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

Dear Mr. Burke:

On May 2, 2006, 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 to be adequate, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

As noted during the IMPEP review and discussed during the MRB meeting, the Arizona Radiation Regulatory Agency (the Agency) is facing considerable staffing issues, both present and future. The Agency has lost a position due to recent budget cuts and is experiencing difficulty in qualifying and retaining staff. During the review period, two staff members left the Agency for higher paying jobs shortly after becoming qualified. Currently, there is one health physicist vacancy in the radioactive materials program. The Agency's low starting salaries will make it difficult to recruit and retain individuals with radiation protection experience.

The Agency is also facing knowledge transfer issues. The Agency is currently performing inspections and licensing actions of high technical quality, as well as responding to incidents appropriately. However, with several impending retirements, the ability of the Agency to sustain performance of regulatory actions of high technical quality is threatened. The Agency has recently hired an inspector, who is in the process of becoming qualified, but the qualification process will take a considerable amount of time due to the lack of available funds for training. The Agency is making commendable efforts to overcome these hardships; however, on-the-job training involving the inspection of low-risk facilities has caused the Agency to delay performing inspections of high-risk facilities. The existing vacancy is also a contributing root cause to the number of overdue high-risk inspections. The review team found the Agency's performance with respect to the timeliness of inspections unsatisfactory.

The MRB expressed concern that without adequate staffing levels and proper knowledge transfer the Agency will continue to get further behind in inspections and, over time, the quality of inspections will decline. The MRB believes that adequate funding and support is essential to maintenance of a healthy program, which can ensure that staffing levels are appropriate to guarantee inspections of radioactive material licensees are completed in a timely manner and that the existing backlog be diminished. Adequate funding will also ensure that new staff will be trained and qualified in a reasonable time frame and that high quality staff will be attracted and retained.

At this time, the NRC is not questioning the State's ability to adequately protect public health and safety. As noted earlier, the inspections that are performed are of high quality. However, given further staff attrition, this picture may change in the future. If the existing issues

mentioned above continue to go unresolved or the status of the program declines, additional action on the part of the NRC may be necessary to ensure continued protection of public health and safety. Additional actions can include placing the State on Heightened Oversight, placing the State on Probation, or temporarily suspending the Agreement until the NRC believes that the State can adequately protect public health and safety. As a result of the findings of this review, the NRC will conduct a periodic meeting with the State approximately one year from the date of the review to assess the State's progress in addressing the identified issues.

Section 5.0, page 15, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations for the State. A letter dated April 10, 2006, from Aubrey Godwin, Director of the Agency, adequately discusses the State's action plan for resolving the recommendations in the report. No further response is requested at this time. The State's actions in response to the recommendations will be evaluated during the periodic meeting. The State's progress in addressing the recommendations, as well as the overall performance of the program, will determine the timing for the next full IMPEP review.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge the continued support for the Agreement State program and the excellence in program administration demonstrated by your staff, as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

If you have any questions regarding this correspondence, please contact Janet R. Schlueter, Director, Office of State and Tribal Programs, at (301) 415-3340.

Sincerely,

/RA/

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

Enclosure: As stated

cc: Aubrey V. Godwin, Director
Arizona Radiation Regulatory Agency

William A. Wright, Program Manager Radioactive Materials and Nonionizing Compliance

Edgar D. Bailey, California
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF ARIZONA AGREEMENT STATE PROGRAM

February 6-10, 2006

FINAL REPORT

U.S. Nuclear Regulatory Commission

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 February 6-10, 2006, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the State of Florida. 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 <u>Federal Register</u> 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 March 1, 2002 - February 10, 2006, were discussed with Arizona management on the last day of the review.

A draft of this report was issued to Arizona for factual comment on March 8, 2006. The State responded by letter on April 10, 2006, from Aubrey Godwin, Director, Arizona Radiation Regulatory Agency (the Agency). The Management Review Board (MRB) met on May 2, 2006, to consider the proposed final report. The MRB found the Arizona Agreement State Program adequate, but needs improvement, and compatible with NRC's program. The MRB directed that a periodic meeting with the State take place approximately one year from the date of the review in order to assess the State's performance and establish a date for the next full IMPEP review.

The Arizona Agreement State Program is administered by the Agency. The Director of the Agency 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). The Program Manager spends approximately one-half of his time on the radioactive materials program. An organization chart for the Agency is included as Appendix B. At the time of the review, the Arizona Agreement State Program regulated 330 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 Arizona.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Agency on December 1, 2005. The Agency provided its response to the questionnaire on January 23, 2006. A copy of the questionnaire response may be found on the NRC's Agencywide Documents Access and Management System (ADAMS) using the accession numbers ML060240432, ML060240429 and ML060240467.

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

Section 2 below discusses the Agency's actions in response to recommendations made following the previous 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 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 March 1, 2002, six recommendations were made and transmitted to Aubrey Godwin, Agency Director, on March 29, 2002. The team's review of the current status of these recommendations is as follows:

- 1. 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 2002 report)
 - Current Status: The Agency has completed a review of most of their licenses and made the appropriate changes to ensure licenses meet the State's financial assurance requirements. The Agency has not completed this review for six of their radiography licenses. This recommendation remains open.
- 2. The team recommends that the Agency reexamine their procedure for handling allegations, consider the key elements of procedures outlined in NRC's Management Directive 8.8, and incorporate the elements that are appropriate for their program. (Section 3.5 of the 2002 report)
 - Current Status: The Agency has prepared and implemented a procedure, effective February 6, 2005, for handling allegations. The procedure specifically references the guidance outlined in NRC's Management Directive 8.8. This recommendation is closed.
- 3. The team recommends that the Agency submit legally binding requirements to NRC for review. (Section 4.1.2 of the 2002 report)
 - Current Status: The Agency has submitted all applicable legally binding requirements to the NRC for review that are being used in lieu of adopting of NRC regulations. This recommendation is closed.
- 4. The team recommends that the Agency review its procedures to improve the timeliness in incorporating new rule changes into their regulatory program, including immediately addressing the reporting requirements for generally licensed device distributors which was due by August 16, 2001. (Section 4.1.2 of the 2002 report)
 - Current Status: All required NRC amendments have been incorporated into the Agency's regulatory program. The proposed regulations for the requirements for generally licensed device distributors were submitted to the NRC for review. The NRC had no comments. The final regulations will be submitted when the Agency's rulemaking process is completed. The timeliness of regulation submittals has greatly improved since the last IMPEP review; however, proposed regulations are still routinely being submitted late. Although the corrective actions for part of this recommendation

have not been completed, for clarity, the team is closing this recommendation and incorporating the objective, timely submission of rule changes, into a new recommendation. See Section 4.1.2 for further discussion. This recommendation is closed.

- 5. The review team recommends that the Agency make corrections to the Sealed Source and Device (SS&D) registration certificates Nos. AZ-244-D-101-S and AZ-244-D-102-S. (Section 4.2.1 of the 2002 report)
 - Current Status: The Agency has made corrections to the SS&D registration certificates for both devices. New registration certificates were issued. This recommendation is closed.
- 6. The review team recommends that the Agency establish qualification requirements for SS&D reviewers and develop a formalized, written training program. (Section 4.2.2 of the 2002 report).

Current Status: The Agency has established written qualification and training requirements for SS&D reviewers. They have sent two staff to the September 2003 SS&D workshop. This recommendation is closed.

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 include: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Agency'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 Agency's questionnaire response relative to this indicator; interviewed Agency management and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Program is authorized for four Health Physicist positions, and one-half of the Program Manager's effort. In addition, the Agency Director also provides managerial support to the Program. The Agency receives approximately 60 percent funding from the State's General Fund and approximately 40 percent from collecting fees. The last fee change was in 1993 and is based upon 1987 costs. For the past three years, one vacancy has not been filled due to budget cuts. This position is contained within the Governor's budget for 2007. Approval will be determined in May 2006. If approved, the Program will have the funding to fill the Health Physicist vacancy in July 2006.

Currently, the licensing and inspection functions are supported by two materials inspectors and one materials licensing specialist. The materials licensing specialist also has lead responsibility

for rulemaking development. Two of the staff are fully qualified to perform regulatory actions independently: one is an experienced inspector and the other is an experienced licensing specialist. The other inspector, previously from the Agency's X-ray program, is working toward qualification. Licensing support and the SS&D Program are augmented by the Program Manager and Agency Director. The Program Manager reviews all licensing actions and the Agency Director signs all licenses.

At the time of the on-site review, there were significant backlogs in the inspection program (see Section 3.2) and no backlogs in licensing actions. The team noted that the Agency has certain licensing restrictions placed on the Agency by law. Section 41-1073, Article 7.1, Chapter 6, Title 41 of the Arizona Revised Statutes requires Agencies to adopt a timeframe for each type of license/amendment approval. The "overall timeframe" consists of the "administrative completeness review timeframe" and the "substantive review timeframe." Section 41-1077 states that failure of the Agency to meet the overall timeframe results in the Agency: (1) to refund the application fee; and (2) in cases where a substantive review was not required, the Agency shall pay a penalty to the State General Fund after the overall timeframe for review was exceeded, equal to one percent each month of the total fees received by the Agency for the licensing action until the agency issues written notice to the applicant granting or denying the license.

Program staff are required to have a Bachelor's degree in science or equivalent experience for a State Health Physicist entry position, and a Master's degree and/or additional radiation-related work experience for positions beyond entry level. The Program has been able to recruit and train staff, however, two individuals resigned for higher paying jobs shortly after qualification during the review period.

The Program has a documented training plan that is consistent with the requirements in the NRC's Inspection Manual Chapter (MC) 1246. The Program also has on-the-job training to supplement the course work so that individuals may broaden their work areas. A new hire is expected to complete certain necessary courses, which are designated as "core" courses, or their equivalent, to be fully qualified according to the Program's training guidelines.

In the past, the Program staff has received "core" course training by attending NRC-sponsored training. The NRC training combined with on-the-job training allowed new personnel to be fully qualified within approximately two years. The Program does not have a budget specifically for training. The only money available to the Program for training has been through the Department of Justice (DOJ). The Program has sent staff members to the five-week Oak Ridge Institute of Science and Education Health Physics course, paid for by DOJ. With Arizona's current budget, it is very unlikely that the newly hired inspector will be fully trained within a two-year period.

The review team discussed with Agency management, their concerns about the effect of an aging workforce. It is expected that all but one staff member will be retired within the next five years. In light of the budget restraints and the loss of qualified staff to both retirement and higher paying jobs, the Program is experiencing difficulty in maintaining a qualified staff. Immediate funding of the vacant Health Physicist position is essential to the transfer of Program knowledge and on-the-job training. 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.

The Radiation Hearing Board of the State of Arizona, as constituted under law, avoids conflicts of interest, as required under Arizona Revised Statutes §38-511.

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

The review team's evaluation of the Agency inspection priorities revealed that inspection frequencies for each type of license were the same as those listed in MC 2800; however, Agency management has set inspection goals that are more frequent, such as conduct of initial inspections of new licensees within six months of license issuance.

The Agency maintains licensee inspection information in a Microsoft Access database. Inspection history for each licensee can be viewed on the "inspection data entry" screen that links to the database. In response to the questionnaire, the Agency used the database to provide a report, containing a list of licensees sorted by priority, that identified the date of the last inspection conducted and the due date of the next inspection.

The review team compared the data in the report with the "inspection data entry" screen for 89 licensees and identified numerous inconsistencies. The team manually reviewed all of the licensees' inspection files in order to resolve these inconsistencies. The team also confirmed the accuracy of other inspection data by reviewing a sampling of additional inspection files. The team discovered that the inspection information in the "inspection data entry" screen was accurate.

In total, the team evaluated 125 inspections that were due during the review period. The review team identified 5 initial and 18 Priority 1, 2 and 3 (core) inspections that were completed overdue as well as 14 initial inspections and 2 routine core inspections that are currently overdue. Based on this data, the review team determined that 31 percent of the core inspections sampled were either completed overdue or were overdue at the time of the review.

The Agency received requests for reciprocity from 173 licensees over the review period, of which 58 were core licensees. The review team determined that the Agency conducted reciprocity inspections of 17 percent of the core licensees in calendar years 2002 and 2005, but conducted no reciprocity inspections of core licensees in 2003 and 2004. The Agency did not meet the 20 percent criterion prescribed in MC 1220 for inspection of licensees operating under reciprocity.

The review team discussed the significant number of overdue core inspections, core inspections completed overdue, and inspection of reciprocity licensees with the Program Manager and the

Agency Director. Several reasons for the inspection delays were identified by Agency management. The Agency has had two inspectors retire and was budgeted to only fill one of the resulting vacancies. Since March 2003, the Agency has filled the one budgeted inspector position with three different staff. Two of the staff were trained by the senior inspector and subsequently left the program for higher paying jobs after becoming fully-qualified. The newest staff member is currently being trained by the senior inspector. As a result, staff had to focus on inspecting the lower priority licenses for training purposes. In addition, the Agency did not have an active inspection program during a six-month period in 2003 and 2004 when the senior inspector was unable to conduct inspections.

The review team concluded that one of the root causes for the inspection delays is directly related to insufficient staffing during the review period (as discussed in Section 3.1). Another contributing root cause is that the Program database is not an adequate tool for management to assess the status of the Program because the reports generated cannot be relied upon for accuracy. 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 MC 2800, and conduct reciprocity inspections in accordance with MC 1220.

Title 41, Chapter 6, Article 1, Section 41-1009 of the Arizona Revised Statutes 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 timeliness of issuance of inspection reports. In all cases except one, the preliminary findings of inspection reports were sent to the licensees within 30 days, and generally within 2-5 calendar days, of the inspection date.

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 the inspection reports, enforcement documentation, and interviewed inspectors for 13 radioactive materials inspections conducted during the review period. The casework included work performed by six of the Agency's radioactive materials inspectors, and covered a variety of license types including: academic broad; medical (broad scope, private practice, and institutional); high dose remote afterloader; manual brachytherapy; nuclear pharmacy; industrial radiography; manufacturing and distribution (broadscope and limited); and service provider. Appendix C lists the inspection casework reviewed, as well as the results of the inspection accompaniments.

Based on the casework evaluated, the review team noted that routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspectors reviewed previous open items and past violations during the inspections. Inspection reports were generally very thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were frequently performed for larger and complex licensees and for training purposes. Based on the casework evaluated, the review team found very detailed documentation of the inspector's

observations, interviews of personnel, and performance of independent and/or confirmatory measurements. The review team noted that a 'notice of inspection' signed by the licensee was maintained in each inspection file reviewed. This notice of inspection is required by State statute to be provided to the licensee at each inspection and outlines the rights of the licensee with regard to being inspected. By Arizona law, failure to provide this document constitutes cause for disciplinary action or dismissal of the inspector. In addition, the Agency cannot use any information collected during this inspection in any administrative or civil proceeding with the exception of criminal or major civil actions.

The inspection findings were appropriate and prompt regulatory actions were taken, as necessary. The Agency issues a 'preliminary findings of inspection' report, if potential violations are identified during an inspection. The Agency identifies proposed violations and any items of concern to the licensee in this report. The items of concern are not violations of any regulatory requirement, but have safety concerns which may lead to a violation if licensee management does not take an appropriate action. The licensee is required to respond to the preliminary findings within 30 days. If the violations are accepted, a notice of violation is then issued with the appropriate sanctions. In addition, the Agency has the ability to impose a civil penalty when it is deemed that the licensee has had a significant breakdown in operations that affect overall health and safety. All inspection findings are clearly stated and documented in the report which is reviewed by the Program Manager and the Agency Director. The Agency Director signs all final inspection actions.

The review team noted the exceptional detail in the documentation supporting inspection findings during the casework review. Program management informed the team of the requirements of Title 12, Chapter 3, Article 5 of the Arizona Revised Statutes. If a licensee challenges an Agency escalated enforcement action in court and prevails by an adjudication on merits, the Agency may be required to pay any costs prescribed by statute and pay for the licensee's expenses for attorneys, expert witnesses, the cost of any study, analysis, engineering report, test, or project which the court finds directly related to the licensee's defense. Agency management stated that as a result of their limited budget they cannot afford to pursue an escalated action against a licensee unless the Agency has adequate documented evidence to support the violations and reasonable assurance that they will prevail in a court case.

The Agency 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 Agency has a contractor calibrate their survey instruments on an annual basis. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers and micro-R meters were observed. Air monitoring equipment is also available for emergency use. Contamination wipes are evaluated at the Agency on-site laboratory. The Agency also maintains a mobile laboratory van for use in emergencies and emergency exercises.

During the review period, the Program Manager performed inspector accompaniments with each of the inspection staff with the exception of the senior inspector in one calendar year due to unusual circumstances. The review team concluded that the Agency actions in this area were acceptable.

The review team accompanied two materials inspectors (one fully qualified and one in training) on February 2 and 3, 2006. The accompaniments included inspections of an industrial radiography home office and a portable gauge. The facilities inspected are identified in

Appendix C. During the accompaniments, each inspector demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were properly trained, well prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted confirmatory measurements and utilized good health physics practices. Interviews with licensee personnel were performed in an effective manner, and the inspections were adequate to assess radiological health and safety at the licensed facilities.

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

3.4 <u>Technical Quality of Licensing Actions</u>

The review team examined completed licensing casework and interviewed Program staff for 17 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes, 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, license 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, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data. The licensing process was also evaluated for tracking of licensing actions, program codes and categories of license types.

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 of licenses: research and development, industrial radiography, medical (institution, private practice, and broad scope), portable gauge and nuclear pharmacy. Licensing actions selected for evaluation included one new license, three renewals, ten amendments, two terminations and one administrative change initiated by the Program. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

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

A recommendation was made during the 2002 IMPEP review (Recommendation 1, Section 2.0). In 2002, the review team recommended 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. The Program has completed a review of most of their licenses and made the appropriate changes to ensure licenses meet the State's financial assurance requirements. Six radiography licenses remain to be evaluated by the Program with respect to financial assurance. Upon review, some

modifications may need to be made with radiography licenses, and therefore this recommendation remains open.

All licensing actions are reviewed by one materials license specialist who closely monitors the timeliness of licensing actions. All completed licensing actions are then reviewed by the Program Manager. The Agency Director conducts a secondary management review on selected actions and signs all licensing documents. The team noted that Section 41-1073, Article 7.1, Chapter 6, Title 41 of the Arizona Revised Statutes requires Agencies to adopt a timeframe for each type of license/amendment approval. The "overall timeframe" consists of "administrative completeness review timeframe" and the "substantive review timeframe." Section 41-1077 states that failure of the Agency to meet the overall timeframe results in the Agency: 1) to refund the application fee; and 2) in cases where a substantive review was not required, the Agency shall pay a penalty to the State General Fund after the overall timeframe for review was exceeded equal to one percent each month of the total fees received by the Agency for the licensing action until the Agency issues written notice to the applicant granting or denying the license.

Licensing checklists are not used routinely due to the experience of the Program staff. The Program does not routinely issue cover letters with completed licensing actions due to time constraints and workload. However, the Program will issue deficiency letters when it believes a formal letter is warranted. The team found that terminated licensing actions were adequately documented. In general, the files included the appropriate material transfer records and survey records. No health and safety issues were identified.

The review team examined the licensees that the State had determined met the criteria for the increased controls, as per COMSECY-05-0028. The review team determined that the Program had correctly identified the Arizona licensees that require increased controls based on this criteria. Each licensee was issued a license amendment requiring increased controls in accordance with the timelines established by the Commission in the SRM for COMSECY-05-0028. The Program has started to plan for the initial set of inspections of these licensees in accordance with the increased control requirements.

In 1977, the NRC initiated a review of terminated NRC licenses to determine whether sites had been adequately decontaminated prior to termination and release of the site. As a result of this effort, a number of sites were identified as lacking proper documentation of termination activities, including disposition of materials. Some of these NRC formerly licensed sites were determined to be located in Agreement States and to be the regulatory responsibility of the State. Five sites were determined to be located in Arizona. The Program was requested to report the resolution of each case to the NRC for tracking. The team was able to determine that all five sites have been closed out and the results were provided to the NRC in a letter dated August 5, 2002, to the Office of State and Tribal Programs (STP).

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 satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Agency's actions in responding to incidents, the review team examined the Agency's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Arizona in the Nuclear Material Events Database (NMED) against those contained in the Agency's Radioactive Incident and Event Response files, and evaluated reports and supporting documentation for 19 material incidents. A list of the incident casework reviewed is included in Appendix E. The team also reviewed the Agency's response to allegations involving radioactive material.

The incidents selected for review included the following categories: defective or failed equipment, lost/abandoned/stolen gauges, transportation of radioactive material, lost radioactive material, leaking sources and medical events. The team found the Agency's documentation in 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. The Agency dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement and follow-up actions.

Initial response and follow up to incidents and allegations involving radioactive materials are coordinated with the Program Manager. Separate written procedures exist for handling incidents and allegations. Interviews and discussions with the Agency staff and the team confirmed that the staff is knowledgeable of the Agency's procedures for handling incidents and allegations. The Agency conducts on-site investigations for all incidents that present an actual or potential hazard to public health and safety. The Agency Director is advised of all incidents reported and the planned response prior to dispatching responders to the site. Review of incident files indicates that this approach provides effective and appropriate response actions and does not delay the response time. The procedures and report forms are available to the staff when responding to any incident, accident or emergency involving radioactive materials. All records of reported incidents are maintained in a master file and a duplicate copy is maintained in individual licensee files.

During the review period, the Agency documented 58 radioactive material incidents in their Radiological Incident Log. All 58 incidents were reported and investigated in accordance with the Agency's procedures for responding to incidents. The team identified and independently reviewed 19 materials incidents that required reporting under the NRC criteria. The review team identified four events occurring in 2005 that have not been closed out through NMED, although the review of incident files revealed that inspection and Agency follow-up actions have been performed and are complete. The four open incidents were discussed with Agency management who stated that no further action is anticipated by the State. The team discussed with Agency Management the procedures for updating and closing incidents with Idaho National Laboratory (INL), the contractor maintaining NMED. Agency management indicated that INL will be contacted for closure and completion of the identified incidents. Except as noted above, the team found that the NMED database accurately reflected the information contained in the Agency's incident files. Overall, the team determined that the Agency reported incidents to the NRC Headquarters Operations Center in a timely manner and appropriate and timely follow-up actions were performed.

The team did not identify any performance issues with the Agency's handling of allegations. During the review period, the Agency received seven allegations involving radioactive materials;

five were referred by the NRC and two were received internally by the Agency. The Agency's responses to all seven allegations were evaluated by the review team. The review team noted that the Agency promptly responded with appropriate investigations, follow up, and close out actions for six of the seven allegations. However, for one of the allegations referred to the Agency in March 2005, the alleger had not been informed of the results of Agency's review, as requested by the alleger and NRC's Region IV office. The review team determined that the Agency took adequate actions in response to the concern raised and plans to follow up with a response to the Alleger.

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 State program does not cover low-level radioactive waste disposal or uranium recovery operations, so only the first two non-common performance indicators were applicable to this review.

4.1 <u>Compatibility Requirements</u>

4.1.1 <u>Legislation</u>

The authority under which the Agency administers the State's Radiation Control Program is Title 30, Chapter 4 of the Arizona Revised Statutes, "Control of Ionizing Radiation." This statute gives the Agency specific powers and duties among which are authorities to allow the State to enter into an agreement with the NRC, promulgate regulations, issue licenses, perform inspections, collect fees, and issue civil penalties. The Arizona Revised Statutes also require the Agency to review all regulations every five years.

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. There had not been legislation passed since the last IMPEP review that affected the radiation control program; however, House Bill 2097 was pending at the time of this review. House Bill 2097, which provides legislative authority for the radiation control program to continue, has since passed.

4.1.2 Program Elements Required for Compatibility

The Agency's regulations are contained in the Arizona Administrative Code under Title 12, Chapter 1, "Radiation Regulatory Agency," Articles 1 through 17. The Arizona Regulations pertaining to radiation control apply to all ionizing radiation, whether emitted from radionuclides or devices. Arizona requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium. To the extent possible, the Arizona

regulations follow the Suggested State Regulations of the Conference of Radiation Control Program Directors, Inc.

The Program has assigned a materials license specialist the responsibility of rulemaking development, including scheduled maintenance, to assure continued compatibility of State regulations with those of the NRC. The review team conducted several interviews with the staff member to determine the effectiveness of the Agency's regulatory process.

The Agency's regulations are reviewed every five 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 State Regulation Status (SRS) data sheet, as maintained by the NRC's STP, reflects that the Agency initially adopts some changes to the NRC regulations by incorporating them into license conditions, then by adopting the NRC regulations through rulemaking. After preparation of a package of draft regulations and incorporation of comments, the Agency obtains approval from the Governor's Regulatory Review Council (the Council). The Council allows opportunity for members of the public to comment on proposed regulations, and evaluate the regulations to avoid duplication and unnecessary burdens. Typically, rule promulgation requires one to three years due to scheduling of the Hearing Board and Council. This rulemaking process appears to be functioning for the Agency; however, no amendments were finalized within the three-year timeframe for adoption as required by the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (Policy Statement).

The review team evaluated the status of the regulations required for adoption by the State under the Policy Statement. The review team compared the adoption of regulations by the State with information contained on the State's SRS data sheet maintained by STP. A spot check review of the Arizona Administrative Code was also done to verify adoption of previously issued NRC regulations. The review team did not find any overdue regulations that had not been submitted as a proposed regulation, license conditions, or other legally binding requirements.

During the review period, 20 amendments were finalized and submitted to the NRC for review. The review team determined that the Agency consolidates several amendments into a rulemaking package in order to lower the expense of promulgation of its regulations. The review team recognized the benefits of this practice in managing the cost of rule development; however, this practice will need to be balanced against timeliness in incorporating new rule changes to meet NRC compatibility requirements.

The team noted that the following was incorporated by license condition since the last IMPEP:

• "Increased Controls for Risk-Significant Radioactive Sources," NRC Order EA-05-090 (70 FR 72128) that became effective December 1, 2005.

The following proposed regulations have been submitted to the NRC for review and comment and were in the rulemaking process at the time of the IMPEP review:

 "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 16298) that became effective April 5, 2005.

- "Security Requirements for Portable Gauges Containing Byproduct Material,"
 10 CFR Part 30 amendment (70 FR 2001) that becomes effective July 11, 2008.
- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2005.
- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, 32 amendments (65 FR 79162) that became effective February 16, 2004.

The review team requested that the Agency submit the final regulations to the NRC using STP Procedure SA-201 as a guide after the final regulations are published.

A recommendation was made during the 2002 IMPEP review (Recommendation 4, Section 2.0) that the Agency review its procedures to improve the timeliness in incorporating new rule changes into their regulatory program, including immediately addressing the reporting requirements for generally licensed device distributors which was due by August 16, 2001. The proposed regulations for the requirements for generally licensed device distributors were submitted to the NRC for review. The NRC had no comments. The final regulations will be submitted when the Agency's rulemaking process is completed. In review of the Agency's timeliness, the review team found that the Agency has made significant improvements on the timeliness of submitted regulations to the NRC; however, during the review period, the Agency's proposed regulations were approximately one year overdue. The review team discussed with Agency management the need to continue to improve the timeliness of regulation submittals so that new rule changes are submitted within the three-year timeframe allowed. Although the corrective actions for part of this recommendation have not been completed, for clarity, the review team is closing this recommendation and incorporating the objective, timely submission of rule changes, into a new recommendation. The review team recommends that the Agency develop a process that allows for the adoption of NRC regulations within the three-year timeframe.

The Agency will need to address the following regulations in upcoming rulemakings or by adopting alternate legally binding requirements by the date indicated for each amendment:

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendments (68 FR 57327) that becomes effective December 3, 2006.
- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety," 10 CFR 71 amendment (69 FR 3697) that becomes effective October 1, 2007.
- "Medical Use of Byproduct Material Recognition of Speciality Boards," 10 CFR 35 amendment (70 FR 16336 and 71 FR 1926) that becomes effective April 29, 2008.

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 sub-indicators were used to evaluate the Program's performance regarding the SS&D Evaluation Program. These sub-indicators include: (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 Program's SS&D evaluation activities, the review team examined information provided by the Program in response to the IMPEP questionnaire on this indicator. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The review team noted the staff's use of guidance documents and procedures, interviewed the staff and the supervisor involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

The Program Manager and a Health Physicist from the Radiation Measurement Program, another program within the Agency, are the reviewers qualified to conduct safety evaluations of SS&D applications. Both of the Agency staff members have academic degrees in engineering and have completed the NRC workshop for SS&D reviewers. The review team interviewed these individuals and found that both are familiar with the SS&D evaluation process and are familiar with and have access to the applicable reference documents. According to Agency procedures, both of these reviewers are required to conduct the safety evaluation, and the Program Manager and the Agency Director signs the certificate. The review team determined that the reviewers meet the technical training required for SS&D reviews as described under the guidance. The review team determined that the staffing level of qualified reviewers is sufficient in view of the relatively low number of Arizona licensees who need registration certificates. However, the review team discussed with Agency management the upcoming retirement of one of the SS&D reviewers. The Agency does not have someone who is qualified to conduct safety reviews in accordance with Agency procedures to replace the current individual upon his retirement.

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

The review team evaluated all six SS&D evaluation amendments and new registrations, representing the work of two SS&D reviewers. The Agency stated that they currently manage two active SS&D manufacturer/distributors. Four of these sheets superseded sheets issued in California. The Agency performed a full SS&D review of the four sheets. A list of SS&D casework examined along with case-specific comments may be found in Appendix F. Analysis of the casework and interviews with staff confirmed that the Agency generally follows the recommended guidance from the NRC SS&D training workshops NUREG-1556, Volume 3. 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. The Agency uses license conditions to incorporate SS&D commitments into the license document for them to be legally enforceable. The Agency performed evaluations based on sound conservative assumptions to ensure public health and safety and also sought the input from other licensing jurisdictions that have experience with similar products. Appropriate review checklists were used to assure that all

relevant materials were submitted and reviewed. Registrations clearly summarized the product evaluation and provided license reviewers with adequate information in the Limitations and Considerations of Use Section on areas requiring additional attention to license the possession, use, and distribution of the products.

The review team determined that product evaluations were thorough, complete, consistent, and adequately addressed the integrity of the products during use and in the event of likely accidents. While the Agency's staff obtains and documents adequate quality assurance and quality control programs (QA/QC) for each SS&D registration, the review team determined that the Agency, during routine inspections, does not determine that these QA/QC programs are actually implemented by the licensee. 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.

The review team discussed a few general issues with Program staff. The review team identified a few SS&D sheets are listed as active but are currently either no longer being manufactured/distributed or the licensee has gone out of business. While NUREG-1556, Volume 3, places the burden of inactivating sheets on the registry holder, it does allow the Agency to inactivate these sheets on their own initiative. The Agency staff indicated that they were aware of these and plan to begin to inactivate these sheets as appropriate. Completion of this task may require additional resources.

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; however, an incident occurred with a Honeywell device. The review team found that Agency staff addressed the incident issue in a comprehensive manner. Specifically, the staff responded to the incident and followed up the case with the equipment manufacturer, DuPont and the Agreement State, Florida. It was determined that the root cause of the incident was the rupture of the krypton 85 (Kr-85) source, manufactured by DuPont. DuPont no longer manufactures the Kr-85 sources, and there have been no source issues since then. The incident was reported to the NRC, and details are included with all other incidents listed in Appendix E.

The 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 the Agency's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Arizona's performance to be unsatisfactory for the performance indicator, Status of Materials Inspection Program; satisfactory but needs improvement for the performance indicator, Technical Staffing and Training; and satisfactory for the five remaining performance indicators. Accordingly, the review team recommended and the MRB agreed in finding the Arizona Agreement State Program to be

adequate, but needs improvement, and compatible with NRC's program. The review team and the MRB agreed that a periodic meeting with the State should take place approximately one year from the date of this review. At that time, a recommendation for the timing of the next full IMPEP review will be made.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

- 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)
- 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 MC 2800, and conduct reciprocity inspections in accordance with MC 1220. (Section 3.2)
- 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 2002 IMPEP report)
- 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)
- 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)

LIST OF APPENDICES AND ATTACHMENT

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 and Device Casework Reviews

April 10, 2006 Letter from Aubrey Godwin Arizona's Response to Draft IMPEP Report Attachment

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name Area of Responsibility

Sheri Minnick, RI Team Leader

Technical Staffing and Training

Andrea Jones, STP Technical Quality of Incident and Allegation

Activities

Ashley Tull, NMSS Compatibility Requirements

James Mullauer, RIII Technical Quality of Licensing Actions

Vivian Campbell, RIV Status of Materials Inspection Program

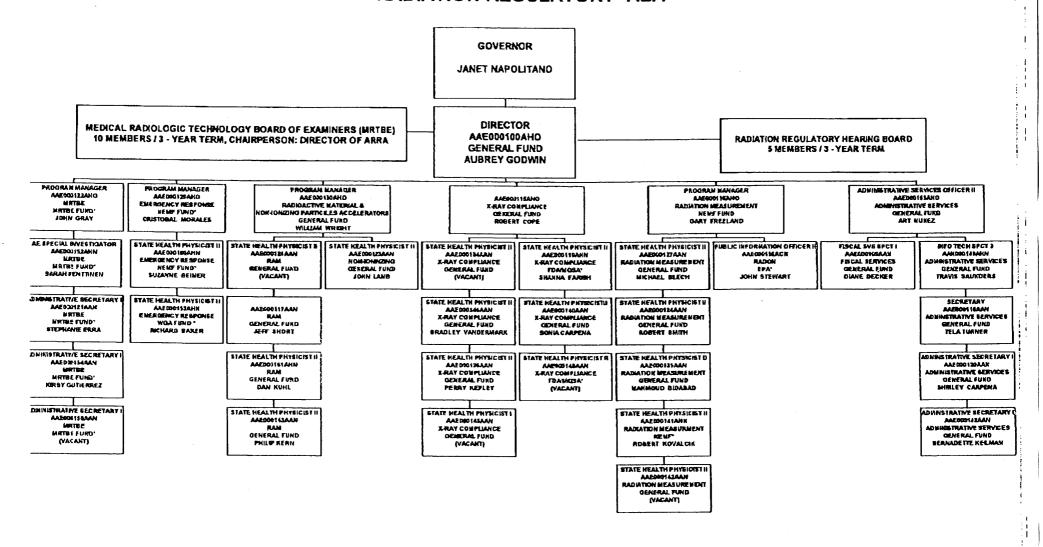
Technical Quality of Inspections Inspector Accompaniments

Mike Stephens, Florida Sealed Source and Device Evaluation Program

APPENDIX B ARIZONA ORGANIZATION CHARTS

ADAMS: ML060240429

STATE OF ARIZONA RADIATION REGULATORY AEA



VACANT

· FUNDEO BY NON-GENERAL SOURCES

GENERAL PUND POSITIONS: 23
NEMF FUND POSITIONS: 4
MRTBE FUND POSITION: 6
EPA POSITIONS: 1
FDA/NQSA FUND POSITIONS: 2
WGA POSITION: 1
TOTAL 36

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: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 7/27/04
License No.: 7-516
Priority: 2
Inspectors: LB, GS

File No.: 2

Licensee: St. Luke's Medical Center

Inspection Type: Routine, Unannounced

Inspection Date: 11/16/04

License No.: 7-716

Priority: 2

Inspectors: LB, GS

File No.: 3

Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 9/1/04
License No.: 10-84
Priority: 2
Inspectors: LB, GS, JL

File No.: 4

Licensee: Southwestern Radiation Oncology, Ltd.

Inspection Type: Routine, Unannounced
Inspection Date: 11/19/02

License No.: 10-59
Priority: 2
Inspector: GS

File No.: 5

Licensee: Arizona Oncology Services
Inspection Type: Routine, Unannounced
Inspection Dates: 6/23-29/05
License No.: 7-161
Priority: 2
Inspection Dates: 6/23-29/05
Inspectors: GS, PK

File No.: 6

Licensee: Millennium Diversified Medical, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 1/14/03

License No.: 2-16
Priority: 2
Inspectors: GS, DK

File No.: 7

Licensee: University Medical Center Corporation

Inspection Type: Routine, Unannounced

Priority: 2
Inspection Dates: 4/5-8/04

Inspectors: GS, JL, LB, DK

File No.: 8

Licensee: Acuren Inspections, Inc.

Inspection Type: Routine, Unannounced
Inspection Dates: 4/21-22/04

License No.: 15-89
Priority: 1
Inspectors: LB, DK, GS

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File No.: 9

Licensee: Team Cooperheat-MQS

Inspection Type: Routine, Unannounced
Inspection Date: 8/23/05

License No.: 7-493

Priority: 1
Inspector: GS

File No.: 10

Licensee: Cardinal Health

Inspection Type: Routine, Unannounced

Inspection Dates: 1/4-5/06

License No.: 7-123

Priority: 2

Inspectors: GS, PK, JL

File No.: 11

Licensee: Phoenix National Labs, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 9/21/05

License No.: 7-415
Priority: 1
Inspectors: GS, PK

File No.: 12

Licensee: Honeywell International, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 9/10/03

License No.: 7-510
Priority: 1
Inspectors: GS, WY

File No.: 13

Licensee: TLS Systems, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 2/9/05

License No.: 10-86
Priority: 5
Inspectors: LB, GS

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: AMEC Earth & Environmental, Inc.

Inspection Type: Routine, Unannounced
Inspection Date: 2/2/06

License No: 7-369
Priority: 1
Inspector: GS

Accompaniment No.: 2

Licensee: Wilcox Professional Services
Inspection Type: Routine, Unannounced
Inspection Date: 2/3/06
License No: 7-554
Priority: 5
Inspector: PK

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1

Licensee: Medi-Physics

Type of Action: Amendment

Date Issued: N/A

License No.: 07-346

Amendment No.: 31

License Reviewer: DK

Comment:

File copy of license was not date stamped or signed. The Program had the licensee fax a signed copy, however, that copy was still not date stamped. This was a 2001 action so no further review was performed.

File No.: 2

Licensee: Medi-Physics License No.: 07-346
Type of Action: Amendment Amendment No.: 46
Date Issued: 11/23/05 License Reviewer: DK

File No.: 3

Licensee: Catholic Healthcare West

Type of Action: Amendment

Date Issued: 9/26/05

License No.: 07-24

Amendment No.: 106

License Reviewer: DK

File No.: 4

Licensee: Catholic Healthcare West
Type of Action: Amendment
Date Issued: 10/28/03
License No.: 07-24
Amendment No.: 104
License Reviewer: DK

File No.: 5

Licensee: Western Technology, Inc.

Type of Action: Renewal

Date Issued: 1/30/06

License No.: 07-49

Amendment No.: 59

License Reviewer: DK

Comment:

This license does not contain possession limits and there is no license condition that either requires the licensee provide a financial assurance program or maintain possession limits below financial assurance limits. (See Section 3.4)

File No.: 6

Licensee: Geotek
Type of Action: Amendment
Date Issued: Still in Review
License No.: 07-495
Amendment No.: 08
License Reviewer: DK

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File No.: 7

Licensee: Team Industrial Services, Inc.

Type of Action: Amendment

Date Issued: 1/30/06

License No.: 07-493

Amendment No.: 32

License Reviewer: DK

Comment:

This license does not contain possession limits and there is no license condition that either requires the licensee provide a financial assurance program or maintain possession limits below financial assurance limits. (See Section 3.4)

File No.: 8

Licensee: Short/Dolan Investments dba

Canyon State Inspection License No.: 10–101
Type of Action: Amendment Amendment No.: 40
Date Issued: 1/19/06 License Reviewer: DK

Comment:

This license does not contain possession limits and there is no license condition that either requires the licensee to provide a financial assurance or maintain possession limits below financial assurance limits.

File No.: 9

Licensee: Banner Health dba

Banner Good Samaritan Medical Center License No.: 07-748
Type of Action: Renewal Amendment No.: 22
Date Issued: 1/30/06 License Reviewer: DK

Comment:

A required license condition was dropped between iterations of the license. The Program will issue a corrected copy of the license with proper conditions to the licensee.

File No.: 10

Licensee: Nuclear Apothecary

Type of Action: New

Date Issued: 2/16/05

License No.: 14-35

Amendment No.: N/A

License Reviewer: DK

File No.: 11

Licensee: Honeywell International, Inc.

Type of Action: Amendment

Date Issued: 11/14/03

License No.: 07-513

Amendment No.: 02

License Reviewer: DK

Comment:

License Condition 9.B(3) authorizes distribution of Generally Licensed devices, however, there is no B(3) device listed on the license. This was discussed with the Program license reviewer who stated that a corrected copy will be issued to the licensee.

File No.: 12

Licensee: LaPaz Regional Hospital

Type of Action: Termination

Date Issued: 11/14/03

License No.: 14-07

Amendment No.: 19

License Reviewer: DK

File No.: 13

Licensee: Hanson Aggregates

Type of Action: Termination

Date Issued: 7/22/02

License No.: 13-17

Amendment No.: 04

License Reviewer: DK

File No.: 14

Licensee: Sun Health Corporation dba

Walter O. Boswell Memorial Hospital

Type of Action: Agency Review

Date Issued: 8/15/05

License No.: 07-138

Amendment No.: 57

License Reviewer: DK

File No.: 15

Licensee: Millennium Diversified Medical, Inc.

Type of Action: Amendment

Date Issued: 5/6/03

License No.: 02-16

Amendment No.: 08

License Reviewer: DK

File No.: 16

Licensee: PETNET Pharmaceuticals, Inc.

Type of Action: Amendment

Date Issued: 10/11/05

License No.: 7-515

Amendment No.: 07

License Reviewer: DK

File No.: 17

Licensee: ATL, Inc.

Type of Action: Renewal

Date Issued: 02/07/06

License No.: 7-116

Amendment No.: 39

License Reviewer: DK

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

Incidents Nos. 10, 14 and 17 were not assigned Incident Log Numbers because the events involved non-Arizona licensees (i.e. reciprocity) or devices or radioactive material not licensed under the Arizona Radiation Regulatory Agency.

File No.: 1

Licensee: Construction Inspection and Testing License No.: 07-098

Date of Incident: 5/31/02 Incident Log No.: 02-03 (NMED 020556)
Investigation Date: 6/4/02 Type of Incident: Stolen Radioactive Material
Type of Investigation: On-site

File No.: 2

Licensee: Arizona Heart Hospital License No.: 07-443

Date of Incident: 2/26/02 Incident Log No.: 02-09 (NMED 020669)
Investigation Date: 6/24/02 Type of Incident: Medical Event
Type of Investigation: On-site

File No.: 3

Licensee: Geotechnical Testing Services License No.: 14-030

Date of Incident: 8/15/02 Incident Log No.: 02-11 (NMED 020776)
Investigation Date: 8/16/02 Type of Incident: Stolen Radioactive Material
Type of Investigation: On-site

File No.: 4

Licensee: Arizona Heart Hospital License No.: 07-443

Date of Incident: 7/10/02 Incident Log No.: 02-07 (NMED 020957)
Investigation Date: 7/10/02 Type of Incident: Equipment Failure
Type of Investigation: On-site

File No.: 5

Licensee: Construction Inspection and Testing License No.: 07-098

Date of Incident: 1/3/03 Incident Log No.: 03-01 (NMED 030017)
Investigation Date: 1/3/03 Type of Incident: Stolen Radioactive Material
Type of Investigation: On-site

File No.: 6

Licensee: Scottsdale Memorial Hospital License No.: 07-265

Date of Incident: 1/29/03 Incident Log No.: 03-03 (NMED 030116)
Investigation Date: 2/7/03 Type of Incident: Lost Radioactive Material
Type of Investigation: On-site

File No.: 7

Licensee: Phoenix Baptist Hospital

and Medical Center License No.: 07-146

Date of Incident: 5/27/03 Incident Log No.: 03-08 (NMED 030440)
Investigation Date: 5/29/03 Type of Incident: Medical Event
Type of Investigation: On-site

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File No.: 8

Licensee: Phelps-Dodge, Inc.

Date of Incident: 8/25/03

Investigation Date: 9/15/03

License No.: 13-005

Incident Log No.: 03-13 (NMED 030683)

Type of Incident: Equipment Failure

Type of Investigation: On-site

File No.: 9

Licensee: Longview Inspections, Inc.

Date of Incident: 8/25/03

Incident Log No.: 03-14 (NMED 030695)

Investigation Date: 8/28/03

Type of Incident: Radiography Source Disconnect

Type of Investigation: Phone

File No.: 10

Licensee: Geotechnical Testing Services License No.: N/A (Reciprocity)

Date of Incident: 9/23/03 Incident Log No.: N/A (NMED 030763)
Investigation Date: 9/24/03 Type of Incident: Uncontrolled Radioactive Material
Type of Investigation: Phone

File No.: 11

Licensee: Western Technologies License No.: 07-080

Date of Incident: 10/9/03 Incident Log No.: 03-19 (NMED 030819)
Investigation Date: 10/9/03 Type of Incident: Transportation
Type of Investigation: Phone

File No.: 12

Licensee: Ninyo & Moore License No.: 07-460

Date of Incident: 12/16/03 Incident Log No.: 03-22 (NMED 031000) Investigation Date: 12/17/03 Type of Incident: Stolen Radioactive Material Type of Investigation: Agency Meeting

File No.: 13

Licensee: Walter O. Boswell Hospital License No.: 07-138

Date of Incident: 4/18/04 Incident Log No.: 04-05 (NMED 040429)
Investigation Date: 6/2/04 Type of Incident: Lost Radioactive Material
Type of Investigation: On-site

File No.: 14

Licensee: Honeywell International License No.: 07-510

Date of Incident: 12/9/03 Incident Log No.: N/A (NMED 050018)
Investigation Date: 12/9/05 Type of Incident: Leaking Sealed Source
Type of Investigation: Phone

File No.: 15

Licensee: Walmart License No.: General Licensee

Date of Incident: 02/18/05 Incident Log No.: 05-02 (NMED 030695)

Investigation Date: 02/21/05

Type of Incident: Lost Radioactive Material
Type of Investigation: On-site

File No.: 16

Licensee: Jerry Huracek

Date of Incident: 4/12/05

Investigation Date: 4/14/05

License No.: 07-496

Incident Log No.: 05-03 (NMED 050257)

Type of Incident: Theft of Radioactive Material

Type of Investigation: On-site

File No.: 17

Licensee: National Aircraft Corp.

Date of Incident: 6/23/05

Investigation Date: 6/23/05

Type of Incident: Uncontrolled Radioactive Material

Type of Investigation: Phone

File No.: 18

Licensee: Ricker, Atkinson, McBee & Associates

Date of Incident: 11/4/05

Incident Log No.: 05-09 (NMED 031000)

Type of Incident: Stolen Radioactive Material

Type of Investigation: Agency Meeting

File No.: 19

Licensee: Quality Testing

Date of Incident: 4/18/04

Investigation Date: 12/16/05

License No.: 07-491

Incident Log No.: 05-10 (NMED 050824)

Type of Incident: Theft of Radioactive Material

Type of Investigation: On-site

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

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

File No.: 1

Registry No.: AZ-0501-D-105-B SS&D Types: (D) Density Gauge,

(E) Beta Gauge

Manufacturer: Honeywell-International Model Nos.: 1201/2201 Series,

1202/2202 Series, 1203 Series,

2204 Series

Date Issued: 9/9/05 Type of Action: New SS&D Reviewers: BW. BK

Comments:

a) Page 1 lists Distributor/Manufacturer phone number on page one contrary to the format listed in NUREG-1556, Vol. 3, Appendix D.

b) "Principal type" lists text first then letter which is the opposite of the format specified in NUREG-1556, Vol. 3, Appendix C.

c) The company moved from California to Arizona, while not required for superseded sheets, the Agency performed a full review of the information submitted.

File No.: 2

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

Manufacturer: Honeywell-International

Date Issued: 9/9/05

SS&D Type: (E) Beta Gauge

Model No.: 4201 Series

Type of Action: New

SS&D Reviewers: BW, BK

Comments:

a) Page 1 lists Distributor/Manufacturer phone number on page one contrary to the format listed in NUREG-1556, Vol. 3, Appendix D.

b) "Principal type" lists text first then letter which is the opposite of the format specified in NUREG-1556, Vol. 3, Appendix C.

c) The company moved from California to Arizona, while not required for superseded sheets, the Agency performed a full review of the information submitted.

File No.: 3

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

Manufacturer: Honeywell-International

Date Issued: 9/12/05

SS&D Type: (E) Beta Gauge

Model No.: 4202 Series

Type of Action: New

SS&D Reviewers: BW, BK

Comments:

- a) Page 1 lists Distributor/Manufacturer phone number on page one contrary to the format listed in NUREG-1556, Vol. 3, Appendix D.
- b) "Principal type" lists text first then letter which is the opposite of the format specified in NUREG-1556, Vol. 3, Appendix C.
- c) The company moved from California to Arizona, while not required for superseded sheets, the Agency performed a full review of the information submitted.

Page F.2

File No.: 4

Registry No.: AZ-0501-D-108-B SS&D Types: (D) Density Gauge,

(E) Beta Gauge

Manufacturer: Honeywell-International Model No.: 4203
Date Issued: 9/9/05 Type of Action: New

SS&D Reviewers: BW, BK

Comments:

a) Page 1 lists Distributor/Manufacturer phone number on page one contrary to the format listed in NUREG-1556, Vol. 3, Appendix D.

b) "Principal type" lists text first then letter which is the opposite of the format specified in NUREG-1556, Vol. 3, Appendix C.

c) The company moved from California to Arizona, while not required for superseded sheets, the Agency performed a full review of the information submitted.

File No.: 5

Registry No.: AZ-0244-D-101-S SS&D Type: (W) Self Luminous Light Source Manufacturer: TLS Systems, Inc.

Date Issued: 10/11/02 Type of Action: Amendment SS&D Reviewers: BW, BK

Comments:

a) Page 2, Details of Construction should reference Attachment 2 instead of Attachment 1.

b) Issuance date listed on Page 1 (10/11/02) does not agree with issuance date on Page 4 (11/8/02).

c) Amended sheet issued prior to format established in NUREG-1556, Vol. 3.

File No.: 6

Registry No.: AZ-0244-S-102-B SS&D Type: (W) Self Luminous Light Source Manufacturer: TLS Systems, Inc. Model No.: 40111 Date Issued: 10/10/02 Type of Action: Amend/New SS&D Reviewers: BW, BK

Comments:

a) While Attachments 1 and 2 listed on Page 2 under "Source Drawing" are in the Agency's sealed source registry (SSR) file, these attachments are not part of the electronic SSR file posted on NRC's SSR web site.

b) Issuance date listed on Page 1 (10/10/02) does not agree with issuance date on Page 4 (10/11/02).

c) Amended sheet issued prior to format established in NUREG-1556, Vol.3.

ATTACHMENT

April 10, 2006 Letter from Aubrey Godwin Arizona's Response to Draft IMPEP Report

ADAMS: ML061020208





Aubrey V. Godwin

4814 South 40th Street

Phoenix, Arizona 85040-2940

(602) 255-4845 Fax (602) 437-0705

April 10, 2006

Sheri Minnick Regional State Agreements Officer Division of Nuclear Materials Safety U.S. Nuclear Regulatory Commission 475 Allendale Road King of Prussia, PA 19406-1415

Dear Ms. Minnick:

The Arizona Radiation Regulatory Agency (ARRA) appreciates the opportunity to review and comment on the draft IMPEP report. We recognize the significance of the periodic reviews of Arizona Agreement State program by the Nuclear Regulatory Commission (NRC) as it helps guide our efforts to continue improving the Department's programs.

The mission of the ARRA is to protect the health and safety of the citizens of State of Arizona from unnecessary radiation exposure from all natural and man-made sources. The Agency has worked hard and diligently implemented the recommendations provided to us by the previous IMPEP review. Generally, we agree with many of the recommendations made in the draft report, however, we differ on others and wish to clarify some of the findings and associated recommendations.

Below is our response to the draft recommendations as listed on page 17 of the IMPEP report.

Recommendation # 1:

The review team recommends that the State develop and implement a staffing plan to fill the current vacancy, meet growing program needs and maintain long-term stability.

Response:

We agree. As a point of clarification, the Agency has developed a staffing plan and a budgetary allocation designed to fill the current vacancies and help address employee turnover within the Agency. Based on the Agency-proposed plan of expenditures and staffing levels, the Executive Budget for the upcoming fiscal year (FY 2007) includes funding restoration for four positions. Additionally, on January 30, 2006, the Governor signed HB 2661 into law (Laws 2006, Chapter 1) to provide for a state employee salary increase averaging approximately 6.3 percent, which should also strengthen the Agency's retention efforts. The Agency will continue to work with the Executive and the Legislature to secure the resources needed to support its mission.

Recommendation #2:

Sheri Minnick April 10, 2006

The review team recommends that the Agency take appropriate measures to conduct core inspections (including initial inspection) in accordance with the inspection priority schedule in MC 2800, and conduct reciprocity inspections in accordance with MC 1220.

Response:

The finding identified by the IMPEP team is agreed to and the recommendation will be implemented.

As recognized by the review team, the Agency's inspection frequencies for each type of license were the same as those listed in NRC MC 2800 and that the preliminary findings of inspection reports were sent to the licensees within 30 days (generally 2-5 calendar days) of the inspection date. This is consistent and compliant with Title 41, Chapter 6, Article 1, Section 41-1009.

Presently, the Agency uses Microsoft Access database to maintain licensee inspection information, which can provide inspection history for each licensee. We have also initiated actions to seek programming assistance from the Arizona Government Information Technology Agency to enable the ARRA to improve the Program database. One of the main purposes for this measure is the ability to conduct core inspections (including initial inspection) in accordance with the inspection priority schedule in MC 2800, and perform reciprocity inspections in accordance with MC 1220.

Recommendation #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 license to ensure that all licenses meet the State's financial assurance requirements.

Response:

Although there are fewer licenses remaining to address this requirement than reported, the finding identified by the IMPEP team is legitimate and the Department agrees to correct it.

Presently, there are no more than three licensees that are outstanding to close this recommendation and the Agency will continue its efforts to fully address this matter. As reported by the review team, the ARRA has already completed a review of most of the licensees and made appropriated changes to ensure licenses meet the financial assurance requirements.

Recommendation #4:

The review team recommends that the Agency develop a process that allows the adoption of NRC regulations within the three-year time frame.

Response:

The ARRA agrees that implementing changes to rules on a timely basis is appropriate. Currently, the Agency is required by State law to review its regulations every five years. As agreed by the review team, the Agency's rulemaking process is functioning and there have been no overdue regulations that have not been submitted within the rulemaking process.

The Agency agrees in principle to a three-year review adoption timeframe and will endeavor to meet this timeline. However, effective implementation of this measure will require the Agency meet all requirements of Arizona's substantial rulemaking process. It is uncertain as to how long it would take to fully close this recommendation.

Clearly, as stated in the draft report over the past ten years, the Agency has improved the timeliness for regulation adoption but will explore ways to develop a process that may allow adopting NRC regulations within a three-year time frame.

The Arizona adoption process is designed to encourage adequate time for public comment on each regulation. In addition to the adoption of NRC suggested regulation, we are required to review and resubmit for public input each regulation every five years. For example this year we have three separate five-year reviews of our regulations. Each of these requires a notice, a report, and if appropriate the opening of a docket, followed by the proposing of a rule, followed by a hearing and finally the adoption of the rule. Then the final rule is again published for another hearing by the Governor's Regulatory Review Council which, if they agree, the rule will be published by the Secretary of State as adopted. In addition we will have to follow the same process in adopting any rules we need to amend this year.

Recommendation #5:

The review team recommends that the State develop and implement a process to ensure that during routine inspections the QA/QC requirements in the SS&D Registry sheets are being followed by the manufacturer.

Response:

The finding identified by the IMPEP team is agreed to and the recommendation will be implemented.

While product evaluations were found to be thorough, complete and adequately addressed the integrity of the products, the ARRA will continue its improvement and will provide a supplemental inspection sheet (s) for these inspections to document the actions that are implemented by the manufacturer and licensee.

The inclusion of our review will allow the reader of the report to come to a reasonable understanding regarding the status of these important programs. We appreciate the opportunity to have our comments incorporated into the final report.

Thank you again for the efforts of your staff in helping us continue to improve the performance of the Department's program.

Sincerely,

Aubrey V. Godwin, Director Arizona Radiation Regulatory Agency