



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 13, 2008

Mr. Dennis Burke
Chief of Staff
Office of the Governor
1700 West Washington St.
Phoenix, AZ 85007

Dear Mr. Burke:

On July 21, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Arizona Agreement State Program. The MRB found the Arizona Program adequate, but needs improvement, to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC's) program. Because of the significance of the findings, the MRB determined that the Arizona Program should undergo a period of Heightened Oversight. Heightened Oversight is an increased monitoring process the NRC uses to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate Arizona and NRC managers and staff members.

Section 5.0, page 16, of the enclosed final report contains a summary of the review team's findings and recommendations for the Arizona Agreement State Program. We request that you prepare and submit a program improvement plan as part of your response to the review team's recommendations. I ask that you have your staff discuss the required elements of this plan with Mr. Robert Lewis, Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, to ensure that the "get-well" path and measures of success are clearly identified. The plan should be submitted within 30 days of receipt of this letter. Upon review of your program improvement plan, NRC staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than October 1, 2008. Based on the results of the current IMPEP review, a followup review will be scheduled approximately one year from the date of the March 2008 IMPEP review. The followup review will cover the State's actions in response to the recommendations in the enclosed final report.

D. Burke

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

Sincerely,

/RA/

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

Enclosure:
Arizona Final IMPEP Report

cc w/encl.:

Tracy Hannah, Policy Advisor
Arizona Office of the Governor

Aubrey Godwin, Director
Arizona Radiation Regulatory Agency

Cheryl Rogers, Wisconsin
Organization of Agreement
States Liaison to the MRB



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE ARIZONA AGREEMENT STATE PROGRAM

March 10-14, 2008

FINAL REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the Arizona Agreement State Program. The review was conducted during the period of March 10-14, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the Commonwealth of Massachusetts, and the State of Minnesota. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of February 11, 2006 to March 14, 2008, were discussed with Arizona managers on the last day of the review.

A draft of this report was issued to Arizona for factual comment on April 10, 2008. The State responded by letter on May 14, 2008, from Dennis Burke, Chief of Staff, Office of the Governor. A copy of the State's response is included as an attachment to this report. The Management Review Board (MRB) met on July 21, 2008, to consider the proposed final report. The MRB found the Arizona Agreement State Program to be adequate, but needs improvement, to protect public health and safety and compatible with NRC's program. Because of the significance of the findings, the MRB determined that the Arizona Agreement State Program should undergo a period of Heightened Oversight by the NRC.

The Arizona Agreement State Program is administered by the Arizona Radiation Regulatory Agency (the Agency). The Agency Director reports directly to the Governor. The day-to-day operations of the Arizona Agreement State Program are managed by the Radioactive Materials & Nonionizing Radiation Compliance Program (the Program). An organization chart for the Agency and Program is included as Appendix B.

At the time of the review, the Agency regulated 375 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Arizona.

The previous IMPEP review of the Arizona Agreement State Program concluded on February 10, 2006. That review identified that the Agency had difficulty with recruiting and retaining qualified staff which resulted in the inability to perform inspections in a timely manner. The review team found Arizona's performance to be unsatisfactory for the performance indicator, Status of Materials Inspection Program, and satisfactory, but needs improvement, for the performance indicator, Technical Staffing and Training. As a result, the MRB directed NRC staff to hold a periodic meeting with the State in 2007 to determine when the next IMPEP review should be scheduled.

On March 1, 2007, a periodic meeting was held with the Agency to review progress made in the Agreement State Program. The reviewers identified that some progress had been made to complete overdue high priority inspections, but that some 187 medium-risk licenses were overdue for inspection. The MRB directed NRC staff to perform a full IMPEP review of the

Arizona Agreement State Program in 2008, due to identified concerns with staff turnover rates and timeliness of inspections.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Agency on November 16, 2007. The Agency provided its response to the questionnaire on March 5, 2008. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML073201200.

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

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 10, 2006, the review team made five recommendations in regard to program performance. The current status of each recommendation is as follows:

1. The review team recommends that the Agency develop and implement a staffing plan to fill the current vacancy, meet growing Program needs and maintain long-term stability. (Section 3.1 of the 2006 IMPEP report)

Current Status: In response to the previous IMPEP review, the Agency submitted a simplified staffing and budget plan covering fiscal years 2007 to 2011, which addressed projected staffing changes, potential salary increases, and Agency budget. The plan was updated for fiscal year 2008. The program staffing is discussed in more detail in Section 3.1. This recommendation is closed.

2. The review team recommends that the Agency take appropriate measures to conduct core inspections (including initial inspections) in accordance with the inspection priority schedule in IMC 2800, and conduct reciprocity inspections in accordance with IMC 1220. (Section 3.2 of the 2006 IMPEP report)

Current Status: The review team determined that 58 of the 86 Priority 1, 2, and 3 and initial inspections (core inspections) selected as a representative sample of inspections

conducted by the Agency during the review period were performed overdue. The review team also identified 15 core inspections that were overdue at the time of the review. Additionally, reciprocity inspections were conducted less frequently than required by Inspection Manual Chapter (IMC) 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." This recommendation remains open.

3. The review team recommends that the Agency review all Arizona licenses to ascertain if they require financial assurance, and take appropriate action on each affected license to ensure that all licenses meet the State's financial assurance requirements. (Section 3.4 of the 2006 IMPEP report)

Current Status: The Agency reviewed all of the Arizona licenses and implemented the appropriate license conditions, when applicable, to ensure that all licenses meet the State's financial assurance requirements. This recommendation is closed.

4. The review team recommends that the Agency develop a process that allows for the adoption of NRC regulations within the three-year timeframe. (Section 4.1.2 of the 2006 IMPEP review)

Current Status: The Agency developed a process after the 2006 review to ensure that rulemaking packages are initiated promptly after notification from NRC of a compatibility-required regulation so that adequate time is allowed for rule promulgation. Arizona regulations are currently up to date. This recommendation is closed.

5. The review team recommends that the Agency develop and implement a process to ensure that, during routine inspections, the QA/QC requirements in the SS&D registry sheets are being implemented by the manufacturer. (Section 4.2.2 of the 2006 IMPEP review)

Current Status: The Agency developed a process that ensures that the quality assurance/quality control (QA/QC) requirements in the sealed source and device (SS&D) registration certificates are being implemented by the manufacturer. Agency inspectors use a checklist to review the licensee's QA/QC procedures when performing an inspection of the licensee's facility. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include staffing levels and turnover, in addition to the staff's technical qualifications and training histories. To evaluate these issues, the review team examined the Agency's questionnaire response relative to this indicator; interviewed managers and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs stemming from turnover and vacancies or inadequate staffing levels.

The Agency is comprised of several regulatory programs, one of which is the Radioactive Materials and Nonionizing Radiation Program (the Program). The Program is responsible for radioactive materials licensing, inspection, and some emergency response activities. At the time of the review, the Program was staffed by a Program Manager and four technical staff members. The technical staff members perform licensing and inspection activities and assist the Emergency Response Program on incident response. New staff members were hired in August 2006 and May 2007 to fill vacancies and are currently being trained. The Program was fully staffed at the time of the review.

Technical staff members are required to have a Bachelor's degree in a science or equivalent Health Physics experience. As was noted during the 2006 IMPEP review, the Agency has been able to recruit staff; however, several personnel have left for higher paying jobs after qualification. This remains an issue for the Agency, as salaries are low compared to nearby industry and academic pay scales. A pay raise is not anticipated in fiscal year 2009.

The review team noted that one of the senior staff members, who performs most of the on-the-job training for newer staff members, is planning to retire at the end of 2008. This issue was discussed with Agency managers, who acknowledged the issue and indicated that they were researching future staffing solutions. During the previous IMPEP review, a recommendation was made that the Agency develop and implement a staffing plan to meet Program needs and maintain long-term stability. In response to the recommendation, the Agency submitted a staffing and budget plan. That plan, recently revised, calls for the conversion of two technical positions from "covered" to "uncovered." An uncovered position provides the Director a 15 percent latitude in salary negotiation. Currently, the Director, the Program Manager, and two of the four technical positions in the Program are uncovered. The Director indicated that this process may help, to a small degree, to retain staff members, but will not alleviate the turnover issue because of the low Agency salary structure.

The Agency has a documented training plan equivalent to the guidance in NRC's IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The Program Manager and the staff members were not aware of the Agency's training plan; therefore, the prescribed qualification journals were not being used for the two staff members currently in training. The review team recommends that the State develop and use qualification journals to track and monitor training for technical staff.

Two Agency staff members attended the NRC's Security Systems and Principles Course and were qualified to perform Increased Controls inspections. During this review, team members provided Agency managers and staff with detailed information regarding the upcoming fingerprinting requirements.

Agency managers stated that NRC's recent policy change to cover Agreement State training costs will allow the State to send staff members to training courses which would not have been otherwise possible. As a result, staff members were recently enrolled in upcoming Inspection Procedures, Irradiator Technology and Security training courses.

As detailed in Section 3.4, the review team identified that many licensing products generated by the Agency were of poor quality. The root cause of the deficiencies was determined to be a lack of training received by the staff member who performs a majority of the licensing actions. This individual has not attended the nuclear medicine or the brachytherapy training courses. The review team recommends that the State ensure that license reviewers be provided appropriate training to ensure familiarity with medical license modalities.

NRC Region IV representatives offered the Agency an invitation for license reviewers to receive on-the-job licensing training in Arlington, Texas. The Agency Director indicated that current budget restrictions may prohibit out-of-state travel.

The Arizona Agreement State Program is funded entirely by general fund allocations. Fees collected from licensees go directly into the general fund. The Agency is authorized to assess and collect fees for specific and general radioactive materials licenses, radiation machine registrations, and medical technologist certifications. The fees collected by the Agency amount to approximately 70 percent of the general fund allocations received. The last fee change was in 1993 and was based upon 1987 costs.

Over the past several years, budgeting for the Agency has been subject to various cuts and restrictions. In early 2008, for a short period of time, travel restrictions were instituted that prohibited the use of State vehicles by inspectors. To perform an inspection, an inspector would have to use a personal vehicle with no cost reimbursement. During this time, inspectors were unwilling to perform inspections outside of the Phoenix area because of the personal costs. This restriction was lifted after a few days, but with continuing budget crises looming, the Agency Director said that similar restrictions may be implemented in the future.

The budget for fiscal year 2009, starting July 1, 2008, has been approved with one new position slated for the Program. The Agency Director indicated, however, that due to State budget deficit projections, serious budget cuts are anticipated.

The Radiation Hearing Board of the State of Arizona, as constituted under law, avoids conflicts of interest, as required under Arizona Revised Statutes in Section 38-511. The Board conducts hearings and reviews orders of the Director or the Agency.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, Technical Staffing and Training, was satisfactory, but needs improvement.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based

on the Agency's questionnaire response relative to this indicator, data gathered from the Agency's database, examination of completed inspection casework, and interviews with the Program Manager and staff.

The review team determined that the Agency's inspection priorities are determined by a license category assigned to each license. The review team identified a significant number of medical licensees authorized for uses requiring a written directive that were incorrectly categorized and assigned a longer inspection frequency than prescribed by IMC 2800, "Materials Inspection Program." As a result, the review team found it difficult to identify the correct inspection frequency for all medical licenses without reviewing 100 percent of the Agency's license files. Due to the miscategorization of medical licenses, the review team elected to evaluate a sample of Priority 1, 2, and 3 inspections; initial inspections; and reciprocity inspection files. The review team determined that other (non-medical) inspection frequencies were at least as frequent as the frequencies prescribed by IMC 2800.

The review team evaluated inspection files for 70 Priority 1, 2, and 3 inspections and 16 initial inspections conducted by the Agency during the review period. The review team determined that 77 percent of these inspections were conducted overdue per the criteria in IMC 2800. In addition, 14 inspections of Priority 1, 2, and 3 licenses and 1 new license were overdue for inspection at the time of the review. This represents a significant decline in the timeliness of inspections since the 2006 IMPEP review, when the Agency was found to have 31 percent of its Priority 1, 2, and 3 and initial inspections performed overdue. The review team noted that the Agency increased its effort to conduct more inspections in the third and fourth quarters of 2007 in an attempt to reduce the backlog.

During the review period, the Agency received reciprocity requests from 63 licensees, of which 27 were candidate for inspection. The review team determined that the Agency conducted 15 percent of the candidate reciprocity inspections during the review period, which represented a small decline in performance since the 2006 review, when the Agency performed 17 percent of the candidate reciprocity inspections during that review period. The Agency did not meet the 20 percent criterion prescribed by IMC 1220.

The review team discussed the significant number of overdue inspections and inspections completed overdue, as well as performance of reciprocity inspections, with the Program Manager and the Agency Director. The review team identified two root causes for the inspection program performance weaknesses.

The review team determined that one of the root causes for the inspection delays is the lack of fully qualified inspectors. Another root cause is that many licenses issued by the Agency were incorrectly prioritized. Because the concerns identified during the 2006 IMPEP review have not been resolved, the review team recommends that the recommendation regarding timeliness of inspections made during that review remains open.

Arizona law requires, in part, that when an agency conducts an inspection, they must provide a copy of the inspection report to the licensee within 30 working days after the inspection. The review team evaluated the Program's timeliness of issuance of inspection reports. In most cases, the preliminary findings of inspection reports were sent to the licensees within 30 calendar days, and generally within 2-5 calendar days of the inspection date.

The review team determined that the Agency adequately planned for the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Agency's prioritization methodology and found it acceptable. The Agency identified 14 licensees that are subject to the Increased Controls and performed all of the first-year inspections in a timely manner.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, Status of Materials Inspection Program, was unsatisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 30 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by the four current Agency inspectors and covered a wide variety of inspection types, including: broadscope medical, broadscope academic, industrial radiography, self-shielded irradiators, medical, nuclear pharmacy, Increased Controls, and reciprocity. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections included all aspects of the licensees' radiation safety programs. The review team found that inspection reports were generally thorough, complete, and consistent, with sufficient documentation to ensure that licensees' performances with respect to health and safety were acceptable. Inspection report documentation supported violations and summarized discussions held with licensees during exit interviews.

Inspection findings were clearly stated and documented. If potential violations are identified during an inspection, the Agency issues a "preliminary findings of inspection" report. The Agency identifies proposed violations and any items of concern to the licensee in this report. The licensee is required to respond to the preliminary findings within 30 days. If the violations are accepted by the licensee, a notice of violation is then issued which can include sanctions such as civil penalties if health and safety is affected. The Agency Director signs all preliminary and final inspection actions.

The review team evaluated 11 Increased Controls inspection reports. The inspections included all aspects of the licensees' security programs, and some inspections identified significant violations and program concerns. The review team found that, although the preliminary findings were issued, several inspection files did not have responses from the licensees. Agency managers believe that the responses from the licensees were misplaced in the Agency files. Inspection staff members were not able to confirm that appropriate corrective actions were taken by the licensees. During the review, the Agency contacted the affected licensees and requested copies of the responses. The review team recommends that the State conduct followup inspections of licensees with unresolved violations or issues with regard to the Increased Controls requirements to ensure that appropriate corrective actions were implemented.

The review team found that inspection and licensing documents involving Increased Controls issues were not appropriately labeled as sensitive information to be withheld from public disclosure. The review team recommends that the State review its Increased Controls files to ensure that all sensitive security-related documents are labeled accordingly.

The review team noted that supervisor accompaniments of the four-member inspection staff had not been consistently performed over the review period, and that only two accompaniments had been conducted in 2007. The review team recommends that an Agency manager accompany each inspector, at least annually, to ensure quality and consistency in the inspection program.

The review team verified that the Agency maintains an adequate supply of appropriately calibrated survey instrumentation to support its inspection program, as well as to respond to radioactive materials incidents and emergency conditions. The instruments are sent either to the manufacturer or to an approved laboratory for calibration. The Agency maintains an in-house laboratory and a mobile laboratory capable of performing a full battery of radiological analyses.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory, but needs improvement.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 20 specific licenses. Licensing actions were reviewed for completeness, consistency, possession authorizations, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 3 new licenses, 4 renewals, 11 amendments (including 1 administrative change initiated by the Agency), and 2 license terminations. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy (including high dose-rate remote afterloaders), industrial radiography, and nuclear pharmacies. A listing of the licensing casework reviewed, with case-specific comments, may be found in Appendix D.

The review team noted that licensing actions, especially those regarding medical licenses, were inconsistent and of poor quality, with health, safety, and security items erratically addressed. The review team identified a broad range of concerns with approximately 75 percent of the licenses reviewed. Several licenses for high dose-rate remote afterloaders omitted key health and safety components, including material receipt, source security, storage, viewing systems and patient monitoring, and annual staff training. Multiple licenses, particularly those with high dose-rate remote afterloaders and medical therapy, had been incorrectly categorized; therefore,

negatively affecting the inspection frequency schedule as discussed in Section 3.2. The review team recommends that the State ensure its licenses are properly categorized and assigned the correct inspection frequency.

Verification of training and experience requirements for medical authorized users and radiation safety officers was inconsistent with current State regulations; therefore, medical material users have been authorized without providing proper documentation of training and experience. This finding potentially has transboundary implications because users would be authorized by other Agreement States and the NRC if they are currently authorized on an Arizona license. Other regulatory programs will not require an applicant to repeat the authorization process if that individual is currently authorized on a license. The review team provided instruction to the principal license reviewer in the medical authorization process used by the NRC and other Agreement States. The review team recommends that the State ensure proper documentation of training and experience for authorized users, authorized medical physicists, authorized nuclear pharmacists and radiation safety officers.

Interviews with the license reviewers indicated that the Agency does not utilize written procedures for license reviews or perform peer reviews. Most licensing actions evaluated by the review team indicated that material submitted by the licensee was taken at face value, and there were few requests for additional information. Licenses are issued for a 5-year term and can continue under timely renewal until the Agency issues a renewed license. The review team assessed two open licensing actions. Both were on track to meet the Agency's mandated 120-day goal for processing licensing actions.

After a license reviewer completes a licensing action, the Program Manager performs a supervisory review. The Director performs a final review prior to signing out the license. The review team determined that these supervisory reviews were not effective, as evidenced by the license quality issues identified by the review team. The review team recommends that the State implement a detailed and documented license review system to ensure accuracy and consistency for all licensing actions.

The review team evaluated the Agency's efforts in response to the 2006 IMPEP review recommendation regarding decommissioning financial assurance. The review team noted that the remaining six licensees required to comply with Arizona's financial assurance requirements have been issued license conditions to ensure compliance with the State's regulations. The Agency currently applies a process to identify new licenses requiring financial assurance that is compatible with the State's regulations.

The review team identified that, of the two terminated licensing actions reviewed, one was well documented, showing appropriate material transfer and survey records. The other did not include verification of transfer of material to another State. The review team noted that confirmatory surveys were reportedly conducted when appropriate; however, they were frequently undocumented. License reviewers indicated to the review team that, in the future, they would put more emphasis on documenting termination actions.

Pre-licensing checklists to ensure radioactive material will be used as intended are sporadically used on new and renewal licenses and not used on amendments. Only two of the licensing actions evaluated by the review team included pre-licensing documentation. Program

managers were reminded of the guidance provided to the Agreement States in the Office of Federal and State Materials and Environmental Management Programs (FSME) All Agreement States Letter FSME-06-114, "Implementation of Pre-Licensing Guidance," dated December 21, 2006, and the recent NRC/Agreement State pre-licensing pilot project. When pre-licensing checklists were used, and indicated that a pre-licensing visit should be performed, the review team confirmed that the Agency completed the visits, as required. The review team recommends that the State implement the pre-licensing checklist and guidance for all licensing actions to provide assurance that radioactive material will be used as specified on the license.

The review team examined the Agency's licensing practices in regard to the Increased Controls. The review team noted that the Agency added legally-binding license conditions to the licenses that met the criteria for implementing the Increased Controls. The review team analyzed the Agency's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team identified several licenses not currently under Increased Controls restrictions that authorized amounts of material exceeding quantities of concern. In these cases, the licensees may not actually possess quantities of concern. Agency managers indicated that corrections would be made to the licenses to clarify that quantities of concern are not authorized.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, Technical Quality of Licensing Actions, was unsatisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Agency's actions in responding to incidents and allegations, the review team examined the Agency's response to the questionnaire relative to this indicator, evaluated all of the incidents reported for Arizona in the Nuclear Material Events Database (NMED) against those contained in the Agency's files, and evaluated the casework for 11 radioactive material incidents. A listing of the incident casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Agency's response to one allegation involving radioactive materials that NRC referred to the State during the review period.

The incidents selected for review included medical events, lost radioactive material, damaged equipment, and stolen equipment. When notification of an incident is received, the Agency Director, Program Manager, and staff determine the appropriate level of initial response. The review team determined that the Agency's response to incidents was complete and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Agency dispatched inspectors for on-site investigations in appropriate situations and took suitable enforcement and followup actions when necessary.

The review team identified eight reportable radioactive materials incidents in NMED for Arizona during the review period. The review team identified three additional incidents that required reporting to the NRC that were not captured in NMED. The Agency believes that the incidents were reported to NRC and submitted to NMED; however, the review team did not find records of

the notifications. Agency managers committed to submitting information regarding the three incidents for inclusion in NMED.

Agency staff members had not been regularly entering incident information in NMED due to miscommunication within the Agency. NRC's contractor responsible for maintaining NMED requested additional information for five incidents; however, Arizona has not responded to the requests. The Agency has put a process in place where the Agency Director will forward incident information requests to the Program staff for resolution. Program staff members also contacted the NRC's contractor to make sure that they are included in any requests for additional information that is needed for incident closure.

In evaluating the effectiveness of Arizona's response to allegations, the review team evaluated the casework for the only allegation received during the review period. The review team's evaluation revealed that the Agency took prompt and appropriate action in response to the concerns raised. The allegation was appropriately closed, and affected individuals were notified of the actions taken. The Agency makes every effort to protect an alleege's identity.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Arizona's Agreement does not cover a uranium recovery program, so only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Arizona became an Agreement State on May 15, 1967. The statutory authority for the Arizona program is found in the State's Radiation Control Program, Title 30, Chapter 4 of the Arizona Revised Statutes, "Control of Ionizing Radiation." The Agency is designated as the State's radiation control agency and implements the radiation control program.

Other statutes that affect the Agency are contained in Title 30, Chapter 5, "Interstate Cooperation in Atomic Energy Matters," and Title 41, Chapter 6, "State Government." These statutes describe the State's administrative procedures for rulemaking, adjudicative proceedings, licensing timeframe, and hearing procedures. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Agency's regulations for control of radiation are found in the Arizona Administrative Code under Title 12, Chapter 1, "Radiation Regulatory Agency," Articles 1 through 17, and apply to all radioactive materials and devices designed to produce radiation.

The Arizona Statutes require the Agency to review all regulations every 5 years. For each regulation, the Agency must describe the effectiveness of the regulation and provide the statutory authority under which the regulation is issued. The Agency must also demonstrate that the regulation is consistent with other Agency regulations, and that the regulation is clear and understandable. In addition, in developing regulations, the Agency is to consider the economic impact on small businesses and consumers.

The review team examined the State's administrative rulemaking process and found that it takes approximately 1 to 3 years to promulgate a final rule. After preparation of a regulation package, the Agency publishes the proposed rules in the State Register, and sends the rules to NRC and the Radiation Hearing Board. The Agency must obtain approval from the Governor's Regulatory Review Council prior to publication of a final rule. The State's process allows opportunity for members of the public and other stakeholders to comment on proposed rules. The State has the authority to issue legally binding requirements (e.g., license conditions) until equivalent State rules become effective.

The review team evaluated the Agency's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains. The review team noted that the State is up to date on all amendments currently required for compatibility with NRC's program.

Since the previous review, the State submitted four packages for compatibility reviews. With these submissions, Arizona is up-to-date on regulation development. The review team reminded Agency managers that NRC-identified comments on three earlier submitted regulation packages that have yet to be answered. Also, final versions of three regulations need to be submitted to the NRC for evaluation.

The review team noted that the Agency expended a good deal of effort in regulation development since the 2006 review. The Agency Director assigned responsibility and oversight for rulemaking actions and regulations to the recently hired Program Manager.

The review team identified the following regulation changes and adoptions that will be needed in the future. The Agency Director related that the regulations would be addressed in upcoming rulemaking or in the adoption of alternate legally binding requirements:

- "Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material," NRC Order EA-07-305 (72 FR 70901), that is due for Agreement State adoption by June 5, 2008.

- “Medical Use of Byproduct Material - Recognition of Specialty Boards,” 10 CFR Part 35 amendment (70 FR 16336 and 71 FR 1926), that is due for Agreement State adoption by April 29, 2008.
- “National Source Tracking System,” 10 CFR Part 20 amendment (71 FR 65685), that is due for Agreement State adoption by January 31, 2009.
- “Minor Amendments,” 10 CFR Part 20, 30, 32, 35, 40 and 70 amendments (71 FR 15005), that are due for Agreement State adoption by March 27, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Part 32 and 35 amendments (72 FR 45147 and 72 FR 54207), that are due for Agreement State adoption by October 29, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Part 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that are due for Agreement State adoption by November 30, 2010.
- “Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Part 30, 31, 32 and 150 amendments (72 FR 58473), that are due for Agreement State adoption by December 17, 2010.
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Part 19 and 20 amendments (72 FR 68043), that are due for Agreement State adoption by February 15, 2011.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona’s performance with respect to the indicator, Compatibility Requirements, was satisfactory.

4.2 Sealed Source and Device Evaluation Program

In conducting this review, three subelements were used to evaluate the Agency’s performance regarding the Sealed Source and Device Evaluation Program. These subelements were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Agency’s SS&D evaluation activities, the review team examined information contained in the Agency’s response to the IMPEP questionnaire for this indicator. The review team evaluated all of the amended SS&D evaluations and supporting documents covering the review period. The Agency conducted no new SS&D evaluations since the last review. The review team noted the staff’s use of guidance documents and procedures, interviewed the staff involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

A health physicist from the Program and a health physicist from the Radiation Measurement Program, another group within the Agency, are the reviewers who conduct safety evaluations of SS&D applications. The Program staff member has a science degree, and the other staff member has a degree in engineering. The Program staff member is a new SS&D reviewer and has not attended the NRC workshop for SS&D reviewers. During the on-site review, the review team suggested to the Program Manager that the Program staff member, who is new to SS&D evaluations, should attend the NRC workshop for SS&D reviewers scheduled for the week of September 15, 2008. The review team informed the Program Manager and staff that NRC will pay for Agreement State representatives to travel to and attend the workshop.

The review team interviewed the staff and found that the reviewer from the Radiation Measurement Program was familiar with the SS&D evaluation process and had access to the applicable reference documents. The review team was confident that this reviewer was sufficiently familiar with the SS&D process to train and assist the Program staff member. Agency procedures require both reviewers to conduct the safety evaluation and that the Agency Director signs the registration certificate. The review team determined that the reviewer from the Radiation Measurement Program met the technical training required for SS&D reviews, as described under the State's training guidance. The Program staff member still needs to complete the workshop for SS&D reviewers and receive additional on-the-job training.

Due to the small number of Arizona licensees that require registration certificates, the review team determined that even though only one staff member was qualified to perform SS&D evaluations at the time of the review, the staffing level was adequate. During the review, the review team offered to the Agency Director the possibility of Arizona returning the SS&D program to NRC, particularly due to the fact that there is little activity and the cost of maintaining trained SS&D reviewers may not be economical for the Agency. The Agency Director declined the offer.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated all four SS&D evaluation amendments, representing the work of the two SS&D reviewers. The Agency currently manages two active SS&D manufacturer/distributors. The Agency performed a full SS&D review of the four sheets. A list of SS&D casework examined, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with staff confirmed that the Agency generally follows the recommended guidance from NRC's SS&D training workshops and that found in NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration." The review team confirmed that all applicable and pertinent American National Standards Institute standards, NUREG-1556 Series, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews.

The four amendments involved the addition of two manufacturing locations outside of the U.S. and an additional distribution location. The Agency's files did not contain the licensee's initial incoming request to amend the registration certificates. Agency staff contacted the licensee and

obtained a copy of the original requests for the amendments. The review team discussed the missing information with Program staff and explained that the information should be included in the Agency's files in order to be able to reference the decision behind the Agency's amendment to the registration certificate. The review team also noted that, with the addition of two manufacturers outside of the U.S., the staff did not confirm that the distributor in Arizona would be able to provide copies of the quality assurance programs and quality control checks. The staff committed to making sure that the required information would be made available at the licensee's facility in Arizona.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&D defects were noted by the State of Arizona during the review period. The review team conducted a search of the NMED system to determine whether other incidents might have taken place that were not registered by the Agency staff. No incidents were identified that could have been related to malfunctioning devices or products considered during the review.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Arizona's performance with respect to the indicator, SS&D Evaluation Program, was 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 Regulatory Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Arizona Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Arizona. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Arizona's performance was found satisfactory for the performance indicators: Technical Quality of Incident and Allegation Activities, Compatibility Requirements, and Sealed Source and Device Evaluation Program. Arizona's performance was found satisfactory, but needs improvement, for the indicators: Technical Staffing and Training and Technical Quality of Inspections. Arizona's performance was found unsatisfactory for the indicators: Status of Materials Inspection Program and Technical Quality of Licensing Actions. The review team made ten recommendations regarding Agency performance. Accordingly, the review team recommended, and the MRB agreed, that the Arizona Agreement State Program was adequate, but needs improvement, to protect public health and safety and compatible with NRC's program. The review team recommended, and the MRB agreed, that NRC institute a

period of Heightened Oversight for Arizona to assess the progress of the State, including bimonthly conference calls and a followup IMPEP review in 1 year.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation by the State, including one open recommendation from the 2006 IMPEP report:

1. The review team recommends that the State develop and use qualification journals to track and monitor training for technical staff. (Section 3.1)
2. The review team recommends that the State ensure that license reviewers be provided appropriate training to ensure familiarity with medical license modalities. (Section 3.1)
3. The review team recommends that the State take appropriate measures to conduct core inspections (including initial inspections) in accordance with the inspection priority schedule in IMC 2800, and conduct reciprocity inspections in accordance with IMC 1220. (Section 3.2) (Open item from 2006 review)
4. The review team recommends that the State conduct followup inspections of licensees with unresolved violations or issues with regard to the Increased Controls requirements to ensure that appropriate corrective actions were implemented. (Section 3.3)
5. The review team recommends that the State review its Increased Controls files to ensure that all sensitive security-related documents are labeled accordingly. (Section 3.3)
6. The review team recommends that an Agency manager accompany each inspector, at least annually, to ensure quality and consistency in the inspection program. (Section 3.3)
7. The review team recommends that the State ensure its licenses are properly categorized and assigned the correct inspection frequency. (Section 3.4)
8. The review team recommends that the State ensure proper documentation of training and experience for authorized users, authorized medical physicists, authorized nuclear pharmacists and radiation safety officers. (Section 3.4)
9. The review team recommends that the State implement a detailed and documented license review system to ensure accuracy and consistency for all licensing actions. (Section 3.4)
10. The review team recommends that the State implement the pre-licensing checklist and guidance for all licensing actions to provide assurance that radioactive material will be used as specified on the license. (Section 3.4)

LIST OF APPENDIXES AND ATTACHMENT

| | |
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| Appendix A | IMPEP Review Team Members |
| Appendix B | Arizona Organization Charts |
| Appendix C | Inspection Casework Reviews |
| Appendix D | License Casework Reviews |
| Appendix E | Incident Casework Reviews |
| Appendix F | Sealed Source & Device Casework Reviews |
| Attachment | May 14, 2008, Letter from Dennis Burke Arizona's Response to Draft IMPEP Report |

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

| Name | Area of Responsibility |
|---------------------------------|---|
| James Lynch, Region III | Team Leader Technical Staffing and Training Inspector Accompaniments |
| Robert Gallagher, Massachusetts | Status of Materials Inspection Program |
| Linda McLean, Region IV | Technical Quality of Inspections Compatibility Requirements |
| Sherrie Flaherty, Minnesota | Technical Quality of Licensing Actions |
| Tomas Herrera, FSME | Technical Quality of Incident and Allegation Activities Sealed Source and Device Evaluation Program |

APPENDIX B

ARIZONA ORGANIZATION CHART

ADAMS ACCESSION NO.: ML080850827

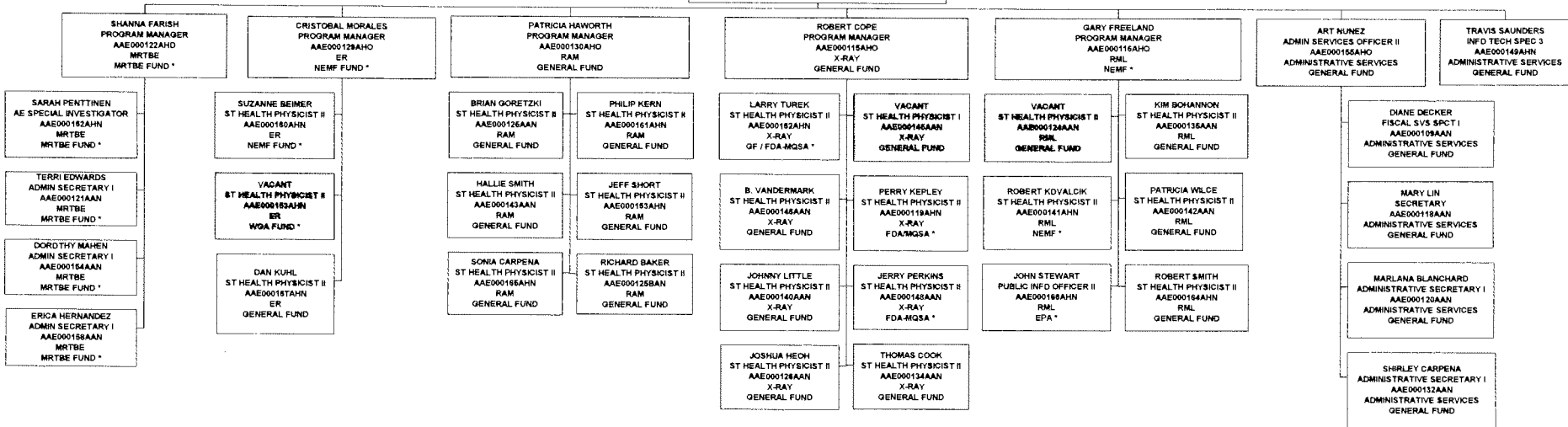
**STATE OF ARIZONA
RADIATION REGULATORY AEA**

JANET NAPOLITANO
GOVERNOR

MEDICAL RADIOLOGICAL TECHNOLOGY BOARD OF EXAMINERS (MRTBE)
10 MEMBERS / 3 - YEAR TERM
CHAIRPERSON: DIRECTOR OF ARRA

RADIATION REGULATORY HEARING BOARD
5 MEMBERS / 3 - YEAR TERM

AUBREY GODWIN
DIRECTOR
AAE000100/AHO
GENERAL FUND



VACANT

| * FUNDED BY NON-GENERAL SOURCES | |
|---------------------------------|-----------|
| GENERAL FUND POSITIONS: | 24.5 |
| NEMF FUND POSITIONS: | 4 |
| MRTBE FUND POSITIONS: | 5 |
| EPA POSITION: | 1 |
| FDA/MQSA FUND POSITIONS: | 2.5 |
| WGA/WPP POSITION: | 1 |
| ADHS POSITION: | 1 |
| TOTAL: | 39 |

MURKIN

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1

Licensee: CHS Arizona, dba St. Joseph
Hospital & Medical Center

Inspection Type: Routine, Unannounced
Inspection Dates: 12/12-13/07

License No.: 7-024

Priority: 1

Inspectors: JS, BG, PK

Comments:

- a) Report mailed late on February 15, 2008.
- b) Inspection conducted overdue; last inspection was March 15, 2006.

File No.: 2

Licensee: Phoenix Memorial Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 8/23/06

License No.: 7-077

Priority: 3

Inspector: PK

Comment:

Inspection conducted overdue; last inspection was October 2, 2002.

File No.: 3

Licensee: Arizona Oncology Services
Inspection Type: Special, Announced
Inspection Date: 2/7/08

License No.: 7-161

Priority: 2

Inspector: JS

File No.: 4

Licensee: Sierra Vista Regional Health Center
Inspection Type: Routine, Unannounced
Inspection Date: 8/9/07

License No.: 2-012

Priority: 3

Inspector: JS

Comment:

Inspection conducted overdue; last inspection was November 13, 2002.

File No.: 5

Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Dates: 1/9-10/08

License No.: 7-123

Priority: 2

Inspectors: JS, BG, HS

File No.: 6

Licensee: Biotech Pharmacy of Arizona
Inspection Type: Initial, Unannounced
Inspection Dates: 8/22-23/06

License No.: 8-036
Priority: 2
Inspector: JS

Comment:

Initial inspection conducted overdue; license issued on January 14, 2005.

File No.: 7

Licensee: Western Technologies, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 11/16/06

License No.: 7-049
Priority: 1
Inspectors: JS, BG

File No.: 8

Licensee: Team Industrial Services, Inc.
Inspection Type: Field, Routine, Unannounced
Inspection Date: 7/10/07

License No.: 7-493
Priority: 1
Inspectors: JS, HS

File No.: 9

Licensee: Medi-Physics, Inc., dba GE Healthcare
Inspection Type: Routine, Unannounced
Inspection Dates: 1/11-12/05

License No.: 7-346
Priority: 2
Inspectors: PK, JL, JS

Comment:

Inspection conducted overdue; last inspection was May 21, 2003.

File No.: 10

Licensee: Payson Hospital Corporation
Inspection Type: Routine, Unannounced
Inspection Date: 3/11/07

License No.: 4-016
Priority: 2
Inspector: JN

Comment:

Inspection conducted overdue.

File No.: 11

Licensee: P.E.T. Net Pharmaceuticals, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 9/16/06

License No.: 7-363
Priority: 1
Inspector: JS

Comment:

Inspection conducted overdue; last inspection was January 23, 2003.

File No.: 12

Licensee: Mayo Clinic Arizona
Inspection Type: Special, Announced
Inspection Dates: 7/17-19/07, 8/15/07

License No.: 7-448
Priority: 1
Inspectors: JS, HS, PK, BG

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- b) No followup inspection was conducted.

File No.: 13

Licensee: University of Arizona
Inspection Type: Routine, Unannounced
Inspection Dates: 7/17-20/06

License No.: 10-044
Priority: 1
Inspectors: JS, WW, JL, DK, PK

Comment:

Inspection conducted overdue; last inspection was April 5-8, 2004.

File No.: 14

Licensee: Phoenix National Laboratory, Inc.
Inspection Type: Special, Announced
Inspection Date: 10/26/06

License No.: 7-415
Priority: 1
Inspectors: BG, DK

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- a) Licensee's response to notice of violation was missing from file.

File No.: 15

Licensee: Western Technologies, Inc.
Inspection Type: Special, Announced
Inspection Date: 11/16/07

License No.: 7-049
Priority: 1
Inspectors: JS, BG

Comment:

Sensitive information contained in file was not marked appropriately.

File No.: 16

Licensee: Arizona State University
Inspection Type: Special, Announced
Inspection Dates: 6/12-13/06

License No.: 7-489
Priority: 1
Inspectors: PK, JL, JS

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- b) No followup inspection was conducted.

File No.: 17

Licensee: St. Joseph's Medical Center
Inspection Type: Special, Announced
Inspection Date: 11/30/06

License No.: 7-424
Priority: 1
Inspectors: DK, BG, PK

Comment:

Sensitive information contained in file was not marked appropriately.

File No.: 18

Licensee: American Red Cross
Inspection Type: Special, Announced
Inspection Date: 10/19/06

License No.: 10-143
Priority: 1
Inspectors: BG, DK

File No.: 19

Licensee: Varian Medical Systems
Inspection Type: Reciprocity
Inspection Date: 10/23/06

License No.: 45-30957-01
Priority: N/A
Inspectors: JS, PK

File No.: 20

Licensee: Alpha-Omega Services, Inc.
Inspection Type: Reciprocity
Inspection Date: 12/19/07

License No.: CA-3925-19
Priority: N/A
Inspector: BG

File No.: 21

Licensee: United Blood services
Inspection Type: Special, Announced
Inspection Date: 9/7/06

License No.: 7-299
Priority: 1
Inspectors: PK, BG, DK

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- b) No followup inspection was conducted.

File No.: 22

Licensee: Banner Good Samaritan Medical Center
Inspection Type: Special, Announced
Inspection Date: 9/13/06

License No.: 7-478
Priority: 1
Inspectors: BG, DK

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- b) No followup inspection was conducted.
- c) Licensee's response to notice of violation was missing from file.

File No.: 23

Licensee: Southwest Veterinary Oncology
Inspection Type: Special, Announced
Inspection Date: 12/14/06

License No.: 10-132
Priority: 1
Inspectors: BG, PK

File No.: 24

Licensee: Team industrial Services, Inc.
Inspection Type: Special, Announced
Inspection Date: 11/15/06

License No.: 7-493
Priority: 1
Inspectors: BG, PK

Comments:

- a) Sensitive information contained in file was not marked appropriately.
- b) No followup inspection was conducted.

File No.: 25

Licensee: University of Arizona
Inspection Type: Special, Announced
Inspection Dates: 7/17-20/06

License Nos.: 10-024, 10-044
Priority: 1
Inspector: WW

File No.: 26

Licensee: St. Joseph's Medical Center
Inspection Type: Special, Announced
Inspection Date: 11/30/06

License No.: 7-424
Priority: 1
Inspectors: DK, BG, PK

File No.: 27

Licensee: Qual-Tek Associates
Inspection Type: Reciprocity
Inspection Date: 6/27/07

License No.: 11-27610-01
Priority: N/A
Inspector: BG

File No.: 28

Licensee: Quality Assurance Services, Inc.
Inspection Type: Reciprocity
Inspection Date: 5/22/97

License No.: 6073-37
Priority: N/A
Inspectors: BG, PK

File No.: 29

Licensee: G.E. Healthcare
Inspection Type: Reciprocity
Inspection Date: 6/4/07

License No.: 133-1197-01
Priority: N/A
Inspectors: BG, PK

File No.: 30

Licensee: Beckman Coulter
Inspection Type: Reciprocity
Inspection Date: 6/28/07

License No.: 0441-30
Priority: N/A
Inspector: WW

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: City of Chandler
Inspection Type: Routine, Unannounced
Inspection Date: 2/19/08

License No.: 7-295
Priority: 3
Inspector: HS

Accompaniment No.: 2

Licensee: AMEC Earth and Environmental, Inc.
Inspection Type: Routine/Special, Unannounced
Inspection Date: 2/20/08

License No.: 7-369
Priority: 1
Inspector: JS

Accompaniment No.: 3

Licensee: Cardiovascular Associates of Mesa
Inspection Type: Routine, Unannounced
Inspection Date: 2/21/08

License No.: 7-487
Priority: 3
Inspector: BG

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1

Licensee: CONAM Inspection & Engineering
Services, Inc.

Type of Action: New

Date Issued: 12/26/07

License No.: 16021

Amendment No.: N/A

License Reviewer: PK

Comments:

- a) Licensee requested authorization for source retrieval in the application. It was not authorized on the license, and there was no documentation regarding denial.
- b) Sensitive information contained in file was not marked appropriately.

File No.: 2

Licensee: Cancer Treatment Services Arizona

Type of Action: New

Date Issued: 9/25/07

License No.: 16017

Amendment No.: N/A

License Reviewer: PK

Comments:

- a) The authorized use condition referenced "storage as indicated in Amendment 2;" however, this was a new license and no such document existed.
- b) The application did not address such items as: material receipt procedures, annual training, facility diagram, and security and storage of the HDR.
- c) There was no documentation regarding type of HDR requested.
- d) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.

File No.: 3

Licensee: Kingman Regional Medical Center

Type of Action: Amendment

Date Issued: 4/11/07

License No.: 8-004

Amendment No.: 43

License Reviewer: PK

File No.: 4

Licensee: Sun Radiology

Type of Action: Renewal

Date Issued: 2/20/08

License No.: 7-514

Amendment No.: 7

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) Licensee requested an additional authorized user/RSO. File contained no correspondence with licensee regarding denial.

- c) Condition 17 authorized mobile medical services; however, the licensee does not perform mobile services.

File No.: 5

Licensee: Accredited Cardiology of Arizona

Type of Action: Renewal

Date Issued: 11/19/07

License No.: 7-442

Amendment No.: 9

License Reviewer: PK

Comment:

File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.

File No.: 6

Licensee: Chandler Regional Hospital

Type of Action: Renewal

Date Issued: 11/27/07

License No.: 7-241

Amendment No.: 49

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) License did not have appropriate security license condition imposed.
- c) License conditions 12 and 16 referenced a nonexistent subitem N.
- d) Application did not address HDR procedures.

File No.: 7

Licensee: Associates in Radiation Oncology

Type of Action: Amendment

Date Issued: 12/3/07

License No.: 7-153

Amendment No.: 37

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) License did not have appropriate security license condition imposed.
- c) Condition 10 did not address location of use for the HDR.
- d) Training requirements for new authorized users were not evaluated properly.

File No.: 8

Licensee: Molecular Imaging Center

Type of Action: Termination

Date Issued: 1/25/08

License No.: 15-090

Amendment No.: N/A

License Reviewer: PK

Comment:

No documentation requesting verification that sources have been disposed of properly.

File No.: 9

Licensee: Ironwood Cancer & Research Center, PC

Type of Action: New

Date Issued: 10/11/06

License No.: 7-571

Amendment No.: N/A

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) License was assigned an incorrect program code.

File No.: 10

Licensee: Arizona Oncology Services

Type of Action: Amendment

Date Issued: 9/10/07

License No.: 7-161

Amendment No.: 61

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) License was assigned an incorrect program code.

File No.: 11

Licensee: Arizona Oncology Services

Type of Action: Amendment

Date Issued: 11/22/06

License No.: 7-161

Amendment No.: 57

License Reviewer: DK

File No.: 12

Licensee: Yavapi Regional Medical Center

Type of Action: Amendment

Date Issued: Pending

License No.: 13-006

Amendment No.: 42

License Reviewer: BG

File No.: 13

Licensee: Banner Mesa Medical Center

Type of Action: Termination

Date Issued: 1/25/08

License No.: 7-127

Amendment No.: N/A

License Reviewer: PK

Comment:

Confirmatory surveys were not documented in file.

File No.: 14

Licensee: Phoenix National Laboratories, Inc.

Type of Action: Amendment

Date Issued: 3/6/08

License No.: 7-415

Amendment No.: 66

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) Sensitive information contained in file was not marked appropriately.
- c) Licensee possesses more material than license allows, as identified in the inspection file.

File No.: 15

Licensee: United Blood Services of Arizona

Type of Action: Amendment

Date Issued: 2/20/07

License No.: 7-299

Amendment No.: 19

License Reviewer: DK

Comment:

Sensitive information contained in file was not marked appropriately.

File No.: 16

Licensee: West Valley Hospital

Type of Action: Amendment

Date Issued: 3/26/07

License No.: 7-528

Amendment No.: 12

License Reviewer: BG

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) Training requirements for new authorized user were not properly evaluated.

File No.: 17

Licensee: Valley Radiologists

Type of Action: Amendment

Date Issued: 1/31/08

License No.: 7-519

Amendment No.: 8

License Reviewer: BG

Comment:

File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.

File No.: 18

Licensee: Scottsdale Heart Hospital

Type of Action: Amendment

Date Issued: 7/2/07

License No.: 7-497

Amendment No.: 3

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) Training requirements for new authorized user were not properly evaluated.

File No.: 19

Licensee: Sierra Vista Regional Health Center

Type of Action: Amendment

Date Issued: Pending

License No.: 2-012

Amendment No.: 37

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) Training requirements for a new authorized user were not properly evaluated and the license reviewer was unaware of the needed evaluation process.

File No.: 20

Licensee: Tucson Heart Hospital

Type of Action: Renewal

Date Issued: 8/3/07

License No.: 10-138

Amendment No.: 10

License Reviewer: PK

Comments:

- a) File did not include pre-licensing checklist to provide assurance that radioactive material will be used properly.
- b) License included authorization for phosphorus-32 from previous license, although the licensee did not request authorization.

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1

Licensee: Western Technologies, Inc.

Date of Incident: 3/8/06

Investigation Date: 3/10/06

License No.: 7-080

NMED No.: N/A

Type of Incident: Damaged Equipment

Type of Investigation: Telephone

Comment:

Incident was not recorded in NMED.

File No.: 2

Licensee: Madhi Sadek, P.E.

Date of Incident: 3/16/06

Investigation Date: 3/20/06

License No.: 7-534

NMED No.: N/A

Type of Incident: Vehicle Accident

Type of Investigation: Site

Comment:

Incident was not recorded in NMED.

File No.: 3

Licensee: Flagstaff Medical Staff

Date of Incident: 8/17/06

Investigation Date: 8/17/06

License No.: 3-003

NMED No.: 060537

Type of Incident: Loss of Control

Type of Investigation: Telephone

File No.: 4

Licensee: MRM Construction Services

Date of Incident: 1/29/07

Investigation Date: 1/29/07

License No.: 7-512

NMED No.: 070071

Type of Incident: Stolen Gauge

Type of Investigation: Site

Comment:

Additional information was requested to complete the incident file in NMED, however, the State had not responded to the request.

File No.: 5

Licensee: Construction Inspection and Testing

Date of Incident: 2/22/07

Investigation Date: 2/23/07

License No.: 7-098

NMED No.: N/A

Type of Incident: Stolen Gauge

Type of Investigation: Telephone

Comments:

a) Incident was not recorded in NMED.

b) Incident was not reported to NRC Headquarters Operations Center in a timely manner.

File No.: 6

Licensee: Geotechnical and Environmental
Consultants

Date of Incident: 3/14/07

Investigation Date: 3/15/07

License No.: 7-402

NMED No.: 070150

Type of Incident: Damaged Equipment

Type of Investigation: Site

Comment:

Additional information was requested to complete the incident file in NMED, however, the State had not responded to the request.

File No.: 7

Licensee: ATL, Inc.

Date of Incident: 6/29/07

Investigation Date: 7/3/07

License No.: 7-116

NMED No.: 070402

Type of Incident: Stolen Gauge

Type of Investigation: Site

Comment:

Additional information was requested to complete the incident file in NMED, however, the State had not responded to the request.

File No.: 8

Licensee: Terracon Consultants, Inc.

Date of Incident: 7/17/07

Investigation Dates: 7/20/07 and 7/24/07

License No.: 10-130

NMED No.: 070443

Type of Incident: Lost Gauge

Type of Investigation: Site

Comment:

Additional information was requested to complete the incident file in NMED, however, the State had not responded to the request.

File No.: 9

Licensee: Walter Boswell Memorial Hospital

Date of Incident: 8/14/07

Investigation Date: 8/17/07

License No.: 7-138

NMED No.: 070534

Type of Incident: Lost Sources

Type of Investigation: Site

Comment:

Additional information was requested to complete the incident file in NMED, however, the State had not responded to the request.

File No.: 10

Licensee: Arizona Oncology Services

Date of Incident: 12/3/07

Investigation Date: 12/3/07

License No.: 7-161

NMED No.: 070748

Type of Incident: Leaking Source

Type of Investigation: Telephone

File No.: 11

Licensee: Acura Engineering

Date of Incident: 1/23/07

Investigation Date: 1/25/07

License No.: 7-550

NMED No.: 080052

Type of Incident: Stolen Gauge

Type of Investigation: Site

APPENDIX F

SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1

Registry No.: AZ-0501-D-105-B

SS&D Type: (D) Gamma Gauge and
(E) Beta Gauge

Applicant Name: Honeywell-International

Type of Action: Amendment

Date Issued: 10/24/07

Reviewers: PK, RK, AG

Comment:

Quality Assurance Program in the U.S. was not confirmed for international manufacturers.

File No.: 2

Registry No.: AZ-0501-D-106-B

SS&D Type: (E) Beta Gauge

Applicant Name: Honeywell-International

Type of Action: Amendment

Date Issued: 10/25/07

Reviewers: PK, RK, AG

Comment:

Quality Assurance Program in the U.S. was not confirmed for international manufacturers.

File No.: 3

Registry No.: AZ-0501-D-107-B

SS&D Type: (E) Beta Gauge

Applicant Name: Honeywell-International

Type of Action: Amendment

Date Issued: 10/25/07

Reviewers: PK, RK, AG

Comment:

Quality Assurance Program in the U.S. was not confirmed for international manufacturers.

File No.: 4

Registry No.: AZ-0501-D-108-B

SS&D Type: (D) Gamma Gauge and
(E) Beta Gauge

Applicant Name: Honeywell-International

Type of Action: Amendment

Date Issued: 10/31/07

Reviewers: PK, RK, AG

Comment:

Quality Assurance Program in the U.S. was not confirmed for international manufacturers.

ATTACHMENT

May 14, 2008, Letter from Dennis Burke
Arizona's Response to Draft IMPEP Report

ADAMS: ML081410324



STATE OF ARIZONA

JANET NAPOLITANO
GOVERNOR

OFFICE OF THE GOVERNOR
1700 WEST WASHINGTON STREET, PHOENIX, AZ 85007

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May 14, 2008

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal State Materials and Environmental Management Programs
United States Nuclear Regulatory Commission Washington, D.C. 20555-0001

Dear Mr. Lewis:

Thank you for personally delivering the report of the Arizona Radiation Regulatory Agency's recent IMPEP review. We appreciate the time and effort by the U.S. Nuclear Regulatory Commission to assist the State of Arizona and we are committed to having the best programs to protect the public health, safety and security of Arizonans.

As mentioned during the meeting, several items in the Draft Review Report have been addressed since the review team was in Arizona in March 2008. Additionally, we ask that the Management Review Board (MRB) consider the following actions taken since our April 24, 2008 meeting before a final report is made.

Draft Report Pg. 3

Last paragraph on page. The staffing is for the RAM portion of the program; the Non-ionizing portion adds 1.5 FTE to the Program. Since the Draft Report was prepared, the Non-ionizing Program has been separated from the Radioactive Materials (RAM) Program and the staffing of the RAM Program is four. This will allow the RAM Program Manager to concentrate on the RAM issues.

Draft Report Pg. 4

Fourth paragraph. A training journal is in place for all program employees.

Next to last paragraph. Several staff has applied to attend the August 2008 "Nuclear Medicine and Brachytherapy/Gamma Knife training," including the license reviewer.

Draft Report Pg. 5

First full paragraph. Mr. Robert J. Lewis, Director, Division of Materials Safety and State Agreements, indicated that the NRC staff was investigating the possibility of having a local qualified license reviewer coach the Arizona licensing staff to improve the quality of licensing. The State would welcome such an effort.

Third paragraph. The FY 2008 budget has been finalized and there will be no additional cuts.

Fourth paragraph. The FY2009 budget is still being discussed by the legislature.

Draft Report Pg. 5, Pg. 6, Pg. 8

Last paragraph, page 6, fourth paragraph, and page 8, last paragraph. The Agency has reviewed and corrected the misclassification of the licenses reviewed during the IMPEP review. In addition a review of all license classifications is underway to assure the validity of the data base information. The primary error identified appears that the medical licenses with HDR units were not given the HDR classification as the prime classification. Further, the State classification code was miss-applied again resulting in a longer re-inspection schedule. All of the medical HDR licenses have been checked and corrected. The entire database is to be reviewed in the next six months to confirm we are accessing correct data.

Draft Report Pg. 6

First full paragraph. As of May 7, 2008, the agency has 0 of 8 priority 1 licenses overdue for inspection; 3 of 21 priority 2 licenses including the HDR units, are overdue for inspection; 13 of 59 priority 3 licenses are overdue for inspection; and 39 of 269 priority 5 licenses are overdue for inspection. The program is making special efforts to inspect reciprocity licensees in the core group.

Draft Report Pg.7

First sentence. We believe that if the review were taking place today, May 8, 2008, this indicator would be "satisfactory, but needs improvement."

Next to last paragraph. All Increased Control licensees have been inspected who did not have a follow up letter on file. One licensee was found in non-compliance

because they had not contacted the local police to get a response time to their facility.

Last paragraph. All document's related to Increased Controls licenses and their correspondence have been reviewed and marked if sensitive information is involved. At least three individuals are required to check filed information for 1) sensitive information, 2) assure the proper markings, and 3) securing of the information.

Draft Report Pg. 8

First paragraph. The Program Manager will accompany all inspectors at least twice annually; in addition, the Agency director will also accompany each inspector annually.

Draft Report Pg. 9

First paragraph. Seventeen of the twenty licenses reviewed by the IMPEP team were medical licensees. All have been reviewed fifteen confirmed that the medical personnel are qualified. For the remaining two, we are 1) awaiting the preceptor's information to document their qualifications, and 2) the application was withdrawn at the applicants request.

Second and third paragraphs. The Agency has re-established peer reviews of all license and amendment applications. Further, a review system is being developed to assure high quality license reviews. A minimum of four reviews will occur on each license action. In addition, written procedures are being developed to assure the quality of reviews remain high.

Last paragraph. The misunderstanding that the checklist was to be utilized for every licensing action has been clarified and now is in place. Further, sensitive information within the application will be so marked.

Draft Report Pg. 10

First full paragraph. The licenses identified as authorizing too much radioactive materials without the Increased Controls requirements has been corrected. All of the licenses have had their possession limits reduced. The licensing ad inspections staff have been alerted to assure that the authorized possession limits of Increased Controls will not be exceeded unless the controls actually are in place.

Robert J. Lewis
May 14, 2008
Page 4

Draft Report Pg. 11

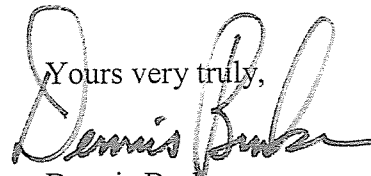
First paragraph. The three events not entered into the NMED have been corrected. In addition, the events have now been closed out for those who had remained open.

Summary

We believe that with the resources now available, we will have all of the overdue inspections up to date by the time of the next review. We will have had several of the staff register for or receive suggested NRC training to improve the technical quality of our inspections and licenses. Further, reviews of the database are on going and it should be much more accurate by the next review. Increased reviews of inspections and licensing actions, together with a questioning attitude of applicants should improve the quality of our licensing program. Arizona is committed to having a top rated radiation program.

Ms. Tracy Hannah and Mr. Aubrey Godwin will be at the MRB June meeting and will offer additional comments, as needed, to any MRB questions.

It was a pleasure to meet you and your staff. Your expertise and guidance offered the Arizona Radiation Regulatory Agency is much appreciated. We look forward to utilizing training opportunities offered by the MRB and we anticipate being in complete compliance by next year's IMPEP review.

Yours very truly,

Dennis Burke
Chief of Staff

cc T. Hannah, Policy Advisor
A.V. Godwin, Director, AZ. Radiation Regulatory Agency
James L. Lynch, Regional States Agreements Officer