June 6, 2001

Mr. Thomas W. Ortciger, Director
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Dear Mr. Ortciger:

On May 21, 2001, 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 compatible with the Nuclear Regulatory Commission's program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's single recommendation. Through various correspondence, we understand what actions you intend to take in response to this recommendation. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

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

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research
and State Programs

Enclosures:
As stated

cc: Paul Eastvold, Manager
Office of Radiation Safety

Richard M. Fry, NC
Agreement State Liaison to
the Management Review Board

T. W. Ortciger June 6, 2001

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Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF ILLINOIS AGREEMENT STATE PROGRAM

March 5-9, 2001

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Illinois radiation control program. The review was conducted during the period March 5-9, 2001, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Maine. 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 November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of March 29, 1997 to March 5, 2001, were discussed with Illinois management on March 9, 2001.

A draft of this report was issued to Illinois for factual comment on April 10, 2001. The State responded in a letter dated April 30, 2001. The Management Review Board (MRB) met on May 21, 2001 to consider the proposed final report. The MRB found the Illinois radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Illinois Agreement State Program is administered by Illinois Office of Radiation Safety (the Office) and is located within the Department of Nuclear Safety (the Department). The Radiation Safety Manager directs the Office. The Office has two Divisions: the Radioactive Materials Division (the Division) and the Electronic Products Division. Within the Division are three Sections: the Materials Licensing Section, the Low-Level Radioactive Waste (LLRW) Licensing and Decommissioning Section, and the Inspections and Enforcement Section. The Department has one field office located in Glen Ellyn, Illinois. Five materials inspectors are based in that location. An organization chart for the Department is included as Appendix B. At the time of the review, the Illinois program regulated 731 specific licenses authorizing agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Illinois.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Department on January 5, 2001. The Department provided a response to the questionnaire on February 5, 2001. A copy of the questionnaire responses is included as Appendix G of the proposed final report.

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 Department's licensing and inspection data base; (4) technical review 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 radiation control program's performance.

Section 2 below discusses the Department's actions in response to recommendations made following the previous IMPEP review. 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 recommendations. Recommendations made by the review team are comments

that relate directly to program performance by the Department. A response is requested from the Department to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on March 28, 1997, one recommendation was made and transmitted to Mr. Thomas W. Ortciger, Director, the Department, on July 8, 1997. The team's review of the current status of this recommendation is as follows:

1. The review team recommends that the Department expedite promulgation of Part 330 at the first opportunity.

   Current Status: The State adopted the restructured Ill. Adm. Code 330, Licensing of Radioactive Material, on June 1, 2000. The final regulations were provided to NRC for comment on July 11, 2000. As a result of the NRC review, the regulations were determined to meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200 on August 21, 2000. This recommendation is closed.

During the 1997 review, nine suggestions were made for the Department to consider. The team determined that the Department considered the suggestions and took appropriate actions.

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) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on the Department's questionnaire responses relative to this indicator, data gathered independently from the Department's licensing and inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with managers and staff.

The team's review of the Division's inspection priorities verified that the Division's inspection frequencies for various types or groups of licenses are as frequent, or more frequent, as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter (IMC) 2800. The Division requires more frequent inspections in some license categories as follows: wireline services were verified to be inspected on a two year frequency as compared to the NRC three year frequency; all type A broad scope licenses are inspected on a one year frequency compared with the NRC two year frequency for type A broad industrial and academic and a one year frequency of type A broad medical; type B and C broad scope licenses are inspected on a two and three year frequency, respectively, compared to the NRC frequencies of three and five years; and general license (GL) distribution type licenses are on a four year frequency compared to NRC's five year frequency.

In their response to the questionnaire, the Division indicated that there were no inspections currently overdue by more than 25 percent of the NRC frequency. This information was verified during the inspection casework reviews and the review of the monthly generated "inspections due" lists provided to the team. The review team noted that out of 21 inspection files examined, one routine inspection and one initial inspection were conducted overdue. Follow-up discussions with Division management revealed that in December 2000, the staff identified several overdue initial and routine inspections. The discrepancy was attributed to a computer programming error. The team found that 20 of the 35 initial inspections completed during the review period were not conducted within the six-month or one-year time frame as per procedure. Delays ranged from 3 to 12 months late. Upon discovering the error, Division staff immediately took steps to resolve the computer programming problem and complete the overdue inspections. The Division completed all overdue inspections identified during December 2000 by February 1, 2001 and continues to monitor the inspection database at least monthly.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. The Division has a goal that the findings to be dispatched within 30 days following the inspection. Out of 21 inspection files examined, only one of the inspection findings sent to the licensees exceeded 30 days, because of the need for additional office review.

The State reported in their response to the questionnaire that 190 licensees had submitted 1,596 requests for reciprocity during the review period, of which 115 were core licensees. The Division reported that 24 reciprocity licenses were inspected, which represents about 21 percent of the reciprocity licenses available for inspection. Fourteen of the inspections were industrial radiography, eight were source exchanges, and two were well logging. During the 1998 periodic review, the Division disagreed with the goals of IMC 1220 as Agreement States did not have substantial input into the guidance. The Division established alternative goals of 10-20 percent of Priority 1 licensees and reactive inspections for other priorities. The team considered that the Division expended considerable resources since the last review and that the number of reciprocity inspections performed was adequate and satisfied the Department's alternative goals.

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.

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 23 radioactive materials inspections conducted during the review period. The casework included all of the Department's materials inspectors, and covered inspections of various types as follows: industrial radiography, medical broad scope, academic broad scope, high dose rate afterloader (HDR), gamma stereotactic radiosurgery, pool irradiator, wireline services, veterinary medicine, laboratory research and development, nuclear pharmacy, nuclear laundry, specific medical, and reciprocity. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. The inspection reports were thorough,

complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, and unresolved safety issues. Exit interviews were held with appropriate licensee personnel and discussions were well documented in the reports. Team inspections were performed when appropriate and for training purposes.

The review team found that routine inspections adequately cover the licensee's radiation protection program and include a written summary of the scope of the licensed activities and a root cause if a noncompliance was identified. The review team noted that the majority of violations cited are recordkeeping infractions. The review team discussed the current performance-based, risk-informed inspection philosophy with the staff. The review team also found that the inspectors observed licensed operations whenever possible. Inspection accompaniments were conducted by the Radiation Safety Manager, the Division Chief, the Inspection and Enforcement Head, as well as the Glen Ellyn Office Supervisor.

Three materials inspectors were accompanied by a review team member during the period of January 31 to February 6, 2001. Other Division inspectors were accompanied during the 1997 review. One inspector was accompanied during the inspection of an industrial radiography program and the other two inspectors were accompanied on medical inspections. During the accompaniments, each inspector demonstrated appropriate inspection techniques and knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted effective interviews with appropriate licensee personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. Their inspections were adequate to assess radiological health and safety at the licensed facilities.

The Department has an adequate number and types of survey meters to support the current inspection program as well as for responding to incidents and emergency conditions. The Department calibrates their own survey instruments at their Conference of Radiation Control Program Directors, Inc., (CRCPD)-certified Regional Calibration Laboratory. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, micro-R meters, and neutron meters were observed. They also have portable multi-channel analyzers that can be used in the field at inspection sites. Air monitoring equipment is also available. Contamination wipes are sent to the State's laboratory for analysis. The Environmental Laboratory maintains a mobile laboratory van for use in emergencies and emergency exercises. Both laboratories are managed by the Office of Environmental Safety.

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.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Division's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed Division management and staff, and considered any possible workload backlogs.

The Division Chief and Assistant to the Division Chief supervise three administrative and 17 technical staff members. The 12 technical staff members in the Materials Licensing and Inspection and Enforcement Sections are classified as Materials Licensing Reviewers and Inspectors, respectively. The remaining technical staff members are in the LLRW Licensing and Site Decommissioning Section.

The Division has an experienced staff and low staff turnover. The Division is fully staffed and there was one departure since the last IMPEP review. The vacancy was filled in an expedient manner. An additional license reviewer position was also created during the review period. The team determined that the Division has a well balanced staff, and a sufficient number of trained personnel to carry out regulatory duties.

All technical staff members are required to have bachelor's degrees or equivalent training in the physical and/or life sciences in addition to prior experience. New hires are allowed to work with the more senior staff until appropriate training and experience is received, and until the individual obtains the confidence to perform the assigned tasks independently. The team confirmed the qualifications of the staff hired since the l997 IMPEP review and verified their performance through the review of licensing and compliance casework.

A training course tracking sheet is used to monitor which classes each staff member has attended. Division staff are familiar with the NRC/Organization of Agreement States (OAS) Training Working Group Report. A complete and updated written training program based on the working group report was established for use by materials license reviewers. The Division Chief stated that a similar program would be created for materials inspectors if a new inspector were hired.

The Illinois Radiation Protection Advisory Council (Council) was created by the General Assembly in 1959. It is composed of seven members appointed by the Governor and two ex officio members from the Department of Labor and the Commerce Commission. The members reflect a variety of backgrounds in the use of radiation sources. The purpose of the Council is to assist the Department in formulation, implementing, and reviewing policies and programs to ensure safe and constructive uses of ionizing radiation. The Council also makes recommendations and provides the Department with technical advice and assistance as required. 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.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 19 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other

supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. 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 that were completed during the review period. The sampling included the following types: large and small irradiator, medical (including broad scope), academic (including broad scope), nuclear pharmacy, research and development, veterinary nuclear medicine, industrial radiography, fixed gauges and devices, and wireline services. Licensing actions included three new licensees, seven renewals, nine amendments, five terminations, and two bankruptcies. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were almost always 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 used the State's licensing guides, license templates, standard conditions and checklists. No potentially significant health and safety issues were identified.

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.

The review team found that the staff follows appropriate licensing guides 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 conversations contained appropriate regulatory language and addressed deficiencies. The use of license templates by the staff 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.

Several licensing actions examined by the team required the licensee to submit financial assurance. The LLRW Licensing and Site Decommission Section determines the financial assurance requirements for the licensing staff. The originals of the financial assurance documents are maintained in the licensee file.

The team found that terminated licensing actions were well documented. The files included the appropriate material transfer records and survey records. Staff from the Office of Environmental Safety, in coordination with the licensing and inspection staff, takes confirmation surveys for license termination. An evaluation of the selected termination records revealed excellent communication between the licensing, inspection, and the Environmental Safety staff

to prevent abandonment of radioactive material. The files showed that documentation of proper disposal or transfer was provided.

Licenses are renewed on a five-year frequency. Licenses that are under timely renewal 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. Deficiencies are addressed by letters and documented telephone conferences, which used appropriate regulatory language. Management reviews the licensing actions prior to issuance. All licenses are signed by the Radioactive Materials Licensing Section Head.

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 Response to Incidents and Allegations

In evaluating the effectiveness of the Department's actions in responding to incidents, the review team examined the Department'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 11 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Department's response to seven allegations involving radioactive materials, including four allegations referred to the Department by the NRC during the review period.

The review team discussed the Department's incident response procedures, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the Division Chief, Inspection and Enforcement Head, Regional Inspection Supervisor, and selected staff.

The Division has primary responsibility for initial response and follow up to incidents involving radioactive materials. Additional aid for incident response can be received from the Office of Environmental Safety when necessary. The State also has the Radiological Assessment and Coordinated Emergency Response (RACER) program that draws staff and expertise from various divisions of the Department in responding to incidents.

The Division does not differentiate between incidents and allegations as defined by the NRC; both are described as incidents under Division terminology. As such, the Division does not have separate procedures for incidents and allegations. The Division's "Investigations and Special Surveys" procedure was last revised April 14, 1995. However, revision 10 of their "Radiological Duty Officer (RDO) Standard Operating Procedure" was dated February 1, 2001. The procedure details the responsibilities of the RDO, a rotating position within the Department, to ensure that a lead is designated and fully prepared for incident response. Though the procedure was complete in detailing steps in responding to an incident, information on NMED reporting or the handling of allegation-related tasks, such as follow up to allegers, was not included in the procedure. A team member and the Division Chief discussed the advantages of updating the Division's procedures to include these topics.

Due to the Division not differentiating between incidents and allegations, the review team was unable to determine how many materials incidents occurred during the review period or how

many incidents the Division should have reported to NRC per STP Procedure SA-300, Reporting Material Events. Legal staff reviews each incident before any materials are released to the public. Eleven incidents were selected for review. The incidents included the following categories: lost or stolen material, leaking source, misadministration, equipment failure, overexposure, damage to equipment, contamination event, and accidental exposure. The review team found that the Department's response to incidents was generally complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the Department took suitable enforcement action.

In reviewing the inspection notes for inspections following incidents where the Division did not conduct an on-site response, inspection notes generally did not mention following up on the incident. Discussions with inspectors and the Inspection and Enforcement Head revealed that inspectors prepare for inspections by reviewing past inspections, including any incident reports, and that past incidents receive follow up, if appropriate. The review team and Division management discussed the importance of documenting follow up of incidents during inspections.

The team found that significant incidents were appropriately reported to the NRC Operations Center in a timely manner. The Division Chief has a copy of the reporting requirements in STP Procedure SA-300, and uses it to determine which events should be reported. All of the eight incidents reviewed by the review team that required reporting to the NRC Operations Center were reported.

During the review period, four allegations were referred to the Division by the NRC. The casework for these allegations was reviewed as well as the casework for three additional incidents, that fit the criteria for allegations as defined by the NRC, reported directly to the Department. The review of the casework and the Division's files indicated that the Division took prompt and appropriate action in response to the concerns raised, including responding to allegers when appropriate. The Department's procedures for handling incidents are incomplete in terms of handling "allegations." A team member discussed the benefits of updating procedures with the Division Chief.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, 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 reviewing Agreement State Programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Program Department; and (4) Uranium Recovery Program.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

The State provided, in their response to the questionnaire, a listing of legislation that affects the radiation control program. The Department is designated as the State radiation protection

agency under the provisions of the Radiation Protection Act of 1990, as amended [420 ILCS 40]. The Act grants the Department the authority to promulgate rules and regulations to be followed in the administration of the radiation protection program. During the review period, the Radiation Protection Act was amended to allow State regulation of Federal entities, if a Federal entity agrees to be regulated by the State.

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]; 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.

4.1.2 Program Elements Required for Compatibility

The Illinois regulations for control of radiation are located in 32 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. Proposed rules are published in the Illinois Register with a minimum 45-day comment period, and may include a public hearing. Proposed rules are sent to NRC for a compatibility ruling. After resolution of comments, the Department 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 and updated on the Department's website. The Department 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 Illinois' responses 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 Assessment Tracking System. Discussions with program staff during this review indicated a good awareness of recently adopted rules. The Department has plans in process to adopt the three rules listed below that were overdue at the time of the review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724) that became effective April 1, 1996.

  Illinois sent a letter to the NRC Office of State and Tribal Programs on February 7, 2001, requesting information which would allow the State to incorporate by reference the transportation requirements of 10 CFR Part 71. The Office of State and Tribal Programs responded by letter dated March 27, 2001 stating that the Illinois Department of Nuclear Safety can adopt 49 CFR Parts 170 - 189 by reference, along with the appropriate sections of 10 CFR Part 71 that are not specifically included in 49 CFR, in order to maintain compatibility. The Department is evaluating that response. Adoption of the rule is planned for 2001.

- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials: Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.

  A compatible rule is in draft and is scheduled for promulgation in 2001.

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998.

  This regulation is under review by the Department's legal staff to determine the feasibility of adopting the rule.

Although the following rule has not been adopted, the Department plans to address this regulation with a Part 335 update, and is awaiting NRC's issuance of the revised 10 CFR Part 35, due in 2001.

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243 and 60 FR 322) that became effective January 1, 1995.

Although, the following rule has not been adopted by the State, the Department Director's exemption process, allows the Department to release patients administered radioactive material on a case-by-case evaluation. Exemptions for licensees have been granted for certain non-Hodgkins lymphoma patients and a thyroid treatment is now being considered for exemption. This policy may meet the Category C compatibility criteria for this rule; however, the review team discussed with the Department that this alternative process needs to be evaluated by NRC following STP Procedure SA-201. The Division has provided information on this exemption process to the NRC for review. NRC will contact the Department when its evaluation is completed.

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective January 29, 1997.

The following rule is currently enforced by the Division through licensing and termination process. A compatible rule is in draft and is scheduled for promulgation in Spring 2001. Either the currently legally binding requirements or the draft rule needs to be evaluated by NRC following STP Procedure SA-201.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.

The following regulations have been adopted by the State; however, there are differences between the State's and the NRC's regulations that need to be addressed. After discussions with the Department, they agreed to reevaluate these regulations. Following this evaluation, either the existing or revised rules will need to be submitted for NRC review following STP Procedure SA-201.

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) that became effective January 27, 1995.

  As noted in the 1997 Illinois IMPEP review final report, the State adopted misadministration requirements on May 2, 1994, in Part 335 "Notifications, Reports and Records of Reportable Events." The State requires licensees to notify the patient of a reportable event within15 days after the licensee ascertains and confirms that a reportable event has occurred instead of within 24 hours as required by NRC regulations. NRC is continuing to defer compatibility findings for Agreement States that have not yet adopted a compatible Quality Management rule until NRC issues a revised Part 35 rule, compatibility designations for the new rule are established, and an effective date for Agreement State implementation has been set.

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 60 FR 25983) that became effective March 1, 1998. Illinois and other Agreement States were expected to have an equivalent rule effective on the same date.

  The State has its own shipping manifest requirements in Part 609 which are different than the uniform shipping manifest requirements in NRC regulations. This regulation is Category B because of its significant direct transboundary implications. The State element should be essentially identical to that of NRC. The uniform manifest rule allows an Agreement State to require additional information on a manifest for the State's regulatory purposes.

The following regulation was imposed by the Department through a compatible legally binding requirement.

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) that became effective July 1, 1993.

  The State reported that all irradiator licenses issued implement the rule through license conditions. This regulation is planned to be incorporated into State regulations and adopted with the issuance of Part 336.

The following regulations will become due in the future and are included here to assist the State in including them in future rulemakings or by adopting alternate generic legally binding requirements:

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.

- "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) that became effective October 26, 1998.

- "Transfer for Disposal and Manifests; Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.

- "Radiological Criteria for License Termination of Uranium Recovery Facilities," 10 CFR Part 40 amendment (64 FR 17506) that became effective June 11, 1999.

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749 and 66 FR 1573) that became effective January 8, 2001.

The review team noted that the State has made progress in the adoption of regulations since the last IMPEP review, and that they have made a commitment to adopt the three outstanding regulations in 2001. Nonetheless, the State has three regulations that have not been adopted within three years of the effective date of NRC's final rule and a number of other compatibility-related issues that are in need of clarification. The review team recommends that the State adopt the regulations, or other legally-binding requirements, which are overdue for adoption.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory with recommendations for improvement.

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

In assessing the Department's SS&D evaluation, the review team examined information provided by the Department in response to the IMPEP questionnaire on this indicator. A review of selected new, amended, corrected, inactivated, converted and transferred SS&D evaluations, deficiency letters and supporting documents covering the review period was conducted. The review team noted the Department's use of guidance documents and procedures, interviewed the staff, technical support professionals, and the Division Chief involved in the SS&D evaluations, and verified the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Department completed approximately 80 actions involving 75 registrations, transferred out 216 registration certificates to the Commonwealth of Massachusetts and another 12 to the State of Texas. Eleven case files were selected for review that included work performed by all reviewers. The cross-section sampling included all the Department's major SS&D manufacturers. The SS&D actions included new certificates, amendments, corrections, transfers, conversions, and inactivations. The certificates reviewed covered the period since March 1997, and represented cases completed by the principal reviewers. The SS&D certificates issued by the Department, and evaluated by the review team, are listed with case-specific comments in Appendix G.

The selected SS&D registration certificates and case files were reviewed for accuracy, appropriateness for authorization, tie-down statements, and over all technical quality. The casework was evaluated for timeliness, adherence to good radiation safety practice, acceptable engineering practices, reference to appropriate regulations, evaluation of safety evaluation reports, manufacturing Quality Assurance/Quality Control, supporting documents, peer and supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and other supporting data.

Analysis of the casework and interviews with staff and engineering technical support professionals, confirmed that the Division generally follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued in July 1998. All applicable and pertinent American National Standards Institute standards, NUREG-1556 Series, NRC Regulatory Guides, and applicable references were confirmed to be available and were used appropriately in performing the SS&D reviews. In reviewing emergent technology related products and new applications, the Department performed evaluations based on good and sound conservative assumptions to ensure public health and safety. Appropriate review checklists were used to assure that all relevant materials were submitted and reviewed. The checklists are retained in the case files. Registrations 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. The 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.

4.2.2 Technical Staffing and Training

The Department attributed about 10-15% of the staff time is spent on safety evaluation of registration certificates. The Department adopted a team approach in performing evaluations of products to be registered, and on an as need basis, can obtain engineering and technical assistance from two registered professional engineers that work in the LLRW and Site Decommissioning Section. The Department discussed with the review team the use of five-person teams to limit safety evaluations performed by external support. All reviewers' work is concurred at the supervisory level. This team approach fosters consistency and acts as a conduit to provide the necessary experience and expertise for this size of program.

The review team examined the training and experience documentation of the staff and management involved in the evaluation program. There have been no additional staff involved

in the evaluation program since 1994. The educational qualifications for the current staff were evaluated and were found adequate.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No safety significant or generic incidents, issues, or defects related to SS&D issues were reported concerning the devices (products) registered by the Department during the review period. The review team also verified that there were no reported incidents through discussions with the SS&D reviewers and a review of the NMED database.

No incidents were identified that were related to any malfunctioning devices or products considered during this review. One of the Department staff demonstrated their ability to conduct computer searches for NMED data concerning specified SS&D devices and manufacturers.

The review team discussed a few general issues with the Department, including the need to closely follow the format for documenting product evaluations in the registry certificates as detailed in NUREG-1556, Volume 3, (i.e., completion of check lists and inclusion of dual units) in order to foster national consistency. Department staff agreed that this is a valid issue which should be brought to the attention of the SS&D working group.

Based on the IMPEP evaluation criteria, the review team recommends that Illinois' performance with respect to the indicator, Sealed Source and Device 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 Program's performance regarding the uranium recovery program. These sub-indicators include: (1) Status of Uranium Recovery Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (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 Department's uranium recovery program is administered under the LLRW Licensing and Site Decommissioning Section. The Department has only one licensee in this program, the Kerr-McGee Chemical Corporation (Kerr-McGee), Rare Earths Facility, located in West

Chicago, Illinois. This facility is in the process of decommissioning, and the material is being shipped out of State for disposal. In addition, off-site residential contamination is authorized by license condition to be brought back on-site for a limited time prior to shipment for disposal. The Department has worked closely with the local community and the licensee to develop a decommissioning plan acceptable to all stakeholders.

4.4.1 Status of Uranium Recovery Inspection Program

The Department has an annual inspection frequency for the Kerr-McGee site. The frequency is consistent with the criteria in IMC 2800 and IMC 2801 and has been applied since the licensee began decommissioning operations in 1994. The Department has a resident health physics inspector at the site who conducts daily, weekly, and monthly operational checks and observes site operations daily. The current resident inspector has been in the position since 1996. Also on-site is an engineering company, under Department contract, that supports the health physics resident. The contractor audits the engineering quality control on the site and performs environmental surveys.

The Department reviews the annual environmental monitoring report submitted by the licensee and determines compliance for the environmental program. This review is conducted on a separate schedule from the annual license compliance inspection. Three annual compliance inspections were conducted by the Springfield office staff since the last review. The review team found that there were no overdue or backlogged inspections for this license.

4.4.2 Technical Quality of Inspections

In reviewing this sub-indicator, the review team examined inspection files, inspection reports, and enforcement documentation for Kerr-McGee, which included the last three annual inspection reports. The file also had documentation for the last environmental monitoring data review and the quality assurance audit. The documentation for these activities show that past inspections and audits adequately covered the scope, completeness, and technical accuracy necessary to determine compliance with regulations, license conditions, and available guidance. Appropriate enforcement actions were taken given the scope of the violation noted. The inspections were thorough and the violation identified was quickly addressed by the licensee.

Given the location of the licensed site, there is an extensive environmental monitoring program with the licensee, the Department, and the Illinois Environmental Protection Agency, all conducting independent monitoring programs. The Department reviews the licensee's annual environmental monitoring report. In addition to the annual compliance inspection, a Quality Assurance inspection was conducted to evaluate the licensee's checks on the construction and clean-up activities at the site. The primary health physics inspector (from the Springfield office) was not accompanied by a team member for this review. However, the site was visited by a member of the review team. The resident inspector conducted a tour of the site and demonstrated his knowledge and understanding of the site activities.

4.4.3 Technical Staffing and Training

The LLRW Licensing and Site Decommissioning Section Head supervises the staff conducting the annual compliance inspections and the resident inspector. The technical staff consists of

two health physicists, two engineers (both professional engineers), and a geologist, with a support contractor supplying additional expertise in these areas. 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 identified as necessary to regulate the radioactive material at the Kerr-McGee site. The Springfield-based inspectors have completed the requisite NRC core courses. The resident inspector has not taken the Inspection Procedures or the Fundamentals of Inspections courses; however, the Department describes his primary responsibilities at the site as project management. The resident inspector's responsibilities include the management of the Department's site contractors, oversight of the on-site health and safety activities, the licensee's work plans, special work permits, and the worker safety training program.

Additional support is provided by the staff in the Office of Environmental Safety for environmental monitoring, verification surveys, and sample analyses on an as needed basis. The Department has a laboratory located in West Chicago, Illinois. The laboratory was visited by a member of the review team and found to be a well equipped facility. The Office of Environmental Safety, Division of Radiochemistry, has a full time chemist assigned to the laboratory.

The review team determined that during the review period, a supervisor did not accompany inspectors each year. During the May 21, 2001 MRB meeting, Department management noted that the inspectors had been accompanied in previous years. The review team found no signs of performance deficiency due to lack of supervisory accompaniment by a supervisor.

4.4.4 Technical Quality of Licensing Actions

The review team evaluated nine amendments issued since the last review of the Kerr-McGee license. In examining the amendments and selected documentation in the file, the review team found that the majority 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 residential clean-up activities. Other actions included authorizing the operation of the Water Treatment Plant, authorizing the use of the Field Verification System, establishing clean-up standards for residual uranium in dry soil, and authorizing Phase IV decommissioning activities. The license included appropriate license conditions for the decommissioning operations at the facility.

The Department has done extensive reviews on the licensee's request for alternate concentration limits (ACLs) during this review period. The ACL request is part of a comprehensive groundwater corrective action plan (CAP). The Department listed 20 groundwater constituents, identified in 10 CFR Part 40, Appendix A, to be included in the licensee's CAP. The final review of the CAP will be performed by the Department and the Department's contractor. The Department is using the appropriate regulations and guidance documents for the 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 regulations and to protect health and safety.

4.4.5 Response to Incidents and Allegations

There were no incidents or allegations 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 found Illinois' performance to be satisfactory for seven performance indicators and satisfactory with recommendations for improvement for the non-common performance indicator, Legislation and Program Elements Required for Compatibility. Accordingly, the review team recommended and the MRB concurred in finding the Illinois Agreement State program to be adequate and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately four years.

Below is the recommendation, as mentioned earlier in 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. (Section 4.1.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Linda McLean, Region IV	Team Leader Uranium Recovery Program
Lance Rakovan, STP	Technical Staffing and Training Response to Incidents and Allegations
James Lynch, Region III	Legislation and Program Elements Required for Compatibility
Deborah Piskura, Region III	Status of Materials Inspection Program Technical Quality of Inspections
Ujagar Bhachu, NMSS	Sealed Source and Device Evaluation Program
Shawn Seeley, Maine	Technical Quality of Licensing Actions

APPENDIX B

ILLINOIS

DEPARTMENT OF NUCLEAR SAFETY

ORGANIZATION CHART

ML011070573

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: ADCO Services, Inc. License No.: IL-01347-01
Location: Tinley Park, IL Inspection Type: Routine, Announced
License Type: Waste Brokerage Service Priority: 0.5
Inspection Date: 11/13 & 17/00 Inspector: AS, RM

File No.: 2
Licensee: Baker Atlas License No.: IL-01508-01
Location: Olney, IL Inspection Type: Routine, Unannounced
License Type: Wireline/tracer studies Priority: 2
Inspection Date: 2/20/01 Inspector: GM

Comment:
a) Inspection report did not indicate that a management representative was contacted during the inspection.

File No.: 3
Licensee: The College of DuPage License No.: IL-01029-22
Location: Glen Ellyn, IL Inspection Type: Routine, Announced
License Type: Academic R&D Priority: 3
Inspection Date: 6/13/00 Inspector: JP

File No.: 4
Licensee: Cook County Hospital License No.: IL-01768-01
Location: Chicago, IL Inspection Type: Routine, Announced
License Type: Broad Scope Medical/Teletherapy Priority: 1
Inspection Date: 8/1-2/00 Inspector: RM, WH

File No.: 5
Licensee: Diagnostic Health Services License No.: IL-01397-01
Location: Bartlett, IL Inspection Type: Routine, Announced
License Type: Mobile Nuclear Medicine Priority: 2
Inspection Date: 9/10/99 Inspector: AG

File No.: 6
Licensee: Diagnostic Imaging Center License No.: IL-01082-01
Location: Des Plaines, IL Inspection Type: Routine, Announced
License Type: Specific Medical, Multi-site Priority: 2
Inspection Date: 3/22-23/00 Inspector: WM

Comment:
a) Notice of Violation issued 5/15/00, three weeks late.

File No.: 7
Licensee: Doctor's Hospital of Hyde Park License No.: IL-01846-01
Location: Hyde Park, IL Inspection Type: Special, Unannounced

License Type: Specific Medical (terminated)
Priority: 3
Inspection Date: 6/5/00
Inspector: JK, JP

File No.: 8
Licensee: Gunite, Corporation
License No.: IL-01616-02
Location: Rockford, IL
Inspection Type: Routine, Unannounced
License Type: Industrial Radiography
Priority: 1
Inspection Date: 1/23/98
Inspector: AG

File No.: 9
Licensee: Jan X
License No.: 77-00123-01
Location: Parma, MI
Inspection Type: Unannounced, Reciprocity
License Type: Industrial Radiography
Priority: 1
Inspection Date: 5/24/00
Inspector: JP

File No.: 10
Licensee: Kraft General Foods
License No.: IL-01585-01
Location: Glenview, IL
Inspection Type: Routine, Unannounced
License Type: Laboratory R&D
Priority: 3
Inspection Date: 6/17/98
Inspector: WH

File No.: 11
Licensee: Mc NDT
License No.: IL-01875-01
Location: Channahon, IL
Inspection Type: Routine, Unannounced
License Type: Industrial Radiography
Priority: 1
Inspection Date: 4/14 and 20/00
Inspector: WH

File No.: 12
Licensee: Memorial Medical Center
License No.: IL-01343-01
Location: Springfield, IL
Inspection Type: Routine, Unannounced
License Type: Specific Medical/ HDR
Priority: 1
Inspection Date: 3/30-31/00
Inspector: GM

File No.: 13
Licensee: Midwest Radiation Protection Services, Ltd.
License No.: IL-02046-01
Location: Naperville, IL
Inspection Type: Announces, Initial
License Type: Service
Priority: 3
Inspection Date: 6/14/99
Inspector: WH

File No.: 14
Licensee: Neutron Products, Inc.
License No.: 77-00113-01
Location: Dickerson, MD
Inspection Type: Unannounced, Reciprocity
License Type: Service (Source Installation)
Priority: 1
Inspection Date: 2/28/01
Inspector: JP

File No.: 15
Licensee: Northwestern Memorial Medical Center
License No.: IL-01037-02
Location: Chicago, IL
Inspection Type: Routine, Announced
License Type: Medical Broad Scope, Gamma Knife
Priority: 1
Inspection Date: 4/13-15/99
Inspector: JK, JP

File No.: 16
Licensee: Northwestern University License No.: IL-01879-01
Location: Evanston, IL Inspection Type: Routine, Announced
License Type: Academic Broad Scope Priority: 1
Inspection Date: 11/8-10/99 Inspectors: RM, BS

File No.: 17
Licensee: Pharmacy Services of Peoria, LLC License No.: IL-01874-01
Location: Peoria, IL Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 12/5/00 Inspector: GM

Comment:
a) Inspection overdue by 3 months.

File No.: 18
Licensee: Professional Laundry Management License No.: IL-01942-01
Location: Gardner, IL Inspection Type: Routine, Unannounced
License Type: Nuclear Laundry Priority: 1
Inspection Date: 7/27-28/99 Inspector: JP

File No.: 19
Licensee: Radiocat License No.: IL-02024-01
Location: Wheeling, IL Inspection Type: Announced, Initial
License Type: Veterinary Medicine Priority: 3
Inspection Date: 7/10/98 Inspector: JP

Comment:
a) Closing letter dated 9/14/98 sent out 51 days after licensee's response dated 7/25/98 to the Notice of Violation.

File No.: 20
Licensee: Rush-Presbyterian-St. Luke's Medical Center License No.: IL-01766-01
Location: Chicago, IL Inspection Type: Routine, Announced
License Type: Broad Scope Medical, HDR Priority: 1
Inspection Date: 5/8-10/00 Inspector: WH, RM

File No.: 21
Licensee: STERIS, Inc. License No.: IL-01123-01
Location: Libertyville, IL Inspection Type: Routine, Unannounced
License Type: Pool Irradiator Priority: 1
Inspection Date: 10/17/00 Inspector: RM

File No.: 22
Licensee: Thyroid Treatment Center of Illinois License No.: IL-01761-01
Location: Peoria, IL Inspection Type: Routine, Unannounced
License Type: Specific Medical Priority: 3
Inspection Date: 12/13/99 Inspector: BS

File No.: 23

Licensee: Valent Biosciences
License No.: IL-02094-01
Location: Long Grove, IL
Inspection Type: Announced, Initial
License Type: Specific R&D
Priority: 3
Inspection Date: 1/4/01
Inspector: RM

Comment:
a) Inspection 3 months overdue following initial license issued 4/18/00.

File No.: 24
Licensee: Kerr-McGee
License No.: STA-285
Location: West Chicago, IL
Inspection Type: Routine, Announced
License Type: Thorium Recovery
Priority: 1
Inspection Date: 2/23-27/98, 3/23-26/99, 4/19-21/00
Inspector: DP

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the IMPEP review.

File No.: 1
Licensee: Evanston Northwestern Healthcare
License No.: IL-01248-02
Location: Highland Park, IL
Inspection Type: Announced, Initial
License Type: Broad Scope Medical (Multi-site)
Priority: 1
Inspection Date: 1/31/01
Inspector: JK

File No.: 2
Licensee: Good Samaritan Hospital
License No.: IL-01041-01
Location: Downers Grove, IL
Inspection Type: Routine, Unannounced
License Type: Medical, Specific
Priority: 3
Inspection Date: 2/2/01
Inspector: AG

File No.: 3
Licensee: XRI
License No.: IL-01787-01
Location: Oak Lawn, IL
Inspection Type: Routine, Unannounced
License Type: Industrial Radiography (fixed only)
Priority: 1
Inspection Date: 2/6/01
Inspector: JP

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Robert Kohn, MD — License No.: IL-02110-01
Location: McHenry, IL — Amendment No.: 0
License Type: Medical - Private Practice — Type of Action: New
Date Amendment Issued: 12/21/00 — License Reviewer: DP

Comment:
a) License condition authorizing generator column disposal, yet no generators are authorized to be possessed on the license.

File No.: 2
Licensee: Syncor Corporation — License No.: IL-01220-01
Location: Springfield, IL — License Type: Nuclear Pharmacy
Amendment No.: 16 — Type of Action: Termination
Date Amendment Issued: 4/16/99 — License Reviewer: MB

File No.: 3
Licensee: Professional Laundry Management — License No.: IL-01942-01
Location: Gardner, IL — License Type: Nuclear Laundry
Amendment No.: 15 — Type of Action: Termination
Date Amendment Issued: 11/20/00 — License Reviewer: CV

File No.: 4
Licensee: Barber-Colman — License No.: IL-01005-01
Location: Loves Park, IL — License Type: Manufacturing & Distribution/R&D
Amendment No.: 2 — Type of Action: Termination
Date Amendment Issued: 9/21/99 — License Reviewer: MB

Comment:
a) Certificate of Disposition date incorrectly referenced on terminated license (should have been 7/9/99, not 7/7/99 as listed on license).

File No.: 5
Licensee: Trace Photonics — License No.: IL-02052-01
Location: Charleston, IL — License Type: R&D-Specific
Amendment No.: 0 — Type of Action: New
Date Amendment Issued: 4/8/99 — License Reviewer: DP

File No.: 6
Licensee: Valent Biosciences Corporation — License No.: IL-02094-01
Location: Long Grove, IL — License Type: R&D-Specific
Amendment No.: 0 — Type of Action: New
Date Amendment Issued: 4/18/00 — License Reviewer: SK

File No.: 7
Licensee: Ordner Well Services
Location: Clay City, IL
Amendment No.: 3
Date Amendment Issued: 7/15/99
License No: IL-01119-01
License Type: Wireline Service
Type of Action: Termination
License Reviewer: DP

File No.: 8
Licensee: Diagnostic Health Services
Location: Bartlett, IL
Amendment No.: 33
Date Amendment Issued: 10/30/00
License No: IL-01397-01
License Type: Mobile Nuclear Medicine
Type of Action: Bankruptcy
License Reviewer: Legal Staff

File No.: 9
Licensee: Pharmacy Services of Peoria
Location: Peoria, IL
Amendment No.: 12
Date Amendment Issued: 7/5/00
License No.: IL-01874-01
License Type: Nuclear Pharmacy
Type of Action: Renewal
License Reviewer: CV

Comment:
a) This license referenced RG DG-0006 in their previous renewal application. RG DG-0006 is no longer used with issuance of NUREG 1556, Volume 13.

File No.: 10
Licensee: Primex Technologies
Location: Marion, IL
Amendment No.: 9
Date Amendment Issued: 12/17/98
License No.: IL-01209-01
License Type: Product Distribution
Type of Action: Renewal
License Reviewer: TH

File No.: 11
Licensee: Cook County Hospital
Location: Chicago, IL
Amendment No.: 10, 11
Date Amendment Issued: 4/19/98; 10/10/00
License No.: IL-01768-01
License Type: Medical Broad
Type of Action: Renewal, Amendment
License Reviewer: DP

File No.: 12
Licensee: Northwestern University
Location: Evanston, IL
Amendment No.: 7, 8
Date Amendment Issued: 9/9/98; 11/22/99
License No.: IL-01879-01
License Type: Academic Broad A
Type of Action: Renewal, Amendment
License Reviewer: DP

File No.: 13
Licensee: Doctor's Hospital of Hyde Park
Location: Chicago, IL
Amendment No.: 7, 8
Date Amendment Issued: 11/30/98; 7/17/00
License No.: IL-01846-01
License Type: Medical-Private Practice
Type of Action: Amendment, Termination
License Reviewer: MB

File No.: 14
Licensee: Matsushita Industrial Equipment Comp. of America (MIECOA) License No.: IL-01112-01
Location: Elmhurst, IL License Type: Instrument Calibration
Amendment No.: 11, 12 Type of Action: Renewal/Amendment
Date Amendment Issued: 8/10/98; In Progress License Reviewer: TH, SK

File No.: 15
Licensee: Steris, Inc. License No.: IL-01123-02
Location: Mentor, OH License Type: Pool Irradiator >10,000
Amendment No.: 13, 14 Ci Type of Action: Amendment/Renewal
Date Amendment Issued: 7/17/00; 10/31/00 License Reviewer: SK, DP

Comment:
a) With the absence of irradiator regulations in Illinois, the staff relies on licensing by standard license condition for renewals.

File No.: 16
Licensee: Gunite Corporation License No.: IL-01616-02
Location: Rockford, IL License Type: Industrial Radiography
Amendment No.: 3 Type of Action: Amendment
Date Amendment Issued: 1/27/00 License Reviewer: MB

File No.: 17
Licensee: Radiocat License No.: IL-02024-01
Location: Springfield, VA License Type: Veterinary Nuclear Medicine
Amendment No.: 3 Type of Action: Amendment
Date Amendment Issued: 1/22/01 License Reviewer: SK

File No.: 18
Licensee: Solutia License No.: IL-01229-01
Location: Sauget, IL License Type: Fixed Gauge
Amendment No.: 16 Type of Action: Renewal
Date Amendment Issued: 3/2/99 License Reviewer: TH

File No.: 19
Licensee: CBI Services Inc. License No.: IL-01813-01
Location: Plainfield, IL License Type: Industrial Radiography
Amendment No.: 6, 7 Type of Action: Renewal, Amendment
Date Amendment Issued: 3/2/99; 10/10/00 License Reviewer: SK, TH

File No.: 20
Licensee: Kerr-McGee License No.: STA-285
Location: West Chicago, IL License Type: Thorium Recovery
Amendment No.: 47-55 Type of Action: Amendments
Date Amendment Issued: 1/27/98, 3/31/98,4/30/98, 11/2/98, 2/26/99, 9/29/99, 11/12/99, 2/28/00, 2/28/01 License Reviewer: DP, CH

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Wayne County Landfill — License No.: N/A
Site of Incident: Fairfield, IL — Incident Log No.: None (NMED #980156)
Date of Incident: 6/27/97 — Type of Incident: Lost or Stolen Material
Investigation Date: 6/30/97 — Type of Investigation: On-Site

Incident Summary and Final Disposition: The Wayne County Landfill reported that a shipment of household waste alarmed their radiation monitor. The waste was determined to contain I-131. Radiation readings at the surface of the bag were 1.5 mrem/hour. The landfill agreed to hold the waste for decay, but on later investigation, transferred the bag to the hauler (Wayne Berger of Noble, IL).

File No.: 2
Licensee: Lufthansa Airlines — License No.: N/A
Site of Incident: O'Hare Airport — Incident Log No.: None
Date of Incident: 8/1/98 — Type of Incident: Leaking Source
Investigation Date: 8/1/98 — Type of Investigation: On-Site

Incident Summary and Final Disposition: A package from Russia that was warm to the touch led airline staff to contact the Division. Readings and wipes revealed no contamination. The package contained 3900 Ci of Ir-192. It was concluded that the package was warm to the touch due to decay heat.

File No.: 3
Licensee: XRI Testing — License No.: IL-01787-01
Site of Incident: Oak Brook Terrace, IL — Incident Log No.: None
Date of Incident: 2/15/98 — Type of Incident: Accidental Exposure
Investigation Date: 2/20/98 — Type of Investigation: Phone

Incident Summary and Final Disposition: XRI was completing a number of radiographic exposures in the offices of Prime Electric. Employees had been notified of the exposures, and XRI staff had completed a thorough walk-down prior to taking any readings to ensure that the offices were vacant. An employee of Prime Electric was unaware of the work and was on-site. Upon finding the employee, XRI halted all testing. A dose assessment of the employee revealed a negligible dose was received.

File No.: 4
Licensee: Rush Presbyterian - St. Luke's Medical Center — License No.: IL-01766-01
Site of Incident: Chicago, IL — Incident Log No.: None
Date of Incident: 12/8/99 — Type of Incident: Overexposure
Investigation Date: 12/9/99 — Type of Investigation: Phone

Incident Summary and Final Disposition: The husband of a patient receiving a Cs-137 brachytherapy implant refused to leave the room, and thus stayed with the patient overnight and through the day. The husband was informed of all pertinent regulations and possible risks. A dose analysis revealed that the husband received approximately 156 mrem. A release of liability was obtained from the husband.

File No.: 5
Licensee: Ravenswood Hospital
License No.: IL-01175-01
Site of Incident: Chicago, IL
Incident Log No.: None (NMED #990399)
Date of Incident: 3/9/99
Type of Incident: Contamination Event
Investigation Date: 3/9/99
Type of Investigation: Phone

Incident Summary and Final Disposition: The licensee reported that a 10 mCi I-131 diagnostic capsule spilled as the dosage was being administered. The capsule was cracked and when it was placed into the patient's hand, an unknown quantity spilled onto the floor and around the chair. Decontamination on 3/10/99 was successful and bioassays showed no intake by the nuclear medicine staff. The licensee's corrective action is to use pill administration cups instead of placing the capsules directly into the patient's hands.

Comment:
a) No mention of incident follow up during next inspection.

File No.: 6
Licensee: Melrose Park Transfer Station
License No.: N/A
Site of Incident: Melrose Park, IL
Incident Log No.: IL010010 (NMED #010207)
Date of Incident: 12/12/00
Type of Incident: Lost or Stolen Material
Investigation Date: 12/13/00
Type of Investigation: On-Site

Incident Summary and Final Disposition: The Melrose Park transfer station reported that a load of waste triggered their radiation monitor alarm. Due to severe weather conditions, an inspector could not investigate the monitor trip until the next day. On 12/13/00, an inspector investigated the load responsible for the monitor trip and identified the radionuclide as I-131. Due to the radionuclide involved and the radiation levels observed, the material was allowed to be released for further processing and disposal.

File No.: 7
Licensee: SENCO Construction
License No.: IL-02002-01
Site of Incident: Robinson, IL
Incident Log No.: IL010005
Date of Incident: 10/26/00
Type of Incident: Equipment Failure, Overexposure
Investigation Date: 11/1/00
Type of Investigation: On-Site

Incident Summary and Final Disposition: While performing radiography using an Ir-192 source at a refinery, a radiographer received a possible overexposure when the source was retracted but not locked in the camera. Survey instrumentation indicated background readings, but the radiographer, who was not wearing his alarming dosimeter, noted that the source was not in the "safe" position. The radiographer's dose was estimated to be approximately 560 mrem. No equipment problems were encountered other than dead batteries in the survey meter. A Notice of Violation was issued.

File No.: 8
Licensee: Applied Soil Mechanics, Inc.
License No.: IL-01473-01
Site of Incident: Oak Brook, IL
Incident Log No.: None (NMED #000086)
Date of Incident: 11/19/99
Type of Incident: Damaged Equipment
Investigation Date: 11/19/99
Type of Investigation: On-Site

Incident Summary and Final Disposition: A Humbolt Scientific portable moisture/density gauge was damaged when it was struck by a steam roller at a temporary job site. The gauge contained 10 mCi Cs-137 and a 40 mCi Am-Be source. The Cs-137 rod was severed and dose

rates at one foot were greater than 100 mrem/hr. Wipes revealed no contamination. Additional shielding was provided and the gauge was placed in a secure area. The gauge was eventually transferred to Humbolt Scientific. A Notice of Violation was issued.

File No.: 9
Licensee: Minwax License No.: General License
Site of Incident: Flora, IL Incident Log No.: DRM 01-02 (NMED #990842)
Date of Incident: 11/1/99 Type of Incident: Contamination Event
Investigation Date: 11/3/99 Type of Investigation: On-Site

Incident Summary and Final Disposition: An individual smashed a tube from a self powered exit sign containing 2 Ci of H-3 inside his residential garage. The garage was surveyed and an estimated dose of 7.1 mrem TEDE was calculated for the man. The employer was not aware that the sign contained radioactive material. A contractor installed the signs and only the newest sign had radiation caution symbols in view. The Division performed an extensive decontamination over the course of several months. The cost of the decontamination was paid by the company.

File No.: 10
Licensee: Provena - St. Joseph Medical Center License No.: IL-01326-01
Site of Incident: Joliet, IL Incident Log No.: IL-990020 (NMED #990204)
Date of Incident: 2/99 and 3/99 Type of Incident: Misadministration
Investigation Date: 3/25/99 Type of Investigation: Next Inspection

Incident Summary and Final Disposition: A decay error involving an HDR source resulted in a 31% underdose to three patients. The apparent cause of the misadministrations was the use of the certificate activity of the source instead of the current/decayed activity for the dose planing. The device was a Nucletron Microselectron HDR with an Ir-192 source. The attending physicians were informed of the incidents. One of the three patients was recalled to complete the plan, another was not given additional dose because the physician decided surgery was necessary, and the third was given no additional dose because the pallative treatment was already successful.

Comment:
a) No mention of incident follow up during next inspection.

File No.: 11
Licensee: Rush Presbyterian - St. Luke's Medical Center License No.: IL-01766-01
Site of Incident: Chicago, IL Incident Log No.: IL000002
Date of Incident: 10/5/99 Type of Incident: Equipment Failure
Investigation Date: 10/11/99 Type of Investigation: None

Incident Summary and Final Disposition: A patient was being treated with a Novoste Corporation Beta-Catheter treatment device containing a total of 18 seeds of Sr-90 (56 mCi). At the conclusion of this treatment, staff could not visually verify the presence of all the seeds within the machine. One seed was lodged in machine, but its location could not be determined. Novoste Corporation personnel dismantled the machine and found the seed stuck to a magnet. One of the seeds involved was determined to be damaged. All of the seeds were leak tested and none, including the damaged one, were leaking.

Comment:
a) No mention of incident follow up during next inspection.

APPENDIX F

SEALED SOURCES AND DEVICE (SS&D) CASEWORK REVIEWS

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

File No.: 1
Registry No.: IL-234-D-102-G SS&D Type: "C-Arm" or Fixed Arm Thickness Gauge
Manufacturer: E.S.C. Resources, Inc. Model No.: SH-6090
Date Issued: 4/1/97

Comments:

a) The registration certificate pages 1-9 show registry number as IL-234-D-102-**G**. Attachments 1-5 of the certificate show the registry number as IL-234-D-102-**S**.

b) Page 1 of the certificate indicates source isotope as Strontium 90 and source Model as SIF.D1, (Now Medi Physics, Inc. IL-136-S-194-S). Attachment 2 & 3 to the certificate indicate source Model Amersham Model AMC.19 which has not been approved for Strontium 90.

c) Page 1 of the certificate indicated maximum activity as 100 mCi +25%/ -10%, however, Page 5 indicated maximum radiation distance dose levels for 100 mCi, Strontium 90 sealed source.

d) Not all dimensions were stated in dual units (Metric & English).

e) The ANSI N538 rating is shown on page 5 as 33-244-775-R-2. Based on the interpretation of the data provided by the manufacturer, the rating should be 33-244-565-R-2.

f) The need and the rationale for impact testing prototype three times from a height of six feet was not available.

g) The second paragraph under the title LIMITATIONS AND CONSIDERATION OF USE should specifically state the safety features to be tested at six month intervals or provide specific references. Paragraph five is redundant and conflicts with paragraph six.

h) The product maximum size, density, and configuration to be measured, and the weight of the device frame structure was not available from the files; as a result, the impact and severity of the curling forces may not have been fully evaluated.

File No.: 2
Registry No.: IL-136-S-195-S
SS&D Type: Industrial Gauge Source
Manufacturer: Amex-sham Buckler, Germany & Amex-sham International, PLC, England
Model No.: SIF.P1
Date Issued: 6/10/97

Comments:

a) Two manufacturers of this source are located in two foreign countries. It was not clear from the files how and who allocated and controlled the serial numbers for the sources.
b) Under heading of MAXIMUM ACTIVITY, the capsule codes are given specific numbers and some times the capsule drawing numbers, and the certificate requires that licenses be issued to a source Model SIF.P1.
c) The rationale for testing the source window to 87 PSI was not available from the case files.
d) The rationale for testing the source window weld as more vulnerable than the weldment imbrittlement zone was not documented.
e) The information on how and at what intervals the records and documents are forwarded by the foreign manufacturers to the USA distributors was not available.

File No.: 3
Registry No.: IL-234-D-101-G SS&D Type: "C-Arm" or Fixed Frame Thickness Gauge
Manufacturer: E.S.C. Resources, Inc. Model No.: SH-6000
Date Issued: 9/25/97

Comments

a) The registration certificate pages 1-9 show registry number as IL-234-D-101-**G**. Attachments 1-5 of the certificate show the registry number as IL-234-D-101-**S**.
b) Page 1 of the certificate indicates source isotope as Strontium 90 and source models, Amex-sham Model AMC.19 and Bebig Trade Inc. G44 and G55. Attachment 2 to the certificate indicates source Model Amersham Model AMC.19 only.
c) Not all dimensions were stated in dual units (Metric & English).
d) The ANSI N538 rating shown on page as 33-443-**765**-R-2. Based on the interpretation of the data provided by the manufacturer the rating should be 33-443-**585**-R-2.
e) The need and the rationale for impact testing prototype three times from a height of six feet was not available.
f) The second paragraph under the title LIMITATIONS AND CONSIDERATION OF USE should specifically state the safety features to be tested at six month intervals or provide specific references. Paragraph five is redundant and conflicts with paragraph six.
g) The product maximum size, density and configuration to be measured, and the weight of the device frame structure were not available from the files; as a result, the impact and severity of the curling forces may not have been fully evaluated.
h) The maximum measuring gap of 8 inches is considered accessible. The State has no guidance for the maximum gap accessibility.
I) Generation and depiction of product run-out was not documented in the files.
g) Adequate safety instructions were not available related to movement of the gauge from the fixed position for maintenance.
h) This certificate was issued on 2/15/96, 6/30/97, and again on 9/27/99. There is no indication on these issues as to why the certificate was reissued.

File No.: 4
Registry No.: IL-605-D-105-S
SS&D Type: Line Source Holder/Attenuation Correction Device
Manufacturer: Siemens Medical System
Model No.: Profile Attenuation Correction System
Date Issued: 2/14/01

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) The certificate was amended in its entirety. Addition of a new supplier and related model was obvious; however, it was not easy to decipher as to what other changes were made to the certificate (i.e., number of pages changed from 7 to 8).
c) Spring operated shutter maximum, measured, and required tension setting at various temperatures were not available (i.e., at what temperature the spring tension will not be adequate to shut the shutter on a loss of power).
d) It was not clear as to how source shutter 0.22" maximum stroke and closing time of 500 msec was assimilated in the prototype testing. The initial application stated 750,000 shutter test cycles were replaced by 187,000, of which 88,000 were done at an elevated temperature. Under PROTOTYPE TESTING heading, the number of cycles tested are indicated as 223,600.
e) A accident report was filed in this application.
f) Although not indicated in the certificate, the review of the file indicated that readings taken by the Micro R Ion Chamber were corrected by using an appropriate absorber. The dose readings appearing under heading MAXIMUM RADIATION LEVELS in μSv/hr should be stated as mrem/hr and not mR/hr.

File No.: 5
Registry No.: IL-495-D-801-S
SS&D Type: Therapeutic Sealed Source
Manufacturer: Molesgaurd Medical, Denmark
Model No.: ND 1100
Date Issued: 5/21/99

File No.: 6
Registry No.: IL-103-S-110-S
SS&D Type: Therapeutic Sealed Source
Manufacturer: BEBIG Isotopentechnik Und Umweltdiagnodtik, Germany
Model No.: 125.S06
Date Issued: 5/25/99

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) 10 CFR 20.203 is an incorrect reference for label requirements.
c) Sv/hr is a biological dose rate and its equivalent is mrem/hr.

File No.: 7
Registry No.: IL-1082-S-102-S SS&D Type: High Energy Gamma Source
Manufacturer: REVISS Services (UK) Limited Model No.: R6000
Date Issued: 9/28/99

Comments:
a) IL-1082-S-102-S supersedes IL-136-S-197-S. This appears this is a new certificate, yet is categorized as AMENDED IN ITS ENTIRETY.
b) Under title DESCRIPTION, it is stated, "Models CDC.PE1 and CDC.PE2 which were formerly included in this directory have been inactivated." As some of these models may still be operating under licenses previously issued, the description could have stated the production and distribution of these models was discontinued, as well as the serial number and date on which the distribution of these models was discontinued in USA.
c) Maximum source activity is shown on page 1 of the certificate as 3,500 Ci, Cesium-137. A note under Table 1 states, .." activity +/- 10% not to exceed maximum. The table shows an activity of 3500 for Model R6060. Under LABELING, the nominal activity is shown as +/- 20%. Furthermore, the activity for model R6060 is shown as 2200 Ci.

File No.: 8
Registry No.: IL-136-S-338-S SS&D Type: Therapeutic Sealed Source
Manufacturer: Medi-Physics, Inc. Model No.: 6711
Date Issued: 5/31/00

Comments:
a) Not all dimensions were stated in dual units (Metric & English)
b) 10 CFR 20.203 is an incorrect reference for label requirements
c) Under PROTOTYPE TESTING, ANSI N43.6-1977 is incorrectly stated. The correct reference is ANSI 43.6-1997.
d) The application is made by Nycomed Amersham and the certificate has been issued to Medi-Physics Inc.

File No.: 9
Registry No.: IL-1083-D102-G SS&D Type: Beta Gauge
Manufacturer: TAPIO Technologies, Finland Model Nos.: BW-2h55 and BW-5h23
Date Issued: 9/1/00

Comments:
a) 1000 shutter cycle test seems unnecessary.
b) First paragraph of the SAFETY ANALYSIS is not clear. (Washington License)
c) On Page 7, the regulatory requirement packages associated with the general license should be supplied by the distributor or the manufacturer to the end user.
d) The files did not address the sequence of events on paper-run out.
e) The registration certificate is for a General License. The registration certificate did not contain a statement that removal of the label is prohibited. The applicant has submitted a label sample that included the statement that the removal of the label is prohibited. This certificate is undergoing a revision.

File No.: 10
Registry No.: IL-422-D-101-S SS&D Type: Portable Flouroscope
Manufacturer: Lixi, Inc. Model Nos.: LS-80X, LS-82X,LSM-80X
Date Issued: 9/22/00 or LSM-82X Where, X=1,2,3..

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) 10 CFR 20.203 is an incorrect reference for label requirements.
c) This certificate deleted all references to the correspondence and the enclosures prior to the re-application of December 1993. The certificate continues to refer to the draft of ANSI N432 although this standard was finalized and reissued. The rationale for the removal of previous referenced documents from the registry and the case files was not available.

File No.: 11
Registry No.: IL-422-S-102-S SS&D Type: Low Energy Photon Source
Manufacturer: Lixi, Inc. Model No.: C-381
Date Issued: 9/22/00

Comments:
a) Not all dimensions were stated in dual units (Metric & English).
b) The year of ANSI N43.6 is given as 1977; it should be 1997 (see pages 3 and 5 of the certificate).
c) As a foreign vendor, Nordion is not required to have offices in USA. Although Nordion inspections are conducted solely by NRC Region 1, this source is specifically manufactured by Nordion-Canada for a specific Lixi Device. The Department reviewed both the source and the device and Lixi is responsible for Nordion's activities related to the fabrication and manufacture of sources in Canada.

Attachment

April 30, 2001 Letter from Thomas W. Ortciger
Illinois' Response to Draft IMPEP Report
ML011230448

RESPONSE TO ILLINOIS COMMENTS
TO THE DRAFT IMPEP REPORT

Comment 1:
First paragraph, 4th sentence of the April 10, 2001 letter transmitting the draft report, states, "The review team's recommendations were discussed with you ... review." There was no recommendation discussed regarding training concerns on the part of the IMPEP team.

Response:
Based on this comment, we will revise the boilerplate letter that accompanies draft IMPEP reports to state that: "The review team's preliminary findings were discussed..." (emphasis added). This language better describes the information discussed on-site and allows for cases when preliminary findings are revised such as the addition of a recommendation. There will be no change to the report based on this comment.

Comment 2:
Page 3, 2nd paragraph, 2nd sentence, states, "The Division's policy requires the findings to be dispatched within 30 days following the inspection." The first part of the sentence needs to be changed to, "The Division has a goal that the findings... inspection."

Response:
We agree with this comment and the report will be revised accordingly.

Comment 3:
Page 5, last two paragraphs: The penultimate paragraph acknowledges that a complete and updated written training program based on the NRC/Organization of Agreement States (OAS) Training Working Group Report was established for use by the materials license reviewer hired during the review period. The report continues, "The review team found the program acceptable for his training. The Division Director (should be changed to Division Chief) stated that a similar program would be created if a new inspector were hired." We have no problem with this paragraph, and we were informed by the IMPEP team that this satisfied any concerns about a documented training program for the Division. However, the first sentence in the last paragraph on page 5, states that, "One topic included in the NRC/OAS report that was lacking in the Division's training program was refresher training." The report then discusses the importance of refresher training and its advantages. We do not disagree with the importance and advantages of refresher training and we spend enormous resources to provide such training routinely. We have an extremely aggressive refresher training program as evidenced by the information contained in Appendix A. This is a listing of all the training accomplishments for our staff. We could have provided this information during the IMPEP visit if asked, but it was not. It astounds us that something that is barely mentioned during the IMPEP visit becomes one of two recommendations in the Draft IMPEP report. This is unacceptable and undermines the constructive efforts of the IMPEP review. Fortunately, the review team recommended that Illinois' performance with respect to the indicator, Technical Staffing and Training, was found to be satisfactory. Unfortunately, the recommendation concerning this item appears on page 17 in the Summary Section of the Draft Report as one of only two recommendations for the entire IMPEP review. This Recommendation should be deleted from the Report.

Response:

We agree with that comment that “Division Director” should be changed to “Division Chief.”

The review team acknowledges that refresher training is indeed provided by the Division and appreciates the materials submitted with the Division’s reply to the draft IMPEP report. Recommendations involving written training programs, however, are not uncommon in IMPEP reports. Similar recommendations have been made in at least a dozen past IMPEP reviews and final reports. Although this topic was not initially discussed as a recommendation during the on-site review, the review team believes that recommending a general written training program follows past IMPEP policy and consistent with the NRC/OAS Training Working Group Recommendations for Agreement State Training Programs. Thus, though the last paragraph on page 5 will be revised as noted below, the review team believes that the MRB should decide if this recommendation should be included in the final report.

> Discussions with staff members confirmed that though inspectors and license reviewers are confident in their training to perform assigned tasks, supplemental or refresher training would be beneficial for experienced staff members. The advantages of this type of training was discussed with Division management, especially with the increased emphasis on performance-based inspections. In their April 30, 2001 reply to the draft IMPEP report, the Division enclosed details of staff refresher training. The review team acknowledges that the Division does indeed focus resources on refresher training, however the Division does not have a documented training program for all technical staff. The review team recommends that the Division establish a documented training program including refresher training for technical staff as recommended in the NRC/OAS Training Working Group Report.

Comment 4:
Page 8, 4th paragraph, 6th line: "The procedure details the responsibilities of the RDO, a rotating position within the Division. ..response." The word "Division" should be changed to "Department" in this sentence.

Response:
We agree with this comment and the report will be revised accordingly.

Comment 5:
Page 8, 5th paragraph, 1st sentence: Due to the Division not differentiating between incidents and allegations and the lack of an internal incident tracking system prior to 1999, the review team was unable to determine how many. ..Events." Prior to 1999, we had an internal tracking system that worked quite well. However, we finally succumbed to the desires of NRC and terminated use of our existing database and converted to sole use of the NMED program, even with all its nuances and inadequacies. If we had not done so we could have continued use of our system and readily provided the information necessary for review.

Response:
The review team agrees that this language does not correctly reflect the circumstances describe. The phrase “and the lack of an internal incident tracking system prior to 1999,” will be removed from the report. We appreciate the effort that the Division puts forth to participate in the NMED program.

Comment 6:

Page 9, penultimate sentence, 2nd paragraph, states, "The Department's procedures for handling incidents are incomplete in terms of handling "allegations." We do treat incidents the same and the sentence before the penultimate acknowledges that the Division took appropriate action on all allegations, including "responding to the allegers when appropriate." Therefore, the performance of the Division was appropriate and satisfactory and, even though the procedure for incidents does not address all items concerning "allegations", the review team found this criteria satisfactory without any associated "recommendation." his is consistent with the performance-based approach of IMPEP and should have been used in the Technical Staff Training criteria.

Response:
There will be no revision to the report based on this comment.

Comment 7:
Page II, first bullet regarding "Radiological Criteria for License Termination:" A sentence should be added that states, "The 25 mrem criteria is currently enforced through licensing and termination procedures." Because this requirement is enforced by the Division, by "other legally binding requirements," this item should not count as one of the four regulations referenced on Page 13 that have not been adopted within three-years of NRC rules and should be moved to Page 12 under the "compatible legally binding requirement" header.

Response:
We agree that this rule should not be included in the list of those regulations not adopted within three years of the NRC rule and the report will be revised accordingly. Either the Division's process noted here or the draft rule needs to be evaluated by NRC following STP Procedure SA-201.

Comment 8:
Page II, 2nd paragraph: We provided all the information concerning the Department's exemption process allowing release of patients administered radioactive material on a case-by-case basis. We suggest adding, "NRC will contact the state when its evaluation is completed." as the last sentence to this paragraph.

Response:
We agree with this comment and the report will be revised accordingly.

Comment 9:
Page 17, Recommendation 1. at the bottom o f the page: delete this recommendation!

Response:
See our response to Comment 3.