

DATED: MAY 7, 1998

SIGNED BY: HUGH L. THOMPSON, JR.

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

Dear Mr. Godwin:

On April 28, 1998, 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 NRC's program.

Section 5.0, page 16, of the enclosed final report presents the IMPEP team's recommendations and suggestions.

Based on the results of the current IMPEP review, the next full review will be scheduled in 4 years, unless program concerns develop that require an earlier evaluation.

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/*

Hugh L. Thompson, Jr.  
Deputy Executive Director  
for Regulatory Programs

Enclosure:  
As stated

cc: Stuart Goodman, Executive Assistant  
Office of the Governor

Mr. Aubrey V. Godwin, Director  
 Arizona Radiation Regulatory Agency  
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 Phoenix, AZ 85040

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cc: Stuart Goodman, Executive Assistant  
 Office of the Governor

bcc: Chairman Jackson  
 Commissioner Dicus  
 Commissioner Diaz  
 Commissioner McGaffigan

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF ARIZONA AGREEMENT STATE PROGRAM

February 9 -13, 1998

# FINAL REPORT

U.S. Nuclear Regulatory Commission

## 1.0 INTRODUCTION

This report presents the results of the review of the Arizona radiation control program. The review was conducted during the period February 9-13, 1998, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Mississippi. 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, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 4, 1995, to February 13, 1998, were discussed with Arizona management on February 13, 1998. The informal results were also discussed with the Arizona Radiation Regulatory Agency (ARRA) Director, Mr. Aubrey Godwin and a representative of the Governor's office, Mr. Stuart Goodman, on February 24, 1998 during a conference call.

A draft of this report was issued to Arizona for factual comment on March 19, 1998. The State responded in a letter dated April 2, 1998 (Attachment 1). The State's factual comments were considered by the team and accommodated in the report. The Management Review Board (MRB) met on April 28, 1998 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 ARRA. The Director of the ARRA reports directly to the Governor of Arizona. The Agency has 23 employees of which five employees including a manager are dedicated to radioactive materials regulation under the Agreement. The manager spends approximately one half of his time on the radioactive materials program (RAM). An organization chart for the ARRA is included as Appendix B.

At the time of the review, the Arizona program regulated 353 specific licenses, including limited scope medical, broad scope, gamma knife, industrial radiography, and nuclear pharmacy licenses.

The review focused on the material's program as it is carried out under the Section 274b. (of the Atomic Energy Act (AEA) 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 State on November 12, 1997. The State provided a response to the questionnaire on December 16, 1997. During the review, discussions with the State staff resulted in the responses being further developed. A copy of the final response is included in Appendix C to this report.

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 radiation control program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; and (5) 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 non-common indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the State'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 indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report. Suggestions made by the review team are comments that the review team believes could enhance the State's program. The State is requested to consider suggestions, but no response is requested.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on March 3, 1995, comments and recommendations were made and the results transmitted to Mr. John Kelly, Executive Assistant, Office of the Governor, on June 7, 1995. The review resulted in six recommendations. The team's review of the current status of these recommendations is as follows:

- (1) At the time of the March 1995 program review, compatibility was withheld because the State had not adopted the "Decommissioning" and "Notification of Incidents" rules. We recommended that the overdue regulations be adopted as soon as possible, and that work on upcoming regulation revisions be started well in advance of the three-year time limit. Because maintaining compatible regulations had been an ongoing problem in Arizona, we recommended that written procedures be developed within ARRA to expedite the promulgation process on a permanent basis. We recommended ARRA seek input into developing these procedures from other offices in the regulatory review chain, including the legal and budget offices. We also recommended an early opportunity for NRC comment be incorporated into the new procedures.

Current Status: This recommendation is closed. The team discussed the progress made on resolving this issue since the last review. The "Notification of Incidents" rule was promulgated. ARRA has resubmitted the proposed "Decommissioning" regulation, with additional language to meet subsequent NRC regulatory requirements, to the Governor's Regulatory Review Council (GRRC) in late 1995 and again in 1997. The GRRC was created by Executive Order in May 1981. The GRRC is composed of six members and is chaired by the Director of Administration or designee, who serves ex-officio. For most State agencies, the GRRC is the final step in the rule making process. The Council reviews most rules to ensure that they are necessary to avoid unnecessary duplication and adverse impact on the public. The Council also assesses whether the rules are clear, concise, understandable, legal, consistent with legislative intent, and whether the benefits of a rule outweigh the cost. If a rule does not meet these criteria, the Council returns it to the agency for further consideration. The rules are presently at the GRRC for review.

The team notes that the decommissioning regulations in question apply only to one ARRA licensee. To maintain compatibility with NRC's requirements, ARRA uses license conditions to implement the decommissioning requirements on the single licensee. ARRA has indicated that they will continue to use license conditions in this situation, and similar situations, until the rule passes GRRC review.

- (2) In order to retain qualified professional staff and effectively manage the program, we recommended an evaluation of the need for salary increases and an evaluation of management alternatives that can provide other incentives necessary to retain qualified staff or that are necessary to effectively manage a program that experiences such turnover.

Current Status: This recommendation is closed. ARRA salaries have increased only slightly since the last review. These increases are the result of cost of living increases and merit pay. Salaries were reported to be less than several adjoining Agreement States. However, ARRA experienced only low staff turnover during the review period. ARRA management continues to plan and budget for improving staff salaries but these efforts have not been approved by the State legislature.

- (3) We recommended that the State:

- a) develop written procedures specific to investigating and reporting misadministrations;

Current Status: This recommendation is closed. The team reviewed ARRA's present event and allegation procedures and recommended closing this issue, since the State now has a highly effective incident reporting system.

- b) improve the procedures for closing incident investigations by revising the close-out cover sheet;

Current Status: This recommendation is closed. ARRA revised their Standard Operating Procedure (SOP) for Response to Incidents Involving Radioactive Materials on January 25, 1996. A review of the State's incident and allegations, discussed in Section 3.5, indicates that the ARRA is using the new guidance and close-out coversheet when conducting incident investigations.

- c) develop a computer system for tracking and closing incident reports and investigations, including prompting management for reports required by the NRC.

Current Status: This recommendation is closed. ARRA continues to use a manual tracking system for following and closing out incident investigations. The manual tracking system works very well and meets their needs. ARRA indicated that it may consider developing a computerized tracking system as time and resources permit.

- (4) We recommended that:

- a) program management monitor the progress of the proposed enforcement rule to expedite its enactment;

Current Status: This recommendation was closed with the adoption of Article 12, Administrative Provisions, Chapter 1, Radiation Regulatory Agency, Title 12, Natural Resources, of the Arizona Regulatory Code on January 2, 1996.

- b) the inspection tracking system be modified to trigger shorter inspection frequencies as part of the escalated enforcement process.

Current Status: This recommendation is closed. The team reviewed ARRA's procedures during this review and found that the Materials Inspection Program Guide, Section 2020-08, Reduction of Inspection Interval provides a process for reducing inspection intervals based on the seriousness of violations, current and prior findings. A point system is used. In general a reduction of the inspection interval should occur when the total of all re-inspection points for violations total 12, or more. A severity level one violation is assigned 12 points, for example, that would result in a reduced inspection interval.

- (5) The State's inspection forms, which were being used on a trial basis, needed several improvements. Specifically, there was no place to document verification that emergency procedures or emergency procedure posting (other than xenon) were being followed; review of brachytherapy and radiopharmaceutical therapy patient release surveys and inventories; verification that HDR afterloader procedures were being followed; verification that nuclear medicine technicians have adequate, signed procedures to act in the absence of an authorized user; observation of operations; or results of interviews with ancillary workers. We recommended that the inspection forms be revised to correct these deficiencies as well as other problems identified during trial use and that the inspection procedures should be updated to include the new forms.

Current Status: This recommendation is closed. While the State has made significant improvements to their inspection forms (field notes), the team's review of the licensing and inspection files indicates that the ARRA needs to continue to focus attention on this issue. The matter is readdressed in Section 3.2 of the report.

- (6) We recommended that when narrative reports are used for routine inspections, a procedure be established to ensure the inspection covers and documents all areas of the licensee's program included in the inspection forms.

Current Status: This recommendation is closed. ARRA's Inspection Reports Program Guide, ARRA-PROG-2004, was revised on April 11, 1996. The agency's procedure establishes guidance for preparing inspection reports and describes their standard content and format.

### 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 inspection of new licenses, and timely dispatch of inspection findings to licensees. This evaluation is based on the Arizona questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of licensing and inspection casework files, and interviews with managers and staff.

The State has a computer specialist working in the RAM to help maintain and retrieve statistical data. Information from filing systems is being updated in a new database to enhance the program.

The review of the State's inspection priorities showed that the State's inspection frequencies for various types of licenses are at least as frequent as similar license types listed in the NRC Inspection Manual Chapter 2800 (IMC 2800) schedule of frequencies. Licensee categories are specified from Priorities 1 through 7, and inspections are conducted at intervals from 1 to 5 years corresponding to the inspection priority. Priority 7 licensees are also inspected at the 5-year interval. Inspection file reviews indicated that the frequency of inspections that were conducted were consistent with the State's policy.

Several spot checks of industrial radiography licensees and an HDR licensee were performed to verify inspection frequencies. In almost every case the files indicated that the proper inspection frequency was followed.

Nine (9) reciprocity files were reviewed to see if the State was inspecting reciprocity licensees as specified in IMC 1220. The State stated in the questionnaire that in 1995 there were 40 licensees that were granted reciprocity with only 2 of these being inspected. In 1996 and 1997, both licensees that performed source installations or exchanges were inspected (100%), as well as 4 industrial radiography licensees out of 9 that were granted reciprocity. However, in Priorities 4 through 7, only 1 inspection has been conducted out of 29 licensees that were granted reciprocity, less than the 10% frequency specified in IMC 1220.

The State's policy for conducting initial inspections of new licensees within a 6 month frequency appears to be followed. This frequency can be extended until the licensee has received radioactive material and may be announced. The State contacts these licensees to find out when licensed activities have started and performs pre-licensing visits. Of the 10 new licensee files that were reviewed, only 2 inspections had been conducted past the 6 month interval. Both initial inspections were conducted within 7 months of the licensee receiving material.



According to the questionnaire, no inspections were overdue by more than 25% of the scheduled frequency. However, it was noted in the file review that during the review period from 1995 to 1997, several inspections were conducted later than the State's inspection frequency policy. The State appears to have conducted inspections according to their inspection frequency since July 1996. The interval between inspections may be extended beyond that specified by the priority system on the basis of exemplary performance on the part of the licensee. All of the licensees that were inspected past the recommended frequency had not been cited with violations during past inspections and received an extension by policy.

The timeliness of the issuance of inspection findings was evaluated during the review of completed inspections. Twenty-one (21) files were examined with several files having more than 1 inspection that was conducted during the review period. Inspection correspondence was sent to the licensee within 30 days after an inspection with the exception of one of the more complex team inspections. Licensee responses to inspection findings appear to be returned in a timely manner. The Agency Director sends out the acknowledgment to the licensee response and determines if further information is needed. It was noted in the correspondence that civil penalties may be assessed if the licensee does not take corrective actions or respond in a timely manner.

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

### 3.2 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes, and interviewed inspectors for 21 materials inspections conducted during the review period. The casework included all 3 of the State's material inspectors and covered high priority inspections of various types including medical broad scope, academic broad scope, high dose rate (HDR) afterloader, industrial radiography, nuclear pharmacy and well-logging. Appendix E lists the inspection cases reviewed in depth with case-specific comments.

Several files were reviewed in coordination with the licensing review. This allowed the review team members to make sure that inspection findings coordinated with licensing actions. Also, it appeared from the review that the inspectors verified that license condition requirements had been implemented and were being followed.

The Program Guides are issued to establish policies and procedures applicable to the Agency Staff for implementing specific programmatic activities, such as inspection guidance. Inspection procedures and techniques were reviewed and were determined to be consistent with inspection guidance provided in IMC 2800. The inspection report forms provide documentation of inspection findings in a consistent manner. The State uses specific inspection report forms for various license types, such as medical, industrial radiography, well-logging, portable gauges, fixed in-plant gauges, laboratory, and service type licensees. The inspection form provides documentation of the radiation safety personnel, management, scope of the licensee's program, uses of materials, operating and emergency procedures, leak tests, surveys and wipes, instrumentation, personnel dosimetry, incidents, transportation, inspector's confirmatory surveys, items of noncompliance and items of concern, and exit interviews. Each report also documents close-out meetings with the

ARRA Manager of RAM and Program Director. The reports are generated in a computer based format.

ARRA policy is to perform all inspections unannounced. The review of the inspection files verified this policy. However the ARRA is also allowed to announce inspections under certain conditions such as an initial inspection, verification that certain personnel will be available, or inspection of specific activities.

A review of the scope of inspections revealed that industrial radiography licensee inspections were only conducted during office visits. The team believes that these inspections cannot adequately verify that licensees are following operating and emergency procedures as well as ARRA regulations. The files that were reviewed were as complete as possible. However, since these licensees only worked at temporary job sites, the inspector could not inspect for posting, wearing proper dosimetry, surveys of radiographic devices and restricted areas, survey instrumentation, and transportation of devices. 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.

Also the supplemental inspection report form that is used for HDR afterloaders does not cover all safety feature checks and requirements of licensure. It was evident the inspectors were very well trained and stated they were observing all aspects of the licensees' activities, but the supplemental inspection report form for HDR afterloaders did not have space to allow them to document the scope of operations. The other inspection forms in use that were observed in the file review appeared to cover the scope of those licensed activities. The review team suggests that the supplemental inspection report form for HDR afterloaders be modified to cover all safety feature checks and requirements of licensure.

The files that were reviewed contained complete inspection findings and enforcement correspondence. Telephone conversations with the licensee were documented on an ARRA form that was maintained in each file folder. The reviewer noted that inspectors conducted inspections in sufficient depth, discussed inspection findings with the manager, and followed up on enforcement actions after the licensee response was received.

The inspection findings are issued by the Program Manager. During the file review, it was noticed that licensees returned their response to the Agency in a timely manner and enforcement actions did not have to be escalated. After the response was received by the Agency, it was reviewed by the inspector, Program Manager, and Program Director with the Program Director issuing the acknowledgment. Agency letters to licensees outlining inspection findings and enforcement actions are written formally using appropriate style, detail and regulatory language. The small size of the staff with its supervisory review process enhanced the quality of the inspection and enforcement documents.

An interview with staff indicated that follow-up inspections occur if there are open items and recurrent violations. Inspection frequencies may be increased by 50% or more as needed. None of the files reviewed indicated a follow-up inspection was needed.

The State has a variety of portable instruments for routine confirmatory surveys and for use during incidents and emergency response. It was noted that calibrated meters are available to monitor alpha, beta, neutron and gamma radiation. The State also has a very capable counting laboratory with liquid scintillation, sodium iodide and high purity germanium detectors for analyses of samples. Each inspector has his own air-mold case that contains a Ludlum Model 14-C with a GM detector, pancake probe, 1x1 NaI detector, and thin crystal NaI detector. There is also a Victoreen 450P ion chamber. The inspectors' survey meters are calibrated at a 3 month interval by a commercial calibration service in accordance with approved calibration procedures. The other available instrumentation is calibrated at least annually by a commercial calibration service.

In response to the questionnaire, the State reported that all three inspectors were accompanied by the Radioactive Material Program Director during the review period. One of the inspection files that was reviewed showed that inspectors had conducted an academic broad scope inspection and a medical broad scope under supervisory accompaniment. The evaluation critically assessed the inspector's ability to conduct inspections for specific types of licensees when an inspector is qualified to perform unaccompanied inspections. All inspectors were accompanied during the past year.

The review team did not perform any accompaniments of inspectors prior to the review or during the period of February 9-13, 1998. The State's inspectors had been previously accompanied by IMPEP review team members and had demonstrated inspection techniques and knowledge of the State's regulations. The inspection files reviewed demonstrated their inspections conformed to State guidance and were adequate to assess radiological health and safety at the inspected facilities.

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

The ARRA is authorized 23 positions that are apportioned as follows: radioactive materials (RAM) activities, 4; x-ray compliance, 7; radiation measurements (laboratory), 6; technician certification, 1; non-ionizing compliance, 1; emergency response, 1; management, 3.

As noted, four personnel are assigned RAM duties and the number appears to be adequate to maintain the program. Also, a manager spends about ½ his time supervising radioactive materials activities. The RAM staff receives direct support from the radiation measurements laboratory that performs sample counting and assay services for the agency.

Resources within the RAM section are divided between licensing (1 FTE) and inspection (3 FTE) activities. Due to the low rate of turnover the ARRA RAM section consists of senior experienced personnel. No vacancies exist in the RAM section at this time and there is no expectation of losses in this area.

The only vacancy identified during the review is a position of State Health Physicist II (SHP II) in the radiation measurements laboratory. The employee who was previously in this position took a new position within the ARRA as an x-ray inspector when a vacancy occurred in that section. This

position has been vacant for approximately 6 months and efforts are being made to hire a replacement. The present laboratory staff is able to adequately handle the RAM workload. The vacancy does not affect the capabilities of the program nor does it impact other IMPEP performance indicators because the position is in a support area that is otherwise well staffed.

The ARRA is fortunate in having an experienced and well seasoned staff. Work is assigned to all inspectors and reviewers commensurate with their training and experience. Turnover within the RAM section has been low since the last review. Minimum qualifications for a new hire are a baccalaureate degree with experience or a master's degree in health physics and experience. Individuals may also qualify who have had a long period of on the job training and extensive experience in an appropriate science.

ARRA has outlined its training requirements for new employees in ARRA-PROG-1245. A training plan would be tailored for each new employee. A new hire is expected to complete "core" courses, or their equivalent, to be fully qualified according to the ARRA's training guidelines. ARRA anticipates providing "core" course training by mixing courses from NRC and State resources. Consideration has also been given to participating in regional training opportunities with other Agreement States. To train personnel to the same standards within an approximate 2 year period will cost much more than in the past. The Authority receives a single annual appropriation and does not receive funds specifically for training. For planning purposes, ARRA estimated 2 - 4 individual training courses at a total estimated cost of \$3,000 - \$6,000. ARRA's estimate can provide for a modest amount of training and is adequate given the low staff turnover. In addition to completing required courses, the ARRA uses an apprenticeship concept to train new employees in inspection and licensing. Qualified inspectors or reviewers accompany new inspectors and coach them during the learning process. When they have gained enough experience and confidence they are authorized to perform inspections or reviews independently. The ARRA also has an excellent management accompaniment and review program that assures highly consistent inspector and reviewer training.

The review team has no recommendations or suggestions in this area.

Based on the team's finding and the IMPEP evaluation criteria, the review team recommends that Arizona's performance with respect to this 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 reviewer for 17 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 reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. 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 authorities. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which had been completed in the review period. The cross-section sampling included all of the State's major licenses as defined by the State in the questionnaire and included the following types: academic and medical broad scope; industrial radiography; medical, including private practice; HDR afterloader; strontium-90 eye applicators; nuclear pharmacy; and well logging. Licensing actions during the review period of 1996-1997 included 37 new licenses, 90 renewals, and 451 amendments, for a total of 616 licensing actions during the review period. In discussions with management, it was noted that there were no major decommissioning efforts underway with regard to agreement material in Arizona. A list of licenses reviewed with case-specific comments can be found in Appendix D.

The licensing process was discussed with the primary license reviewer. Application packages containing guidance are sent to license applicants. The applications are reviewed following standard procedures which are similar to those used by the NRC. The reviews were generally complete, ensuring that all issues related to public health and safety were addressed. Licensing checklists are not used routinely due to the experience of the reviewer. All license actions are reviewed and signed by management. Deficiencies are addressed either by phone or by written letter for more complicated issues. For uncomplicated telephone deficiencies, there is a lack of detailed deficiency information in the license files. The review team recommends that staff include more detailed documentation related to telephone deficiency calls, describing the issues and notating 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 were denied.

Licensing guides, as well as other applicable guidance from NRC, such as that for HDR afterloading brachytherapy, are available. Standard License Conditions (SLC) are used and are maintained in the computer by license type. The SLC are similar to those used by NRC. Licenses are issued in entirety with each licensing action. License files are organized by license, license application correspondence, general correspondence, and inspection reports.

Pre-licensing visits are made for more complicated or unusual license applications, the latest of which was for a facility requesting a gamma stereotactic radiosurgery device. There is close interaction with the license reviewer and the inspection staff. Additionally, there are weekly staff meetings, which include discussions of major licensing and compliance issues.

There is a system to track licensing actions when they are received. State law now requires all actions to be completed within a specified time period, which varies depending on the complexity of the licensing action. If the State fails to meet the time period, the State must reimburse the licensee's fee and pay a penalty. The State began this program in August 1997 as a trial, with full compliance expected in December 1998. Of concern to the team is the provision within the law that the State cannot go back to the license applicant with additional questions once an initial deficiency is addressed to the license applicant. This is of concern to the team should the licensee's response be deficient or raise additional questions. The staff is evaluating options for working with this provision without compromising public health and safety, including the possibility

for rejection of applications, pending submittal of all necessary information. The ARRA has not had sufficient time to study the impact of this law on a process that typically relies on more than one round of questions and licensee responses when issuing a radioactive materials license. 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. The review team also suggests that staff and management continue to evaluate and develop a plan to accommodate the new legislation mandating time lines in which to process applications without impacting the technical quality of license reviews.

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 State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire relative to this indicator, reviewed the State's incident log and allegation files for the review period, and compared the incidents reported for Arizona in the "Nuclear Material Events Database (NMED)" against the Arizona incident files. The ARRA uses the Draft NMED guidance when reporting incidents to NRC. The team reviewed the incident log and briefly reviewed all 52 incidents that occurred during the review period. Nineteen of these incidents involved AEA material. Of these, seven were reviewed by the team in depth including two instances of stolen gauges, one abandoned source which tripped the alarm on a load of scrap steel, one stolen radioactive exit sign, and three accidents which damaged equipment or devices. A list of the incident casework with comments is included in Appendix F. The team also reviewed the State's response to the one allegation reported during the review period.

The NMED report for the review period lists 11 incidents reported by the State. Review of the Arizona incident files showed that one of the incidents on the NMED list occurred at an NRC licensee located in the State, not an Arizona licensee. The team found files for two incidents that the State had reported to the NRC but which were not included in the NMED report. Both of these incidents occurred early in the NMED program and the records indicated the State had reported the incidents to NRC Region IV. Presently, the State faxes the report directly to the NRC Operations Center and follows up with a telephone call to the Center to make certain the information is received and is clear and complete. Although this practice appears to be working well, it was noted that the State does not consistently advise the NRC Operations Center of closure information. The review team suggests that the State advise the NRC Office for Analysis & Evaluation of Operational Data when incidents are closed so that the NMED records may be updated.

Arizona's hazardous materials response plan assigns ARRA responsibility for responding to incidents and allegations involving radioactive materials. Procedures for response to materials incidents are contained in ARRA's SOP, last updated in August 1997. The review team evaluated the SOP and found it provides adequate guidance for emergency response actions. Within ARRA, the Emergency Response (ER) Program Manager has the primary responsibility for coordinating all emergency responses including notification of the Director or Acting Director. If the incident involves a licensee, ER Program Manager will coordinate the response with the

radioactive materials (RAM) Program Manager and normally will assign an inspector as primary responder. However, responders may include any of ARRA's technically qualified staff. An ER Duty Officer is designated to provide response capability during non-working hours. This duty is performed on a rotating basis by designated technical staff members. The team noted that Arizona inspectors respond on site to all incidents involving lost or missing radioactive material and to all incidents that present an actual or potential hazard to public health and safety. Six of the seven incidents reviewed included on-site investigations. The team found the investigations were prompt, thorough, and resulted in appropriate enforcement actions. Information provided by the licensee was verified and independent measurements were made. Incidents were consistently followed up in the next inspection. The team verified that all incident and allegation responses are discussed and approved by program management.

Apparently, because of the readily available resale market for portable gauges south of the U.S. border, approximately 50 percent of the Arizona incidents involve stolen gauges. When a portable gauge is reported stolen, the State investigates, has the licensee file a police report, makes a press release, notifies the NRC Operations Center, contacts the adjacent Agreement States, and the regulatory agency in Mexico. A small percentage of the gauges are recovered.

The team reviewed the State's system of tracking and following incidents. The SOP instructs the individual taking the initial incident report to enter background information on the ARRA form, "Radiological Incident or Event Report." Because there are no written procedures for maintaining and distributing incident records, the team relied on interviews with program management and staff to determine the current practice. During these discussions, the team learned that a copy of the form is placed in an incident file folder in the ER section, and if the incident involves an Arizona license, another copy is placed in the licensee's file. The incident is entered in the incident log and assigned a unique incident identification number. Incidents meeting the NMED reporting requirements are faxed to the NRC Operations Center, and as explained previously, followed up by a telephone call. When appropriate, First Notices (similar to NRC Preliminary Notifications) are issued. Incidents meeting the routine event reporting criteria were not being forwarded to the NMED reporting system at the time of the review. The SOP requires that the staff member responding to an incident prepare a follow-up report for the Director, the ER manager, and the incident file. According to program management, the incident is reviewed and, if possible, closed at the next inspection. The incident report form is then updated with the final disposition and dates of closure, and an updated copy placed in the licensee's file. However, in reviewing the incident log and casework, the review team found that the incidents are not being recorded or filed consistently. Some incidents were reported only by memos and others only by First Notices. Closure information was not always included in the file, and incident reports were not always found in the license/compliance files. The review team recommends that all incident reports be recorded and closed out as directed in ARRA's SOP, and that written procedures be developed to ensure that the reports are consistently maintained, distributed, and cross-referenced between the incident and licensee files. The team also recommends that the State follow the procedural guidance for reporting all incidents to NRC as described in the latest NMED manual.

Misadministrations are handled in the same manner as other incidents, but the forms and records are logged separately and kept in a separate file. It is the State's policy to respond on site to any misadministration that exceeds the new reporting criteria. The review team examined the records of the 76 misadministrations reported during the review period and agreed with the State that no therapeutic misadministrations or diagnostic misadministrations exceeded the reporting levels. At the time of the review, Arizona was in the process of adopting the revised misadministration rule. The review team suggests that ARRA develop written procedures to be used as guidance for tracking, evaluating, and reporting misadministrations at the time the rule becomes effective.

The team reviewed the State's allegation procedures and reviewed in depth the one allegation that had been received during the review period. This allegation, which was referred to the State by NRC Region IV, was reviewed in depth by the review team, and the State's actions were found to be prompt and appropriate during the almost three-year investigation of this lengthy and complicated allegation. In handling allegations, the State must follow Arizona law which protects the identities of individuals. ARRA's written allegation procedure requires prompt evaluation of the allegations and an initial written response to the alleege. The procedure was revised on February 12, 1998, to include the requirement to furnish the alleege with a copy of the final investigative report.

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 does not authorize regulation of uranium recovery activities.

##### 4.1 Legislation and Program Elements Required for Compatibility

###### 4.1.1 Legislation

Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in Arizona Revised Statutes, Title 30, Chapter, 4. The ARRA is designated as the State's radiation control agency. The team noted that the legislation had not changed since the previous review, and finds that the State's legislation is adequate. It is noted that the ARRA is subject to a review every 10 years to ascertain the continued need for the agency.

###### 4.1.2 Program Elements Required for Compatibility

The team verified that the State's present regulatory agenda includes those NRC regulations that are necessary to assure the regulation compatibility criteria are satisfied. ARRA regulations are reviewed every five years to determine if the requirements are still appropriate and necessary.



The ARRA provides, under State law, opportunity for public comment on proposed regulation changes. Draft regulations are sent to NRC for approval and when necessary, changes suggested by NRC are incorporated before final adoption.

The ARRA provided, in its response to the questionnaire, a rulemaking schedule. Regulations required since the last review have been adopted or are in the final approval stage with the GRRC. Regulations not yet required are on the schedule and if the pace is maintained the agency will meet its timeliness goals in the future. Since the last review, the ARRA has designated a single staff member the rulemaking responsibility and to maintain a schedule to assure continued compatibility of State regulations. This process appears to be working well, and, if continued, should assure that ARRA will maintain timely promulgation of necessary regulations. While several other agreement States have implemented similar mechanisms, the team notes that identifying a single point of contact for rulemaking and maintaining a regulatory schedule is a good technique.

The team notes that several minor Decommissioning Rule changes, identified in the 1995 review, have not been fully implemented. The ARRA has attempted to implement this rule since 1993. It was resubmitted in 1995 and 1997 to GRRC, and is presently being reviewed. The agency indicated several times during the review that they have imposed the requirements on the single licensee several years ago pending completion of the rule. Implementation of a legally binding requirement is an acceptable way of maintaining consistency and compatibility with NRC requirements.

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

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

##### 4.2.1 Technical Quality of the Product Evaluation Program

During the review period, only one SS&D certificate was issued by the State. The team performed an in-depth review of the State's evaluation of this SS&D, a luminous calibration light source. All necessary elements were covered and a second full evaluation was performed by another qualified individual. The SS&D certificate is identified and listed with case-specific comments in Appendix G.

The team found that the State's evaluation of the background information was complete and technically accurate and that the State determined that the device has adequate safety features. The State visited the manufacturer to verify the quality assurance program before the device was approved for distribution. Prototype testing for this device is not required by American National Standards Institute (ANSI) N540. The registry certificate, however, had two errors that need to be corrected. First, the sheet did not list the maximum amount of radioactive material used in the device. Second, the certificate authorizes distribution to persons exempt from licensing as well as to general and specific licensees, however, the authority to approve exempt distribution is reserved for the NRC. 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.

Also, it was noted that the licensee's license for distribution does not list model 40111. The review team recommends that the TLS license for distribution (10-135) be amended to include model 40111.

Review of this file and interviews with the staff indicated that Arizona follows the recommended guidance from the NRC SS&D training workshop. The registration file contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. In addition, the checklist received at the workshop was used to assure all relevant materials had been submitted and reviewed. The checklist was contained in the registration file. The team observed that the staff will issue the guidance in NUREG-1556, V.3, issued September 1997. All pertinent ANSI Standards and Regulatory Guides are available and will be used.

#### 4.2.2 Technical Staffing and Training

Although Arizona has only one manufacturer who infrequently manufactures and distributes a new or changed device, the State wishes to keep the SS&D evaluation program. They are willing to provide sufficient resources to maintain an adequate program. The principal SS&D reviewer has been through the current NRC training and has been evaluating SS&Ds in Arizona for several years. He also evaluated SS&Ds during his military service prior to joining ARRA. He has a degree in nuclear engineering with a minor in mechanical engineering. A second mechanical engineer is available in ARRA as necessary for assistance with engineering problems. The third individual trained and qualified for SS&D evaluation is the ARRA Director, a Certified Health Physicist. In order to provide more depth to the SS&D evaluation program, the State intends to send an additional person to the NRC SS&D workshop the next time it is offered.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&Ds occurred during the review period, nor were there any defects reported.

Based on the IMPEP evaluation criteria, the review team recommends that Arizona's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

## 5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found that Arizona's performance with respect to each of the performance indicators to be satisfactory. Accordingly, the team recommends that the Management Review Board find the Arizona program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State.

#### RECOMMENDATIONS:

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)
2. The review team recommends that staff include more detailed documentation related to telephone deficiency calls, describing the issues and notating 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 were denied. (Section 3.4)
3. 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.)
4. The review team recommends that all incident reports be recorded and closed out as directed in ARRA's SOP, 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)
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)
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)
7. The review team recommends that the TLS license for distribution (10-135) be amended to include model 40111. (Section 4.2.1)

#### SUGGESTIONS:

1. The review team suggests that the supplemental inspection report form for HDR afterloaders be modified to cover all safety feature checks and requirements of licensure. (Section 3.2)
2. The review team suggests that staff and management continue to evaluate and develop a plan to accommodate the new legislation mandating time lines in which to process applications without impacting the technical quality of license reviews. (Section 3.4)

3. The review team suggests that the State advise the NRC Office for Analysis & Evaluation of Operational Data when incidents are closed so that the NMED records may be updated. (Section 3.5)
4. The review team suggests that ARRA develop written procedures to be used as guidance for tracking, evaluating, and reporting misadministrations at the time the rule becomes effective. (Section 3.5)

## **LIST OF APPENDICES AND ATTACHMENTS**

Appendix A	IMPEP Review Team Members
Appendix B	Arizona Organization Chart
Appendix C	Arizona's Questionnaire Response
Appendix D	Inspection File Reviews
Appendix E	License File Reviews
Appendix F	Incident File Reviews
Appendix G	Sealed Source and Device Reviews
Attachment 1	Arizona's Response to Review Findings

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

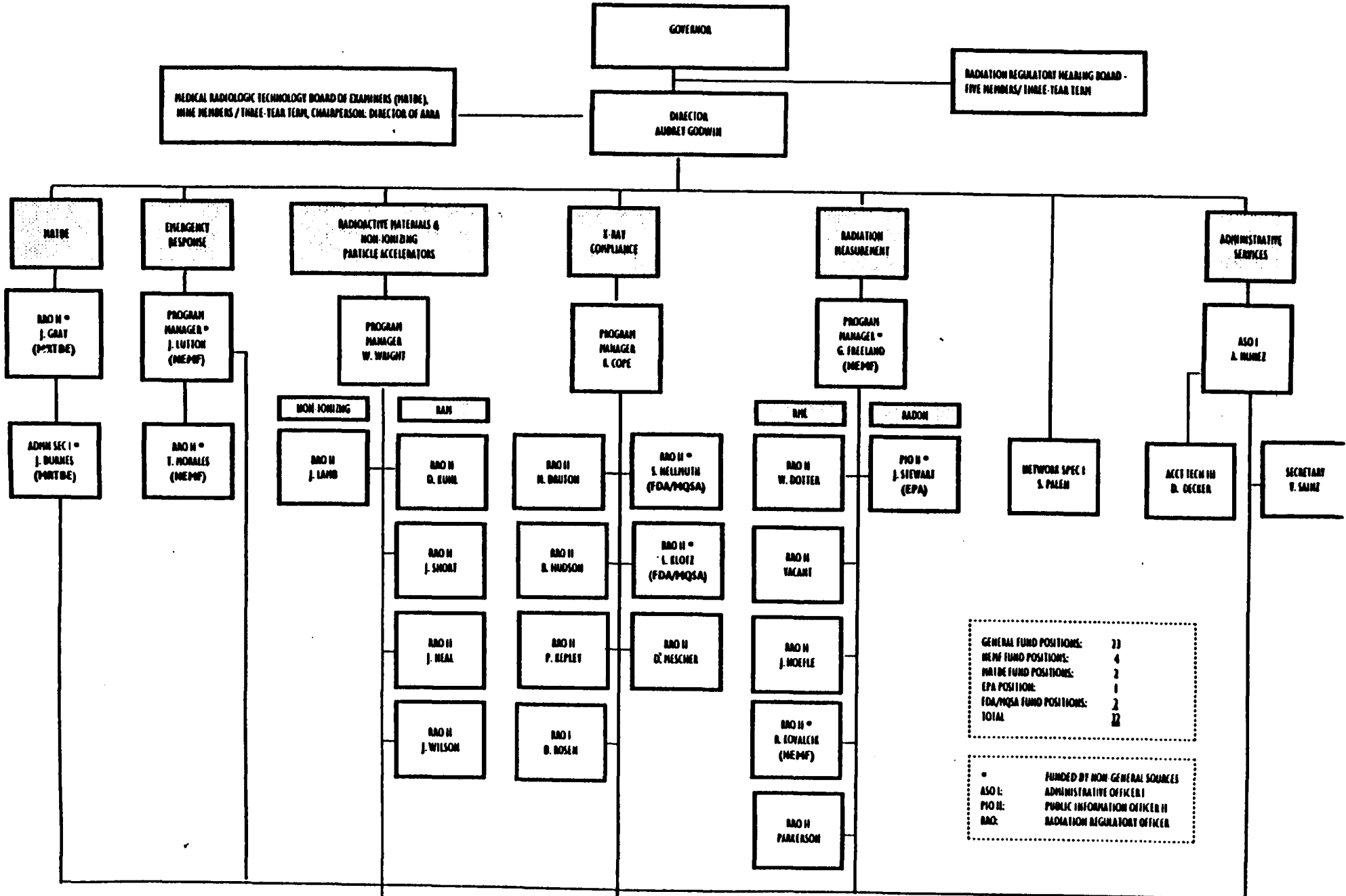
<b>Name</b>	<b>Area of Responsibility</b>
James Myers, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
B. J. Smith, Mississippi	Status of Materials Inspection Program Technical Quality of Inspections
Torre Taylor, NMSS M. Linda McLean, RIV	Technical Quality of Licensing Actions
Jack Hornor, WCFO	Response to Incidents and Allegations Sealed Source and Device Evaluation Program

APPENDIX B

ARIZONA RADIATION REGULATORY AGENCY

ORGANIZATION CHART

**STAT IZONA  
RADIATION REGULATORY AGENCY AEA  
ORGANIZATION CHART**



GENERAL FUND POSITIONS:	23
MEMPF FUND POSITIONS:	4
NMTBE FUND POSITIONS:	2
EPA POSITION:	1
FDA/MSA FUND POSITIONS:	2
TOTAL:	32

\* FUNDED BY NON-GENERAL SOURCES  
 ASO I: ADMINISTRATIVE OFFICER I  
 PIO II: PUBLIC INFORMATION OFFICER II  
 RMO: RADIATION REGULATORY OFFICER

ADMIN SEC I - B. DECKER

ADMIN SEC I - B.





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April 2, 1998

Richard L. Bangart, Director  
Office of State Program  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Dear Mr. Bangart:

Thank you for the draft copy of the IMPEP report on Arizona. We appreciate the team members who conducted the review. Their professionalism is demonstrated by the report. The State will benefit from their efforts and the citizens' public health and safety improved.

We have several comments which are attached. These comments are based on our understanding of the report and the comments of the team members while here. The IMPEP is an improvement over the prior program review process. Their comments to our staff were very helpful and improved staff attention to details. We welcome them back at any time.

Again thank you and the IMPEP team for their review and comments.

Sincerely

A handwritten signature in cursive script, appearing to read "Aubrey V. Godwin".

Aubrey V. Godwin,  
Director

50 APR -5 PM 2:26  
NCS

ATTACHMENT 1