Mr. Gary Wright, Assistant Director Illinois Emergency Management Agency Division of Nuclear Safety 1035 Outer Park Drive Springfield, IL 62704

Dear Mr. Wright:

On June 26, 2005, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Illinois Agreement State Program. The MRB found the Illinois program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB recognized the excellence in program administration demonstrated by your staff, as reflected in the team's findings. The MRB also agreed with the team finding that the Illinois program needs to complete the process of adopting regulations, or other legally binding requirements, which are overdue for adoption and send them to the NRC for review. Adoption of these outstanding regulations will allow the State to meet compatibility requirements as addressed in the Non-Common Performance Indicator: Compatibility Requirements. Section 5.0, page 19, of the enclosed final report presents the IMPEP team's recommendation for the State of Illinois.

Because of the overdue regulations, the MRB determined the Illinois program should undergo a period of heightened oversight. Heightened oversight is an increased monitoring process used by NRC to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate Illinois and NRC staffs.

We request that you prepare and submit a program improvement plan as part of your response to the recommendations in Section 5 of the enclosed final report, "Integrated Materials Performance Evaluation Program, Review of Illinois Agreement State Program - Final Report." I ask that you have your staff dialogue with Paul Lohaus on the required elements of this plan to ensure that the "get-well" path and measures of success are clearly identified. The plan should be submitted within 30 days of this letter. Upon review of the program improvement plan, the staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than September 6, 2005. Based on the results of the current IMPEP review, a follow-up review will be scheduled during the period April - August 2006 or sooner if final regulations are adopted at an earlier date. The follow-up review will cover the State's action on the recommendations from the April 2005 review.

G. Wright - 2 -

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Radiation Control Program and I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

### /RA Paul H. Lohaus Acting for/

Martin J. Virgilio
Deputy Executive Director for Materials, Research,
State and Compliance Programs
Office of the Executive Director for Operations

Enclosure: As stated

cc: William C. Burke, Director

Illinois Emergency Management Agency

Paul Eastvold Bureau of Radiation Safety Illinois Emergency Management Agency

Pearce O'Kelley, SC OAS Liaison to the MRB

G. Wright - 2 -

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Paul Eastvold

Bureau of Radiation Safety

Illinois Emergency Management Agency

Pearce O'Kelley, SC OAS Liaison to the MRB

bcc: Chairman Diaz

Commissioner Merrifield Commissioner Jaczko Commissioner Lyons

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# INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF ILLINOIS AGREEMENT STATE PROGRAM

April 4 - 8, 2005

# **FINAL REPORT**

U.S. Nuclear Regulatory Commission

#### 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 draft of this report was issued to Illinois for factual comment on May 5, 2005. 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 Management Review Board (MRB) met on June 28, 2005 to consider the proposed final report. The MRB found the Illinois radiation control program adequate to protect public health and safety and not compatible with the NRC's program. Due to the non-compatible finding, the length of time that rules had been overdue for adoption, and the fact that Illinois has rules in draft, not final form, the MRB placed the Illinois program on Heightened Oversight.

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 Agencywide 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 Inspection Manual Chapter (MC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Program 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 recommended and the MRB concurred 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 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; 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 recommended and the MRB concurred 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 recommended and the MRB concurred 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 recommended and the MRB concurred 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 recommended and the MRB concurred 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 STP Procedure 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 for adoption on February 2, 2003 [RATS ID 1999-3].
- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) was due for adoption on January 8, 2004 [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 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 comments were provided to State staff. Final rule was 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 were provided to State staff. Final rule was 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 had no comments. Final rule was 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 comments were provided to State staff. Final rule was 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.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB concurred 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 <u>Technical Staffing and Training</u>

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 <u>Technical Quality of the Product Evaluation Program</u>

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 recommended and the MRB concurred 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 <u>Technical Staffing and Training</u>

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 four 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.

#### 4.4.2 <u>Status of Uranium Recovery Inspection Program</u>

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.

#### 4.4.3 <u>Technical Quality of Inspections</u>

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.

#### 4.4.4 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 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."

#### 4.4.5 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 recommended and the MRB concurred 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 recommended and the MRB concurred in finding the Illinois Agreement State program adequate to protect public heath and safety and not compatible with NRC's program. The review team recommended and the MRB concurred that a period of heightened oversight be implemented to assess the progress of the State, including preparation of a program improvement plan, bimonthly conference calls, status reports before each call, and a follow-up IMPEP review in one year.

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, and the MRB concurred, 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** 

Appendix B Illinois Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E **Incident Casework Reviews** 

Appendix F Sealed Source and Device Casework Reviews

Attachment

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

#### 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:

a) 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:

a) 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

Inspection Casework Reviews

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:

a) 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:

a) 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

**Inspection Casework Reviews** 

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. a)

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

License No.: IL-01772-01 Licensee: Illini Hospital

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

License No: IL-01123-01 Licensee: Steris Isomedix Services

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.

Type of Action: Renewal

Date Issued: Pending

License No.: 86-02062-01

Amendment No.: pending

License Reviewer: MEB

File No.: 2

Licensee: Bard Brachytherapy, Inc.

Type of Action: Amendment

Date Issued: 1/28/05

License No.: 86-02062-01

Amendment No.: 18

License Reviewer: MEB

File No.: 3

Licensee: STERIS, Inc.

Type of Action: Amendment

Date Issued: 1/24/05

License No.: IL-01123-01

Amendment No.: 12

License Reviewer: GWM

File No.: 4

Licensee: STERIS, Inc.

Type of Action: Renewal

Date Issued:

License No.: IL-01123-01

Amendment No.: 11

License Reviewer: SMK

File No.: 5

Licensee: Sterigenics USA, Inc. (formerly Ion Beam Applications) License No.: IL-01220-01

File No.: 6

Licensee: Cardinal Health, Inc.

Type of Action: Amendment

Date Issued: 3/11/05

License No.: IL-01721-01

Amendment No.: 36

License Reviewer: MEB

File No.: 7

Licensee: Cardinal Health, Inc.

Type of Action: Renewal

Date Issued: 4/25/03

License No.: IL-01721-01

Amendment No.: 33

License Reviewer: MEB

File No.: 8

Licensee: Rush University Medical Center

Type of Action: Amendment

Date Issued: 5/24/04

License No.: IL-01766-01

Amendment No.: 18

License Reviewer: SMK

Illinois Final Report Page D.2 Licensing Casework Reviews

File No.: 9

Licensee: Rush University Medical Center

Type of Action: Renewal

License No.: IL-01766-01

Amendment No.: 14

Date Issued: 6/25/02 License Reviewer: MEB

File No.: 10

Licensee: G. D. Searle LLC

Type of Action: Termination

License No.: IL-01469-01

Amendment No.: 16

Date Issued: 8/2/04 License Reviewer: GWM

File No.: 11

Licensee: G. D. Searle LLC

Type of Action: Amendment

Date Issued: 10/8/03

License No.: IL-01469-01

Amendment No.: 14

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

Type of Action: Termination

License No.: IL-01097-02

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

Type of Action: Renewal

License No.: IL-01204-01

Amendment No.: 47

Date Issued: 3/11/03 License Reviewer: TLH

Licensing Casework Reviews

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: Amendment 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

Type of Action: Amendment

License No.: IL-01825-01

Amendment No.: 8

Date Issued: 6/30/04 License Reviewer: DP

File No.: 22

Licensee: Veterinary Specialty Center

Type of Action: Expedited renewal

License No.: IL-02071-01

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 Amendment No.: 2

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 No.: 61
Date Issued: 12/17/04
Amendment No.: 61
License Reviewer: DSP

Licensing Casework Reviews

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:

a) 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

File No.: 5

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

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

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File No.: 7

License No.: IL-01225-22 Licensee: Conam Inspection, Inc. 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

License No.: IL-01052-01 Licensee: Rush Copley Medical Center

Date of Incident: 7/28/03 NMED No.: 030624

Type of Incident: Medical Event (Abnormal Occurrence) Investigation Date: 7/30/03

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.: II-02179-01

NMED No.: 040851 Date of Incident: 11/8/04 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:

Custom evaluation, Matsushita Industrial Equipment Corporation of America

Reference letter dated 11/12/1998 not in file b)

File No.: 2

Registry No.: IL-8127-D-803-S SS&D Type: (G) Moisture Density Gauge

(was NR-610-D-103-S)

Manufacturer: Soiltest. Inc. Model No.: NIC-5 Series Date Issued: 2/20/03 Type of Action: Inactivation SS&D Reviewers: MEB, CGV

File No.: 3

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

Comment:

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 SS&D Type: High Energy Gamma Source

Manufacturer: REVISS Services, Inc.

Model No.: RSL2089 (formerly CKC.LSA Type of Action: Amendment

Type of Action: Amendment SS&D Reviewers: CGV, JGK

File No.: 7

Registry No.: IL-136-S-338-S S&D Type: (AA) Manual Brachytherapy Manufacturer: Medi-Physics, Inc. SS&D Type: (AA) Manual Brachytherapy Model No.: 6711 (OncoSeed)

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

Date Issued: 2/27/03

File No.: 8

Registry No.: IL-136-S-338-S SS&D Type: (AA) Manual Brachytherapy

Manufacturer: Medi-Physics, Inc.

Date Issued: 10/18/04

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