

June 18, 2002

Mr. Aubrey V. Godwin, Director
Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040

Dear Mr. Godwin:

On June 6, 2002, 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 to protect public health and safety and compatible with the Nuclear Regulatory Commission's program.

NRC recognizes the efforts of Arizona and the other Agreement States to maintain an adequate and compatible program. During the meeting, the MRB discussed the recent reductions in funding for the Arizona Agreement Program and its impact on funding travel for training. The review team also discussed with you their concerns with an aging workforce. The MRB recognized that Program performance can be affected by the reductions in funding and by the potential loss of qualified staff to retirement.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the State of Arizona. We received your April 25, 2002 letter which described your staff's actions taken in response to the recommendations in the draft report. We request no additional information.

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

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

Sincerely,

/RA/

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

Enclosure:
As stated

cc: William Wright, AZ

Steve Collins, IL
OAS Liaison to MRB

Don Hughes
Regulatory Agencies Executive Assistant
Office of the Governor

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Arizona Radiation Regulatory Agency
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bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF ARIZONA AGREEMENT STATE PROGRAM

February 25 - March 1, 2002

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Arizona Agreement State program. The review was conducted during the period February 25 - March 1, 2002, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of North Carolina. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of February 14, 1998 to March 1, 2002, were discussed with Arizona management and a representative of the Governor's office on March 1, 2002.

A draft of this report was issued to Arizona for factual comment on March 29, 2002. The State responded in a letter dated April 25, 2002. The Management Review Board (MRB) met on June 6, 2002 to consider the proposed final report. The MRB found the Arizona radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Arizona Agreement State program is administered by the Arizona Radiation Regulatory Agency (the Agency). The Director of the Agency reports directly to the Governor of Arizona. 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 292 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 indicators was sent to the Agency on December 19, 2001. The Agency provided its response to the questionnaire on February 11, 2002. A copy of the completed questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML020860719.

The review team's general approach for conduct of this review consisted of: (1) examination of Arizona' responses to the questionnaire; (2) review of applicable Arizona statutes and regulations; (3) analysis of quantitative information from the Agency's licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two Agency inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Arizona Agreement State program'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 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 13, 1998, seven recommendations were made and transmitted to Mr. Aubrey Godwin, Agency Director on May 7, 1998. The team's review of the current status of these recommendations is as follows:

1. The review team recommends that industrial radiography inspections need to be conducted at temporary job sites in addition to office inspections, to verify compliance to operating procedures and regulations. (Section 3.2)

Current Status: The review team found that the Agency has conducted industrial radiography inspections at temporary job sites. The Agency has experienced difficulty in locating industrial radiography job sites and plans to institute additional measures to increase the number of job site inspections. The Agency is planning to institute a policy which would require licensees to notify the Agency of field work prior to conducting industrial radiography operations. This recommendation is closed.

2. The review team recommends that staff include more detailed documentation related to telephone deficiency calls, describing the issues and noting the applicant's response. Additionally, the staff should ensure that all requests within license applications are addressed, either in the amended license or by letter, if certain aspects of the amendment request are denied. (Section 3.4)

Current Status: The Administrative Procedures Act of December 1998 eliminated deficiency phone calls as a means of official communication with applicants. During this review, the team noted that the Agency uses letters to officially communicate deficiencies with licensees, and uses telephone discussions, as appropriate, to direct licensees to submit additional information. In the files reviewed, the team noted licensees' written responses to Agency requests for additional information. The Agency's licensing actions were appropriately documented. This recommendation is closed.

3. During the 1998 review, the team noted that an Arizona law, referred to as the deficiency rule, required the Agency to complete licensing actions within a predetermined period of time and prevented the Agency from obtaining additional information from a license applicant once an initial deficiency letter had been sent. The 1998 IMPEP team noted that the deficiency rule could potentially adversely impact public health and safety if the technical quality of the Agency's licensing actions was compromised due to the inability to obtain additional information from the applicant or due to the need to meet a prescribed time line. The review team recommends that the State closely monitor the impact of this deficiency rule and provide NRC with information

about the Agency's experience with this law. (Section 3.4)

Current Status: The team interviewed staff, reviewed licensing files and concluded that the Agency has effectively and efficiently implemented the deficiency rule without compromising public health and safety. This recommendation is closed.

4. The review team recommends that all incident reports be recorded and closed out as directed in the Agency's operating procedures, and that written procedures be developed to ensure that the reports are consistently maintained, distributed, and cross-referenced between the incident and licensee files. (Section 3.5)

Current Status: The Agency has developed detailed written procedures for handling incidents. Agency management meets with staff on a weekly basis to discuss the status of any incidents along with other program related issues. The Program Manager periodically performs checks to ensure that the procedures are being followed as directed. This recommendation is closed.

5. The team also recommends that the State follow the new reporting procedures for all incidents as described in the latest NMED manual. (Section 3.5)

Current Status: The Agency is following the new incident reporting procedures and is reporting Agreement materials events to the NRC. This recommendation is closed.

6. The review team recommends the certificate AZ 244 D 102S, for TLS Systems model 40111 be amended to include the maximum amount of radioactive material used in the device and to remove the authorization for exempt license distribution. (Section 4.2.1)

Current Status: The Agency corrected the registration certificate and submitted it to the NRC National Sealed Source and Device Registry on April 16, 1998. The NRC distributed the corrected certificate to all Agreement States and placed the document into the electronic data base in accordance with the applicable NRC procedure. This recommendation is closed.

7. The review team recommends that the TLS license for distribution (10-135) be amended to include model 40111. (Section 4.2.1)

Current Status: The Agency appropriately amended the license. This recommendation is closed.

During the 1998 review, four suggestions were made for the Agency to consider. The team determined that the Agency considered the suggestions and took appropriate actions.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

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

The team's review of the Agency's inspection priorities verified that inspection frequencies for various types of Arizona material licenses are generally the same as those listed in the NRC Inspection Manual Chapter (IMC) 2800. However, there are three categories of licenses that have been assigned an inspection frequency less than those currently prescribed in the IMC 2800, yet the Agency currently has no licensees in these categories. These three categories of licensees are "Byproduct Material Possession Only," "Source Material Possession Only," and "SNM Possession Only-Other than Reactor Fuel." These categories are currently assigned an inspection priority of "3" by the Agency, while they are assigned a Priority of "2" by the NRC. The Agency indicated that when their inspection procedures were written, they incorporated the NRC priority codes that were in effect at that time and have not updated the procedure to reflect the current priorities. Agency management stated that if the Agency received license applications in these categories, they would revise their inspection priorities to be consistent with those of the NRC. In addition, the team noted that a High Dose Remote Afterloader (HDR) license was assigned a Priority 2 as opposed to a Priority 1, yet the Agency was inspecting the license annually. The team discussed the issue with the Program Manager. The Program Manager indicated that the priority for HDR licenses would be changed to a Priority 1 to be consistent with IMC 2800.

In their response to the questionnaire, the Agency indicated that there were currently no overdue inspections of core licensees. This information was verified during the inspection casework reviews and the review of the monthly generated "inspections due" list provided to the team. The review team noted that out of 10 inspection files examined, only one inspection was conducted overdue during the review period; a Priority 1 license was inspected 5 months past its inspection due date. During the review period, there were no other overdue inspections. The review team also evaluated the Agency's initial inspections. The team noted that the Agency conducted initial inspections in accordance with the IMC 2800 guidelines.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. The Agency has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. During each inspection, Agency staff presents a Notice of Inspection to the licensee for signature. The Notice of Inspection informs the licensee that within 30 working days of completing the inspection, the Agency will mail a letter indicating that there were no potential violations identified or a letter detailing the

potential violations and requesting the licensee's response by a certain date. The Notice also includes the licensee's rights and the Agency's responsibilities. For the 20 inspection files examined, all inspection findings were sent to the licensees within 30 days.

During the review period, the Agency granted 170 reciprocity permits, of which, 82 permits were core licensees based upon IMC 1220. The 82 core licensees consisted of 33 Priority 1 and 49 Priority 3 licensees. The Agency met the IMC 1220 inspection frequencies for Priority 1 licensees by conducting 16 inspections. At the time of the review, the Agency did not meet the IMC 1220 inspection guidance for Priority 3 licenses. The Agency completed four Priority 3 inspections, while the IMC 1220 guidance provided that 14 inspections be conducted. New NRC guidance requires totaling all of the Priority 1, 2, and 3 reciprocity (core) licensees, and conducting inspections of 20% of this total. Thus, the Agency met the revised NRC guidance by completing 19 inspections of the 82 permits issued for core licensees.

The Agency indicated that a lower priority is given to reciprocity inspections because of the limited resources provided to the Program. The Agency indicated that they rely upon the regulatory program which issued the license to conduct routine inspections for Priorities 2 through 7 licensees operating under reciprocity in Arizona. The Agency further indicated that it concentrates its reciprocity inspection efforts on Priority 1 licenses and tries to comply with the 50% inspection requirement for these licenses. The review team concluded that this approach is acceptable, especially in light of the revised IMC 1220 guidance.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 10 radioactive materials inspections conducted during the review period. The casework included all of the Agency's fully trained materials inspectors, and covered inspections of various types as follows: industrial radiography, medical broad scope, limited industrial, nuclear pharmacy, limited medical, and health physics consultants. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation adequately supported the cited violations, and recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

The review team found that routine inspections adequately cover the licensee's radiation protection program. Inspection reports include a written summary of the scope of the licensed activities and categorize violations into severity levels which can be used for escalated enforcement, if necessary. The review team noted that the majority of violations cited are recordkeeping infractions. The review team discussed the current performance-based, risk-informed inspection philosophy with the accompanied inspectors. As discussed below, the review team also found that the inspectors observed licensed operations, interviewed personnel, and performed excellent performance-based inspections during both accompaniments.

The Program Manager conducts supervisory accompaniments of each material inspector once a year. During the year 2000, the Program Manager did not formally document accompaniments but confirmed that supervisory accompaniments are performed annually. The team noted that the Agency has two experienced materials inspectors and one newly hired inspector, who is currently in training status.

The team accompanied two materials inspectors during the period of February 25 to February 26, 2002. The accompaniments included inspections of an industrial radiography home office and a medical institution. The facilities inspected are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were 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. Their inspections were adequate to assess radiological health and safety at the licensed facilities. 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 quarterly to meet the requirement placed upon industrial radiographers. 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's onsite laboratory. The Agency also maintains a mobile laboratory van for use in emergencies and emergency exercises.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the 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 responses relative to this indicator, interviewed Agency management and staff, reviewed job descriptions, training records, and considered any possible workload backlogs.

The Program is authorized for four State Health Physicist positions, and one half of the Program Manager's effort. In addition, the Agency Director also provides managerial support to the Program. Since Arizona is a small program, the licensing and inspection functions are supported by three materials inspectors and one materials licensing specialist. Licensing

support is 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 onsite review, there were no backlogs in inspections or licensing actions. The team determined that there was proper balance between the licensing and inspection functions.

The materials licensing specialist also has lead responsibility for rulemaking development. Of the four staff, three are experienced (2 inspectors and the licensing specialist). One inspector retired during the review period and the Program hired an inspector who was previously from the Agency's X-ray Program. At the time of the review, no vacancies existed in the Program. In addition, the Program Manager and Agency Director support the Sealed Source and Device Program.

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 team noted that the Program has been able to recruit and retain qualified staff.

The Agency has a documented training plan that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and IMC 1246. The Agency 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 "core" courses, or their equivalent, to be fully qualified according to the Agency's training guidelines. In the past, the Agency 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 trained within approximately two years. However, with the severe cuts in the Arizona budget it is very unlikely that the newly hired inspector will be fully trained within the two-year period.

The Agency receives funding from the State's General fund and does not receive funds specifically for training. The State is currently experiencing a billion-dollar or more shortfall over the next 16 months (March 2002 to September 2003) and has directed State Agencies to develop plans and strategies to incorporate funding reductions to their programs. The Agency's FY 2002 budget was cut by 6%, which is equivalent to \$86,200.00 and an additional 0.25% cut, \$3,000.00, is proposed. Currently, the Agency's expenses are exceeding their funding. This has resulted in the Agency suspending all travel which will require State reimbursement, except for the use of State vehicles.

In addition, the review team discussed with Agency management their concerns about the effect of an aging workforce. In light of the budget restraints and the potential loss of qualified staff to retirement, the Agency may experience difficulty in maintaining a qualified staff in the near future.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 15 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

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, well logging, industrial radiography, medical (institution, private practice, and broad scope), portable gauge, nuclear pharmacy, veterinary medicine, and broad scope academic. Licensing actions selected for evaluation included three new licenses, three renewals, eight amendments, and one termination. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The materials licensing specialist appropriately used the Agency's licensing guides and standard license conditions, in most cases. However, the team determined that some modifications need to be made with the Program with regard to financial assurance.

The review team determined that the Program had not fully implemented the decommissioning financial assurance requirements adopted by the State in May 1999. The team examined licenses issued by the Program. The team noted that Arizona licenses contained materials, including unsealed materials, meeting the financial assurance limits, yet no decommissioning funding plan was submitted and the licenses were not conditioned to limit possession to quantities not requiring financial assurance. 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.

All licensing actions are reviewed by the materials license reviewer 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 also found that licensing checklists are not used routinely by the Program due to the experience of the Program staff.

The team also found that terminated licensing actions were adequately documented. In general, the files included the appropriate material transfer records and survey records. No potentially significant health and safety issues were identified.

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. In an effort to reduce the resource impacts on Agreement States, the NRC established a grant program for Agreement States to conduct file reviews and initial surveys of the NRC formerly licensed sites. Five sites were determined to be located in Arizona. The State of Arizona submitted a grant proposal to the NRC and was awarded a grant of \$33,970.00 to review the five sites within the State. The Agency is also requested to report the resolution of each case to the NRC for tracking.

During the Arizona IMPEP, the team examined the Agency's activities with regard to the five NRC formerly licensed sites. The review team interviewed staff, and reviewed the five license files for the sites, which included radiological survey and analysis results. The team determined that the Agency was applying good health physics practices in conducting radiological surveys and sample collections. The team determined that the Agency's laboratory facilities and equipment were sufficient to provide appropriate analysis of samples. At the time of the onsite review, the team was informed that the Agency had gathered sufficient information to close the termination files of four sites. One site remains open because the Agency has not yet been able to locate it. The specifics of each case are found in Appendix D.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the 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 files, and evaluated the casework and supporting documentation for 15 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Agency's response to four allegations involving radioactive materials referred by the NRC during the review period.

The review team discussed the Agency's incident and allegation procedures, tracking system, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with Agency's management and staff.

The primary responsibility for coordination of all emergency responses rests with the Emergency Response Program Manager. However, the initial response and follow up to incidents and allegations involving radioactive materials are coordinated with the Program Manager for radioactive materials. Separate written procedures exist for handling incidents and allegations (referred to as "complaints" by the Agency). The Agency conducts onsite

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 casework 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 by the Emergency Response Program Manager in a master file and a duplicate copy is maintained in the license file.

The incidents selected for review included the following categories: overexposure, damage to equipment, lost and stolen gauges, loss of radioactive material, release of radioactive material, and loss of administrative control. The review team found that the Agency's response to incidents was generally complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Agency dispatched inspectors for onsite investigations when appropriate, and took suitable enforcement and follow-up actions.

The Agency listed 31 radioactive material incidents involving Agreement material in their response to the questionnaire. The team found 21 of the events in the NMED database. The team reviewed 15 incidents, including the 10 events not included in NMED. The team found that three of the event files indicated that reports or follow-up information had been provided to the NRC yet the information was not in the NMED database. The team provided these discrepancies to the NRC NMED Project Manager for follow up.

The 15 incidents reviewed included seven significant events, three 30-60 day notification events, and five events not requiring reports as defined in the Office of State and Tribal Programs (STP) Procedure SA-300, "Reporting Material Events." Of the seven significant incidents, the review team noted that two events which met the reporting criteria were not reported to NRC. In addition, the team identified one event where follow-up information was available in the file, but was not reported to NRC. The team discussed the procedure for reporting incidents with the Agency management. The Agency management indicated that they would update the NMED data to include this additional information.

During the review period, the NRC referred four allegations to the Agency. The review team noted that the Agency promptly responded with appropriate investigations, follow up, and close out actions for all the allegations referred by the NRC. However, the team noted that no allegations were received directly by the Agency for the current or the prior review period.

It is not clear whether the Agency has a written procedure in place for managing allegations received directly from members of the public. The team noted that the 1998 IMPEP report provided that the Agency's written allegation procedure required prompt evaluation of the allegations, an initial written response to the allegor and indicated that the procedure was revised on February 12, 1998, to include the requirement to furnish the allegor with a copy of the final investigative report. However, when the team requested a copy of the Agency's procedures for managing allegations, the Agency management was unable to locate the 1998 document. Rather, the Agency provided a one page procedure dated January 1, 1995, which focused on the State's implementation of 10 CFR 19.16, "Requests by workers for inspections."

The 1995 procedure also indicated that all official complaints must be filed in writing, unless

circumstances prohibit such action and that anonymous complaints are not subject to action by the Program unless they have another independent reason to believe that some violations are occurring. In addition, the procedure was unclear on whether the State could protect the alleged's identity. The procedures implied that workers' identities may be protected from disclosure; however, they were silent about the Agency's policy on protecting the identity of members of the public.

In discussions with the review team, Agency management indicated that once an allegation was identified, the staff would use the Agency's procedure for response to incidents to investigate the allegation. The Agency management also provided copies of a complaint log and a report form that is used to document the receipt and resolution of allegations. Consequently, the team concluded that the Agency takes appropriate action in response to allegations but procedures for handling allegations received from members of the public are not clearly documented. The team discussed NRC Management Directive 8.8, Management of Allegations, with the Program Manager, and the team noted that the Program had a copy of the document. 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.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

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 time frame, and hearing procedures. There has been no legislation passed since the last IMPEP review that affected the radiation control program.

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 (SSRs) of the Conference of Radiation Control Program Directors, Inc.

The Program has assigned a materials license specialist the responsibility of rulemaking development, including schedule 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. Team members also witnessed two public hearings held at the Agency's main office during the onsite IMPEP review, and found that the public and other interested parties are offered an opportunity to comment on proposed regulations.

The Agency's regulations are reviewed 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 found that draft regulations are sent to NRC for approval, although not in the format required by the Office of State and Tribal Programs Procedure SA-201, "Review of State Regulations." The Agency's regulation submittals to NRC were discussed with management and the Agency was provided information on the format and content for rule submittals.

The information provided in the questionnaire reflects that the Agency initially adopts 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 1 to 1½ years due to scheduling of the Hearing Board and Council. This rulemaking process appears to be functioning for the Agency, although in several cases it did not meet the 3-year time frame for adoption as required by the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs (Policy Statement).

The team reviewed the status of the regulations required for adoption by the State under the

Policy Statement. The team compared the adoption of regulations by the State with data obtained from the STP Regulation Assessment Tracking System, and NRC Chronology tables. A spot check review of the Arizona Administrative Code was also done to verify adoption of previously issued NRC regulations. Interviews were conducted with the Program staff confirming that the Program uses license conditions when regulations were not adopted within the 3-year time frame. The team noted that license conditions or other legally binding requirements were being used for the following rules.

- “Frequency of Medical Examinations for Use of Respiratory Protection Equipment,” 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995. A proposed regulation has been drafted and submitted for NRC review.
- “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71 and 150 amendments (62 FR 28948) that became effective June 27, 1997. A proposed regulation has been drafted and submitted for NRC review.
- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. A proposed regulation has been drafted and submitted for NRC review.
- “Deliberate Misconduct by Unlicensed Persons,” 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998. The Program indicated that other legal mechanisms are in place in Arizona Administrative Code §30-673, “Unlawful Acts” and in the Agency’s “Civil Penalties Procedures” R12-1-1213 to address this requirement.
- “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations, Clarifying Amendments and Corrections,” 10 CFR Part 34 amendment (63 FR 37059) that became effective on July 9, 1998.

These legally binding requirements have not been submitted for NRC review. The team recommends that the Program submit legally binding requirements to NRC for review.

During the onsite review, the review team found the following five regulations had not been adopted, are overdue, and are not incorporated in license conditions or other legally binding requirements.

- “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243, and 60 FR 322) that became effective on January 1, 1995. The Agency has not drafted this regulation.
- “10 CFR Part 7: Compatibility with the International Atomic Energy Agency,” 10 CFR Part 71 amendments (60 FR 50248; 61 FR 28723) that became effective April 1, 1996.
- “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective on

June 17, 1996. The Agency has drafted this regulation. The Agency anticipates submitting a proposed regulation within 6-9 months for NRC review.

- “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65120) that became effective on January 9, 1997. The Agency has drafted this regulation. The Agency anticipates submitting a proposed regulation within 6-9 months for NRC review.
- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR 32.52(a) and 32.52(b) amendments (65 FR 79162) that became effective February 16, 2001 and was to be implemented by States within 6 months, August 16, 2001. This regulation has not been addressed by the State.

In addition, the following two regulations were submitted to the NRC for review.

- “Respiratory Protection and Controls to Restrict Internal Exposures,” 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.
- “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000. The due date for the Agency to adopt this rule is May 17, 2003.

The Agency will need to address the following two regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001. The due date for the Agency to adopt this rule is January 8, 2004.
- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” entire amendment except 10 CFR 32.52(a) and 32.52(b), (65 FR 79162) that became effective February 16, 2001. Although the State will need to address a portion of this rule immediately, as discussed above, the remaining portion of this amendment is due by February 16, 2004.

In evaluating the Agency’s program, the team determined that the Agency consolidates several amendments into a rulemaking package in order to lower the expense of promulgation of its regulations. The team recognizes 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 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.

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

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

In conducting this review, three sub-indicators were used to evaluate the Agency's performance regarding their SS&D Evaluation Program. These sub-indicators include: (1) Technical Quality of the Product Evaluation; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Agency's SS&D Evaluation Program, the review team examined information provided by the Agency in response to the IMPEP questionnaire on this indicator. A review of selected SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, and interviewed the staff and Program Manager involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The Agency did not process any new SS&D applications since the last review in February 1998. However, the Agency issued one amendment correcting deficiencies identified during the previous IMPEP review. The review team noted that in 1993, preceding the previous IMPEP review period, the Agency issued two SS&D registration certificates for self-luminous light sources. During the review of the Agency's casework supporting the revision of the certificate issued April 16, 1998, the review team noted deficiencies in the supporting information for the amendment. Although a final certificate had been transmitted to NRC for inclusion into the NRC national registry, the review team found only a draft, marked-up copy of the certificate which showed that the recommended corrections had been made. There were no Agency records documenting the amendment and issuance of the certificate or the transmittal of the document to the NRC for national distribution. The review team identified additional concerns with this certificate during casework review. Due to the limited experience of the Agency with SS&D evaluations, the other certificate issued during the previous review period was examined and similar deficiencies were identified. The specific comments are listed in Appendix F. The scope of these corrections involve technical issues, including the accuracy of the description of the sources. The team found no safety issues relative to the corrections needed to the certificates. The team discussed the corrections with the Agency staff. They agreed to revise the certificates to correct the deficiencies identified in Appendix F. The review team recommends that the Agency make corrections to the SS&D registration certificates Nos. AZ-244-D-101-S and AZ-244-D-102-S.

As noted in Appendix F, the review team also reviewed the Honeywell, Inc. license files. A description to manufacture and distribute a fuel gauge for various aircraft containing 2.5 mCi (9.25 MBq) of Am-241 was imbedded in a 1987 license application from Honeywell. The Agency issued a materials license to Honeywell in response to the application. At the time of the review, the team was unable to determine whether a safety evaluation of the device had been conducted. Following the review, the team confirmed through NRC records that prior to moving to Arizona from Minnesota in 1987, NRC conducted a safety evaluation of the Honeywell fuel gauge and approved the manufacture and distribution of the generally licensed device. The Agency indicated that they reviewed the information that had been submitted to the NRC and concluded that the device was acceptable for distribution. At present, there is no certificate on the device because there is no regulatory requirement to issue registration certificates. However, the issuance of registration certificates is a common practice and the Agency has indicated that they will provide the NRC an information certificate on the current status of the device.

The team also reviewed all other Arizona licensees to determine whether there is a need to issue other registration certificates to those who may be manufacturing or distributing sealed sources and devices. The team found that there are no other licensees requiring action.

4.2.2 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 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 to conduct the safety evaluation, and the Program Manager and the Agency Director sign the certificate. The team determined that the reviewers meet the technical training required for SS&D reviews as described under the guidance. Similarly, the 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.

The review team noted that the qualified staff has not conducted a full safety evaluation for nine years. Given the deficiencies identified in the Technical Quality of the Product Evaluation Program sub-indicator, the review team discussed that rotational assignment of the Agency staff to NRC or other Agreement States, where a large number of SS&D safety reviews are conducted on a continual basis, would be most beneficial for maintaining the skills obtained in their initial training. Such rotational opportunities, which usually last for a two week period, are routinely available. For example, NRC usually hosts two SS&D reviewers from Agreement States each year. If a new SS&D application was submitted to the Agency, the review team concludes that some type of refresher training would be crucial for the current staff.

The training requirements for Agency staff are delineated in Procedure No. ARRA-PROG-1245, "Inspector Qualifications." However, the team noted that the training and qualification requirements for SS&D reviewers is not addressed. The qualification requirements usually include the basic SS&D related courses or workshop, the number of casework reviews necessary to qualify as a reviewer, and refresher training needed. The Agency has not developed formalized, written training requirements for SS&D reviewers. Formal training requirements would facilitate qualification of other staff in case replacement of the currently available persons would be needed and address the necessity of refresher training and current experience. The review team recommends that the Agency establish qualification requirements for SS&D reviewers and develop a formalized, written training program.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Two incidents related to SS&D defects were noted by the State of Arizona during the review period. The team found that Agency staff addressed the issues in the incidents in a comprehensive manner. Specifically, the staff responded to the incidents with inspections, in one of the cases within an hour, prepared inspection reports, and followed up the cases with the licensee, the equipment manufacturer, and other Agreement States. Incidents were reported to the NRC. The incidents that the team reviewed regarding SS&D issues are 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 recommends that the Agency's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. 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 which 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 and 4 above, the review team found Arizona's performance to be satisfactory for the five common performance indicators and the non-common performance indicator, Sealed Source and Device Evaluation Program, and satisfactory with recommendations for improvement for the non-common performance indicator, Legislation and Program Elements Required for Compatibility. Accordingly, the review team recommended and the MRB concurred in finding the Arizona Agreement State program to be adequate and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately four years.

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

RECOMMENDATIONS:

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)
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)
3. The team recommends that the Program submit legally binding requirements to NRC for review. (Section 4.1.2)
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)
5. The review team recommends that the Agency make corrections to the SS&D registration certificates Nos. AZ-244-D-101-S and AZ-244-D-102-S. (Section 4.2.1)
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).

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Arizona Organization Chart
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
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Appendix F	Sealed Source & Device Casework Reviews
Attachment	April 25, 2002 Letter from Aubrey V. Godwin Arizona's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Cardelia Maupin, STP	Team Leader Technical Staffing and Training
Vivian Campbell, RIV	Technical Quality of Licensing Actions Response to Incidents and Allegations
Roberto J. Torres, STP	Legislation and Program Elements Required for Compatibility
John Jankovich, NMSS	Sealed Source and Device Evaluation Program
Lee Cox, NC	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments

APPENDIX B
ARIZONA ORGANIZATION CHART
ML020860628

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: St. Luke's Medical Center
Location: Phoenix, AZ
License Type: Medical Institution
Inspection Date: 9/22 & 25/00

License No.: 07-76
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: JW

File No.: 2

Licensee: Phoenix National Laboratories, Inc.
Location: Phoenix, AZ
License Type: Industrial Radiography
Inspection Date: 4/10/01

License No.: 07-415
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: JN

File No.: 3

Licensee: Mayo Clinic Arizona
Location: Scottsdale, AZ
License Type: Broad Medical
Inspection Date: 10/30/01

License No.: 07-448
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: JN, GS, WY

File No.: 4

Licensee: Syncor International Corporation
Location: Tucson, AZ
License Type: Nuclear Pharmacy
Inspection Date: 3/29/01

License No.: 10-84
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: JN, GS

File No.: 5

Licensee: University of Arizona
Location: Tucson, AZ
License Type: Broad Medical
Inspection Date: 2/26/01

License No.: 10-44
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: JN, GS, JW, WW

File No.: 6

Licensee: Good Samaritan Regional Medical Center
Location: Phoenix, AZ
License Type: Broad Medical
Inspection Date: 5/1/01

License No.: 07-478
Inspection Type: Routine, Announced
Priority: 1
Inspector: JN, GS, JW

File No.: 7

Licensee: Radiation Safety Engineering, Inc.
Location: Chandler, AZ
License Type: Health Physics
Inspection Date: 3/30/99

License No.: 07-192
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: JW

File No.: 8

Licensee: Valley Lutheran Medical Center
Location: Mesa, AZ
License Type: Medical
Inspection Date: 1/24/00

License No.: 07-251
Inspection Type: Routine, Unannounced
Priority: 2
Inspector: JN

File No.: 9
Licensee: Mesa Lutheran Hospital
Location: Mesa, AZ
License Type: Medical
Inspection Date: 11/30/99

License No.: 07-127
Inspection Type: Routine, Announced
Priority: 2
Inspector: JN

File No.: 10
Licensee: Honeywell, Inc.
Location: Phoenix, AZ
License Type: Limited Industrial
Inspection Date: 11/4/99

License No.: 07-316
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: GS, JW

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: AMEC Earth and Environmental
Location: Phoenix, AZ
Type: Industrial Radiography
Inspection Date: 2/25/02

License No.: 07-369
Inspection Type: Unannounced, Routine
Priority: 1
Inspector: JN

Accompaniment No.: 2
Licensee: Arrowhead Community Hospital
Location: Glendale, AZ
License Type: Medical Institution-HDR
Inspection Date: 7/25/01

License No.: 07-328
Inspection Type: Unannounced, Routine
Priority: 1
Inspector: GS

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1

Licensee: Phoenix Regional Medical Center
Location: Phoenix, AZ
License Type: Medical Institution
Date Issued: 3/10/00

License No.: 07-120
Amendment No.: 61
Type of Action: Termination
License Reviewer: DK

File No.: 2

Licensee: AMMTEC Consulting, Inc.
Location: Tempe, AZ
License Type: Portable Gauge
Date Issued: 5/2/00

License No.: 07-473
Amendment No.: 0
Type of Action: New
License Reviewer: DK

Comment:

- a) License authorizes Am-241 sealed sources with no total possession limit. The license does not contain a condition limiting possession to quantities not requiring financial assurance.

File No.: 3

Licensee: Sonora Veterinary Specialists
Location: Phoenix, AZ
License Type: Veterinary Medicine
Date Issued: 1/28/02

License No.: 07-498]
Amendment No.: 0
Type of Action: New
License Reviewer: DK

File No.: 4

Licensee: Scottsdale Cardiovascular Center, P.C.
Location: Scottsdale, AZ
License Type: Medical Private Practice
Date Issued: 9/8/00

License No.: 07-479
Amendment No.: 0
Type of Action: New
License Reviewer: DK

File No.: 5

Licensee: Welenco, Incorporated
Location: Bakersfield, CA
License Type: Well Logging (temporary job site only)
Date Issued: Pending

License No.: 07-300
Amendment No.: 18
Type of Action: Amendment
License Reviewer: DK

File No.: 6

Licensee: Radiocat, L.L.C.
Location: Phoenix, AZ
License Type: Veterinary Medicine
Date Issued: 5/29/01

License No.: 07-455
Amendment No.: 4
Type of Action: Amendment
License Reviewer: DK

File No.: 7

Licensee: Regenesis Biomedical, Inc.
Location: Scottsdale, AZ
License Type: Research and Development, Limited
Date Issued: 2/5/01

License No.: 07-439
Amendment No.: 2
Type of Action: Amendment
License Reviewer: DK

File No.: 8

Licensee: University Medical Center Corporation
University Medical Center Board of Regents
University of Arizona
Location: Tucson, AZ
License Type: Broad Scope, Medical
Date Issued: 2/11/02

License No.: 10-44
Amendment No.: 49
Type of Action: Amendment
License Reviewer: DK

Comment:

- a) The license authorizes quantities of radioactive material that require financial assurance but does not contain a condition limiting possession to amounts below that requiring financial assurance.

File No.: 9

Licensee: Catholic Healthcare West II
St. Joseph's Hospital and Medical Center
Location: Phoenix, AZ
License Type: Broad Scope, Medical
Date Issued: 12/19/01

License No.: 07-24
Amendment No.: 99
Type of Action: Amendment
License Reviewer: DK

Comment:

- a) The license authorizes quantities of radioactive material that require financial assurance but does not contain a condition limiting possession to amounts below that requiring financial assurance.

File No.: 10

Licensee: Board of Regents, University of Arizona
Location: Tucson, AZ
License Type: Broad Scope, Academic
Date Issued: 1/18/01

License No.: 10-24
Amendment No.: 59
Type of Action: Amendment
License Reviewer: DK

File No.: 11

Licensee: Board of Regents, Arizona State University
Location: Tempe, AZ
License Type: Broad Scope, Academic
Date Issued: 4/13/01

License No.: 07-37
Amendment No.: 71
Type of Action: Amendment
License Reviewer: DK

Comment:

- a) The license authorizes quantities of unsealed radioactive material that require financial assurance. However, during the renewal, the licensee's statement of intent addressed only the cobalt-60 sealed sources. The license does not contain a condition limiting possession of unsealed radioactive material to amounts below that requiring financial assurance.

File No.: 12

Licensee: Midwestern University - Glendale Campus
Location: Glendale, AZ
License Type: Limited Academic, Research and Development
Date Issued: 2/13/02

License No.: 07-466
Amendment No.: 3
Type of Action: Amendment
License Reviewer: DK

Comment:

- a) The license authorizes quantities of radioactive material that require financial assurance but does not contain a condition limiting possession to amounts below that requiring financial assurance.

File No.: 13

Licensee: Short/Dolan Investments, Canyon State Inspection
Location: Tucson, AZ
License Type: Industrial Radiography
Date Issued: 2/16/00

License No.: 10-101
Amendment No.: 23
Type of Action: Renewal
License Reviewer: DK

File No.: 14

Licensee: Medi-Physics, Incorporated, Amersham Health
Location: Phoenix, AZ
License Type: Nuclear Pharmacy
Date Issued: 9/24/99

License No.: 07-346
Amendment No.: 25
Type of Action: Renewal
License Reviewer: DK

File No.: 15

Licensee: Catholic Health Care West II
Saint Joseph's Medical Center
Location: Phoenix, AZ
License Type: Gamma Stereotactic Radiosurgery
Date Issued: 10/2/01

License No.: 07-424
Amendment No.: 3
Type of Action: Renewal
License Reviewer: DK

FORMERLY LICENSED SITES

In addition, these sites formally licensed by the NRC were reviewed:

File No.: 16

Licensee: Western Technologies

Location: Phoenix, AZ

License Type: Moisture Density Gauge

Date Issued: 06/87

License No.: 02-21033-01

Docket No.: 30-19684

Type of Action: Termination

Comment:

- a) The license only listed sealed sources and provided no final disposition. This project was never activated. The Troxler Model 3411 moisture/density gauges for measurement of properties of construction materials were never possessed by the licensee in Arizona. The site will be closed with no further action.

File No.: 17

Licensee: International Harvester, Co.

Location: Phoenix, AZ

License Type: Tracer and Material Wear

Date Issued: 07/64

License No.: 12-920-01

Docket No.: Unknown

Type of Action: Termination

Comment:

- a) The license authorized the use of isotopes P-32, La-140, Cr-51, Mn-56, Fe-59, Au-198 and various irradiated hardware for oil and parts wear analyses and provided no final disposition. Ten soil samples were taken at the site. No tracer materials were detected according to results from the Agency Laboratory dated February 5, 2002. The site will be closed in the near future.

File No.: 18

Licensee: Southwest Metal Industries

Location: Phoenix, AZ

License Type: Fabrication

Date Issued: 07/61

License No.: C-05180

Docket No.: 40-2113

Type of Action: Termination

Comment:

- a) The license authorized the use of up to 290 pounds of mag-thorium alloy and sands and provided no disposition of material, final close-out survey or AEC inspection. Four soil samples were taken at the site. It appears that there is no thorium/magnesium alloy present at the site according to results from the Agency Laboratory dated February 4, 2002. The site will be closed in the near future.

File No.: 19

Licensee: INFILCO

Location: Tucson, AZ

License Type: Research and Development

Date Issued: 09/58

License No.: C-03575

Docket No.: 40-1479

Type of Action: Termination

Comment:

- a) The license authorized the use of uranium in pilot plant studies demonstrating acid leaching and extraction using ion exchange and provided no disposition of material, final close-out survey or AEC inspection. Sixteen soil samples were taken at the site and evaluated for the presence of uranium oxide. No presence of uranium oxide was found according to results from the Agency Laboratory dated February 13, 2002. The site will be closed in the near future.

File No.: 20

Licensee: Airsearch Manufacturing, Co.,

Location: Phoenix, AZ

License Type: Research and Development

Date Issued: 08/63

License No.: 02-07592-01

Docket No.: Unknown

Type of Action: Termination

Comment:

- a) The license authorized the use of uranium in aircraft and missile systems and provided no disposition of material, final close-out survey or AEC inspection. The Agency is currently unable to locate the site.

APPENDIX E

INCIDENT 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: Superior Testing Inc.

Site of Incident: Show Low, AZ

Date of Incident: 8/8/98

Investigation Date: 8/10/98

Licensee No.: 09-013

Incident Log No.: None

Type of Incident: Stolen Portable Gauge

Type of Investigation: Telephone

Summary of Incident and Final Disposition: On August 8, 1998, the licensee advised the Agency that their office had been vandalized and a portable gauge had been stolen. The gauge was returned to the owner on August 24, 1998.

Comment:

- a) The Agency's records indicate that NRC was notified, however, the event is not identified in NMED. The record will be provided to INEEL.

File No.: 2

Licensee: Ricker, Atkinson, McBee and Associates

Site of Incident: Mesa, AZ

Date of Incident: 2/13/01

Investigation Date: 2/13/01

Licensee No.: 07-406

Incident Log No.: NMED 010138

Type of Incident: Stolen Portable Gauge

Type of Investigation: Onsite

Summary of Incident and Final Disposition: The licensee reported the theft of a portable Troxler moisture/density gauge. The gauge was stolen from the cab of a truck parked in Mesa, Arizona. A licensee employee had secured the gauge within its transport container and chained it in the cab of the vehicle for overnight storage. The gauge was recovered from a pawn shop with locks intact.

Comment:

- a) The Agency's records indicate that NRC was provided the supplemental information. However, the updated information is not in NMED. The record will be provided to INEEL.

File No.: 3

Licensee: Phelps Dodge
Site of Incident: Bagdad, AZ
Date of Incident: 10/30/00
Investigation Date: 11/1/00

Licensee No.: 13-005
Incident Log No.: None
Type of Incident: Lost Radioactive Material
Type of Investigation: Phone

Summary of Incident and Final Disposition: On October 30, 2000, the licensee advised the Agency that a cadmium-109 source was missing. The licensee was unsure of the date of the incident. The source was last accounted during an inventory conducted January 1998. The Agency planned to investigate at the next scheduled inspection.

Comment:

- a) The Agency's records indicate that NRC was provided the supplemental information. However, the updated information is not in NMED. The record will be provided to INEEL.

File No.: 4

Licensee: Board of Regents, University of Arizona
Site of Incident: Tucson, AZ
Date of Incident: 7/22/00
Investigation Date: 9/6/00

Licensee No.: 10-024
Incident Log No.: NMED 000698
Type of Incident: Release of Radioactive Material
Type of Investigation: Telephone

Summary of Incident and Final Disposition: The licensee reported that approximately 3.7 megabecquerel (100 microcuries) of hydrogen-3 had been removed from a laboratory by the custodial staff. While investigating this event, the licensee discovered that a release of 1.15 megabecquerel (31 millicuries) of hydrogen-3 was released for a fume hood stack. The Agency required the licensee to conduct an evaluation. The Agency reviewed the licensee's report and accepted the results.

Comment:

- a) There is no record that the follow-up information has been reported to NMED.

File No.: 5

Licensee: Board of Regents, Arizona State University
Site of Incident: Tempe, AZ
Date of Incident: 11/17/99
Investigation Date: 12/20/99

Licensee No.: 07-037
Incident Log No.: NMED 990961
Type of Incident: Lost Radioactive Material
Type of Investigation: Onsite

Summary of Incident and Final Disposition: The licensee reported that a vial containing 4.6 megabecquerel (0.123 millicuries) phosphorus-32 labeled ATP was missing from a laboratory. The material was placed in storage on November 17, 1999. The loss was detected on December 15, 1999. The licensee and the Agency conducted an investigation. The material has not been recovered.

File No.: 6

Licensee: Maxim Technologies, Inc

Site of Incident: Chandler, AZ

Date of Incident: 3/20/01

Investigation Date: 3/21/01

Licensee No.: 07-168

Incident Log No.: NMED 010285

Type of Incident: Stolen Portable Gauge

Type of Investigation: Onsite

Summary of Incident and Final Disposition: The licensee reported the theft of a Troxler moisture/density gauge. The truck with the gauge secured in the bed were stolen from a shopping area in Chandler, AZ. The local police were immediately notified and the licensee offered a reward for the return of the gauge. The material has not been recovered.

File No.: 7

Licensee: Maxim Technologies Inc.

Site of Incident: Phoenix, AZ

Date of Incident: 11/14/98

Investigation Date: 11/16/98

Licensee No.: 07-168

Incident Log No.: NMED 981135

Type of Incident: Stolen Portable Gauge

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On November 14, 1998, the licensee reported the theft of a Troxler moisture/density gauge from an open bed truck while parked in front of an employee's home. The gauge was secured to the bed of the truck. On November 16, 1998, the Agency reported that the gauge case was recovered. However, the gauge is still missing.

File No.: 8

Licensee: FNF Construction Inc.

Site of Incident: Tempe, AZ

Date of Incident: 7/11/98

Investigation Date: 7/15/98

Licensee No.: 07-373

Incident Log No.: NMED 980810

Type of Incident: Lost Portable Gauge

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On July 11, 1998, the licensee reported the loss of a Troxler density gauge. The gauge was reported missing from a temporary job site north of Phoenix, AZ. On July 14, 1998, the gauge was recovered.

File No.: 9

Licensee: AllState Service Environmental Inc.

Site of Incident: Phoenix, AZ

Date of Incident: 7/10/00

Investigation Date: 7/24/00

Licensee No.: 07-458

Incident Log No.: None

Type of Incident: Loss of Radioactive Material

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On July 24, 2000, the licensee notified the Agency that a lead paint analyzer containing cobalt-57 was missing. A former employee had taken the device to conduct work, but has not reported for work since. The licensee finally contacted the former employee, who had been out-of-town on personal business, and recovered the gauge.

File No.: 10

Licensee: Maxim Technologies, Inc.

Site of Incident: Framonto jobsite

Date of Incident: 5/15/01

Investigation Date: 5/15/01

Licensee No.: 07-168

Incident Log No.: None

Type of Incident: Damage to Equipment

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On May 15, 2001, the licensee notified the Agency that a portable gauge had been run over by a water tanker while at a temporary job site at Highway 17 and Carefree Highway. The source was maintained in the shielded position. Only the device was damaged. The device was leak tested and the results were negative. The Agency conducted a special inspection.

File No.: 11

Licensee: Geotech and Environmental

Site of Incident: Chandler, AZ

Date of Incident: 11/3/00

Investigation Date: 11/3/00

Licensee No.: 07-402

Incident Log No.: None

Type of Incident: Damage to equipment

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On November 3, 2000, the licensee notified the Agency that a portable gauge had been run over by a front-end loader. The depth rod had been bent and broken. However, there was no damage to the source. The Agency conducted an onsite investigation and confirmed that the source was not damaged. The gauge was repaired and put back in service.

File No.: 12

Licensee: Foree and Vann Inc.

Site of Incident: Horizon, AZ

Date of Incident: 3/9/00

Investigation Date: 3/9/00

Licensee No.: 07-263

Incident Log No.: None

Type of Incident: Damage to the equipment

Type of Investigation: Onsite

Summary of Incident and Final Disposition: On March 9, 2000, the licensee notified the Agency that a vehicle carrying a portable gauge had been involved in a traffic accident. The Agency conducted a site investigation and determined that only the licensee's vehicle was damaged. The incident was closed.

File No.: 13

Licensee: Northwest Surveying

Site of Incident: Lake Havasu City, AZ

Date of Incident: 9/18/00

Investigation Date: 9/18/00

Licensee No.: 08-24

Incident Log No.: None

Type of Incident: Loss of Control

Type of Investigation: Telephone

Summary of Incident and Final Disposition: On September 18, 2000, the licensee notified the Agency that a portable gauge had been taken by the wife (co-owner) of the owner because of a domestic dispute. The gauge was returned to the permanent storage facility on the same day. Although the police were notified, no charges could be filed. The incident was closed.

File No.: 14

Licensee: Speedie & Associates
Site of Incident: Tucson, AZ
Date of Incident: 11/11/00
Investigation Date: 11/13/00

Licensee No.: 07-209
Incident Log No.: None
Type of Incident: Stolen Portable Gauge
Type of Investigation: Telephone

Summary of Incident and Final Disposition: On November 11, 2000, the licensee notified the Agency that a portable gauge and truck had been stolen. The local police were notified. The truck and the gauge were recovered the same day. The gauge found undisturbed in the bed of the truck.

Comment:

- a) No record reporting the loss and recovery of the gauge could be found by the team.

File No.: 15

Licensee: Navapache Hospital
Site of Incident: Show Low, AZ
Date of Incident: 2/25/99
Investigation Date: 3/23/99

Licensee No.: 09-011
Incident Log No.: None
Type of Incident: Overexposure
Type of Investigation: Telephone

Summary of Incident and Final Disposition: On March 23, 1999, the Agency received written notification from the licensee informing them of a possible overexposure. However, the licensee expressed doubt regarding the validity of this overexposure. The licensee had received film badge results on February 25, 1999, indicating that a whole body exposure of 21,375 millirem and extremity exposure of 9223 millirem for one of their nuclear medicine personnel. On April 21, 1999, the Agency requested additional information by letter. On April 27, 1999, the technologist provided a statement describing his activities during that period and acknowledging his belief that the exposure was not real. The licensee obtained the services of a consultant to evaluate the exposure. In a letter dated June 23, 1999, the consultant provided his evaluation of the exposure and demonstrated that the exposure was not possible. In a letter dated August 11, 1999, the Agency acknowledged that they accepted the licensee's evaluation.

Comments:

- a) No record reporting the potential overexposure could be found by the team.

File No.: 16

Licensee: Scottsdale Memorial Hospital

Site of Incident: Scottsdale, AZ

Date of Incident: 11/18/99

Investigation Date: 11/22-29/99

Licensee No.: 07-265

Incident Log No.: 99-17

Type of Incident: I-125 seed rapture

Type of Investigation: Onsite Inspections

Summary of Incident and Final Disposition: The licensee reported that they identified an I-125 seed source during brachytherapy procedure which contained only three seeds instead of five. The Agency conducted site inspections after the incident, and notified NRC and the Agreement State who licensed the seed manufacturer. The Agency also compiled quality assurance reports from the manufacturer, distributor, and the user (licensee) showing no defective units in the product lot of the seed source. The Agency compiled technical reports from the attending physician and the radiology staff. The Agency analyzed the information and concluded that the cause was indeterminable, but requested that the licensee provide training for the hospital staff. The analysis as well as the training records for the hospital staff are well documented.

Comments:

- a) The inspection report was not generated shortly after the inspection. The inspection report, dated February 29, 2000, was generated in response to the "Information Request for NMED Item 000074," e-mail to the Agency from INEEL/Hunstman, dated February 17, 2000.
- b) The Agency's RAD report properly documented the disposition. The person who made the disposition dated his resolution only, but did not sign or initialize the decision, making traceability of this one record incomplete. The team found the rest of the file complete.

File No.: 17

Licensee: Good Samaritan Regional Medical Center

Site of Incident: Phoenix, AZ

Date of Incident: 11/30/01

Investigation Date: 11/30/01

Licensee No.: 07-478

Incident Log No.: 01-11

Type of Incident: Beta-Cath Source Train Failure

Type of Investigation: Onsite

Summary of Incident and Final Disposition: The licensee reported that, during a test run of a Novoste Beta-Cath system before commencing the procedure for the patient, a catheter failed and five seeds were found on the floor, and one seed was trapped in the device. The Agency responded to the incident with a site response within an hour, and determined with the licensee that all seeds were accounted for. The device was sent back to the manufacturer to determine the cause of the failure. The Agency prepared a comprehensive inspection report, dated December 3, 2001, in a timely manner shortly after the incident. The Agency notified the NRC and the Agreement State who licensed the manufacturer. The file contained complete records about the Agency's contacts with the manufacturer. The case was still open at the time of the review. The team noted that the Agency was properly tracking the incident. Specifically, the Agency requested a final report on the incident and reminded the licensee that such an incident should be concluded in a timely manner (letter to the licensee dated February 13, 2002).

APPENDIX F

SEALED SOURCE AND DEVICE (SS&D) CASEWORK REVIEWS

File No.: 1

Registry No.: AZ-244-D-101-S

Manufacturer: TLS Systems, Inc.

Date Issued: 3/5/93

SS&D Type: Reference Light Source

Model No.: 40108A

Comments:

- a) Assignment of the registration number is incorrect. The product is a source which is distributed to both general and specific licensees. The registration number that expresses these conditions is: AZ-244-S-101-B.
- b) Typographic error: Section entitled "DETAILS OF CONSTRUCTION" refers to Attachment 1. It should read Attachment 2.

File No.: 2

Registry No.: AZ-244-D-102-S

Manufacturer: TLS Systems, Inc.

Date Issued: 1/24/98

SS&D Type: Reference Light Source

Model No.: 40111

Comments:

- a) File did not contain the final certificate as transmitted to NRC, only a draft, marked-up copy of the certificate. In addition, the review team was unable to locate Agency records documenting the amendment and issuance of the certificate or the transmittal of the document to the NRC for national distribution.
- b) Assignment of the registration number is incorrect. The product is a source which is distributed to both general and specific licensees. The registration number that expresses these conditions is: AZ-244-S-102-B.
- c) The certificate did not include the section entitled "External Radiation Level."
- d) The illustrations that are referenced in Section "DETAILS OF CONSTRUCTION" as Attachments 1 and 2 were not part of the registration and were not marked as the attachments. These attachments need to be added to complete the registration certificate.

File No.: 3

Registry No.: None

Manufacturer: Honeywell, Inc.

License No.: 07-316, 7-320, 7-395

Date Issued: Not applicable (see comments)

SS&D Type: Fuel Gauge
Model No.: Model WG1136AA01

Comment:

- a) During the review of Honeywell licensing files, the team noted that Honeywell applied for a materials license in a letter dated September 17, 1987. The enclosure to the letter contained an imbedded application for a device in one of the sections which was entitled "Manufacturing License Application" (Appendix D) to manufacture and distribute the Model WG1136AA01, Fuel Quantity Indicating System (FQIS). The FQIS is a fuel gauge for various aircraft. The device contains a source with 2.5 mCi (9.25 MBq) of Am-241. The Agency issued a materials license to Honeywell in response to the application. Following the review, the team confirmed through NRC records that prior to moving to Arizona from Minnesota in 1987, NRC conducted a safety evaluation of the Honeywell fuel gauge and approved the manufacture and distribution of the generally licensed device. The Agency indicated that they reviewed the information that had been submitted to the NRC and concluded that the device was acceptable for distribution. At the time of the review, there was no certificate on the device because there is no regulatory requirement to issue registration certificates. However, the issuance of registration certificates is a common practice and the Agency has indicated that they will provide the NRC a information certificate on the current status of the device.

ATTACHMENT

April 25, 2002 Letter from Aubrey V. Godwin
Arizona's Response to Draft IMPEP Report

ML021330507