's material inspectors, and covered a variety of license types including: academic; medical; nuclear pharmacy; industrial radiography; pool irradiator; service provider; manufacturing and distribution; well logging; and research and development. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments, as well as the results of the inspection accompaniments.

Based on the casework reviewed, the review team noted that the inspections covered all aspects of the licensees' radiation programs. The review team determined that inspection reports were generally very 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 the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed for larger and complex licensees and for training purposes.

The previous IMPEP evaluation in 2001 identified that the majority of violations cited by Bureau staff were record keeping infractions and that many inspections were not conducted in a performance-based, risk-informed manner. Inspections evaluated during this review identified that a performance-based, risk-informed approach is now utilized by the program.

The Inspection Unit Supervisor, who signs compliance letters to licensees, reviewed completed inspection reports. Field Compliance Reports are sometimes issued in the field by inspectors when no violations are identified during an inspection. Supervisory accompaniments were conducted annually for all inspectors.

The team identified that inspection findings were appropriate, and prompt regulatory actions were taken, as necessary. All inspection findings were clearly stated and documented in the reports, and reviewed by the inspection supervisor. The Bureau has the ability to require management meetings and impose civil penalties when it is deemed that the licensee has had a significant breakdown in operations affecting health and safety. The enforcement program and administrative proceedings are detailed in the State's regulations found in Title 32 of the Illinois Administrative Code, Parts 310 and 200, respectively. Escalated enforcement actions are issued by the Assistant Director of the Agency.

The Bureau has adequate numbers and types of radiation survey instruments to support their radiation control program efforts. These instruments are calibrated by Agency laboratory personnel at their Regional Calibration Laboratory located in Springfield, which is managed by the Bureau of Nuclear Facility Safety. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, micro-R-meters, and neutron meters were observed. Portable multi-channel analyzers are used in response to incidents and recycling facility alarms. Air monitoring equipment is also available.

The Radiochemistry Laboratory, in Springfield, which is managed by the Bureau of Environmental Safety, evaluates water samples, soil samples and wipe tests. The Bureau has a satellite radiochemistry laboratory in West Chicago, near the Kerr-McGee decommissioning site.

Three Bureau inspectors were accompanied during inspections by a review team member in February and March 2005. Inspection accompaniments included: a pool irradiator; a well logger; and a reciprocity transportation inspection, as identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were trained, prepared, and thorough in their audits of the licensees' radiation safety programs. Each inspector also utilized good health physics practices during the inspections. Interviews with licensee personnel were performed in an effective manner, and the inspections were adequate to assess radiological health and safety at the licensed facilities.

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

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 27 licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate 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 files were also evaluated for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions, which were completed during the review period by eight different license reviewers. The cross-section sampling focused on the new licenses, amendments, renewals, and license terminations issued during the review period. The sampling included the following types of licenses: academic (including broad scope); pool irradiator; well logging; industrial radiography; research and development (including broad scope); source manufacturing and distribution; nuclear pharmacy; veterinary medicine; mobile nuclear medicine; medical private practice; and medical institution (including therapy and broad scope). Licensing actions evaluated included 3 new licenses, 8 renewals, 13 amendments, 1 financial assurance update, and 2 termination files. A listing of the casework licenses evaluated with case specific comments may be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. Reviewers appropriately utilize the State's licensing guides, license

templates, standard conditions, and application review checklists to ensure consistency on licensing actions. The exemptions noted in the questionnaire response were determined to be appropriate, implemented uniformly, and well documented by license conditions.

Licensing actions are all tracked via “blue sheets.” The blue sheets are generated by the clerical staff upon receipt, the information entered into the database, and then the action is assigned to a license reviewer. The blue sheets follow the status of the licensing action throughout the process. Good communication was recognized between licensing and inspection staff via “green sheets” placed in license files. These sheets are utilized for license reviewers and inspectors to communicate any issues or problems identified during the review process or inspection. Additionally, for some complex licensing actions, license reviewers performed a pre-licensing inspection of the facility prior to issuance of the license. This inspection provided the reviewer with a more in-depth understanding of the licensee’s program, which aided in an effective licensing action.

The review team found that the staff follows appropriate licensing guides, similar to NRC’s NUREG 1556 series, during the review process to ensure that licensees submit information necessary to support their request. The review team found the checklists used for each type of program to be comprehensive and incorporated excellent notes to assist the staff with their review of the applications. Letters and documented telephone and electronic conversations contained appropriate regulatory language and addressed deficiencies. The use of license templates by the staff, incorporating standard conditions, also resulted in notable consistency between reviewers. Overall, the review team found that the licensing actions were thorough, complete, consistent, of high quality, and properly addressed health and safety issues.

The review team found that terminated licensing actions were well documented. The files included the appropriate material transfer reports and survey records. An evaluation of the selected termination records indicated excellent communication between the licensing, inspection, and decommissioning staff to prevent abandonment of radioactive material. The files showed that documentation of proper disposal or transfer was provided.

When a licensing action is completed by a reviewer, the entire package is given to the Materials Licensing Unit Supervisor who approves and signs the licensing action. Licenses are issued for a five-year term. The Bureau has instituted an expedited renewal process, where a licensee submits an application and identifies any parts of his radiation safety program that have changed, and confirms that all other portions are still current. Licenses that are under timely filed status are amended as necessary to assure that public health and safety issues are addressed during the period that the license is undergoing the renewal process.

The Bureau requires certain licensees to maintain financial assurance for decommissioning. Surety instruments are maintained in a locked cabinet in the Decommissioning Section Head’s office. The Decommissioning Section determines the financial assurance requirements for the licensing staff. The review team noted good communication between the Materials Licensing Unit and the Decommissioning Section, and evaluated the contents of several financial assurance folders, which were found to be in good order.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois’ performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Illinois in the Nuclear Material Events Database (NMED) against those contained in the Illinois files, and evaluated the casework and supporting documentation for ten material incidents. A list of the incident casework examined is included in Appendix E. The team also reviewed the Bureau's response to 30 allegations involving radioactive materials including 12 allegations referred to the State by NRC during the review period.

The review team discussed the Bureau's incident procedure, file documentation, the State's equivalent to the Freedom of Information Act, Nuclear Materials Event Database, and notification of incidents to the NRC Operations Center with the Program Manager and selected staff.

The Bureau maintains a telecommunications center that is operational 24 hours a day, 7 days a week. The on-duty staff maintains contact with the Radiological Duty Officer who will assess the reported hazard, provide advice and verbal assistance, and, if appropriate, dispatch a response team to the scene. The Bureau uses the NMED data entry software program and provides updates to the NMED national database in a timely manner per the Office of State and Tribal Programs Procedure, SA-300: *Reporting Material Events*. The Bureau has worked directly with the NMED contractor to identify and suggest fixes to bugs found in the software.

The Bureau responded to 147 radioactive material incidents as reported to NMED during the review period, and of those, 97 were NRC required reportable incidents. During the last four years there were no incidents involving occupational or public exposures that exceeded the regulatory dose limits. A sample of 10 incidents was selected for review. The incidents included: loss of radioactive material, damaged gauges, leaking sources, medical events, and an abnormal occurrence. The review team found that the Bureau's response to incidents was complete and comprehensive. Initial responses were prompt and well coordinated. Staff communicated well with each other and provided back up when needed. Inspectors were dispatched for on-site investigations, when appropriate, and the State took suitable enforcement action including coordination with the license reviewers and follow up, as appropriate. Staff use the NMED local data entry program and database to store and upload incident data to the NMED national database. The Bureau provides complete and timely incident reports to NMED.

The Bureau has instituted an orphan source program that is funded through a "Recovery and Remediation Fee" assessed over the first two-year period to all new licensees. These fees go into a special fund to be used for the recovery and remediation of radioactive materials. When sources are abandoned, the Bureau stores these sources in a secure storage facility and tracks the status of these sources in a database. Periodically, the Bureau sends their staff to collect these sources and package them for disposal. The Bureau then contracts with a broker to pickup and arrange for disposal of the orphan material using the special funds. This fund would be used when the costs cannot be recovered from a responsible party or available financial assurance. The review team recommends the Bureau's orphan source program as a good practice.

The team reviewed the Bureau's response to 30 allegations received during the review period involving radioactive materials including 12 allegations referred to the Bureau by NRC. The evaluation of the 30 allegation cases indicated that the Bureau took prompt and appropriate action in response to the allegers' concerns. Through review of the casework and interviews with staff, the review team determined that the Bureau provided feedback to allegers either verbally or in writing when possible. Any alleger requesting anonymity is informed that every effort will be made to protect his/her identity, but it cannot be guaranteed. All interviewed staff was knowledgeable of the Bureau's allegation procedure. There were no performance issues identified from the review of allegation files and documentation.

Based on the IMPEP evaluation criteria the review team recommends that Illinois' performance with respect to the indicator, Technical Quality of Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in evaluating Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program.

4.1 Compatibility Requirements

Legislation

The State provided, in their response to the questionnaire, a listing of legislation that affects the radiation control program. The Agency is designated as the State radiation protection agency under the provisions of the Radiation Protection Act of 1990, as amended [420 Illinois Compiled Statutes (ILCS) 40]. The Bureau implements the program for the Agency. The Act grants the Agency the authority to promulgate rules and regulations to be followed in the administration of the radiation protection program. The Illinois Emergency Agency Act [20 ILCS 3305] and the Nuclear Safety Law of 2004 [20 ILCS 3310] resulted in the subsuming of the Illinois Department of Nuclear Safety into the Illinois Emergency Management Agency in July 2003. The current legislation that affects the radiation control program is as follows:

The Radioactive Waste Storage Act [420 ILCS 35], the Illinois Low-Level Radioactive Waste management Act [420 ILCS 20] and the Uranium and Thorium Mill Tailings Control Act [420 ILCS 42] statutes provide authority for the low-level radioactive waste disposal and uranium recovery programs.

Other statutes which affect the radiation control program include: Central Midwest Radioactive Waste Compact Act [45 ILCS 140]; Department of Nuclear Safety [20 ILCS 2005]; Freedom of Information Act [5 ILCS 140]; Freedom of Information Act [5 ILCS 140/1 - 140/11]; and Illinois Administrative Procedure Act [5 ILCS 100].

Public Act 91-752, which was effective June 2, 2000, extended the sunset date for the Radiation Protection Act until January 1, 2011. The other aforementioned statutes do not have sunset provisions.

Program Elements Required for Compatibility

The State regulations for control of radiation are located in Title 32 of the Illinois Administrative Code and apply to all ionizing radiation, whether emitted from radionuclides or devices. Illinois requires a license for possession and use of radioactive materials, including naturally occurring and accelerator-produced radionuclides.

The review team examined the State's rulemaking process and found that the process takes approximately six months after preparation of a draft rule. An additional review of regulations by the Governor's office has been implemented since the last IMPEP review. The Bureau staff does not believe this will affect the normal time for rule promulgation. Proposed rules are published in the Illinois Register with a minimum 45-day comment period, and may include a public hearing. At this point, the proposed rules are sent to NRC for review. After resolution of comments, the Bureau provides the comments and responses to the Joint Committee on Administrative Rules (JCAR), a bipartisan committee consisting of legislators from the Illinois House of Representatives and Senate. After resolution of JCAR comments, the rule must be re-published for comment if substantial changes were made or scheduled for a vote at the next available monthly JCAR meeting. Approved rules are published as final in the Illinois Register. Final rules are sent to the NRC for a final review and compatibility determination and updated on the Bureau's website. The Bureau has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

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 regulation status with data obtained from the Office of State and Tribal Programs' Regulation Action Tracking System (RATS). Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective.

The Bureau has had continuing challenges in this area of their program, as identified during the 1997 and 2001 IMPEP reviews. In 1997, the review team recommended that the Bureau's performance be found unsatisfactory for this indicator. However, based on information provided during the MRB meeting, the MRB determined that the State's performance was satisfactory. During the 2001 IMPEP, the review team found the Bureau was continuing to face challenges. The review team recommended that the State adopt regulations, or other legally binding requirements, which were overdue for adoption. The MRB affirmed the finding of satisfactory with recommendations for improvement (now "satisfactory, but needs improvement") for this indicator. The status of this recommendation was discussed during the 2002 and 2004 periodic meetings and continued to be unresolved.

Bureau staff explained to the current review team that there has been a "philosophical shift" in the last two years and the Bureau intends to comply with the requirement that Agreement State regulations be adopted and compatible with NRC regulations. The Bureau also faced staffing challenges in this area during the last two years. As discussed in Section 3.1 of this report, the Bureau lost the senior project manager for regulatory affairs to the Bureau of Nuclear Safety during the 2003 reorganization. The Radioactive Materials Section Head assumed these responsibilities, but was deployed for military duty on October 1, 2004. In the meantime, the Materials Licensing Unit Supervisor is acting for the Section Head.

Based on information contained in the State Regulation Status Sheet (SRS), the State has ten rule amendments overdue. Seven of the overdue rule amendments are in draft form at various stages in the Bureau's legal review process. The State agreed to send the NRC the draft version of these seven rules for review. The remaining three overdue amendments will be superceded when the State adopts the amendment "Medical Use of Byproduct Material" (RAT ID 2002-2 due for adoption October 24, 2005). This amendment is currently in draft form within the Bureau. In addition to the ten currently overdue amendments, during the review period, the State adopted 14 amendments late, (i.e. past the three-year window for Agreement State adoption). All the rules mentioned above are summarized below with their current status.

The following seven rule amendments are overdue for adoption but they are currently in draft form and undergoing legal review within the Bureau. They have not been sent into the NRC for review as required by SA-201. The State has agreed to send these draft rules to the NRC for review.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724) was due for adoption on October 20, 1998 [RATS ID 1996-1].

- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials: Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) was due for adoption on January 9, 2000 [RATS ID 1997-1].

- "Transfer for Disposal and Manifests; Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127) was due for adoption on November 20, 2001 [RATS ID 1998-6].

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) was due on February 2, 2003 for adoption [RATS ID 1999-3].

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) was due on January 8, 2004 for adoption [RATS ID 2000-2].

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30,31,32 amendments (65 FR 63749) were due for adoption on February 16, 2005 [RATS ID 2001-1].

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 1629) was due for adoption on April 5, 2005 [RATS ID 2002-1].

The following three amendments are overdue for adoption. The team notes that they will be superceded when the State adopts the amendment "Medical Use of Byproduct Material," 10 CFR Parts 20,32, and 35 amendments (67 FR 20249) that will become due for adoption on October 24, 2005 [RATS ID 2002-2]. The State has drafted rules to meet the requirements of 2002-2. The State has agreed to send in the draft rules for NRC review.

- Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) was due for adoption and on January 27, 1995 [RATS ID 1992-1].

- “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” 10 CFR Parts 30, 32, 35 (59 FR 61767; 59 FR 65243; 60 FR 322) was due for adoption and on January 1, 1998 [RATS ID 1995-1].

- “Frequency of Medical Examinations for Use of Respiratory Protection Equipment,” 10 CFR part 20 amendment (60 FR 7900) was due for adoption on March 13, 1998 [RATS ID 1995-2].

For the following 14 amendments, the State has final regulations or other legally binding requirements in place. These amendments have not been submitted to NRC for a final compatibility determination. The State adopted all of these amendments late (i.e. past the three-year window for State adoption). The State has agreed to send in the final, as adopted, rule for NRC review.

- “Safety Requirements for Radiographic Equipment,” 10 CFR Part 34 amendment (55 FR 843) was due for adoption on January 10, 1994 [RATS ID 1991-1].

- “Radiation Protection Requirements: Amended Definitions and Criteria,” 10 CFR Parts 19, 20 amendments (60 FR 36038) was due for adoption on August 14, 1998 [RATS ID 1995-5].

- “Clarification of Decommissioning Funding Requirements,” 10 CFR Parts 30, 40, seven amendments (60 FR 38235) were due for adoption and on November 24, 1998 [RATS ID 1995-6].

Status: The rule will be superceded when the State adopts the amendment ”Financial Assurance for Materials Licensees,” 10 CFR Parts 30, 40, 70 amendments (69 FR 3697) [RATS ID 2003-1] which will become due for adoption and a final compatibility review on December 3, 2006. The State has drafted rules to meet the requirements of RATS ID 2003-1.

- ”Medical Administration of Radiation and Radioactive Materials ,” 10 CFR Parts 20, 35 amendments (60 FR 48623) were due for adoption and on October 20, 1998 [RATS ID 1995-7]

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) was due for adoption on February 12, 2001 [RATS ID 1998-1].

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 39477 and 63 FR 45393) was due for adoption on October 26, 2001 [RATS ID 1998-5].

- “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendment (56 FR 64980) was due for adoption on October 15, 1994 [RATS ID 1991-4].

Status: The proposed rule was reviewed by NRC in January 2004 and multiple comments on compatibility were generated. Final rule promulgated.

- “Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20, 61 amendments (60 FR 15649, 60 FR 25983) was due for adoption on March 1, 1998 [RATS ID 1995-3].

Status: NRC reviewed the proposed rule in November 1999 and comments on compatibility were generated. Final rule promulgated.

- “Performance Requirements for Radiography Equipment,” 10 CFR Part 34 amendment (60 FR 28323) was due for adoption on June 30, 1998 [RATS ID 1995-4].

Status: NRC reviewed the proposed rule in January 2004 and no comments on compatibility were generated. Final rule promulgated.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) were due for adoption on August 20, 2000 [RATS ID 1997-6].

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) was due on May 17, 2003 for adoption [RATS ID 2000-1].

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendment (63 FR 37059) was due for adoption on July 9, 2001 [RATS ID 1997-5].

Status: NRC reviewed the proposed rule in January 2004 and multiple comments on compatibility were generated. Final rule promulgated.

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) was due for adoption on July 1, 1996 [RATS ID 1993-2].

Status: The Bureau has implemented the rule through generic license condition. A final rule has been promulgated.

- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) were due for adoption on May 29, 2000 [RATS ID 1997-3]

Status: The Bureau has implemented the rule through generic license condition. The amendment will be addressed when the regulations identified in RATS ID 2002-2 are approved.

The following two amendments are overdue for adoption. However, the State does not have any current facilities subject to this provision and until they receive a license application subject to these provisions, they do not need to adopt RATS ID 1994-2. In addition, the State has identified that the current uranium recovery facility is grandfathered under the last sentence of 10 CFR 40, Appendix A, Criterion 6 (6) and, therefore, does not need to adopt RATS ID 1999-1. Therefore neither of these amendments are being counted as overdue with respect to this indicator. The States SRS will be updated to reflect these conditions.

- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendment (59 FR 28220) was due for adoption and on July 1, 1997 [RATS ID 1994-2].

- "Radiological Criteria for License Termination of Uranium Recovery Facilities," 10 CFR Part 40 amendment (64 FR 17506) was due on June 11, 2002 for adoption and final compatibility determination [RATS ID 1999-1].

The following amendment will become due during the next IMPEP review cycle and is included here to assist the Bureau in including them in future rulemakings or by adopting alternate generic legally binding requirements:

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) is due for adoption and a final compatibility review on October 1, 2007 [RATS ID 2004-1].

  The team recommends that the 2001 IMPEP recommendation discussed above remain open and that the State adopt the regulations, or other legally binding requirements, which are overdue for adoption and send them to the NRC for review. In addition, the review team recommends that a periodic meeting be scheduled in one year to review the Bureau's progress in adopting regulations. The result of the periodic meeting should be presented at a subsequent MRB meeting.

  Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

In assessing the Illinois SS&D Evaluation Program, the review team examined the information provided in response to the IMPEP questionnaire. The team evaluated SS&D registry sheets issued during the review period and the supporting document files. The team also evaluated SS&D staff training records, certain reported incidents involving products authorized in Illinois SS&D sheets, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations. Three sub-indicators were used to evaluate the Bureau's performance regarding their SS&D Evaluation Program. These sub-indicators were (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

4.2.1 Technical Staffing and Training

Presently, the SS&D Evaluation Program is under the Materials Licensing Unit, and three staff members conduct the reviews. The Bureau has budgeted .3 FTE for this program. One previously qualified and experienced SS&D reviewer is currently on military duty. Additionally, the staff can obtain engineering and technical assistance from engineering staff in the Decommissioning Section. The review team evaluated the qualifications of the individuals authorized and currently performing SS&D evaluations. All reviewers were qualified through previous training and experience, as was documented in a staff memorandum dated October 30, 2004. All have regulatory experience, have attended the NRC SS&D Workshop, and have been performing reviews for greater than ten years. The review team noted that

SS&D reviewers have degrees in engineering, environmental science, or equivalent training and experience.

The SS&D Evaluation Program has had a constant staffing level during the review period, attributing approximately ten percent of the staff time to SS&D reviews. When compared with the previous review period, there have been fewer SS&D actions, mainly attributable to the relocation of two large manufacturers out of Illinois. This staffing is deemed adequate.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated 8 of the 62 SS&D evaluation actions completed during the review period. The 62 actions consisted of 26 amendments, 32 inactivations, and 4 new registrations, that represented the work of all SS&D reviewers. The cases selected were representative of the Bureau's licensees and SS&D reviewers. A list of SS&D casework examined along with case-specific comments may be found in Appendix F.

The team's review of the casework and interviews with the staff confirmed that the SS&D reviewers used NUREG-1556, Volume 3, and the American National Standards Institute (ANSI)/Health Physics Society (HPS) standards. All pertinent ANSI/HPS standards, regulatory guides, and applicable references were confirmed to be available and were used when performing SS&D reviews. The appropriate review checklist was used to assure relevant materials had been submitted and reviewed. The checklists were retained in all of the registration files examined. In reviewing emergent technology related products and new applications, the SS&D reviewers performed evaluations based on sound health physics principles and used conservative assumptions to ensure the protection of public health and safety. Registration certificates clearly summarized the product evaluation and provided license reviewers with adequate information on areas requiring additional attention to license the possession, use, and distribution of the products. Overall, the review team found the evaluations were of high quality with health and safety issues properly addressed.

The registration files contained all correspondence, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The files were well organized in a consistent manner. Deficiency letters clearly stated regulatory positions and health and safety issues were properly addressed. The review team determined that product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

4.2.3 Evaluation of Defects and Incidents Regarding SS&D

The Bureau responded to one incident/product failure or defect concerning devices registered by the Bureau. This incident is included in Appendix E. At the time of this review, the investigation was still being conducted. The SS&D staff, in conjunction with inspection staff, conducted a thorough review of the event history, as well as a comparison with similar reported events, to establish the root cause. Currently, the staff is conducting an audit of the licensee's QA/QC program. The outcome of the investigation will determine if there is a generic design or performance issue with this product. The Bureau provided a timely and adequate response in the investigation and resolution of the events. No allegations related to SS&Ds were reported during the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. The State's LLRW program is currently inactive, and it is anticipated that there will be no further activity with the program for several years. Therefore, the staff are working on other projects. Accordingly, the review team did not review this indicator.

4.4 Uranium Recovery Program

In conducting this review, five sub-indicators were used to evaluate the Bureau's performance regarding the uranium recovery program. These sub-indicators include: (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) Response to Incidents and Allegations. The results of the uranium recovery program review will be discussed under each of these sub-indicators. In 1990, the Illinois Agreement was amended to include the authority for 11e. (2) byproduct material and the facilities that generate such material.

The Decommissioning Section administers the Bureau's uranium recovery program. The Bureau has only one licensee in the program, the Kerr-McGee Chemical Corporation (Kerr-McGee), Rare Earths Facility, located in West Chicago, Illinois. This facility is in the process of decommissioning. During the review period, the operations at the site included excavation of contaminated material, transport and handling of contaminated materials, water treatment and groundwater monitoring.

4.4.1 Technical Staffing and Training

The technical staff consists of two engineers (mechanical and mining), one health physicist, and a geologist with a support contractor supplying additional expertise in these and other technical areas. The Bureau has 4 FTE budgeted for contractor support in addition to the Decommissioning Section FTE discussed in Section 3.1 of this report. The health physicist is the onsite resident inspector located in West Chicago and has been in the position since 1996. Other staff in the Bureau of Environmental Safety provides additional technical support. The Bureau has outlined the training requirements for staff in the Employee Training Requirements. The requirements consist of technical training, personal instruction, in-house training, outside training and on-the-job training. The review team examined the training, education, and experience of the staff members and found that the qualifications of the technical staff are commensurate with the expertise needed to regulate the radioactive material at the Kerr-McGee site.

The Bureau has contracted with consultants for support of quality assurance at the Kerr-McGee site and technical review of licensing actions. The review team reviewed the qualifications of the consultants. Both the prime and sub-contractors are well qualified. The consultants have employed staff that are well trained in a variety of technical fields. The prime

contractor appropriately utilizes sub-contractors for actions with technical issues outside of their specialization. The Decommissioning Section Head has oversight responsibility for the work performed by the contractor staff.

The review team determined that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate the uranium recovery facilities. Bureau management has developed and implemented a satisfactory training program for staff that is consistent with the review requirements.

4.2.2 Status of Uranium Recovery Inspection Program

The Bureau has an annual inspection frequency for the Kerr-McGee site. The frequency is consistent with the criteria in NRC's MC 2801 and has been applied since the licensee began decommissioning operations in 1994. The Bureau's resident inspector conducts daily, weekly and monthly operation checks, and observes site operations daily. In addition, an engineering company under contract with the Bureau supports the resident inspector and performs environmental surveys. The contractor reports its findings to the resident inspector or directly to the Decommissioning Section Head.

The Springfield office staff conducted four annual compliance inspections since the last review. One inspection was outside the 30-day reporting period (31 days) due to the unique nature and extent of decommissioning activities on the project and the depth of the reporting documentation. The review team determined that the inspections were performed at intervals that are consistent with NRC's guidance.

The Bureau reviews the annual environmental monitoring report submitted by the licensee and determines compliance for the environmental program. These reviews are conducted by a consultant and are conducted on a separate schedule from the annual compliance inspections. The Environmental Monitoring and Transportation Section Head has oversight responsibility for these reviews.

4.2.3 Technical Quality of Inspections

The review team examined inspection reports and files, and reviewed documentation for the Kerr-McGee site, including the last four annual inspection reports. The last two environmental monitoring data reviews and quality assurance audits were also reviewed. The review team determined that the reports for the inspections and audits were thorough, complete, consistent, and of high quality, with adequate documentation to determine compliance with regulations, license conditions, and available guidance. Findings noted in earlier inspections were investigated and the proposed resolutions verified at the next inspection.

The onsite resident inspector regularly inspects site operations and reviews data and sampling information required under license condition. Regular meetings are held between the resident inspector, contractors and Springfield staff. These meetings are documented in meeting minutes.

During the review period, the Bureau performed two audits of Kerr-McGee's quality assurance program in order to evaluate the licensee's checks on activities. The Bureau's contractor performed the audit under the supervision of the Bureau staff. Findings were identified as a result of the audits and recorded in an Audit Finding Notice.

4.2.4 Technical Quality of Licensing Actions

The review team evaluated 10 amendments for the Kerr-McGee license issued since the last review. In examining the amendments and selected documentation in the file, the review team found that the many of the license amendments were to change the volume of material leaving the site for disposal and to authorize the receipt of radioactive material brought on to the site from the adjacent areas and residential clean-up activities. Other actions included revision of the air-monitoring program and an application for alternate concentration limits for groundwater. A significant license amendment incorporated new groundwater protection requirements, specifying groundwater constituents and monitoring frequency. The Bureau and its contractors have performed extensive review on the groundwater monitoring plan and application for alternate concentration limits, which were approved in 2001. The listed groundwater constituents are identified in 10 CFR Part 40. The review team determined that the Bureau used the appropriate regulations and guidance documents for this review.

Based on a review of the licensing file, the team concluded that licensing actions were appropriate and that the license conditions were clear and well written. Requirements associated with these conditions were based on a need to meet the regulation and to protect health and safety. The review team informed Bureau staff of updated NRC guidance to be used in the future, NUREG-1620, “Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act of 1978.”

4.2.5 Response to Incidents and Allegations

There were no incidents or allegation pertaining to the Kerr-McGee activities during this review period.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois’ performance with respect to the indicator, Uranium Recovery Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team recommends that Illinois’ performance be found satisfactory for seven performance indicators reviewed, but unsatisfactory for the Compatibility Requirements indicator. Accordingly, the review team recommends that the Illinois Agreement State program be found adequate to protect public health and safety, but not compatible with NRC's program. The next full review should take place in approximately four years.

Below is the recommendation, as mentioned in an earlier section of the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATION

1. The review team recommends that the State adopt the regulations, or other legally binding requirements, which are overdue for adoption and send them to the NRC for review. (Section 4.1)

GOOD PRACTICE:

The review team identified a good practice, in noting that the Bureau has instituted an orphan source program that is funded through a “Recovery and Remediation Fee” assessed over the first two-year period to all new licensees. These fees go into a special fund to be used for the recovery and remediation of radioactive materials. When sources are abandoned, the Bureau stores these sources in a secure storage facility and tracks the status of these sources in a database. Periodically, the Bureau sends their staff to collect these sources and package them for disposal. The Bureau then contracts with a broker to pickup and arrange for disposal of the orphan material using the special funds. This fund would be used when the costs cannot be recovered from a responsible party or available financial assurance.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Vivian Campbell, Region IV Technical Staffing and Training	Team Leader
James Lynch, Region III	Technical Quality of Inspections Program Inspector Accompaniments
Terry Brock, STP Compatibility Requirements	Technical Quality of Incident and Allegation Activities
Shawn Smith, STP	Status of Materials Inspection Program
Jill Caverly, NMSS	Uranium Recovery Program
Eric Jameson, Georgia	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program

APPENDIX B

ILLINOIS ORGANIZATION CHARTS

ML051230486

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: JANX — License No.: IL-02168-01
Inspection Type: Initial, Unannounced — Priority: 1
Inspection Date: 3/11/03 — Inspector: GM

File No.: 2
Licensee: Bard Brachytherapy, Inc. — License No.: IL-02062-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 6/29/04 — Inspector: WH

File No.: 3
Licensee: Medi-Physics, Inc. — License No.: IL-01052-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 2/8/05 — Inspector: AG

Comment:
No mention of second pharmacy location authorized on license.

File No.: 4
Licensee: NuClin Diagnostics, Inc. — License No.: IL-01551-01
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 5/18/04 — Inspectors: JK, RM, DP

File No.: 5
Licensee: Methodist Medical Center of Illinois — License No.: IL-01204-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Dates: 8/3-4/04 — Inspector: GM

Comment:
Inspection letter issued late (42 days).

File No.: 6
Licensee: Schlumberger Well Services — License No.: 77-00347-01
Inspection Type: Reciprocity, Unannounced — Priority: 2
Inspection Date: 1/20/05 — Inspector: GM

File No.: 7
Licensee: Cardinal Health, Inc. — License No.: IL-01721-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Dates: 2/2-3/05 — Inspector: WH

File No.: 8
Licensee: Abbott Laboratories — License No.: IL-01478-02
Inspection Type: Initial, Announced — Priority: 1
Inspection Date: 12/3/04 — Inspector: JK

Comment:
Supervisory review of Field Compliance Report not documented in report.

File No.: 9
Licensee: REVISS Services, Inc. — License No.: IL-02058-01
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 12/22/04 — Inspector: JP

File No.: 10
Licensee: Lixi, Inc. — License No.: IL-01339-01
Inspection Type: Initial, Announced — Priority: 1
Inspection Date: 6/30/04 — Inspector: JP

File No.: 11
Licensee: Loretto Hospital — License No.: IL-01378-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 9/23/04 — Inspector: JP

File No.: 12
Licensee: Sterigenics U.S., Inc. — License No.: IL-01220-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 6/15/01 — Inspector: WH

File No.: 13
Licensee: Illinois Institute of Technology — License No.: IL-01739-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 2/18/05 — Inspectors: RM, AG

Comment:
Supervisory review of Field Compliance Report not documented in report.

File No.: 14
Licensee: Team Cooperheat-MQS, Inc. — License No.: IL-01136-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 12/22/04 — Inspector: GM

File No.: 15
Licensee: Steris, Inc. — License No.: IL-01123-01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 3/2/05 — Inspector: WH

File No.: 16
Licensee: Landauer, Inc. License No.: IL-01376-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 8/30/04 Inspector: RM

File No.: 17
Licensee: Northern Illinois University License No.: IL-01773-01
Inspection Type: Routine, Announced Priority: 1
Inspection Dates: 3/24-25/04 Inspector: JP

File No.: 18
Licensee: Baxter Healthcare Corporation License No.: IL-01278-02
Inspection Type: Special, Announced Priority: 3
Inspection Date: 3/8/04 Inspector: KG

Comment:
Decommissioning wipe test results were not in file, but were located by inspector. License file will be updated.

File No.: 19
Licensee: Rush Copley Medical Center License No.: IL-01207-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 11/12/04 Inspector: JK

File No.: 20
Licensee: Illini Hospital License No.: IL-01772-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/25/03 Inspector: JK

Comment:
Supervisory review of Field Compliance Report not documented in report.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: MDS Nordion License No: 77-00129-01
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 2/2/05 Inspector: RM

Accompaniment No.: 2
Licensee: Steris Isomedix Services License No: IL-01123-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 3/2/05 Inspector: WH

Accompaniment No.: 3
Licensee: Warrior Well Services License No: IL-01825-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/9/05 Inspector: GM

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Bard Brachytherapy, Inc. License No.: 86-02062-01
Type of Action: Renewal Amendment No.: pending
Date Issued: Pending License Reviewer: MEB

File No.: 2
Licensee: Bard Brachytherapy, Inc. License No.: 86-02062-01
Type of Action: Amendment Amendment No.: 18
Date Issued: 1/28/05 License Reviewer: MEB

File No.: 3
Licensee: STERIS, Inc. License No.: IL-01123-01
Type of Action: Amendment Amendment No.: 12
Date Issued: 1/24/05 License Reviewer: GWM

File No.: 4
Licensee: STERIS, Inc. License No.: IL-01123-01
Type of Action: Renewal Amendment No.: 11
Date Issued: License Reviewer: SMK

File No.: 5
Licensee: Sterigenics USA, Inc. (formerly Ion Beam Applications) License No.: IL-01220-01
Type of Action: Amendment Amendment No.: 29
Date Issued: 2/23/05 License Reviewer: SMK

File No.: 6
Licensee: Cardinal Health, Inc. License No.: IL-01721-01
Type of Action: Amendment Amendment No.: 36
Date Issued: 3/11/05 License Reviewer: MEB

File No.: 7
Licensee: Cardinal Health, Inc. License No.: IL-01721-01
Type of Action: Renewal Amendment No.: 33
Date Issued: 4/25/03 License Reviewer: MEB

File No.: 8
Licensee: Rush University Medical Center License No.: IL-01766-01
Type of Action: Amendment Amendment No.: 18
Date Issued: 5/24/04 License Reviewer: SMK

File No.: 9
Licensee: Rush University Medical Center — License No.: IL-01766-01
Type of Action: Renewal — Amendment No.: 14
Date Issued: 6/25/02 — License Reviewer: MEB

File No.: 10
Licensee: G. D. Searle LLC — License No.: IL-01469-01
Type of Action: Termination — Amendment No.: 16
Date Issued: 8/2/04 — License Reviewer: GWM

File No.: 11
Licensee: G. D. Searle LLC — License No.: IL-01469-01
Type of Action: Amendment — Amendment No.: 14
Date Issued: 10/8/03 — License Reviewer: GWM

File No.: 12
Licensee: University of Illinois – Champagne-Urbana — License No.: IL-01271-01
Type of Action: Renewal — Amendment No.: 26
Date Issued: 5/7/04 — License Reviewer: SMK

File No.: 13
Licensee: Michael Reese Medical Center Corporation — License No.: IL-01097-02
Type of Action: Termination — Amendment No.: 12
Date Issued: 9/30/02 — License Reviewer: SMK

File No.: 14
Licensee: Advanced Radiation Oncology Center — License No.: IL-02178-01
Type of Action: Amendment — Amendment No.: 4
Date Issued: 6/25/04 — License Reviewer: SMK

File No.: 15
Licensee: Advanced Radiation Oncology Center — License No.: IL-02178-01
Type of Action: New — Amendment No.: 00
Date Issued: 2/25/03 — License Reviewer: MEB

File No.: 16
Licensee: Methodist Medical Center of Illinois — License No.: IL-01204-01
Type of Action: Amendment — Amendment No.: 53
Date Issued: 11/30/04 — License Reviewer: TLH

File No.: 17
Licensee: Methodist Medical Center of Illinois — License No.: IL-01204-01
Type of Action: Renewal — Amendment No.: 47
Date Issued: 3/11/03 — License Reviewer: TLH

File No.: 18
Licensee: Resurrection Medical Center — License No.: IL-01034-02
Type of Action: Expedited renewal — Amendment No.: 26
Date Issued: 6/9/04 — License Reviewer: CGV

File No.: 19
Licensee: Resurrection Medical Center — License No.: IL-01034-02
Type of Action: Emendment — Amendment No.: 27
Date Issued: 6/28/04 — License Reviewer: TLH

File No.: 20
Licensee: Michael Reese Medical Center Corporation — License No.: IL-01097-01
Type of Action: Amendment — Amendment No.: 25
Date Issued: 3/18/05 — License Reviewer: JCB

File No.: 21
Licensee: Warrior Well Services — License No.: IL-01825-01
Type of Action: Amendment — Amendment No.: 8
Date Issued: 6/30/04 — License Reviewer: DP

File No.: 22
Licensee: Veterinary Specialty Center — License No.: IL-02071-01
Type of Action: Expedited renewal — Amendment No.: 5
Date Issued: 10/6/04 — License Reviewer: SMK

File No.: 23
Licensee: U.S. Inspection Services — License No.: IL-02188-01
Type of Action: Amendment — Amendment No.: 2
Date Issued: 8/31/04 — License Reviewer: MEB

File No.: 24
Licensee: U.S. Inspection Services — License No.: IL-02188-01
Type of Action: Amendment — Amendment No.: 1
Date Issued: 4/15/04 — License Reviewer: MEB

File No.: 25
Licensee: U.S. Inspection Services — License No.: IL-02188-01
Type of Action: Amendment — Amendment No.: 00
Date Issued: 11/19/03 — License Reviewer: MEB

File No.: 26
Licensee: Diagnostic Health Services — License No.: IL-01397-01
Type of Action: Amendment — Amendment No.: 61
Date Issued: 12/17/04 — License Reviewer: DSP

File No.: 27
Licensee: Alion Science and Technology License No.: IL-02187-01
Type of Action: New Amendment No.: 00
Date Issued: 9/9/03 License Reviewer: MEB

Comment:

License Condition 19 states that closeout records of facilities prior to their release for unrestricted use shall be maintained for two years. The standard condition states a five-year retention period. Staff commits to issue a corrected copy of the license.

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Crompton Corp. License No.: IL-01314-01
Date of Incident: 8/21/01 NMED No.: 010794
Investigation Date: 8/22/01 Type of Incident: Damaged Gauges by Fire
Type of Investigation: Inspection

File No.: 2
Licensee: Non-licensee License No.: NA
Date of Incident: 10/30/01 NMED No.: 011012
Investigation Date: 10/30/01 Type of Incident: Abandoned Source Found at a scrap yard
Type of Investigation: Inspection

File No.: 3
Licensee: Saint Alexius Medical Center License No.: IL-01512-01
Date of Incident: 1/22/02 NMED No.: 020130
Investigation Date: 1/23/02 Type of Incident: Radioactive Material Released in a Hospital
Type of Investigation: Phone, Written Report

File No.: 4
Licensee: Medi-Physics License No.: IL-01109-01
Date of Incident: 2/14/02 NMED No.: 020451
Investigation Date: 2/20/02 Type of Incident: Lost and Found Radioactive Material
Type of Investigation: Phone, Written Report

File No.: 5
Licensee: Children's Memorial Hospital License No.: IL-01165-01
Date of Incident: 5/14/2002 NMED No.: 020640
Investigation Date: 5/15/02 Type of Incident: Radioactive Material Released in a Research Lab
Type of Investigation: Phone, Written Report

File No.: 6
Licensee: SCI Engineering Inc. License No.: IL-01413-01
Date of Incident: 9/17/02 NMED No.: 020893
Investigation Date: 9/18/02 Type of Incident: Lost and Recovered Gauge
Type of Investigation: Phone, Written Report

File No.: 7
Licensee: Conam Inspection, Inc. License No.: IL-01225-22
Date of Incident: 3/17/03 NMED No.:
Investigation Date: 3/20/03 Type of Incident: Lost and Found Radioactive Material
Type of Investigation: Phone, Written Report

File No.: 8
Licensee: Rush Copley Medical Center License No.: IL-01052-01
Date of Incident: 7/28/03 NMED No.: 030624
Investigation Date: 7/30/03 Type of Incident: Medical Event (Abnormal Occurrence)
Type of Investigation: Inspection

File No.: 9
Licensee: Saint James Hospital & Health Center License No.: IL-01289-01
Date of Incident: 8/3/04 NMED No.: 040603
Investigation Date: 8/4/04 Type of Incident: HDR Equipment Failure
Type of Investigation: Phone, Written Report

File No.: 10
Licensee: Construction & Geotechnical Material Testing, Inc. License No.: Il-02179-01
Date of Incident: 11/8/04 NMED No.: 040851
Investigation Date: 11/9/04 Type of Incident: Damaged Gauge
Type of Investigation: Inspection

File No.: 11
Licensee: Bard Brachytherapy License No.: IL-02062-01
Date of Incident: 10/26/04 NMED No.: 040777
Investigation Date: 10/29/04 thru present Type of Incident: Transportation, Product QA
Type of Investigation: Phone, Written report, QA audit

Comment:
Investigation is on going; staff is evaluating licensee's QA/QC procedures

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Registry No.: IL-1072-D-101-S SS&D Type: (J) Self-Contained Gamma Irradiator
Manufacturer: Hopewell Designs, Inc. Model No.: PI1C APD Irradiator
Date Issued: 1/3/01 Type of Action: initial issue, custom device
SS&D Reviewers: SMK, CGV

Comments:
a) Custom evaluation, Matsushita Industrial Equipment Corporation of America
b) Reference letter dated 11/12/1998 not in file

File No.: 2
Registry No.: IL-8127-D-803-S (was NR-610-D-103-S) SS&D Type: (G) Moisture Density Gauge
Manufacturer: Soiltest, Inc. Model No.: NIC-5 Series
Date Issued: 2/20/03 Type of Action: Inactivation
SS&D Reviewers: MEB, CGV

Comments:
a) Good attempt to track down 25-year old information

File No.: 3
Registry No.: IL-1074-S-101-S SS&D Type: (AA) Manual Brachytherapy
Manufacturer: Bard Brachytherapy, Inc. (SourceTech Medical) Model No.: STM 125I
Date Issued: 9/25/01 Type of Action: Amendment
SS&D Reviewers: DMP, CGV

File No.: 4
Registry No.: IL-1074-S-101-S SS&D Type: (AA) Manual Brachytherapy
Manufacturer: Bard Brachytherapy, Inc. (SourceTech Medical) Model No.: STM 125I
Date Issued: 10/7/03 Type of Action: Amendment
SS&D Reviewers: MEB, CGV

Comments:
a) telefax dated 3/27/03 not in file

File No.: 5
Registry No.: IL-1079-D-101-G SS&D Type: (D) Gamma Gauge; (E) Beta Gauge
Manufacturer: Indev Gauging Systems Model No.: DRN 07736 (was 105.002)
Date Issued: 9/24/02 Type of Action: Amendment
SS&D Reviewers: MEB, CGV

File No.: 6
Registry No.: IL-1082-S-101-S
Manufacturer: REVISS Services, Inc.
Date Issued: 4/6/04

SS&D Type: High Energy Gamma Source
Model No.: RSL2089 (formerly CKC.LSA
Type of Action: Amendment
SS&D Reviewers: CGV, JGK

File No.: 7
Registry No.: IL-136-S-338-S
Manufacturer: Medi-Physics, Inc.
Date Issued: 2/27/03

SS&D Type: (AA) Manual Brachytherapy
Model No.: 6711 (OncoSeed)
Type of Action: Amendment
SS&D Reviewers: MEB, CGV

File No.: 8
Registry No.: IL-136-S-338-S
Manufacturer: Medi-Physics, Inc.
Date Issued: 10/18/04

SS&D Type: (AA) Manual Brachytherapy
Model No.: 6711 (OncoSeed)
Type of Action: Amendment
SS&D Reviewers: SMK, CGV

ATTACHMENT

June 3, 2005 Letter from Gary Wright
Illinois' Response to Draft IMPEP Report

ADAMS: ML051580351

RESOLUTION OF COMMENTS

RESPONSE TO ILLINOIS COMMENTS FROM THE DRAFT 2005 IMPEP REPORT

The IMPEP review team evaluated each of the comments from the State of Illinois and either agreed, agreed in part, or disagreed with the comments, or acknowledged the additional information provided by the State. Changes were made as noted in the responses below.

Comment 1: Second paragraph of the June 3, 2005 letter from Gary Wright, Illinois to Vivian Campbell states:

> Illinois, however, is extremely disappointed with the "incompatibility" finding for regulations. Illinois has worked extremely hard to draft the regulations, and all were adopted or drafted and awaiting legal concurrence at the time of the review. These were available at the time of the review. In discussions with NRC staff prior to the audit, Illinois was under the impression that these new/draft regulations would be more than acceptable for a compatibility finding. These drafts could have been sent to State Programs (STP) several months before if we had known they could be reviewed in draft form for compatibility. STP apprised us of this the Monday after the IMPEP review. Illinois agrees with your assessment that there are no health and safety concerns that have not been addressed through licensing. In light of these circumstances, the Agency requests the compatibility indicator of unsatisfactory for this element be reconsidered.

Response: The review team appreciates the effort that Illinois has undertaken to revise their regulations. However, under the current procedure, a finding that specific Illinois regulations meet compatibility and health and safety categories of the equivalent NRC regulations is only made based on the review of final Illinois regulations. Regulation reviews are not conducted during the on-site portion of the review, but submitted to the Office of State and Tribal Programs as described in STP Procedure SA-201. The review team does not agree to revise the finding at this time and will discuss the issue and Illinois' position with the Management Review Board (MRB) during the MRB meeting on the Illinois draft report. There will be no revision to the finding based on this comment.

Comment 2: Third paragraph of the June 3, 2005 letter from Gary Wright, Illinois to Vivian Campbell states:

> A number of these regulations have long been adopted in Illinois. Some have been in effect since 1994. The Agency is not sure why these have not been approved by NRC during previous correspondence. The Agency sent a letter to NRC STP Deputy Director Fred Combs and John Zabko asking for a resolution of this matter in 2000 and again in 2002 (as a fax, attachment 1). It is unfortunate that NRC failed to assist Illinois in resolving these rules at that time.

Response: The review team agrees that it is unfortunate that a written response to the 2000 letter (which was sent as a fax in 2002) was not sent. The 2005 review team was unable to locate a response by STP to this correspondence. However, the 2000 letter from Kathy Allen requested that NRC update the Regulation Assessment Tracking System based on an annotated chart attached to the letter. No regulations were submitted with the letter or the fax in 2002 with a request for an NRC review of the regulations in question. The regulation assessment tracking

system, commonly referred to as RATS, is an internal program used by STP to track the status of NRC's review of draft and final State amendments equivalent to those made to the NRC regulations. The State Regulation Status (SRS) Data Sheet as discussed in SA-201, is posted on the STP website and summarizes our knowledge of the status of Agreement State regulations with links to both the draft and final regulations submitted by the Agreement State for NRC review. There will be no revision to the finding based on this comment.

Comment 3: First paragraph of the May 5, 2005 letter from Vivian Campbell, NRC to William Burke, Illinois states, "The review team's proposed recommendations are that the Illinois Agreement State program be found adequate to protect public health and safety, but not compatible with NRC's program." Illinois replied that the "not compatible" finding should clearly state that this finding is related only to the status of rulemaking.

Response: The review team disagrees with Illinois' position. The 1997 NRC Policy Statement on Adequacy and Compatibility of Agreement State Programs describes the program elements for an Agreement State program to be found compatible. As implemented through Management Directive 5.6, adequacy and compatibility are overall program findings. We agree that the unsatisfactory finding under the non-common performance indicator compatibility requirements is the basis of the "not compatible" program finding. However, NRC does not limit overall findings in the manner requested by Illinois. There will be no revision to the letter or draft report based on this comment.

Comment 4: The statement at the end of the second paragraph of the May 5, 2005 letter from Vivian Campbell, NRC to William Burke, Illinois: NRC did not look at the General Licensing (GL) Program. The GL program has previously been reviewed in detail by other IMPEP teams. Illinois takes great pride in this program and believes it to be the premier GL program in the Nation. The Illinois GL database has been the model used by NRC and other states to track sources nationwide. The Agency would like comments about this program included in the report.

Response: The 2005 review team agrees with the statement that the Illinois' GL Program was not reviewed during the 2005 IMPEP. The 2005 review team focused on core licenses in the materials licensing and inspection programs. The 2005 team cannot comment on a program that was not reviewed. With regard to previous IMPEP reviews, Illinois's program may have been reviewed in the past. However, after reviewing the past IMPEP reports, the team found no documented evidence that the GL program had been included in those reviews. There will be no revision to the draft report based on this comment.

Comment 5: The statement at the end of the second paragraph of the May 5, 2005 letter from Vivian Campbell, NRC to William Burke, Illinois: Illinois would also like comments included about our participation in the 274i agreement either in the cover letter or in the good practices section of the report. The Agency understands that this agreement is not part of the IMPEP criteria. However, providing additional oversight for high -risk sources is certainly a "good practice." 274i is a major program that we have voluntarily committed to and deserve recognition for."

Response: The review team appreciates Illinois' participation in the 274i Agreement for the security of high risk sources. However, the participation of Illinois in the 274i Agreement program is outside of the scope of the IMPEP reviews. The identification of good practices through the IMPEP reviews was developed to share innovative and effective practices developed by either NRC Regions or Agreement States in the material safety arena which might benefit and enhance other materials

programs by adopting the good practices of other regulators. This information is shared with other regulators periodically through issuance of a report. There will be no revision to the letter or draft report based on this comment.

Comment 6: Draft report, Section 2.0, Current Status: This paragraph is not correct. A number of rules were adopted and final in Illinois prior to the review. In addition, all overdue rules have either been adopted or sent to NRC as drafts as of May 2, 2005. NRC needs to revise language in the report regarding "adopted" vs. "sent" to NRC. A number of rules have apparently been adopted since 1994 that NRC does not consider complete under the compatibility process.

Response: The review team appreciates the comment and will revise the report to reflect the status of the regulations at the time of the on-site portion of the review. As discussed in the response to Comment 1, a finding that specific Illinois regulations meet compatibility and health and safety categories of the equivalent NRC regulations is only made based on the review of final Illinois regulations. Regulation reviews are not conducted during the on-site portion of the review, but submitted to the Office of State and Tribal Programs as described in STP Procedure SA-201.

Comment 7: Draft report, Section 3.2, second paragraph: A number of inspections and their frequencies have been left out of this section. Illinois inspects almost every licensee more frequently than NRC. We would like these included to clearly demonstrate Illinois' commitment to the inspection process.

Response: The review team agrees that as written, the reader might expect to find a listing of all the types of inspection that Illinois inspects at a more frequent basis than NRC. The review team proposes to revise the paragraph to reflect those categories listed as examples. The revision will be as follows:

> As examples, the Bureau requires more frequent inspection in the following license categories: Type A broad scope academic licenses are inspected on a one-year frequency compared with the NRC three-year frequency; nuclear laundry licenses on a two-year frequency compared with the NRC three year frequency; nuclear pharmacy licenses on a one-year frequency compared with the NRC two-year frequency; Type A broad scope research and development licenses on a one-year frequency compared with the NRC three-year frequency; and Type B and C broad scope academic licenses on a two-year frequency compared with the NRC five-year frequency.

Comment 8: Draft report, Section 3.2, third paragraph: NRC states our database was difficult to use for tracking inspections in accordance with IMPEP criteria. We provided all the appropriate data. The Agency is able to ensure that inspections are performed in accordance with standards that are more restrictive than NRC. Although we are reviewing the database to see if changes are warranted, the current system has served our purposes very well, and it should be noted that it is not required that we design our database solely to meet IMPEP queries.

Response: The team acknowledges the comment, and agrees that the State is not required to design their database to meet IMPEP queries. The team will revise the text as follows:

> The Bureau's database did not have the capabilities to provide status information for all inspections conducted during the review period. The review team obtained the information manually through examination of the review files.

Comment 9: Draft report, Section 3.4, seventh paragraph: The Section Head does not approve licensing actions. Once staff completes the review and prepares the license, the Licensing Unit Supervisor approves and signs the action.

Response: The review team agrees to the change and will revise the report.

Comment 10: Draft report, Section 4.1, ninth paragraph: This paragraph states that staff began working on rules in 2003. This not entirely accurate. A number of the rules in question were adopted by Illinois but not recognized by NRC. Correspondence was sent to NRC regarding this in 2000 and 2002.

Response: The review team appreciates the clarification and the sentence will be deleted from the report.

Comment 11: Draft report, Section 4.1, tenth paragraph: All of the RATS currently due were submitted to the review team on 4/4/05 and NRC STP on 5/2/05. The statement that the 'Medical Use of Byproduct Material" and "Financial Assurance For Materials Licensees" are overdue is incorrect. These were not due until 4/24/05 and 10/25/05 for medical and 12/3/06 for financial assurance. These findings should be removed from the report.

Response: The review team acknowledges that as written in the draft report the reader may believe that the two above referenced amendments were also overdue. The review team will revise the text to clarify that these amendments were not overdue and the State had prepared drafts ahead of schedule.

Comment 12: Draft report, Section 4.1, eleventh paragraph: The following nine rule amendments are overdue for adoption **(incorrect, some of these are adopted and final in Illinois)** but they are currently in draft form and undergoing legal review within the Bureau.

Response: The review team appreciates the clarification and the sentence will be modified to reflect the updated number of rules not adopted during the review period of March 9, 2001 to April 8, 2005.

Comment 13: Draft report, Section 4.1, twelfth paragraph: Part 341 (NRC Part 71) was proposed in the Illinois Register on 12/3/04 and was final on May 2, 2005. This finding should be removed from the report.

Response: The review team disagrees that this rule should be removed from the report. The rule was not adopted and had not been submitted to NRC for a compatibility determination during the review period of March 9, 2001 to April 8, 2005. There will be no revision to the report based on this comment.

Comment 14: Draft report, Section 4.1, fourteenth paragraph: Part 330.320 of the Illinois regulations outlines the termination rule. Each case is evaluated using this rule and the NRC's MARSIM guide. Surveys of sites using unsealed materials are required of each licensee and confirmed by follow-up surveys by our inspection staff. For sealed sources each source is tracked cradle to grave by serial number using the licensees inspection records, leak tests and our form KLM.007 (see attachment 3)

certifying where they went and under what license it was authorized. Illinois terminates sites to standard at least as restrictive as NRC if not more so. This finding should be removed from the report since it is addressed by rule and the licensing process.

Response: The review team appreciates the clarification. We disagree that this finding should be removed from the report. However, we will move this finding from the original list of amendments not adopted during the review period to the list of amendments that had been adopted, but not reviewed by NRC for compatibility as a "Final" rule.

Comment 15: Draft report, Section 4.1, seventeenth paragraph: Part 351 (NRC Part 39) was submitted to NRC and two comments were made by NRC that turned out not to be valid as leak test requirements were included in 351.1050(a) and the exchange/replacement of dosimetry is specifically requested on our application forms (see attachment 4). Therefore, this Part should have been found compatible in November of 2003 when initially submitted. This rule was final in Illinois in August 27, 2004. This finding should be removed from the report.

Response: The initial submittal for RATS ID 2000-1 was reviewed as a "Proposed" regulation and NRC's review was documented in a January 16, 2004, correspondence to the Bureau. We disagree that this finding should be removed from the report. However, we will move this finding from the original list of amendments not adopted during the review period to the list of amendments that had been adopted, but not reviewed by NRC for compatibility as a "Final" rule.

Comment 16: Draft report, Section 4.1, nineteenth paragraph: This rule was adopted by reference in all applicable license documents (see attachment 5 for letter of commitment from licensees). This was found acceptable during the last IMPEP and should be eliminated from this report. Certain other rules incorporated by license condition were found to be acceptable by STP after the 2005 IMPEP. We have adopted this rule by reference for each licensee. This meets the compatibility standard. This finding should be removed from the report.

Response:
The team agrees that rules incorporated by license condition is an acceptable method to adopt a rule. However, the license condition needs to be reviewed by the NRC to determine if the license condition is compatible, per guidance provided in SA-201. Our records indicate this license condition had been submitted to NRC for a compatibility review and found compatible only for the requirements of 10 CFR 32.52 (a) & (b). The Bureau needs to address the entire GL rule amendment and submit their rules to NRC for a compatibility determination. There will be no revision to the report based on this comment.

Comment 17: Draft report, Section 4.1, twenty-first paragraph: This rule has long been superseded by the new Part 35. Illinois and most Agreement States agreed that this rule was unfeasible from the start as NRC also did, as evidenced by its omission from the new part 35. This finding should be removed from the report.

Response:
The review team acknowledged in the draft report that this rule would be superceded with the adoption of the new medical rule. However, the amendment was due for adoption on January 27, 1995. STP has no record that the State had addressed this amendment. The report will not be revised based on this comment.

Comment 18: Draft report, Section 4.1, twenty-fourth paragraph: We adopted this rule (RATS 1995-7) on May 2, 1994 concurrently with NRC. In addition, it will be superseded by our new draft of Part 35. This should be deleted from the report.

Response:
The review team appreciates the clarification on the status of the rule. However, our records indicate the rule has not been sent to the NRC for a compatibility determination review. The rule will be moved to the list of amendments that had been adopted, but not reviewed by NRC for compatibility as a "Final" rule.

Comment 19: Draft report, Section 4.1, twenty-sixth paragraph: Illinois adopted this rule (RATS ID 1995-6) on June 1, 2000. The Agency requires financial assurance for facilities to a level much more restrictive than NRC financial assurance arrangements are required for facilities possessing or using sealed sources greater than 37 GBq (1 Ci). financial assurance arrangements and reclamation plans are required for other facilities possessing or using significant nuclides/activities of radioactive material as specified by the regulation. We are uncertain why NRC does not consider this RATS competed. We have sent this version to STP again for review.

Response:
The team appreciates the clarification. The text will be modified and the rule will be moved to the list of amendments that have been adopted, but not reviewed by NRC for compatibility as a "Final" rule.

Comment 20: Draft report, Section 4.1, twenty-ninth paragraph: The Agency has always maintained that these (RATS 1999-1) do not apply to Illinois. Finally, after several rounds of discussion NRC has agreed. These should be removed from the report.

Response:
Illinois' agreement authorizes 11e.(2) material, and therefore, these regulations do apply to the State. However, the State currently has only one uranium mill licensee. Prior to NRC's Termination Rule for Uranium Recovery Facilities becoming effective, the State had reviewed and approved a decommissioning plan for this specific licensee. The team agreed that at this time it is not necessary for the State to promulgate these rules, but if the State receives other uranium recovery applications, they will need to promulgate these amendments. The team believes that it is important to document this decision in the report for future IMPEP review teams. There will be no revision to the draft report based on this comment.

Comment 21: Draft report, Section 4.1, forty-eighth paragraph: Part 341 was effective in Illinois on May 2, 2005 and was in final notice during the April 4 IMPEP. This adopts all of the applicable portions of 49 CFR and 10 CFR 71 by reference and should be removed from the report.

Response:
The rule was not adopted during the review period of March 9, 2001 to April 8, 2005. The State can discuss this at the MRB meeting. There will be no revision to the draft report based on this comment.

Comment 22: Draft report, Section 4.1, fiftieth paragraph: All of the RATS applicable to Illinois are either currently adopted or been submitted to STP as drafts as of May 2, 2005. This clearly represents Illinois' commitment to compatibility issues, As previously noted,

we sent a letter to STP on September 26, 2000 and again by fax on January 28,2002 to try and resolve a number of the outstanding RATS. We believe NRC should have been more responsive to these inquiries at the time. The RATS lists for Illinois is not reflective of actual events. As noted above, a number of RATS are not applicable or have been superseded and should be removed from the status list.

Response:
The team appreciates the recent attention the State has given to adopting overdue rules. However, we disagree with the State that the RATS list for Illinois is not reflective of actual events. Please see our response to Comment 2.

Comment 23: Draft report, Section 5.0, Good Practice: This paragraph states that Recovery and Remediation fees are a onetime fee. Licensees are billed each of the first two years for this. In addition, these are required for everyone including those that pay financial assurance. The report says only licensees not paying financial assurance pay this fee. This error also occurs on page 8, last paragraph. In addition, Illinois would like other good practices reflected in this section such as the 274i security inspections, our outstanding general license program, our incident response activities (we investigate each incident and scrap yard alarm in person, perform characterization of the material and provide waste disposal options) and our licensee survey program (a satisfaction survey is sent out with each license action and inspection report).

Response:
The review team appreciates the correction regarding the Recovery and Remediation fees and will revise the text. Regarding the recognition of other good practices, see the response to Comment 5.

Comment 24: Draft Report, Appendix C, File 1: Identified as “routine” versus “initial” in inspection report. JANX had been inspected as a reciprocity licensee many times before so this was not an initial inspection.

Response:
NRC’s Manual Chapter 2800 defines an initial inspection as the first inspection after a license is issued to a licensee. The document also describes circumstances that require a new license be issued to a licensee, but an initial inspection is not warranted. However, being inspected as a reciprocity licensee is not identified as an exception from performing an initial inspection. In this case, the licensee was inspected within the appropriate interval and therefore, this is a moot issue. The team will remove the comment.

Comment 25: Draft Report, Appendix C, File 3. Inspection was for only Chicago site, not complete license. Each site is inspected independently.

Response:
The license authorizes two nuclear pharmacy facilities. Only one of the pharmacy locations was mentioned in the inspection report. Consequently, it was unclear to the review team when or if the second location was to be inspected. The text will not be revised based on this comment.

Comment 26: Draft Report, Appendix F, File 2. SMK (MEB reviewer, not SMK)

Response:
The text will be revised as noted.

Agenda for Management Review Board Meeting
June 28, 2005, 3:00 p.m. - 5:00 p.m., O-3B4

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 representatives participating through telephone bridge or video conferencing. (OAS Liaison is Pearce O'Kelley from South Carolina)

3. Consideration of the Illinois IMPEP Report.

   A. Presentation of Findings Regarding Nevada 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
   - Uranium Recovery Program
   - Sealed Source and Device Evaluation Program

   B. IMPEP Team Recommendations:
      - Adequacy and Compatibility Rating
      - Recommendation for Next IMPEP Review

   C. MRB Consultation/Comments on Issuance of Report.

4. MRB Consideration of General License Amendment (see attached)

5. Request for Comments from Illinois Management, OAS Liaison and State IMPEP Team Member. (State IMPEP team member is Eric Jameson from Georgia)

6. Adjournment

Invitees:

Martin Virgilio, EDO	Dennis Rathbun, STP
Paul Lohaus, STP	Vivian Campbell, RIV
Karen Cyr, OGC	John Zabko, STP
Jack Strosnider, NMSS	Jill Caverly, NMSS
Gary Wright, IL	Pearce O'Kelley, SC
Steve Collins, IL	Jennifer Tobin, STP
Osiris Siurano, STP	

ATTACHMENT 3

Management Review Board Consideration of General License (GL) Amendment

Background:

A) Due to an oversight in the regulation review process, whereby the Review Summary Sheets used by staff did not include a specific review of 10 CFR Part 31.5 and 31.6, staff conducted a re-review State GL regulations. The text of these sections was not revised by the GL amendment, but the compatibility designations were changed from Compatibility Categories C and D respectively, to Category B. Upon re-review, staff has identified that 13 Agreement States have regulations that are inconsistent with the compatibility criteria.

B) The Commission received a petition for rulemaking from the State of Florida to change the compatibility determination. The petition is currently under review by NRC staff.

C) The Commission also expects to receive a petition for rulemaking to modify the GL rule from the OAS in early July 2005.

Issue:

How should the staff treat and consider the status of a State's GL rule during IMPEP reviews and in comments to the States which have GL rules that do not meet the compatibility criteria?

Option 1: Staff will notify the 13 Agreement States (and any other potential States in the future) of the findings of the re-review and indicate that in order to meet the compatibility requirements of these sections, staff comments will need to be addressed through changes to their regulations.

Option 2: Staff will hold in abeyance in IMPEP and in the responses to each of these Agreement States, until there is a determination on the State of Florida petition and the petition for rulemaking expected from the OAS.

Next Steps:

1) If the MRB approves Option 1, staff will send the attached letters to the States. These letters differ based upon whether the re-review was on final or proposed regulations.

2) If the MRB approves Option 2, staff will hold the responses in abeyance until there is a determination on the State of Florida petition and the petition for rulemaking expected from the OAS. Staff will reflect this in the Illinois IMPEP review, in future IMPEP reviews, and in letters to the States.

DRAFT

Dear [RCPD]:

By letter dated [Date], we sent you the results of our review of the proposed changes to the [State] regulations in [State regulation citation] which were submitted to the NRC by letter dated [date]. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 30, 31, and 32, and the requirements of the General License (GL) amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. The review we conducted omitted a specific review of Sections 10 CFR Parts 31.5 and 31.6. The text of these sections was not revised by the GL amendment, but the compatibility designations were changed from Compatibility Categories C and D respectively, to Category B. By letter dated February 18, 2005 (STP-05-015), we indicated that STP staff was conducting a re-review of all final and proposed regulations for compatibility to ensure State rules meet the Agency's compatibility criteria.

As a result of our re-review, we have [number] comments **[if needed: ,[number] of which were previously provided,]** that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the [State] regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final [State] regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in STP Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes and provide a copy to STP.

The SRS Data Sheet summarizes our knowledge of the status of other [State] regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Mr. William R. Rautzen at (301) 415-7206 or by e-mail at wrr@nrc.gov.

Sincerely,

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures:
As Stated

DRAFT

Dear [RCPD]:

By letter dated [Date], we sent you the results of our review of the final changes to the [State] regulations in [State regulation citation] which were submitted to the NRC by letter dated [date]. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 30, 31, and 32, and the requirements of the General License (GL) amendment identified in the enclosed State Regulation Status (SRS) Data Sheet. The review we conducted omitted a specific review of Sections 10 CFR Parts 31.5 and 31.6. The text of these sections was not revised by the GL amendment, but the compatibility designations were changed from Compatibility Categories C and D respectively, to Category B. By letter dated February 18, 2005 (STP-05-015), we indicated that STP staff was conducting a re-review of all final and proposed regulations for compatibility to ensure State rules meet the Agency's compatibility criteria.

As a result of our re-review against the Compatibility Category B designation, we have [number] comments **[if needed: ,[number] of which were previously provided,** that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. However, we have determined that these comments must be addressed to meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.

We request that when a final amended version of [State] regulations are adopted and published in response to our comments, that a copy of the "as published" regulations be provided to us for review as requested in STP Procedure SA-201, Review of State Regulatory Requirements.

The SRS Data Sheet summarizes our knowledge of the status of other [State] regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Mr. William R. Rautzen at (301) 415-7206 or by e-mail at wrr@nrc.gov.

Sincerely,

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated