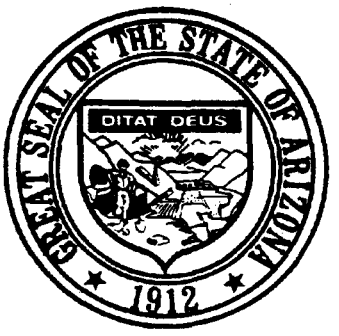

PERFORMANCE AUDIT

ARIZONA RADIATION REGULATORY AGENCY

RADIATION REGULATORY HEARING BOARD

Report to the Arizona Legislature
By the Auditor General
October 1995
Report #95-8

STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

DOUGLAS R. NORTON, CPA
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October 31, 1995

Members of the Arizona Legislature

The Honorable Fife Symington, Governor

Mr. Aubrey V. Godwin, Director
Arizona Radiation Regulatory Agency

Dr. James Woolfenden, Chairman
Radiation Regulatory Hearing Board

Transmitted herewith is a report of the Auditor General, A Performance Audit of the Arizona Radiation Regulatory Agency and the Radiation Regulatory Hearing Board. This report is in response to a May 5, 1993, resolution of the Joint Legislative Audit Committee. The performance audit was conducted as part of the sunset review set forth in A.R.S. §§41-2951 through 41-2957.

The report addresses the Agency's current inspection backlog for x-ray and mammography machines. Reasons for this backlog include inefficient use of staff resources and ineffective scheduling of inspections. For example, x-ray and mammography machine inspectors spend an average of only one day a week performing inspections. We recommend that Agency management shift non-inspection duties from inspectors, which would allow them to spend more time performing inspections. We also recommend that the Agency take stronger and more timely enforcement action against radioactive materials violations. We reviewed 81 cases with violations and found that the Agency took some form of enforcement action in only 3 (4 percent) of those cases. The Agency's inability to assess civil penalties due to a discrepancy within its rules partially contributes to the limited enforcement. The report also presents other

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pertinent information regarding the statutes of the Southwestern Low-Level Radioactive Waste Disposal Compact and alternatives for disposing of low-level radioactive waste.

Finally, the report also addresses the statutorily mandated Sunset Factors for the Radiation Regulatory Hearing Board.

My staff and I will be pleased to discuss or clarify items in the report.

This report will be released to the public on November 1, 1995.

Sincerely,

Douglas R. Norton
Auditor General

Enclosure

SUMMARY

The Office of the Auditor General has conducted a performance audit and sunset review of the Arizona Radiation Regulatory Agency and the Radiation Regulatory Hearing Board, pursuant to a May 5, 1993, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review set forth in A.R.S. §§41-2951 through 41-2957.

The Arizona Radiation Regulatory Agency (ARRA) is responsible for protecting the public health, safety, and welfare by regulating the use and sources of radiation. ARRA accomplishes this responsibility by:

- Licensing and inspecting radioactive materials such as radioactive isotopes used in the medical profession and gauges used to determine material content and density;
- Registering and inspecting x-ray and mammography machines;
- Coordinating emergency response activities for any incidents, accidents, or emergencies involving radiation in the State including the Palo Verde Nuclear Generating Station; and
- Conducting laboratory functions to detect radiation levels in the State's air, water, and soil.

Additionally, the Agency and its Director perform administrative and enforcement duties assigned to the State by the Southwestern Low-Level Radioactive Waste Disposal Compact.

The Radiation Regulatory Hearing Board, consisting of five appointed members, serves as an independent check on the actions taken by the Agency. Licensees, registrants, or individuals who wish to appeal ARRA actions may do so through the Board. Because the Board has not met in the past two fiscal years, our work on the Board was limited to a review and preparation of sunset factors (see pages 33 through 35).

Failure to Perform Timely X-Ray Inspections Threatens Public Health and Safety (See pages 5 through 13)

ARRA inspections protect the public from unnecessarily high and dangerous exposure to man-made radiation and its detrimental health effects. However, the Agency currently faces nearly a 30 percent inspection backlog for x-ray tubes, and over a 77 percent backlog for mammography tubes.[1] Beyond this backlog, several extreme examples of overdue inspections exist. For example, two separate mammography machines have awaited inspection for two and five years, respectively. Similarly, a dental facility is almost four years overdue for inspection.

Several reasons, including inefficient use of staff resources and ineffective scheduling of inspections, contribute to ARRA's inability to meet its inspection schedule. For example, x-ray machine inspectors, including mammography inspectors, spend an average of only one day per week performing inspections. Much inspector time is consumed with administrative and registration activities that support staff could easily perform. Additionally, ARRA's self-imposed mandate to conduct unannounced inspections wastes significant time because inspectors arrive at facilities during times when machines are being heavily used or when facilities are closed. Several states report that announced inspections reduce wasted time and, because of the nature of inspections, do not decrease their effectiveness.

Finally, for ARRA to address its inspection backlog and meet current inspection schedules for x-ray and mammography machines, inspectors should increase the number of machines they inspect. Several states, including Wisconsin, Oregon, and Louisiana, report a much higher inspection rate per inspector than that achieved by ARRA inspectors. Our analysis shows that the Agency can meet its inspection workload if inspectors perform a minimum average of 450 inspections per year, a rate comparable to that achieved in other states.

Radioactive Materials Enforcement Needs Improvement (See pages 15 through 22)

The dangerous nature of radioactive materials and the requirement that users adhere to strict safety and administration policies and procedures demands a strong and consistent enforcement stance. However, ARRA's untimely response to violations endangers the

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[1] Tubes are the parts of x-ray machines that emit x-rays. Each machine may have more than one tube and each tube requires inspection.

public health and safety. For example, even though prompt notification and correction of violations is important, in nearly half of its cases, ARRA takes too long to notify licensees of violations, gives the licensees too lenient a deadline to respond to the violation, and then takes no action when over one-quarter of the licensees fail to respond by the deadline.

In addition to untimely notification, ARRA rarely takes enforcement action when a violation occurs. Historically, ARRA has relied on civil penalties to enforce compliance with its rules. From June 1992 through November 1993, the Agency assessed civil penalties against 11 licensees. However, ARRA discovered a discrepancy within its rules governing civil penalties and the Attorney General advised the Agency to cease using civil penalties until it could correct the discrepancy. As a result, several violations that merited civil penalties, including at least 10 licensees with repeat violations and over 20 late licensee responses to notices of violation, were not assessed civil penalties.

The Agency's reluctance to use other available enforcement options further compounds this problem. Statute and rule provides a range of enforcement actions that the agency does not use, including license modification, informal hearings, injunctions, radiation source impoundment, and license suspension or revocation. We reviewed 81 cases with violations and found ARRA took some form of enforcement action in only 3 (4 percent) of those cases.

ARRA's lenient enforcement philosophy partially contributes to its untimely and inadequate enforcement within the radioactive materials program. Both management and staff display a preference to avoid strong enforcement actions, even when statute mandates such actions.

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INTRODUCTION AND BACKGROUND

The Office of the Auditor General has conducted a performance audit and sunset review of the Arizona Radiation Regulatory Agency and the Radiation Regulatory Hearing Board, pursuant to a May 5, 1993, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review as set forth in A.R.S §§41-2951 through 41-2957.

ARRA and Hearing Board Responsibilities

In 1980, the Legislature established the Arizona Radiation Regulatory Agency (ARRA), which replaced the Arizona Atomic Energy Commission. By creating ARRA, the Legislature wished to:

> *"...protect the public health and safety by regulating the use and sources of radiation...."*

ARRA is authorized to regulate man-made sources of radiation except those used by federal agencies and certain nuclear reactors. Statutes provide authority for ARRA to license or register such radiation sources, conduct inspections to ensure adequate compliance with agency rules, and assess fees to registrants and licensees. Additionally, ARRA has entered a special agreement with the Nuclear Regulatory Commission (NRC) to control radioactive source materials, small quantities of special nuclear material, and radioactive by-products from reactors. The agreement allows Arizona to provide local response to radioactive materials emergencies as well as charge fees that are lower than NRC rates to the State's radioactive materials users. The agreement also requires Arizona to follow NRC regulations.

The Agency's additional statutory responsibilities include monitoring off-site radiation in the air, water, and soil surrounding fixed nuclear facilities; responding to incidents, accidents, and emergencies involving radiation; and performing administrative and enforcement duties related to the Southwestern Low-Level Radioactive Waste Disposal Compact, to which Arizona, California, North Dakota, and South Dakota belong.

The Radiation Regulatory Hearing Board, consisting of five appointed members, is responsible for conducting hearings involving ARRA enforcement action appeals. The Board may also review rules and regulations promulgated by ARRA and make recommendations to the Agency and the Legislature.

Organization

ARRA oversees five programs:

- **Radioactive Materials (4.5 FTEs)** — This program oversees the licensing of 290 medical, industrial, and academic users of radioactive materials. For example, ARRA regulates hospitals that use radioactive isotopes to perform diagnostic procedures and construction companies that use gauges to determine material density. Program inspectors conduct periodic site inspections, involving a review of policies and procedures, treatment records, and material storage records, to ensure that licensees follow proper techniques for the use, storage, and shipment of radioactive materials.

- **X-ray, Mammography, and Non-Ionizing Radiation (7.5 FTEs)** — This program registers and periodically inspects 6,960 x-ray (ionizing radiation) producing machines, including medical, dental, and industrial radiography machines. Legislation adopted in 1992 specifically requires annual inspection of the 210 registered, x-ray producing mammography machines. This program also licenses and inspects non-ionizing radiation sources, such as lasers and tanning beds.

  Although the term "radiation" is very broad and includes such things as light and radio waves, it is most often used to mean "ionizing" radiation, which is radiation that can produce charged particles ("ions") in materials that it strikes. Ionizing radiation can present a health hazard to the public. Non-ionizing radiation may also pose a health risk, although the extent of this risk is not well known or documented and is more inconclusive than its ionizing counterpart.

- **Environmental Surveillance Laboratory (7 FTEs)** — The lab maintains surveillance over radiation levels near Palo Verde Nuclear Generating Station (PVNGS), as well as other areas such as the Navajo Reservation, where radiation levels in the water have been notably high. Surveillance includes the sampling of air, water, and soil. This program also provides public information and technical assistance in assessing radon in Arizona.

- **Emergency Response (2 FTEs)** — The Emergency Response program provides technical assistance to handle any incidents, accidents, or emergencies involving radiation or sources of radiation within the State. The program also prepares for and participates in off-site radiation emergency response at PVNGS. Additionally, the program provides first response training for police, fire, and medical personnel who may respond to accidents.

- **Medical Radiologic Technology Board of Examiners (MRTBE) (2 FTEs)** — MRTBE certifies operators of medical radiologic equipment by requiring minimum training and experience.

Budget and Personnel

ARRA's operating budget consists of both appropriated and nonappropriated funds. The Agency expended over $1.5 million in appropriated funds and over $270,000 in federal funds in fiscal year 1994-95. The $1.5 million in appropriated funds represents approximately $1 million from the general fund, $399,000 from the Nuclear Emergency Management Fund (NEMF), and $102,000 from the State Radiologic Technology Certification Fund. The Legislature established the NEMF to fund Arizona's nuclear generating station emergency response activities. The consortium that operates PVNGS reimburses the State for amounts appropriated to this fund by the Legislature. The State Radiologic Technology Certification Fund reflects fees radiology technicians pay to become certified by the State.

In addition to the FTE numbers indicated for each program, the Agency is authorized 5 FTEs for administration/support staff and 1 FTE for the Director, for an authorized total of 29 FTEs. Each program within the Agency reports to a program manager, with the exception of the radioactive materials (RAM) and x-ray programs, which are managed by a single program manager.

Audit Scope

This audit focuses on the need for the Arizona Radiation Regulatory Agency and its efforts to protect the public health and safety from dangers associated with sources of radiation and their use. We also performed limited work on the Radiation Regulatory Hearing Board which is found in the sunset factors. The Medical Radiologic Technology Board was not reviewed as part of this audit since it is scheduled for sunset review as part of the 1997 audit cycle.

Our work included a review of the Agency's ability to perform timely inspections of x-ray machines and radioactive materials, adequacy and timeliness of all enforcement actions it takes, ability to respond effectively to radiation emergencies, complaint handling, and current status of the Southwestern Compact for Low-Level Radioactive Waste disposal. Additionally, we contacted ten states, the Conference for Radiation Control Program Directors (CRCPD), and the Nuclear Regulatory Commission.[1]

While our work found problems, we also found that ARRA is performing well in some areas. Unlike x-ray inspections, ARRA performs radioactive materials inspections in a timely manner. Additionally, while we found problems in radioactive materials license

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[1] We contacted radiation officials in states with a similar number of registered x-ray tubes and/or an agreement with the Nuclear Regulatory Commission to control radioactive source materials. States contacted were North Carolina, Minnesota, Maryland, Oregon, Tennessee, Louisiana, Oklahoma, Wisconsin, Colorado, and Washington.

enforcement, we found minimal problems pertaining to x-ray enforcement. Also, we determined that the Agency responds adequately to radiation emergencies and/or incidents as demonstrated by its response to a Tucson incident, reviews it has received on past Palo Verde Nuclear Generating Station response exercises, and previous Auditor General and federal inspection comments regarding the Agency's response abilities.

Our report presents findings and recommendations in two areas:

- The need for improved productivity in ARRA's x-ray/mammography program in order to eliminate inspection backlogs.

- The need for more frequent, timely, and aggressive enforcement actions against licensees who violate radioactive materials regulations.

In addition to these audit areas, we present other pertinent information concerning the status of the Southwestern Low Level Radioactive Waste Disposal Compact and alternatives for disposing low-level radioactive waste. This report also contains responses to the 12 Sunset Review Factors for the Agency (see pages 27 through 30) and for the Radiation Regulatory Hearing Board (see pages 33 through 35).

The findings in this report are similar to those in our previous report on the Radiation Regulatory Agency and Radiation Regulatory Hearing Board which was issued in November 1984. That audit found that the Agency did not conduct all its inspections in a timely manner, it could take stronger or more timely enforcement actions, and that the x-ray machine registration and fee collection process could be improved. The report also noted that the Agency had not received sufficient funding from the Nuclear Emergency Management Fund (NEMF) to finance its costs relating to Palo Verde Nuclear Generating Station activities.

This audit was conducted in accordance with government auditing standards.

The Auditor General and staff express appreciation to the Director, staff, and board members of the Arizona Radiation Regulatory Agency and the Radiation Regulatory Hearing Board for their cooperation and assistance throughout the audit.

FINDING I

FAILURE TO PERFORM TIMELY X-RAY INSPECTIONS THREATENS PUBLIC HEALTH AND SAFETY

X-ray machine (including mammography machine) inspections should occur at regular intervals to protect the public from unnecessary radiation exposure. However, nearly 30 percent of x-ray tube and over 77 percent of mammography tube inspections are past due. Because staff time and activities are poorly managed, inspectors spend an average of only one day a week performing inspections. ARRA's management should strive to meet other states' productivity levels by reducing staff time spent on tasks other than inspections, holding inspectors accountable for number of inspections performed, and scheduling inspections more efficiently.

ARRA's 5 x-ray inspectors conduct inspections of 3,393 facilities with registered x-ray tubes. Such facilities include medical, dental, veterinary, and chiropractic offices; hospitals; and industrial facilities. During inspections, inspectors monitor the amount of radiation emitted from each x-ray tube, the adequacy of radiation barriers such as walls, and the quality of the x-ray images taken. Additionally, ARRA has trained 2 inspectors to perform inspections of mammography machines at an additional 156 facilities. These inspections must conform to the United States Food and Drug Administration (FDA) standards.[1]

Inspections of Man-Made Radiation Sources Important

ARRA inspections are necessary to protect the public from unnecessarily high and dangerous exposure to ionizing radiation and its detrimental health effects. Even though x-ray inspections yield nearly a 91 percent compliance rate, the health threat posed by tubes that emit too much radiation mandates a comprehensive and timely inspection program. According to the National Research Council, ionizing radiation's "well demonstrated late effects include the induction of cancer, genetically determined ill-health, developmental abnormalities, and some degenerative diseases such as cataracts."[2]

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(1) ARRA has a contract with the FDA to perform inspections in accordance with the Mammography Quality Standards Act of 1992. Such inspections also satisfy Arizona statutory requirements for mammography machine inspections.

(2) *Health Effects of Exposure to Ionizing Radiation*, National Research Council, National Academy Press, Washington, D.C., 1990.

Ensuring the safety of x-ray tubes is critical since the healing arts (x-ray and nuclear medicine) represent approximately 83 percent of the U.S. population's total exposure to man-made ionizing radiation. Also, in recent years, the importance of mammography inspections has been increasingly stressed due to the large number of women (one in eight) who develop breast cancer over the course of a lifetime.

Inspections Backlog Plagues ARRA

ARRA fails to conduct x-ray and mammography inspections in a timely manner. Inspections are required at regular intervals established by the Agency itself and by statute. Nonetheless, hundreds of ARRA's registered x-ray and mammography tubes are overdue for inspection.

X-ray inspections far behind schedule — ARRA does not keep current with its own schedule for registered x-ray tube inspections. This schedule requires that inspections occur at regular intervals from two to four years based on the type of facility where the machine is used. However, nearly 30 percent of x-ray tube inspections are late according to ARRA's timetable for inspections, as shown in Table 1.

Table 1

Overdue X-Ray Inspections According to ARRA's Inspections Time Frame as of April 14, 1995

Type of Facility	ARRA's Timetable for Inspections	Number of Tubes Registered	Number of Tubes Late for Inspections	Percent Overdue
Hospital	Every Two Years	1,036	575	55.5%
Medical Educational Chiropractic	Every Three Years	1,796	528	29.4%
Dental Veterinary Industrial Podiatry	Every Four Years	5,094	1,250	24.5%
Total		**7,926**	**2,353**	**29.7%**

Source: Auditor General analysis of ARRA database as of April 14, 1995.

Our analysis also found many extreme examples of overdue inspections, including:

- A Sierra Vista dental facility that is almost four years overdue for inspection. Since the inspection due date, the facility has taken an estimated 63,200 x-rays.

- Two Tucson hospitals that were almost three years overdue for inspection. Since our initial analysis, ARRA subsequently inspected one hospital and found that one machine's radiation filtration was inadequate, resulting in excessive radiation exposure.

- An Ajo dental facility that went 17.7 years between inspections. Even though this facility is open only twice a month, which may warrant a more lenient inspection schedule, ARRA's director indicated the facility should be inspected every 8 to 12 years.

Mammography inspections also overdue – Like other types of x-ray inspections, many mammography inspections are also past due. Since September 1992, state statute has required yearly inspections of mammography machines. (Previously, mammography inspections occurred as part of ARRA's routine inspection of x-ray facilities.) Nonetheless, ARRA has failed to perform these inspections as required. One-hundred sixty-one of the 208 registered mammography tubes (77 percent) are overdue for inspection, with 72 tubes (35 percent) overdue by more than one year. Extreme examples of overdue inspections also exist. For instance, ARRA has not inspected a mammography machine in a rural hospital for over three years and a Maricopa County gynecologist's machine for over six years. Since their last inspections, an estimated 19,500 and 45,460 mammography exposures have occurred at these facilities.

Poor Management of Staff Resources Leads to Backlog

Management's failure to maximize the time inspectors devote to inspections contributes to the current x-ray inspections backlog. ARRA inspectors currently devote less than 20 percent of their time to inspections, instead devoting time to administrative tasks. Additionally, management's failure to hold inspectors accountable for the quantity or quality of inspections further affects the number of inspections performed. Furthermore, the absence of advanced scheduling of x-ray inspections thwarts the number of inspections that can be performed.

Small percentage of time dedicated to inspections – Inspectors dedicate few hours to inspections, thus contributing to inspection backlogs. As shown in Figure 1 (see page 8), x-ray and mammography machine inspectors spend 20 percent of their time, or only one

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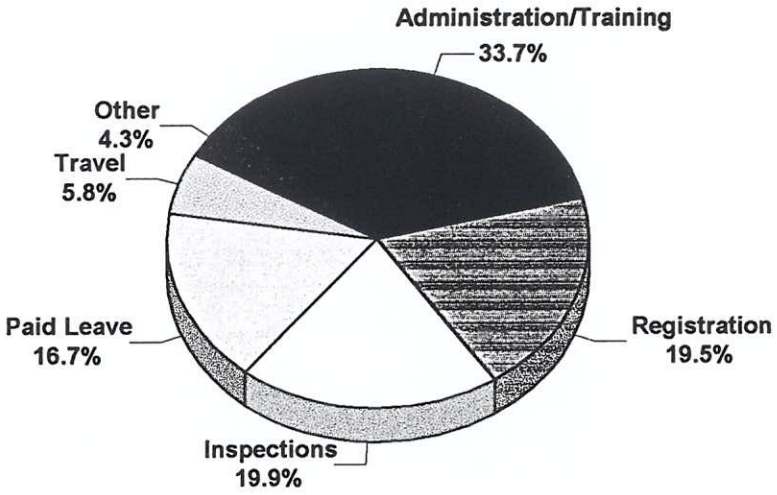
day a week, performing inspections. Inspectors spend approximately 34 percent of their time on administrative activities such as staff meetings, training, fee collection activities, and responding to public inquiries. Registration activities also absorb a great percentage of time (19.5 percent).

Figure 1

Time Allocation by X-Ray/Mammography Inspectors



Source: Auditor General Staff analysis of time sheets and interviews with ARRA Staff.

Several factors contribute to the large quantity of time inspectors dedicate to administrative activities.

- **Unnecessary delegation of managerial responsibilities** – Our observations and comments from staff suggest that the program manager responsible for the x-ray, mammography, and radioactive materials regulatory programs may be unproductive, ineffective, and unnecessarily spending time performing tasks not associated with these programs. As a result, one x-ray/mammography inspector spends approximately

40 percent of her time handling administrative duties that should be performed by this manager. These duties include writing contracts, writing employee evaluations, and reviewing inspections completed by other inspectors. Therefore, this inspector spent only 19 percent of her time conducting inspections during the 21-month period ending March 31, 1995. If the program manager resumed performing these administrative duties, this inspector could spend more time performing inspections.

Subsequent conversations with the program manager and the Director did not adequately explain why the program manager spends little time administering the x-ray program he is charged with overseeing. Although the program manager explained he has additional duties involving power line siting and the Southwestern Low-Level Radioactive Waste Compact, these tasks should not detract from his primary responsibilities as program manager.

- **Inefficient record-keeping** – Inspectors spend unnecessary time updating inspection records. This problem results from management's failure to use support staff for this task. Additionally, problems with the computerized database contribute to inefficiencies as inspectors record inspection information on two databases, a card file, and a case file. ARRA management recently began addressing the former problem by shifting more record-keeping tasks to existing support staff.

- **Time wasted on registration** – Inspectors unnecessarily spend nearly 20 percent of their time registering x-ray machines. Rather than requiring x-ray machine owners to be responsible for providing and updating all the necessary information to register their machines, inspectors do much of this clerical work. Inspectors personally gather registration information during inspections and update registration forms between inspections when registrants provide new or updated information. These processes could better be handled between the x-ray machine owners and ARRA's support staff, freeing inspector time for their primary duties. ARRA management cited staff errors, incorrect registration reporting by x-ray machine owners, and data entry performed by inspectors rather than support staff as reasons for the significant amount of time spent on registration.

- **Time spent on fee collection** – Administrative activities include time spent by x-ray inspectors on annual fee collection from registrants. Interviews with inspectors suggest that support staff can perform most fee collections activities, including updating change of address information to ensure accurate billings.

In order to shift additional administrative activities to support staff, management should assess the adequacy of its current support staff levels. If existing support staff is inadequate, ARRA could consider hiring additional permanent staff or temporary support staff. Both ARRA and one of ARRA's divisions, the Medical Radiologic Technology Board

of Examiners, already hire some temporary staff to assist with fee collection, thus allowing them to handle this task without the addition of permanent support staff.

Management neglects to hold inspections staff accountable — When staff devote more time to inspections, inspection rates increase, as shown in Table 2. The ARRA inspector who spent the most time (37 percent) on x-ray inspections performed over 550 x-ray tube inspections. Nonetheless, management does not hold inspectors accountable for time spent on inspections, the types of inspections each inspector performs (inspections of some types of facilities take longer than others), nor the actual number of inspections accomplished. In other states such as Louisiana and Minnesota, goals are set for the number of inspections each inspector must perform. While Arizona's program has set inspection goals in the past, management has not adequately considered these goals in performance evaluations.

Table 2

X-Ray and Mammography Tube Inspections Performed and Percentage of Time Spent on Inspections Per Inspector, Fiscal Year 1994[a]

Inspector	Percentage of Time Devoted to X-Ray Inspections	Tube Inspections Performed
Inspector One	37%	556
Inspector Two	11%	288
Inspector Three	8%	154
Inspector Four	12%	146

[a] A fifth inspector was added in July 1994, and a sixth inspector will be added in fiscal year 1995-96. The unit also employs a non-ionizing x-ray (lasers and tanning beds) inspector and shares its program manager with the Radioactive Materials units.

Source: Auditor General analysis of ARRA x-ray inspection records and time sheets for fiscal year 1994.

Management also does not hold staff accountable for the quality of inspections. Interviews suggest that one inspector continuously makes mistakes during routine inspections, thus requiring other inspectors to check his work or repeat these inspections. These mistakes include his failure to note serious machine problems that could result in exces-

sive radiation exposure. While the compliance program manager acknowledges that the quality of this inspector's work is problematic, performance evaluations have not characterized his work as unacceptable.

Lack of scheduling leads to wasted time — Further compounding productivity problems, unannounced or unscheduled inspections contribute to wasted time. Based on our observations, inspectors often arrive at facilities for unannounced inspections when the offices are closed or extremely busy, forcing inspectors to wait or return at more convenient times. In these instances, we documented much time wasted. Also, the lack of basic information in ARRA's files, such as a facility's hours of operation, partially contributes to this problem.

ARRA's Director indicated that an interagency agreement between the Industrial Commission (ICA) and ARRA prohibits announced inspections.[1] However, interviews with ICA officials revealed that announced inspections do not violate any such agreement. Other states such as Louisiana, Minnesota, Wisconsin, Washington, and Maryland perform announced inspections. Additionally, our observations suggest ARRA could do the same without decreasing quality since facility staff are 1) generally unaware of problems with their machines and 2) often eager to learn about any problems. Hence, announced inspections should not be any less effective than unannounced inspections.

ARRA Could Perform Many More Inspections

ARRA's average x-ray inspection rate compares poorly to inspection rates achieved in other states. If ARRA improved its inspection rate, it could meet its schedule for performing x-ray machine inspections, as well as the statutorily defined schedule for mammography machine inspections.

As seen in Table 3 (see page 12), productivity rates for six of the seven states reporting this data exceed the average number of inspections performed by ARRA inspectors during fiscal year 1994. Four states exceed an average staff inspection rate of 450 tubes per year. While differences exist between states regarding inspection procedures due to a lack of federal or nationally mandated inspection procedures or standards, these states indicated they do conduct comprehensive x-ray machine inspections. These inspections not only cover the quality, safety, and accuracy of the machines themselves, but also encompass safety procedures for and the protection of workers, the general public, and the environ-

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[1] This agreement recognizes ARRA's authority in conducting inspections of facilities that handle radiation in order to protect workers from unnecessary radiation exposure.

ment. All of these states have adopted regulations for x-ray machines that are similar to the Conference of Radiation Control Program Directors (CRCPD) suggested state regulations and/or FDA performance standards for machines. Additionally, a CRCPD official commented that inspectors in other state programs usually inspect 400 to 500 tubes annually.

ARRA's management states that 600 annual tube inspections should be an achievable goal for each inspector. Indeed, one ARRA inspector's productivity rate of 556 inspections per year achieved at only 37 percent time spent on inspections (see Table 2, page 10) suggests that such a goal is attainable. The official from the CRCPD noted that some states exceed such figures, particularly states with high concentrations of x-ray facilities in large metropolitan areas. For example, in Wisconsin, a state that, like Arizona, has two-thirds of its x-ray tubes in one large metropolitan area, inspectors accomplished an average of 886 tube inspections in fiscal year 1994.

If ARRA x-ray inspectors performed as few as 450 annual inspections, we estimate that the Agency could meet its inspection schedule. ARRA could devote 1.5 FTEs to mammography machine inspections and still perform the 2,384 state x-ray inspections required on average each year according to ARRA's current timetable for inspections.[1]

Table 3

Average Number of X-Ray and Mammography Tubes Inspected Per Inspector, Fiscal Year 1994

State	Number of Tubes Inspected Annually Per Inspector
Wisconsin	886
Oregon	489
Louisiana	460
Washington	457
North Carolina	439
Minnesota	414
Arizona	**360**
Tennessee	171

Source: Auditor General interviews of radiation program officials in other states and analysis of ARRA's fiscal year 1994 inspection figures.

[1] Our estimate is based on the addition of two inspectors that are authorized to be added by fiscal year 1997. Also, 1.5 FTEs are necessary for performing the 210 annual tube inspections since mammography inspections take considerably longer than other x-ray inspections. Additionally, the program has experienced an annual growth rate of 60 to 70 tubes for the past few years. If this growth continues, x-ray inspectors would need to perform more than 450 annual inspections in future years and/or ARRA would need additional inspectors.

RECOMMENDATIONS

1. ARRA should shift administrative and registration duties from x-ray inspectors to management and support staff. Management should consider whether additional support staff is necessary, and consider the hiring of temporary clerical staff to perform duties associated with seasonal fee collection.

2. Management should hold inspectors accountable for number and types of inspections accomplished and/or time spent performing inspections. Also, management should establish performance goals as is done in other states.

3. X-ray inspections should be performed on an announced, prescheduled basis.

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FINDING II

RADIOACTIVE MATERIALS ENFORCEMENT NEEDS IMPROVEMENT

While radioactive materials (RAM) inspections appear to be timely and adequate, RAM enforcement actions are slow and inadequate. Our review of agency enforcement revealed instances where the RAM program took excessive amounts of time to begin and complete enforcement actions, including instances extending well over a year. Further, we identified cases that may have merited stronger enforcement action. The Agency's inability to assess civil penalties and its lenient enforcement philosophy contributes to untimely and weak enforcement.

Per agreement with the Nuclear Regulatory Commission, ARRA has direct oversight responsibilities, including licensure, inspection, and enforcement for radioactive materials. Uses for radioactive materials include soil- and asphalt-testing gauges, industrial and medical imaging, and research activities. ARRA conducts inspections of radioactive materials at different intervals based on the user's license and type of radioactive material in use. Inspections include an examination of the user's policies and procedures, treatment records, and radiation safety activities. An inspector will also observe personnel using or administering radioactive material.

Importance of Strong Enforcement Program

As noted previously, adequate and timely enforcement is important because research has shown that exposure to sources of radiation can harm the public health and safety. Although it is impossible to predict the amount of radiation exposure necessary to cause damage, it is critical to reduce the amount of radiation received by the public to reasonably achievable low levels. Consequently, ARRA efforts to enforce compliance with its rules and regulations become extremely important. These efforts should ensure that radioactive materials users do not endanger the public health. The following example illustrates the importance of ensuring compliance with ARRA rules.

- In November 1989, a Phoenix hospital incorrectly administered a radioactive treatment that destroyed a woman's thyroid gland. As a result, the woman received more than 1,000 times the intended dose and inadvertently exposed her children to radia-

tion. Following this misadministration, ARRA conducted an investigation and determined that the technician on duty did not comply with rules that require confirmation of the prescription and dosage before giving it to the patient. Although ARRA assessed a $12,000 civil penalty, this woman faces an increased risk for developing cancer and must now medically treat her condition for life.

Violation Notification Is Not Timely

ARRA fails to act promptly on radioactive materials violations. Under ARRA's agreement with the NRC, ARRA must abide by NRC regulations that require it to notify licensees of violations within 30 days. However, ARRA frequently misses these deadlines. Additionally, many licensees also respond late to notices of violation. Excessive report review and lack of procedures for ensuring timely violation notices and responses contribute to delays.

Notification and response correspondence are slow —Notices of violation are untimely. NRC regulations require that Arizona notify licensees of violations within 30 days following an inspection. We conducted a file review of 80 RAM licensee files with violations, and determined that on average (excluding four files for abnormally late notices), ARRA sends notices of violation to licensees in 33 days. While this average does not greatly exceed the NRC requirement, we also determined that for 37 of the 80 files (approximately 46 percent), ARRA mailed notices late, effectively delaying prompt resolution of violations. Additionally, ARRA transmitted several notices extremely late, including 4 mailed from approximately 74 to 380 days later than the 30-day requirement. Late violation notices can negatively affect the Agency's ability to enforce its regulations as illustrated by the following case examples.

- A medical facility received ARRA's notice of violation 410 days after an inspection. Violations resulted from not checking incoming packages for radioactive material leakage, and the radiation safety officer's failure to properly oversee the program. As a result of this late violation notice, the licensee demanded an explanation for the delay. The licensee also questioned how, if it had committed violations, the public's welfare could be protected by the Agency's delay in transmitting the results of the inspection. ARRA eventually apologized for the late violation notice.

- A nuclear medicine supplier received a notice of violation 60 days after an inspection. The licensee had failed to monitor radiation levels in clothing after performing a medical radiation procedure. In their response, the licensee pointed out that ARRA dated the notice almost one month before mailing it. The response also noted the unfairness of giving a licensee less time to respond than ARRA took to transmit the violation.

In addition to informing licensees of violations in an untimely manner, ARRA often receives late responses to violation notices. ARRA requires a licensee response to ensure licensees appropriately address violations, explain why the violation occurred, and detail steps it will take to prevent its recurrence. However, approximately 26 percent of licensees responded later than ARRA's 40-day requirement, further delaying timely resolution of the violation. On average, ARRA received these late responses 13 days beyond the 40-day deadline. Additionally, ARRA received several responses over two months late. According to the RAM program manager, licensees may have violations with severe health and safety ramifications that require a rapid response. For example:

- An industrial company responded to a violation notice 98 days following its receipt. An ARRA inspection found three violations, including the licensee's failure to conduct leak tests on radioactive materials and perform physical inventories of its radioactive materials at least every six months. The licensee had repeated these two violations from its previous inspection. Even though these violations and their repeat nature indicate potential problems with the licensee's radiation safety program, ARRA made no effort to ensure a timely response, nor did it take action for the untimely response.

ARRA's 40-day response deadline also appears lenient. NRC guidelines recommend that licensees respond to a violation notice within 20 to 30 days following its receipt. Additionally, Table 4 (see page 18) shows that Kentucky, Maryland, Tennessee, and Oregon require licensee responses within at least 20 days. ARRA has submitted a proposed rule changing the 40-day response deadline to 30 days and is currently awaiting Attorney General approval.

Table 4

Violation Notice and Licensee Response Time Frames

Agency or State	Notices of Violation	Licensee Responses to Notices of Violation
ARRA	Strives for 30 days after inspection	Requires response within 40 days
NRC	Specifies 30 days	Recommends 20 to 30 days
CRCPD	Recommends 30 days	Recommends 30 days
Oregon	Mailed within 20 days after inspection	Requires response within 20 days after receiving notice of violation
Kentucky	Attempts to mail within 14 days after inspection	Requires response within 15 days after receiving notice of violation
Tennessee	Mailed within 15 days after inspection	Requires response within 15 days after receiving notice of violation
Maryland	Might send a notice as soon as 4 days after an inspection with a report to follow	Requires response within 20 days after receiving notice of violation

Source: Auditor General interviews of radiation program officials in other states and review of NRC and Conference for Radiation Control Program Directors (CRCPD) documentation.

Untimely review and lack of procedures lead to delays — Untimely report review impairs ARRA's ability to act quickly upon finding violations. Before mailing a notice of violation, the inspector must have his work reviewed by at least one co-worker, the program manager, and ARRA's Director. While the manager points to delays with inspectors, inspectors commented that management contributes to delays due to indecisiveness regarding possible actions against licensees. Additionally, the program manager indicated that his workload causes delays as do reports that are routed through the Attorney General. The Director also indicated that technical issues, which require additional re-

search or laboratory work, frequently delay the completion of violation notices. However, the agency can and should transmit notices in a timely manner and indicate on notices where required that additional follow-up may be needed. This would allow ARRA to remain timely, but ensure all issues are adequately addressed.

Additionally, ARRA should institute procedures to ensure the timely completion and transmittal of violation notices within 30 days. Currently, ARRA has no procedures governing the review process and detailing when all levels of review are needed, how much time each review stage should take, and when Attorney General review is needed. According to the CRCPD, radiation programs should have written procedures for response to licensee noncompliance.

RAM Enforcement Is Not Adequate

In addition to untimely notification, ARRA enforcement actions against licensee violations are virtually nonexistent. Historically, ARRA has at times used civil penalties as its primary enforcement tool; however, civil penalties are currently unenforceable. As a result, ARRA took action against only 4 percent of licensees with violations during July 1, 1993, through December 31, 1994, even though several merited strong enforcement action. Additionally, the Agency has not made use of other available enforcement options.

Civil penalties are currently unenforceable — Historically, ARRA has relied on civil penalties to ensure compliance with its rules and regulations; however, ARRA currently cannot enforce its civil penalties. A.R.S. §§30-687 and 30-688 provide ARRA the authority to assess civil penalties. Through rule the Agency has set the penalty range from $250 to $4,000 per violation. ARRA used civil penalties until November 1993, at which time the Agency discovered an internal discrepancy within its rules governing the assessment of civil penalties. As a result, the Attorney General advised ARRA that it should cease assessing civil penalties until the rule discrepancy could be corrected. While we agree that ARRA acted appropriately in ceasing to assess civil penalties, more than 12 months passed before it submitted draft rules to the Governor's Regulatory Review Council for review. At this time, the amended civil penalty rules are in the State's rule approval process.

Until ARRA discovered the rule discrepancy, it had imposed 11 separate civil penalties between June 1992 and November 1993. However, since that time at least ten licensees with repeat violations that warranted civil penalties have not been assessed automatic civil penalties due to the rule discrepancy.

ARRA enforcement is inadequate — In our review of inspections that ARRA performed during the 18-month period July 1, 1993, through December 31, 1994, ARRA took enforce-

ment action against only 4 percent (3 of 81 cases) of licensees with violations. While ARRA's inability to use civil penalties partially explains the lack of enforcement actions, it appears that the Agency often takes little action beyond sending the notice of violation and obtaining the licensee's written response. Our review found that several cases deserved stronger enforcement action, which ARRA did not take. For example:

- A recent inspection at a large hospital yielded 8 violations and 13 items of concern. (Items of concern can lead to violations in the future if not corrected.) ARRA conducted the inspection after the hospital lost a minor radiation source used for medical purposes. ARRA found multiple violations that directly contributed to the loss of the radiation source, including not taking inventory of the source after the procedure, and allowing an untrained doctor to complete the removal of the source from a patient. The source was never found, and is believed to be buried in a landfill.

  The licensee has a history of numerous violations and items of concern. ARRA has repeatedly found the same items of concern related to radiation-contaminated areas in laboratories and a pharmacy (four times), and radioactive trash included with regular or unmarked trash. These items of concern, which would have been violations if the level of radioactivity had been higher, indicate carelessness on the part of the licensee and are important because the contamination can end up in public areas.

  The numerous violations and items of concern merit some type of enforcement action. However, in three inspections that found violations between 1988 and 1994, ARRA took no action.

- Another large hospital has performed four radiation source misadministrations from 1989 through 1993. In 1989, a patient in the hospital received the wrong radioactive diagnostic medication. In 1991, a patient was mistakenly given the radioactive medication intended for his hospital roommate. In 1992, a tube containing radioactive material exposed a patient and nurse to a small amount of radiation for approximately an hour. Finally, in 1993, another misadministration of radioactive medicine occurred. Despite this history of misadministration and numerous violations, including one repeat violation found during an inspection in 1993, ARRA has never taken enforcement action against this licensee.

ARRA seldom uses enforcement options – ARRA has many enforcement tools at its disposal, but seldom makes use of them. Based on our file review, ARRA assessed civil penalties against 3 of 15 licensees with repeat violations, but did not take action against the remaining licensees nor a licensee with a severe violation which involved falsifying radiation safety records. Additionally, ARRA did not take enforcement action against any of 21 licensees that provided late responses to notices of violation.

Other than civil penalties, which are currently unavailable, ARRA rarely takes enforcement action. Statute and rule provides a range of enforcement actions that the Agency can

use including license modification, informal hearings, injunctions, radiation source impoundment, and license suspension or revocation. However, the program manager indicated that ARRA has modified licenses only four or five times during the Agency's existence. In addition, ARRA uses informal hearings to communicate the imposition of civil penalties, rather than an enforcement tool itself to encourage prompt violation resolution and compliance with rules and regulations. Moreover, the Agency has never used injunctions, radiation source impoundments, license suspensions, and/or revocations.

Other agencies employ a variety of enforcement tools to ensure compliance with their rules and regulations. For example, the Arizona Department of Environmental Quality (ADEQ) uses consent agreements and compliance orders to enforce compliance with its rules and regulations. Consent agreements offer many benefits, including a court-enforceable order which both parties agree to and understand their obligations. Compliance orders differ in that the Agency mandates compliance; however, the licensee retains the right to appeal. In explaining their preference to use consent and compliance orders, an ADEQ official indicated that the Agency wants licensees to spend their money to return to compliance, rather than paying an administrative penalty.

In addition to these enforcement tools, ARRA might also ensure licensees correct identified violations through follow-up inspections and/or an accelerated inspection schedule. The RAM program rarely performs follow-up inspections, although the Conference for Radiation Control Program Directors recommends that agencies do so. Additionally, Kentucky, Maryland, and Oregon conduct follow-up inspections and/or accelerate the licensee's inspection schedule to ensure licensees return to and remain in compliance.

Lenient Philosophy Contributes to Weak, Untimely Enforcement

ARRA's untimely and inadequate enforcement of the radioactive materials program results in part from the Agency's accommodating relationship with the regulated community. Instead of mandating licensee compliance with its rules through a strong enforcement attitude, ARRA prefers to work with licensees in an effort to arrive at compliance. While maintaining good working relationships with licensees is beneficial, it should not detract from the Agency's primary mission of regulation. The program manager indicated they do not want licensees to suffer monetary setbacks and prefer to use other enforcement methods. However, based on our review of inspections performed between July 1, 1993, through December 31, 1994, the Agency did not take enforcement action against the majority (96 percent) of licensees with inspection violations. Additionally, in our November 1984 report on the Agency, we commented on its lenient enforcement philosophy, noting that ARRA feared damaged working relationships with licensees if it pursued strong enforcement action.

This philosophy toward enforcement filters down to some RAM staff. In one of its reviews, NRC found inspectors inappropriately issuing items of concern instead of viola-

tions because of inspector perceptions that penalties are too severe. Items of concern identify problems that can lead to violations if not remedied. The following case example illustrates ARRA's reluctance to take enforcement action.

- A licensee (a city) repeated a violation (failure to perform leak tests) from a previous inspection, thus meriting a mandatory $1,250 civil penalty. After receiving and reviewing the city's response, ARRA notified it that the response did not provide a basis for mitigating or waiving the proposed civil penalty. If the city did not appeal this order within 20 days, the civil penalty would be assessed. No appeal was received. However, the inspector, who was under the impression that this city faced bankruptcy, advised it that ARRA might not impose the civil penalty if they disposed of the particular piece of equipment involved. The licensee sold the equipment almost five months later and ARRA dropped the mandatory civil penalty.

  Despite disposal of the equipment, ARRA violated its own rule in dropping the penalty. While the rule provides for penalty mitigation if the licensee responds in a timely manner, the rule specifically states that in the case of repeat violations, the penalty cannot be avoided by compliance. ARRA has submitted a rule change that will allow the agency to mitigate penalties in the case of repeat violations. This change currently awaits Attorney General approval.

RECOMMENDATIONS

1. ARRA should send licensees notices of violations within 30 days after inspection.

2. ARRA should complete revisions to the civil penalties rules and ensure their continued validity.

3. Once civil penalties are again available, ARRA should impose civil penalties as intended by the regulations on repeat violators and on licensees with late responses to notices of violation.

4. ARRA should use other enforcement actions, including consent agreements, compliance orders, and informal hearings. The Agency should also consider performing follow-up inspections and accelerating the inspection schedule for licensees with violations.

OTHER PERTINENT INFORMATION

During the audit, we collected information regarding the status of and alternatives to the Southwestern Compact, an agreement between California, Arizona, North Dakota, and South Dakota, for the disposal of low-level radioactive waste generated in each state.The lack of a Low-Level Radioactive Waste (LLRW) disposal site threatens the ability of LLRW generators in the State to continue their work and may eventually affect public health and safety. To provide for permanent disposal of low-level radioactive waste, Congress enacted legislation requiring states to assume this responsibility, either alone or through interstate compacts. However, the Southwestern Compact, to which Arizona belongs, has yet to develop its disposal site resulting in current and potential costs to Arizona LLRW generators. Other alternatives for disposing of LLRW may exist if the proposed disposal site in California remains undeveloped.

History of Low-Level Radioactive Waste

Low-level radioactive waste consists of material contaminated by radioactive material used in medical practice and scientific research, industrial processes, and nuclear power plants. These contaminated materials include paper, rags, tools, protective clothing, laboratory glassware, gloves, wood, and filters. For example, medical institutions produce low-level radioactive waste by using radioactive elements to diagnose heart problems and treat hyperactive thyroids. Universities generate low-level radioactive waste in cancer and AIDS research, drug testing, and carbon-14 dating for archaeological and anthropological studies. Many industries, including nuclear power plants, also produce this type of waste.

The U.S. Nuclear Regulatory Commission (NRC) regulates LLRW disposal and classifies the type of LLRW disposed. Class A wastes, the least dangerous, comprise over 95 percent of the volume of LLRW and will decay to acceptable levels in 100 years or less. Class C waste, the most dangerous, must have additional physical safeguards to prevent environmental or public harm.

In 1980, Congress enacted the *Low-Level Radioactive Waste Policy Act* that gave each state the responsibility for managing and disposing its own low-level radioactive waste. The act also encouraged states to enter multi-state compacts for LLRW disposal. Each compact, upon receiving congressional approval, could limit LLRW disposal to generators within the compact region, select a disposal site, and develop a disposal facility. Additionally, until states formed compacts and constructed disposal facilities, they could re-

tain access until December 31, 1992, to the only three operating disposal facilities in the country: Beatty, Nevada; Richland, Washington; and Barnwell, South Carolina.

In July 1988, Arizona joined California in forming the Southwestern Compact. North and South Dakota joined the compact in 1989. Legislation designates ARRA as the Arizona agency responsible for performing any administrative and enforcement duties assigned to the State by the Southwestern Low-Level Radioactive Waste Disposal Compact. The compact, governed by the Southwestern Low-Level Radioactive Waste Commission, designated California as the host state for its disposal facility. As a result, California contracted with US Ecology, a private firm, to identify a site and develop a disposal facility. Upon completing the necessary environmental studies, US Ecology selected a site on federal land in Ward Valley, approximately 22 miles west of Needles and the Colorado River. On September 16, 1993, the California Department of Health Services (CDHS) issued a license to US Ecology for the construction and operation of a LLRW disposal facility in Ward Valley.

Current Status of Southwestern Compact

Although licensed by CDHS, US Ecology has been unable to construct a disposal facility in Ward Valley. Several factors, including the U.S. Department of Interior's delay in transferring ownership of the land to California and various legal actions, have prevented US Ecology from developing the Ward Valley site.

CDHS granted a license to US Ecology pending transfer of the Ward Valley land from the U.S. Department of Interior, Bureau of Land Management, to California. California must purchase the land from the U.S. Department of Interior to ensure full control and immediate access should problems arise. However, the Secretary of Interior placed the land sale on hold and requested a National Academy of Sciences (NAS) review of issues raised by the "Wilshire Report," a report prepared by three geologists employed by the U.S. Geological Survey,[1] which details concerns regarding the appropriateness of the Ward Valley site. The NAS issued its report in May 1995 finding that the issues raised by the Wilshire Report are not significant and recommending additional monitoring activities for the site. California now awaits a federal decision on the land sale.

Also, opponents of the disposal facility are pursuing legal action in an attempt to prevent its development. In a lawsuit filed in the State of California, opponents seek to void the license granted to US Ecology based on US Ecology's questionable qualifications, CDHS' failure to conduct proper hearings on the license, and locating a disposal site in an area

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[1] The Wilshire Report was written in 1993 by three geologists, Howard Wilshire, Keith Howard, and David Miller, who acted as individuals rather than in official U.S. geological capacities. The geologists prepared the report at the request of a California U.S. Senator.

designated as a critical habitat for the desert tortoise. Additionally, the Wilshire Report was introduced into the lawsuit. The California Superior Court found that virtually all issues raised by the opponents were without merit, but the Wilshire Report constituted new evidence, and ordered CDHS to consider the report in the licensing process. Both parties appealed and a decision is expected in 1995.

Impact and Alternatives

The delay in developing a disposal facility leaves few viable options for generators of LLRW in Arizona. The most optimistic estimate would have the disposal facility constructed and operating by summer 1996; however, many stakeholders agree legal actions could continue for many months, delaying the opening of a disposal facility until 1998 or beyond. Since no authorized disposal facility is available, Arizona LLRW generators have undertaken waste reduction efforts and/or substituted non-radioactive materials where feasible in their operations. Generators have also constructed temporary storage facilities for waste storage until a permanent site becomes available.

While these actions do not offer a permanent solution for the disposal of LLRW, they buy time for LLRW generators until a disposal site becomes available. However, LLRW generators have incurred significant costs to construct temporary storage sites and store waste. For example, the consortium that operates the Palo Verde Nuclear Generating Station recently completed construction of a $4.6 million LLRW temporary storage facility. Additionally, the University of Arizona will spend approximately $630,000 on a LLRW temporary storage facility, plus an estimated $15,000 in annual operational costs. LLRW generators in Arizona estimate they only have approximately five years of storage space available.

In addition to the costs incurred for temporary storage, some LLRW generators fear a direct impact on their operations if a disposal site remains unavailable. Research organizations that use radioactive materials, including the University of Arizona, may have to curtail research activities if there is no place to dispose of the waste. Organizations may have to devote some research dollars to finance temporary storage costs. Additionally, important medical treatments and research may be negatively impacted.

The State can explore various permanent or temporary alternatives to the Ward Valley disposal site, some with significant drawbacks.

- Barnwell, South Carolina disposal facility opening – One alternative involves shipping and disposing of LLRW at the Barnwell, South Carolina disposal facility. The South Carolina Governor and Legislature recently enacted legislation that opened Barnwell on July 1, 1995, to all states, except North Carolina.[1] Additionally, the South-

western Compact Commission issued a blanket approval authorizing generators within the Southwestern Compact to export LLRW to this facility, if individual shipments meet the terms of the approval. As part of its legislation, South Carolina will also begin to explore new compacting arrangements. However, the Barnwell facility could become a superfund clean-up site, meaning that liability for cleanup could extend to the disposers of the waste. For this reason, the University of Arizona has not and stated they will not dispose of their LLRW at Barnwell. Also, in September 1995, a lawsuit was filed in South Carolina in an effort to reverse the legislation that opened Barnwell to all states.

- **Arizona disposal or temporary storage site** – Alternatively, Arizona might consider developing its own disposal site or temporary storage site. However, these options may be difficult to implement. First, Arizona must go through the same lengthy process in siting a disposal facility and performing all the requisite environmental studies as California. Additionally, Arizona would likely experience similar opposition. Second, Arizona would be unable to restrict a disposal or storage facility to only Arizona generators of LLRW. Such a restriction would violate interstate commerce laws. Arizona generators also do not produce sufficient quantities of LLRW to entice a private company to operate a disposal or storage facility. Such an operation would require waste from additional sources outside the State.

- **Possible legal remedies** – Finally, Arizona could seek legal remedies from California for its failure to develop a disposal site by January 1, 1993, as legislated and agreed. Arizona could either seek monetary damages or force California to accept the LLRW generated in the State. Some stakeholders suggest that California might welcome such a lawsuit as it might provide the additional impetus needed to counter opposition and construct the disposal facility. Other stakeholders indicate that California is doing all it can to build the facility and a lawsuit would be counterproductive and possibly damage relations between the states.

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(1) South Carolina believes that North Carolina has not kept its agreement with the Southeast Compact to construct an LLRW disposal facility. As a result, the South Carolina legislation denies access to Barnwell to North Carolina generators of LLRW.

SUNSET FACTORS

In accordance with A.R.S. §41-2954, the Legislature should consider the following 12 factors in determining whether the Arizona Radiation Regulatory Agency should be continued or terminated.

1. The objective and purpose in establishing the Agency.

In 1980, the Arizona Radiation Regulatory Agency (ARRA) was established, replacing its predecessor agency, the Arizona Atomic Energy Commission. The intent in establishing ARRA is to reduce the risks to the public resulting from exposure to radiation. Laws 1980, Ch. 206 §1 state:

> *"It is declared to be the policy of this state to protect the public health and safety by regulating the use and sources of radiation to provide for: (1) use of methods and procedures relating to radiation which are demonstrated to be safe; and (2) maintaining exposure to sources of radiation in amounts as low as is reasonably achievable by means of good radiation protection planning, practice and enforcement."*

According to A.R.S. §30-654.B (1) and (4), ARRA shall regulate the use, storage and disposal of sources of radiation; and assume primary responsibility for and provide necessary technical assistance to handle any incidents, accidents, and emergencies involving radiation or sources of radiation occurring within this State.

2. The effectiveness with which the Agency has met its objectives and purpose and the efficiency with which it has operated.

The Agency has generally met its objectives and purpose. To comply with its objectives, the Agency licenses radioactive materials and registers all types of radiation machines in the State. The Agency also inspects licensees and registrants. However, we found that the Agency can do more to further safeguard the public health and safety by:

- Meeting inspection schedules for x-ray and mammography machines. The Agency currently faces almost a 30 percent backlog in inspections for x-ray tubes and a 77 percent inspection backlog for mammography tubes. (See Finding I, pages 5 through 13.)

- Taking timely and adequate enforcement actions against radioactive materials violations. (See Finding II, pages 15 through 22.)

ARRA has effectively responded to radiation-related emergencies and incidents within the State. During the course of our audit, ARRA immediately and effectively responded to a radiation incident in Tucson. Additionally, ARRA has performed effectively during federal test exercises that evaluate the State's ability to respond to radiation emissions from the Palo Verde Nuclear Generating Station.

3. The extent to which the Agency has operated within the public interest.

The Agency has generally operated within the public interest through its inspection, emergency response, and environmental surveillance (laboratory) activities. In addition to these activities, the Agency maintains a radon program that provides public information to organizations and individuals, handles approximately 700 radon-related inquiries per year, and provides ongoing assessment of potential radon hazards in Arizona. However, the public interest could be better served if ARRA quickly addressed its backlog of x-ray and mammography machine inspections and stayed current with its inspection schedule. (See Finding I, pages 5 through 13.)

4. The extent to which rules and regulations promulgated by the Agency are consistent with the legislative mandate.

Rules and regulations promulgated by the Agency appear consistent with the legislative mandate. Additionally, several articles are in various stages of development, including an article to correct the rule discrepancy associated with the Agency's ability to assess civil penalties. Despite these efforts, the Nuclear Regulatory Commission (NRC) has cited ARRA for its failure to maintain regulations consistent with NRC federal regulations as required by its agreement. The NRC noted this problem in its June 1992 and March 1995 review of Arizona's radiation control program. ARRA cites the State's lengthy rule-making process and insufficient staff to promulgate rules as reasons for not maintaining rules consistent with NRC federal regulations.

5. The extent to which the Agency has encouraged input from the public before promulgating its rules and regulations and the extent to which its has informed the public as to its actions and their expected impact on the public.

The Agency appears to comply with open meeting law requirements regarding public rules and regulation hearings. The Agency posts its meeting notices in a timely manner and in accordance with the statement filed with the Secretary of State. According to the Agency Director, the Agency will revive a newsletter to inform the public of proposed rulemaking actions.

6. **The extent to which the Agency has been able to investigate and resolve complaints that are within its jurisdiction.**

Based on a limited review of consumer complaints received by the Agency, it appears that the Agency adequately investigates and resolves complaints. The Agency reported receiving 14 complaints regarding its non-ionizing radiation program during the past year and very few in its other program areas.

7. **The extent to which the Attorney General or any other applicable agency of state government has the authority to prosecute actions under enabling legislation.**

According to A.R.S. §30-685, the Attorney General has authority to make application to the appropriate court for an order prohibiting any act that violates ARRA's statutes, rules, or regulations. Additionally, the Agency has specific statutory authority to assess civil penalties, impound radiation sources, and modify, suspend, or revoke licenses. A.R.S. §30-687.A requires the Attorney General to bring actions for collecting civil penalties.

8. **The extent to which the Agency has addressed deficiencies in the enabling statutes which prevent it from fulfilling its statutory mandate.**

Currently, the Agency perceives the inability of the State to order a person to clean up an area that he contaminated, and that endangers the public health, as a statutory deficiency. The Council of State Governments Suggested State Legislation for radiation control programs recommends that states possess this authority. However, the Governor can only order the State to remedy a contaminated area, not the person who caused the public health problem. The Agency has proposed legislation addressing this concern in the past, but legislation has not been enacted.

9. **The extent to which changes are necessary in the laws of the Agency to adequately comply with the factors listed in the subsection.**

Other then the inability of the State to order a person to clean up an area that he contaminated, we identified no additional changes that are necessary in the laws of the Agency to comply with the statutory requirement of protecting public health and safety.

10. The extent to which the termination of the Agency would significantly harm the public health, safety, and welfare.

Termination of the Agency could significantly harm the public health, safety, and welfare. Radiation exposure poses considerable health risks, including cancer, genetically determined ill-health, and developmental abnormalities. ARRA's regulation programs including inspection, licensing and registration, emergency response, and environmental surveillance serve to mitigate risks associated with radiation, both man-made and naturally occurring.

11. The extent to which the level of regulation exercised by the Agency is appropriate and whether less or more stringent levels of regulation would be appropriate.

Our review found that ARRA is not exercising appropriate regulation over licensees and registrants. As discussed in Finding I (pages 5 through 13) and Finding II (pages 15 through 22), ARRA faces a large inspection backlog for registered x-ray and mammography machines; and rarely takes enforcement action against licensees with violations.

12. The extent to which the Agency has used private contractors in the performance of its duties and how effective use of contractors could be accomplished.

The Agency does not use private contractors in the performance of its primary duties. Even though several states employ private contractors to perform inspections of licensees and registrants, the Agency believes that privatizing the inspection function would not reduce the costs to the State for administering the program and would likely lead to higher costs for the regulated community. According to radiation officials in Colorado, which has privatized inspections, privatization has proven costlier for registrants, requires significant staff expertise to review reports and monitor contractors, and has been difficult to implement. Colorado also reports that privatization requires a sophisticated tracking system to ensure timely inspections and information flow between the state, contractors, and registrants. Other states and the Conference for Radiation Control Program Directors confirm this information.

The Agency does contract out for the analysis of its employees' film badges, which are used to assess the radiation exposure of individuals who work near radiation. The Agency also uses contractors for instrument calibration, specialized employee training, and radiation source cleanup and disposal.

INTRODUCTION AND BACKGROUND

The Radiation Regulatory Hearing Board was established in 1980 to serve as a vehicle for appeal by any person adversely affected by an order of the ARRA. The Board consists of five members appointed by the Governor to five year-terms. The Board last met on January 27, 1993, and March 25, 1993, to decide appeals of ARRA orders. The Board has not met during fiscal years 1993-94 and 1994-95.

Given the infrequent nature of Board meetings and activities, our review was limited to a review and preparation of sunset factors for the Board.

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SUNSET FACTORS

In accordance with A.R.S. §41-2954, the Legislature should consider the following 12 factors in determining whether the Radiation Regulatory Hearing Board should be continued or terminated.

1. The objective and purpose in establishing the Board.

According to A.R.S. §30-653 the Radiation Regulatory Board was established in 1980 as part of the act that also established the Arizona Radiation Regulatory Agency. The Hearing Board provides a vehicle for appeal by any person adversely affected by an order of the ARRA or its director. The Board may also review and make recommendations to ARRA and the Legislature regarding rules and regulations promulgated by ARRA, as stated in A.R.S. §30-655.D.

The Board, which consists of five members appointed by the Governor, last met on January 27, 1993, and March 25, 1993, to decide appeals of ARRA orders. The Board has not met during fiscal years 1993-94 and 1994-95. This coincides with ARRA's inability to assess civil penalties. Consequently, there has been no appeal of a civil penalty, which would require the Board to meet.

2. The effectiveness with which the Board has met its objectives and purpose and the efficiency with which it has operated.

According to the Board, it has reviewed appeals in a timely manner, and in the majority of cases, affirmed ARRA's decision. In some cases, the Board has modified the amount of civil penalty assessed; however, the Board has never revoked an order of the agency. Additionally, no Hearing Board decisions have been appealed to the Superior Court. Finally, the Board reviews and comments on draft rules and regulations proposed by the Agency.

Based on our review of Board decisions since 1990, we found that it had reduced three civil penalties ordered by ARRA. In other instances, the Board upheld the order of ARRA. Also, the Board rendered its decisions within approximately four to eight months following appeal.

3. **The extent to which the Board has operated within the public interest.**

The Board believes it acts in the public interest by providing an appellate review of ARRA enforcement actions. The Board's independence and action in the public interest are demonstrated in those cases where the Board has reduced a proposed civil penalty.

4. **The extent to which rules and regulations promulgated by the Board are consistent with the legislative mandate.**

Since the Board only performs an appellate function, it does not promulgate rules and regulations.

5. **The extent to which the Board has encouraged input from the public before promulgating its rules and regulations and the extent to which its has informed the public as to its actions and their expected impact on the public.**

The Board does not promulgate its own rules and regulations.

6. **The extent to which the Board has been able to investigate and resolve complaints that are within its jurisdiction.**

The Board does not receive complaints from consumers.

7. **The extent to which the Attorney General or any other applicable agency of state government has the authority to prosecute actions under enabling legislation.**

The Board has no enforcement authority.

8. **The extent to which the Board has addressed deficiencies in the enabling statutes which prevent it from fulfilling its statutory mandate.**

The Board has not proposed any changes to its enabling statutes.

9. The extent to which changes are necessary in the laws of the Board to adequately comply with the factors listed in the subsection.

We did not identify any changes that are needed in the Board's enabling legislation to adequately comply with the Sunset Factors.

10. The extent to which the termination of the Board would significantly harm the public health, safety, and welfare.

Terminating the Board would not harm the public health, safety, or welfare. However, the Board appears to provide a check and balance on the actions of the agency and provides a timely, less expensive alternative to court actions.

11. The extent to which the level of regulation exercised by the Board is appropriate and whether less or more stringent levels of regulation would be appropriate.

This factor does not apply because the Board has no regulatory functions of its own.

12. The extent to which the Board has used private contractors in the performance of its duties and how effective use of contractors could be accomplished.

The Board uses private hearing officers to conduct hearings on appeals of ARRA actions. The full Board then acts on the recommendations of the hearing officer. Contracts for hearing officers are handled through the Department of Administration. According to the Board, this mechanism has proven to be effective.

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Agency Response

Arizona Radiation Regulatory Agency

ARIZONA
RADIATION REGULATORY AGENCY

Fife Symington
Governor

Aubrey V. Godwin
Director

4814 South 40 Street Phoenix, Arizona 85040 (602) 255-4845
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October 19, 1995

Douglas R. Norton
Auditor General
Office of the Auditor General
2910 North 44th Street, Suite 410
Phoenix, AZ 85018

Dear Mr. Norton;

Thank you for the opportunity to respond to the Draft Report of the performance audit of the Arizona Radiation Regulatory Agency. We appreciate the professionalism exhibited by the audit team during the review process. They should be commended for their grasp of the many technical issues facing the Agency.

Due to the highly technical nature of this program, I request that the enclosed Conference of Radiation Control Program Directors' "Review of Radiation Control in Arizona" be attached to this report. Even though referenced in our response, I am not requesting that the U.S. Nuclear Regulatory Commission review and evaluation, dated June 7, 1995, be included with the report but to be available on request.

We have some comments which should be associated with and attached to the report to give the reader a better perspective of the Agency operations and perhaps clarify the information in the report. These comments are as follows;

1. We believe that it would be clearer to the readers if the report did not intermingle the situation at the time of audit with the current status without specifying which period is applicable. For example on page 2 of the report, the FTEs listed for **X-ray, Mammography, and Non-ionizing Radiation** are 7.5. Actually, during the period audited by this report, the Agency was authorized only 6.5 FTEs for x-ray, mammography, and non-ionizing program. The 7.5 became effective on July 1, 1995, after the audit portion was closed.

2. The data presented in this paragraph were calculated for a period prior to the end of the audit portion of the review. Although close to the end of the review, had the data been corrected for the end of the review period, it would have shown 76.0% overdue by one year and 34.5% overdue by two or more years. As of October 1, 1995 the percentages are 55.3% and 34.1% respectively. We believe that these changes in percentage overdue support the actions identified by Agency management, and the Conference of Radiation Control Program Directors. Some of these are the same as identified by the Auditor General while others are more technical.

3. Figure 1. on page 8, does not indicate that the Paid Leave includes 5% for legal holidays and 6% for coffee break time. Further, all state employees are authorized 4% of the year as annual leave. Many time studies leave out coffee break time.

4. The last paragraph on page 8 does not recognize that the employee involved was the "lead inspector"

and had some supervisor/managerial responsibility. It is within management's authority to assign management activities to subordinates, otherwise, since a given manager is responsible for all activities under their control, he could not ask any subordinate to perform any activity. Management recognized the difficulties associated with this arrangement and began discontinuing this practice prior to the Auditor General's review. The use of "lead inspectors" was necessitated by the reduction in managerial staff in the Agency and the subsequent reorganizations.

The Auditor General's Report appears to have a total lack of recognition that even though staffing is limited, the total administrative workload for approximately 8,000 x-ray tubes remains the same, and must be performed by the few available staff. In fact in 1985 when the last Auditor General's Review was conducted, the Agency had 4 x-ray inspectors for 5,632 tubes. Since 1985, the number of x-ray tubes has increased to 8,125 or a 44% increase by 1995. During the same period the inspection staffing increased 20%. The additional inspector was for the Mammography program funded by the U.S. Department of Health and Human Services. The Agency was behind in its x-ray inspection program in 1985 and has not received the resources to catch up. The Conference of Radiation Control Program Directors in their criteria for x-ray programs indicate that smaller programs have an increased administrative workload per inspector. In their 1995 review, page 5, clearly recognized that smaller staffs have to spend more time per person on administrative duties than large staffs by quoting the range of FTE/1,000 x-ray tubes. The 1.4 FTE/1,000 x-ray tubes is for the large staff and the 2.1 FTE/1,000 x-ray tubes is for the small staff. Further, for FY 1989 to FY 1993 the staff available to the Agency was reduced each year, which limited trained support and technical staff within the Agency.

5. The last sentence of this paragraph (on page 9) appears to be based on information supported by the discussion in the next paragraph. Unfortunately, the reviewers did not recognize that the power line siting actions are a part of the non-ionizing radiation management duties nor that the Low Level Radioactive Waste activities are a part of the radioactive material management duties. These are the primary duties of this individual and he is not in a position to pick and chose about performing them. Agency management has recognized that this particular manager was over tasked and is taking steps to correct the situation.

6. The third full paragraph on page 9 indicates that technical staff time is wasted on registration. The paragraph does not recognize that the registration by non-technical staff resulted in significant errors in the records and has increased the time required by the technical staff to correct the errors. The Agency has moved data in-putting to the administrative staff.

7. The last paragraph on page 9 is quite correct when the Auditor General recommended that we use temporary help for processing the fees. As a matter of fact, both the Agency and the Medical Radiological Technology Board of Examiners used temporary staffing January 1995 which is not mentioned in the report.

8. On the top of page 10, omitted in these statements in the first paragraph is, currently management does hold the inspectors accountable for the quantity and quality of work. Further, during the period reviewed, initial steps were being taken by the current management to identify the problem and establish performance goals. The ability to receive a pay raise is directly tied to the performance of

each individual inspector.

We have suggested that calendar 1994 is a better indicator than FY 1994 data for several reasons. A. Several of the inspectors had less than one year experience as an independent inspector during this period. Indeed, two had not completed their training to be independent inspectors. B. One inspector was phasing into non-ionizing radiation, and while not included in the table, did influence the activities of the x-ray program.

9. The last paragraph on page 10 indicates that one employee is not being held accountable for his actions and that his performance evaluations do not reflect the worker performance. Contrary to the statements in the report, the individual's performance was graded below standard in 1995 and 1992 for several areas of work. Management was careful to document the quality of work and base the performance evaluations on the documentation rather than contemporaries opinions in order to preserve the individual's civil and employment rights. See also response 8. above.

10. Notwithstanding the comments in the first full paragraph on page 11, A.R.S. §23-408 C. clearly states that notice of an intended inspection shall not be given to an employer prior to the time of actual entry upon the workplace. While it is true the interagency agreement does not address this point specifically, it is clear that the Director of the Division of Occupational Safety and Health did not grant an exemption to this portion of the statue. Further, in other states, the U.S. Occupational Safety and Health has determined that occupational inspections should be unannounced. The basis of the selection of the states listed is not clear to this point, for example, does each state have an occupational safety and health program approved by the U.S. Department of Labor? Is the Radiation Control Program a portion of that agreement?

The experience of the director in another state radiation program which performed both scheduled and unannounced inspections, is that for the inspectors time it makes no difference which is used. This is due to;

A. The inspector must take time to call and set inspection appointments, attempting to get them in close proximity with each other.

B. For a significant number of the appointments, the facility is not ready for the inspector due to patient considerations.

C. When scheduling appointments, some extra time must be allowed so that when a problem arises, the inspector will not be late for the next appointment.

D. When appointments are made, if a problem occurs, the inspector is pushed to ignore or the rush through the problem rather than taking the time to resolve the problem correctly.

E. On occasion a facility has refused to set an appointment for an inspection.

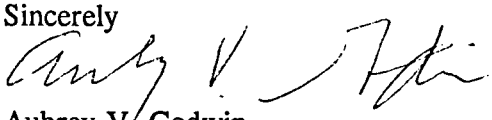
11. The Auditor General's Report glosses over the effects of the differences between states in their

compliance programs. The differences are very significant in the number of inspections per inspector. In assessing the appropriateness of the states selected in Table 3, the Auditor General's Report does not indicate how many support staff these states legislatures have authorized for these programs; the ratio of each type of x-ray tube usage to the total number of x-ray tubes; the computer support available; any independent review of these states inspection programs to assure that the regulations are being followed. Without this and similar data it is impossible to conclude that the information is comparable with Arizona. In fact, 30% of the states contacted by the Auditor General apparently consider inspection performed per year per inspector to be such a poor basis for judging performance that they do not even track the number of inspections performed by each inspector, Maryland, Colorado, and Oklahoma.

12. The Nuclear Regulatory Commission review did not indicate any problems with slow enforcement. Specifically, 2. and 4. of Enclosure 2 and 21., 22., and 23. of Enclosure 3 of that review do not indicate any problems with our enforcement actions. Further, the Nuclear Regulatory Commission review did not find a problem with our follow up on non-compliances.

Thank you again for this opportunity to respond.

Sincerely



Aubrey V. Godwin
Director

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Review of

Radiation Control in Arizona

by the

Conference of Radiation Control

Program Directors, Inc.

August 1995

Prepared and published by the
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CRCPD, 205 Capital Avenue
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Table of Contents

Executive Summary

The Conference of Radiation Control Program Directors, Inc., (CRCPD) is a professional association for governmental radiation control program personnel in the United States and Canada. The CRCPD promotes adequate, uniform control of radiation hazards. As one of its services, the CRCPD will review the radiation control program of a state and recommend improvements.

The Director of the Arizona Radiation Regulatory Agency (ARRA) requested, in May 1995, a comprehensive review of radiation control in Arizona. A team of six volunteers from state and federal radiation control programs, and one CRCPD staff person, was promptly enlisted to carry out this review. The team reviewed the statutory basis for the program, the forms and procedures used, information retained in the files, and interviewed staff and legislators June 25-30.

The review of radiation control in Arizona found the program to be quite well developed by professional standards, active, and well equipped except as noted in the following findings.

The empowering legislation is comprehensive of all types of radiation, and lacks only provisions for the emergency impoundment of sources and for the certification of radioassay laboratories.

The regulations for radiation control conform to the requirements for the federal programs with which Arizona is involved and to the *Suggested State Regulations*. Unfortunately, Arizona's process for regulation adoption, even for improvement of a radiation source registration form, is entirely too cumbersome to maintain compliance with the ever-changing federal requirements and to be responsive to new information on radiation hazards. Also, the few revisions should be made to meet the requirements for CRCPD recognition of the Arizona licensing of naturally occurring and accelerator produced radioactive materials. This is a national program that enhances the uniform and adequate control of these materials, and it provides for reciprocal recognition of licenses at considerable cost savings to both the licensee and the regulatory agencies.

The management plan for the ARRA, with a scope of five years, should be updated annually to define goals, utilize resources, assure coordination among the components of government that have responsibility for radiation control, and stem the continuing loss of qualified staff.

More numerous state position categories and pay grades are sorely needed in the ARRA. The ARRA inspectors and clerical staff need relief from the burden of fee collection. They must instead give more attention to legally sound documentation of their radiation control activities.

Priority should be given to enhancing inspection, guidance to users, and enforcement of regulations on medical x-ray because this is by far the largest source of exposure to man-made radiation and for which the largest reduction of unnecessary exposure can be accomplished.

Detailed recommendations for actions by the legislative and executive branches of government, and the radiation control program of Arizona government are provided in this report.

Introduction

The Conference of Radiation Control Program Directors, Inc., (CRCPD) is a professional association for the staff of government radiation control programs throughout North America. The objective of the CRCPD is to promote adequate, uniform control of radiation hazards.

One of the services of the CRCPD is, upon request by a state, to review the radiation hazards and the radiation control program in that state, and to recommend improvements in regulation and control. Following such a request, the CRCPD Executive Director assembles a review team that consists of technical staff of relevant federal agencies and their regional offices, a director of the radiation control program in another state, and staff of the CRCPD Office of Executive Director. This team interviews members of the radiation control program and other persons involved with the use or the control of radiation. The on-site review concludes with a presentation to state government officials of a summary of the significant findings and recommendations. The review team then prepares a detailed written report which is submitted to the director of the radiation control program.

The Director of the Arizona Radiation Regulatory Agency, in May 1995, requested a comprehensive review of the radiological health program in Arizona. On-site interviews were conducted during the week of June 25-30, 1995.

The aspects of radiation control that were reviewed were x-ray, radioactive materials, low-level radioactive waste, indoor radon, environmental surveillance, nuclear safety, emergency response, contaminated sites, non-ionizing radiation, and administration of the radiation control program.

The recommendations were based on information in the following documents:

Council of State Governments, 1983, *Suggested State Legislation, Radiation Control Act.*

Conference of Radiation Control Program Directors, 1991, *Suggested State Regulations for Control of Radiation, 8th edition*

Conference of Radiation Control Program Directors, 1981, *Criteria for Adequate Radiation Control Programs, X-Ray*

Conference of Radiation Control Program Directors, 1982, *Criteria for Adequate Radiation Control Programs, Radioactive Materials*

Conference of Radiation Control Program Directors, 1985, *Criteria for Adequate Radiation Control Programs, Nonionizing*

Conference of Radiation Control Program Directors, 1986, *Criteria for Adequate Radiation Control Programs, Environmental Monitoring and Surveillance*

Conference of Radiation Control Program Directors, 1990, *Criteria for Adequate Radiation Control Programs, Radon*

CRCPD Recognition of Licensing States for the Regulation and Control of NARM, 1994

Arizona X-Ray and Radioactive Materials Program Review

Narrative Report

An assessment of the population radiation exposure, made by the National Council on Radiation Protection and Measurements (NCRP 93) in 1987, found that uses of radiation in the healing arts represent approximately 83% of the total man-made exposure to the U.S. population. In contrast, occupational exposures were less than 2% and exposure to the entire nuclear fuel cycle was less than 0.5% of the total man-made exposure. Not only is diagnostic x-ray by far the single largest source of exposure to man-made radiation, it is also the source for which the biggest dose reduction gains in man-made exposures can occur without having a negative impact on the benefits for the public.

The review of the x-ray program revealed that the Arizona statutes (especially Title 30 Chapter 4, Section 651, et seq. last amended in several ways in 1992) provide for a program that is consistent with that suggested by the Criteria for an Adequate Radiation Control Program. Therefore the limitations of the program are the limitations of resources and perhaps design rather than statutory. The regulations were last updated in 1986; further modifications to update these regulations are difficult because of increasingly arduous procedures established by the legislature (1995 changes to the Chapter 251 have further complicated the process). The current process requires not only the typical public process of rules promulgation, but there are now two review groups involved as well, one at the Governor's level (the Governor's Review Council) and one at the legislative level (the Administrative Rules Oversight Committee). The result is that even more personnel resources than would be normal must be applied to this aspect of managing the radiation control program. Periodic adjustments in the regulations are necessary for several reasons, some will be the result of needs internal to the radiation control program but perhaps most are external forces that must be accommodated, e.g. new sources of radiation, new procedures or changes required by federal law.

> A note of caution, (an item not discussed during the exit interview) - it appears that some program vulnerability may result from potential uneven regulatory practices. The 1995 changes in the administrative rules section of the Arizona statutes suggests a reduced burden of proof necessary for a complainant to receive a financial award against the Agency. The complaint could be a simple one suggesting that the agency's regulatory requirements were more strictly enforced on his operations than they were on another facility. Since the Agency's "practice or substantive policy statement" (sec. 41-1030 and 41-1033) are held in the same light as formal rules, it appears that all actions of the Agency are made much easier to contest and subject to fee/cost recovery from the Agency's operating funds.

The opinions formed about the x-ray and radioactive materials programs as recorded here are the

result of a review of the statutory basis for the program; a review of the forms and procedures used in registration/licensing and inspections; information retained in the files; and interviews with several of the staff and management. No attempt was made to evaluate the quality of the inspections by accompanying the inspectors during an actual inspection, nor was any attempt made to evaluate the inter-inspector consistency of inspection except through reviews of the data in the inspection reports and compliance letters currently being issued.

Findings and Recommendations

X-ray and Certification Program

The Arizona x-ray program has the normal inspection and compliance functions. The Agency also has the Medical Radiologic Technology Board of Examiners (MRTBE), who manage the certification of ionizing radiation machine operators other than dental hygienists. The MRTBE is currently staffed by two persons, a professional FTE and a clerical assistant. The MRTBE staff is able to maintain (with difficulty) pace with the applications for certification and renewals of the currently 3,500 registered x-ray technologists in the State. Clearly this is possible because of the strategy of utilizing the examinations of the American Registry of Radiologic Technologists (ARRT). Although authorized to develop other tests, the MRTBE believes that this is the fairest since the ARRT has had a psychometrician validate all of the questions used as appropriate for the profession. Although dated, the Agency has copies of past examinations which could be used if the ARRT examination were unavailable. The prime workload of the MRTBE staff appears to be routine review of applications and assuring the renewal of certificates. Much of the work is devoted to responding to routine telephone calls from technologists who have not completed applications within the required time frames. A significant portion of the professional FTE is devoted to receiving and investigating complaints about illegal or unethical conduct. Because of the workload, there is little room for difficulties in the program. Should the staffing become compromised, the impact on technologists and on public health and safety would be appreciable because of not only expiring certificates but the potential for uncertified practitioners.

The X-ray inspection and compliance group is currently staffed at 4 FTE's and is responsible for 8,198 tubes in 3,574 facilities. An additional FTE is dedicated to mammography inspections under FDA contract. The program manager must split his attention between the x-ray program and the radioactive materials program.

Radioactive Materials Program

Arizona regulates certain of the radioactive materials covered by the federal Atomic Energy Act under an agreement with the Nuclear Regulatory Commission (NRC). Because the NRC completed its last program review of Arizona in March 1995, the CRCPD review team did not

focus on the licensing and inspection activities that are evaluated during the NRC evaluation.

The periodic reviews of the materials program by the NRC have been effective in maintaining the adequacy of the radioactive materials program. However, until this CRCPD review, there has been no outside, systematic, peer review of the x-ray program. "Sunset review" of the overall program was recently completed; however, no information about the findings were available. A previous sunset review occurred in 1985.

Recommendation #1

CRITERIA: A radiation control program should have adequately trained staff to provide the necessary professional service for a comprehensive program in radiation protection. The x-ray program should have between 1.4 and 2.1 professional/technical FTE per 1,000 tubes.

FINDINGS: Recent staffing restrictions have made a poor staffing situation in the x-ray inspection and compliance program even worse. Inspection reports do not document that all appropriate sections of Arizona's regulations are being met, nor would they be able to withstand a legal challenge.

In addition to the problems cause by under-staffing, the x-ray program has lost a management position. The technical demands, diversity and differences between the x-ray program and the radioactive materials program is such that one person has difficulty overseeing both programs.

While the existing staff are reasonably well trained, they seem overwhelmed with the workload. Pressures to increase the inspection rates to levels of 500 tubes per year for each person are not realistic for the inspection frequencies and the mix of x-ray facilities found in Arizona.

The inspection routine has been modified, as a result of severe under-staffing to the following frequency (CRCPD recommendations provided for comparison):

Current Arizona Frequency		CRCPD Recommended Frequency	
Hospitals	2 years	Hospitals	1 year
Radiology clinics	2 years	Radiology clinics	1 year
Other medical	3 years	Other medical	2 years
Dental	4 years	Dental (½ visited)	5 years
Industrial	4 years	Industrial	2-4 years

Recommendation #1

Arizona should have 14 professional/technical FTE and 3 clerical FTE to support a comprehensive x–ray inspection and compliance program with facility inspection frequencies approaching those suggested by the CRCPD. At least one additional FTE supervisor/manager is required.

COMMENT: The current staffing levels prevent the Agency staff from providing facilities with the kind of assistance that would improve the recognized benefits of medical x-ray procedures. As one example, it appears that no attention is being paid to the objective evaluation of film processing techniques even though the procedures have been readily available to the staff for several years though the CRCPD Nationwide Evaluation of X-ray Trends (NEXT) program.

The CRCPD frequencies cannot be met by Arizona without significant additional resources. The staffing levels recommended by the CRCPD (note the special approach to dental facility inspections) to achieve the recommended frequency would require approximately 17 FTE (including 3 clerical FTE). In addition to providing the recommended inspection frequency, this staffing level would also afford the opportunity for the inspectors to provide the facilities with help in improving the quality of the radiological practices in many of the same ways currently required by the Mammography Quality Standards Act.

Adequate clerical support would free up the professional/technical staff to concentrate on the health and safety issues rather than registration issues.

Recommendation #2

CRITERIA: The day-to-day operations of the x-ray and the radioactive materials programs should each be guided by their overall written management plans of the respective programs.

The plans should be based on data showing the extent to which workers and patients are exposed to sources of radiation. The long and short term objectives should be established with specific targets for priority and accomplishment. The plan should include periodic evaluation of program effectiveness and a method to demonstrate the changes in exposure to the workers and public that have occurred.

FINDINGS: Currently the program operates on a basic management plan that is known by the individuals involved but appears to be limited to inspection goals (i.e. numbers of inspections completed). The plan is only short term, that is, it is based on recent changes in regulations and the need to inspect facilities against new rules. Measures of program effectiveness are limited to

1) statistical accounting of the numbers of inspections by county and type of practice; 2) some notations about whether or not the facilities have been found to be in (presumably significant) non-compliance; and 3) recently by the addition of inspection quotas as part of the staff's employee evaluations. While some information is often obtained during inspections of x-ray facilities regarding the exposures received by patients from typical types of x-ray examinations, no attempt has been made to compare this information to national averages which are routinely published by the CRCPD, nor to present this information in a public way.

Perhaps the most important impediment to developing an overall management plan for the two programs is the lack of an effective and responsive data management program (see below). The current program is admittedly incomplete, however the inspection staff seem to want to return to the "simple, old days" with a familiar but extremely limited data base system that could not be easily modified for changes in the inspection process, nor could it be the kind of effective program management tool required by modern management methods.

Recommendation #2
Operational plans should be developed for the x-ray and radioactive materials programs. The plans should include the following basic components: The problems; objectives; methodologies; and evaluation. An inspection schedule should be developed semiannually. The inspection frequency should be based upon the hazard and the inspection history.

COMMENT: Operational plans should be developed. The registration, licensing and inspection criteria should be grounded on public health and safety. These documents should be derived from a series of management retreats with staff to clearly identify achievable goals. The plans should be translated into individual personal goals and personal development plans. Staff training should be part of the plan.

A written program plan with goals and objectives agreed upon by staff and management would help to bring staff and management together in planning and priority setting so that the goals are practical for them to achieve. There should be periodic staff meetings so that priorities can be shifted if necessary to meet short-term goals. Potential short-falls can be identified in a timely manner, and course corrections can be made before anyone goes too far away from the overall direction.

If the goals are not coincident with staff career goals, then it will be clear that staff should consider changing their position.

Recommendation #3

CRITERIA: The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, and placing appropriate emphasis on major program functions. It should have adequate secretarial and clerical support.

FINDINGS: It is the practice of the program to be responsible for the billing and collection of the fees charged radiation source registrants. This includes all aspects except the actual maintenance of the funds in an account. At times, the program must hire temporary staff to support the billing process. Since the funds are placed in the State treasury and are not available to the program for use, there is no need for a separate account. At the same time, the effort required by the staff to issue the bills and track payment and collection takes away from the staff time available for the more important (from a public health perspective) inspection and compliance activities. While the program must continue to be involved in this activity because of the need to assure accuracy in the billing process, there is no need for the staff to be responsible beyond the most minimal activities required to assure accurate billing data transfer to a separate billing and collection function.

Recommendation #3
Effort should be made to minimize the radiation control staff workload requirements to support the fee billing system. Alternatives to the current system should be identified that are consistent with Arizona law and with the collection practices of the State.

COMMENT: The current system not only requires the technical staff to accomplish administrative functions significantly different from those necessary for their primary inspection and compliance functions, it also requires an additional, if small, audit requirement on the administrative support functions of the State. By combining the collection and audit functions with other similar programs, administrative oversight and auditing requirements should be reduced to an appropriate minimum. As with most States, the fees collected by the program have no positive fiscal impact on the program and therefore no fiscal incentives for timely collection management.

Recommendation #4

CRITERIA: The Radiation Control Program should have a data management system that provides an objective means for evaluating and demonstrating the public health and environmental impacts of the program. It should also provide the data that is necessary for program planning, evaluation, and efficiency. Statistical data from inspections should be developed to permit program management to assess the status of the program on a periodic basis.

FINDINGS: The x-ray and radioactive materials programs previously used a data based program to track licensing and compliance. The information provided by the computer program had been based on input from staff. Because the old program was difficult to modify, and because it did not contain necessary information or allow for the relational analysis to other data information systems necessary for a modern regulatory program, a decision was made to convert and modify the program to dBase IV. The new system is being programmed by a person(s) outside of the agency. It does not function as desired or as necessary.

The fact that the program does not function properly has led to frustration. Additionally, some staff do not appear to accept the need for an information system of the type that allows comprehensive planning and evaluation of program activities that are necessary to achieve efficiencies, or to justify program activities.

The program did have one FTE available for computer programming, but that position had been eliminated.

> Recommendation #4
>
> A functional management information system should be developed that will permit the evaluation of 1) regulatory activities; 2) program effectiveness, e.g., patient, worker and public dose assessments; and 3) program efficiency and consistency.

COMMENT: An integrated, flexible management information system is necessary in a modern program in order to document the program's activities, to simplify administrative procedures, and to obtain the data that is required to identify needed changes in program direction. Before an adequate Operational Plan can be developed (see above), a modern information management system must be made available.

The Radiation Control Program should obtain the services of a data management system planner to optimize the use of their computers. The development of an effective data management system will be difficult unless the staff supports such a program and are committed to the utilization of such a system once in place. As part of the development process, both management and staff must evaluate what information is needed for the program to protect public health and safety in the most effective and efficient manner. The system must be developed in a manner which permits not only the current information needs of the program to be easily obtained by the staff, but it should provide for easy updates and frequent and unique reports.

Statistical data from inspection and licensing/registration activities should be developed to permit the analysis of the status of the agency's programs on a periodic basis. A mechanism should be established for periodic, detailed reporting of achievements and shortfalls, based on monthly reports. The report of program activities should be widely circulated to enhance communications within the agency, and with outside agencies and customers.

Recommendation #5

CRITERIA: The x-ray program should have written procedures to insure that uniform inspections are conducted. Inspections should be capable of determining whether a facility is in compliance with the agency's regulations.

FINDINGS: The x-ray inspection reports do not document that facilities are in compliance with all applicable regulations. Additionally, items that could improve image quality and reduce patient exposure do not appear to be evaluated. For example:

> While some reports reviewed had information about exposure rates in areas adjacent areas, one of the survey meters used was not calibrated since 1993.
>
> Reports did not document whether or not the facility had an ALARA program subject to annual reviews.
>
> It appears that no attention is being paid to the objective evaluation of film processing techniques during routine inspections of all facilities.

Recommendation #5
Inspection reports should be modified to assure inspection uniformity and to assure facility compliance with regulations.

COMMENT: The inspections currently are rather basic and have not kept up with current practices. Consistent and comprehensive inspections are needed to ensure that public health is protected and that all facilities are being treated in a uniform manner. Additionally, data about patient and radiation worker exposures could be collected and used to identify program accomplishments, trends and needs.

Recommendation #6

CRITERIA: The Radiation Control Program shall have regulations essentially in conformity with the *Suggested State Regulations for the Control of Radiation.* Further, it is the Conference position that States should obtain Conference recognition as a NARM Licensing State.

FINDINGS: While a detailed evaluation of Arizona statutes, regulations and procedures was not conducted relative to the Licensing State criteria, it appears that Arizona should be able to meet the Licensing State criteria. It was determined that the state has not developed criteria relative to allowing NARM from non-Licensing States into Arizona.

Recommendation #6
The ARRA should initiate the necessary steps to become a Licensing State.

COMMENTS: There is no federal or other uniform regulation for the use of naturally occurring or accelerator produced radioactive materials (NARM). As a result of non-uniform regulation of NARM, difficulties have developed for those states that have attempted to regulate NARM. This creates potential public health and occupational safety consequences. Specifically, states wishing to license NARM sealed sources/devices manufactured in another state for which there has been no validation of NARM licensing criteria or authority find it is difficult, if not impossible, to license such items other than to issue a single license for each individual source or device. Except for the Conference recognition of a State for the licensing of NARM, there is no mechanism for the reciprocal recognition of a license to manufacture, since no validated license exists. Likewise, there is no basis to accept, under reciprocity, a NARM licensee from another state.

If Arizona obtained Conference recognition for the licensing of NARM, it would enable its NARM licensees to work in other Licensing States under reciprocity. It would also provide the program with a basis for evaluating requests for NARM source approval and reciprocity from other states.

Arizona Non-Ionizing Program Review

Narrative Report

The CRCPD has published guidance for States in establishing an adequate program for the control of hazardous sources of non-ionizing radiation, and the review team recommends that this guidance be followed. However, the review of this program area in Arizona is limited to the varied experiences of the review team members.

Arizona's regulatory authority to control sources of non-ionizing radiation stems from the Title 30, Chapter 4 sections authorizing other aspects of the program. The regulations controlling sources of nonionizing radiation are found at Title 12, Chapter 1, Article 14 of the Arizona Administrative Code. The sources specifically covered by regulation include laser sources, RF sources and sources of ultraviolet radiation produced by electronic products. The statutory authority and the regulatory framework appear to appropriately cover these sources and if these standards are enforced will help to assure Arizona residents of protection from unnecessary and hazardous exposures.

The staffing for this developing program is limited to a single individual. With this staffing level, the program must focus on the most important issues. Often this will mean following up on suspected injuries and other non-routine problems. It is clear that the number of potentially important sources that might be in Arizona will outstrip the capacity of this one individual to adequately manage. Additionally, the lack of a flexible and reliable information management system would prevent even the reliable tracking of these sources.

For those sources which represent the most important opportunities for acute injury, e.g. lasers used in medicine and the entertainment industry, possible industrial RF sources (heaters, driers, and sealers) and poorly maintained tanning facilities, the agency must rely on these users identifying and utilizing appropriate consultative expertise to assure that the hazards are reduced. Clearly the Arizona program cannot routinely inspect these facilities on a reasonable frequency to assure the competent use of these devices.

The person currently filling the nonionizing control responsibility was recently able to present a paper before the annual meeting of the Conference of Radiation Control Program Directors. This paper was important to the attendees because of the findings presented regarding the compliance status of tanning salons in the State.

Arizona Environmental Monitoring Program Review

The following are some general comments that relate to an adequate Environmental Monitoring and Surveillance unit within a State Radiation Control Program. The comments are based upon CRCPD Publication 86-4, printed May 1986, *Criteria for adequate Radiation Control Programs (Environmental Monitoring and Surveillance).*

An environmental unit should have equal organizational status with other units of the program. This will allow independent environmental assessments distinct from the program's licensing and compliance function, and will allow a greater degree of independence.

The environmental monitoring unit should be in the state radiation control program, rather than in another agency or university setting. Persons responsible for sample collection, analysis and reporting should all be under the chain of command of the radiation control program director. If, however, responsibilities for different aspects of the environmental unit exist outside the radiation control program, then administrative letters of agreement should be established to document respective roles and understandings to promote coordination and cooperation in conducting an effective program.

Program functions should be assigned to two or more persons to assure continuous program coverage and continuity in the event of sickness, promotion, leave or other unavailability of program principals. However, one person needs to have overall responsibility for ensuring all aspects of the environmental monitoring program are properly addressed.

Provisions should be made for significant increases in effort when emergencies occur. Details should be addressed as part of the state's emergency response plan.

The environmental unit should use advisory committees, consultants and other resources such as the Nuclear Regulatory Commission, Environmental Protection Agency, U.S. Department of Energy or the Conference of Radiation Control Program Directors for guidance and direction on the latest trends and/or developments applicable to monitoring and surveillance.

A mechanism for the exchange of environmental information among the states, other appropriate organizations and interested individuals should be in place so that major public health concerns can be adequately addressed when the need arises.

The review of the ARRA Environmental Unit was based upon the above criteria. The environmental program was found to conform with national standards except where noted in the following recommendations:

Recommendation #1

CRITERIA: All aspects of an environmental monitoring program should be within the direct responsibilities of the radiation control program.

FINDINGS: The Department of Health Services (DHS), not ARRA, currently has radiochemical laboratory certification for the State. DHS does not have the specific expertise needed to properly assess the unique requirements of a radiochemical laboratory. The ARRA laboratory personnel have a very loose and unofficial agreement with DHS to assist in the certification process. However, there appears to be many instances when assistance is not sought, thus the validity of the certification is certainly open to question.

> Recommendation #1
>
> Arizona should designate the ARRA as the lead agency to certify radiochemical laboratories.

COMMENT: This recommendation relates to the radiological analysis component for drinking water laboratories as well as solely radiochemical labs. Radiochemical laboratories have some unique requirements not normally associated with conventional ones. Expertise exists within ARRA to evaluate these unique requirements. If the State opts not to implement this recommendation, then the agreement between DHS and the ARRA should be formalized and strengthened to assure that ARRA is involved in every laboratory certification review that involves radiochemical procedures.

Recommendation #2

CRITERIA: The Environmental Unit should have adequate staff to assure continuous program coverage and continuity in the event of sickness, promotion, leave or other unavailability of program principals. The staffing should also be at a level to properly maintain an adequate documented quality assurance program.

FINDINGS: The existing staff are so busy they do not have time to adequately document work in progress. The quality of the work being done appears to be sufficient. However, there is not enough documentation to assure laboratory generated data could survive a court challenge. The following were weaknesses observed: a proper chain-of custody system is not being used to track samples; there were no records that showed how samples were processed, such as samples being acidified, dried, ground or otherwise prepared; quality control charts were laudable, but they were not used to follow trends; standard operating procedures were out of date, or non-existent.

Recommendation #2
Arizona should add one additional staff person to the environmental laboratory unit.

COMMENT: The expertise of the laboratory staff is excellent. The attitude of the people was good and they seemed have congenial relationships and a high sense of commitment. Everyone seemed to know what they were doing, and took pride in their particular area of work. Staff have made some innovative equipment and should be encouraged to submit a paper to a professional journal for publication. Management should allow time for writing the paper. Implementing recommendation #2 would allow flexibility for such morale boosting activities. Additional staff would also provide the critically needed time to properly document the shortcomings stated in the FINDINGS above. This recommendation will allow time to review qualitative and quantitative information to assist in decision making. For example, reviewers observed quality control charts reflecting a degradation of a counting system that staff did not see, or if they did, nothing was done to correct the trend.

Recommendation #3

CRITERIA: The CRCPD document *Criteria for Adequate Radiation Control Programs (Environmental Monitoring and Surveillance)* did not specifically address facility health and safety concerns. However, during the review several observations were made that could impact the health and safety of staff.

FINDINGS: There was no certification or documentation on hoods, showers, and eyewashes to indicate they had been tested for proper functioning; the laboratory door appeared to be hollow-core which would not be adequately rated for such a facility, the door should also have a window so conditions in the laboratory could be observed without entering; there were no fire or smoke alarms in the laboratory; staff had to walk through laboratory area to get to the facility break room. Eating and drinking in a lab area is not acceptable. The laboratory floor was in poor condition and would be impossible to clean if radioactive contaminants were spilled on it. Notwithstanding the laboratory staff having several projects going during the review, the area should be kept more clean and tidy.

Recommendation #3
Facility improvements should be made to enhance health and safety.

COMMENTS: It would be beneficial to designate a "Health and Safety Officer" within the ARRA. The local fire marshal would provide site specific recommendations commensurate with building codes.

Arizona Emergency Response Program Review

A state should have an emergency response program that addresses transportation accidents, spills, incidents at fixed radioactive material licensed facilities, nuclear power generating units, accidental overexposures, and contaminated material from such places as steel mills, scrap yards or landfills. The emergency plan key components should include:

1. Possible sites where emergencies could happen along with the specific location of the material.

2. On-site authorities and responsibilities.

3. Off-site agency contacts including an up-to-date call list of all applicable responders and decision makers.

4. Action guideline levels

5. Emergency equipment

6. Training programs for first responders and those nearest the sites as appropriate

7. Public information services

The Arizona Emergency Response Program is very good. It conforms with national guidance except where noted in the following recommendations. Staff were extremely knowledgeable in every aspect required by the reviewers. Documentation was readily available and procedures were written in up-to-date format. Only two areas were found that could use some improvement. One relates partially to laboratory concerns but is addressed here.

Recommendation #1

CRITERIA: An emergency response mobile laboratory needs to be able to process samples at an incident scene quickly.

FINDINGS: The ARRA mobile laboratory has a very low sensitivity germanium detector. This could slow down important analyses during an emergency. It is recognized that the detector is adequate for highly contaminated samples, but there are times when samples slightly contaminated need to be analyzed in a short time frame also. In these instances, the existing detector would cause serious delays in getting the needed information.

Recommendation #1
Arizona should purchase a detector for the mobile laboratory with higher efficiency. They should also purchase an alpha and beta counter for the mobile unit.

COMMENTS: The laboratory and emergency response program is well funded for equipment purchases through an agreement with the Palo Verde Nuclear Station. It appears that upgrading the detector via this agreement would be beneficial to the utility as well as the state. An alpha and beta counting system for the mobile unit would give the agency the ability to make better health and safety decisions in the field during times of emergencies.

Recommendation #2

CRITERIA: Prevention of sample cross-contamination is extremely important during times of emergencies. It is no less critical during normal operations; however, emergency situations present unique problems because samples are coming from so many different locations.

FINDINGS: An automatic charcoal cartridge counter, with the cartridges in a stacked geometry, is used in the laboratory. This could easily cause cross contamination of exterior filter cartridges since all the bare cartridges touch one another. Because of the stacked arrangement, changes in barometric pressure and temperature could liberate gaseous iodine and cause a low bias in some samples and contamination in others.

Recommendation #2
Place the charcoal cartridges, while still in plastic bags from being collected in the field, in a large marinelli beaker and count for a set period. If contaminants are found, then count each cartridge until the one contaminated is found.

COMMENT: The ARRA laboratory staff may have other alternatives for preventing this potential for cross contamination for counting the charcoal cartridges. The main factor is to eliminate the stacked geometry of bare cartridges so that direct contact and/or changes in barometric pressure do not contribute to cross contamination problems.

Arizona Administrative Program Review

Administrative functions, including management and leadership issues, of any organization are vital for determining how effective and efficient an organization will be. There are numerous factors that directly impact production, morale and/or the overall "heartbeat" of a group. The CRCPD does not have a specific document addressing administrative issues, however reviewers with senior level positions looked at these areas within ARRA. The recommendations are based upon sound principles that have worked in other organizations.

Recommendation #1

CRITERIA: A radiation control program should have well defined goals outlined in a strategic plan or other type of long range planning document.

FINDINGS: The Arizona Radiation Regulatory Agency (ARRA) prepared a strategic plan in 1990 and the document has not been updated since that time. A cursory review of the 1990 plan revealed that it contained recommendations and goals for improving the radiation program, but no evidence was found during the review that any action had been taken to put in place most of the recommended changes or improvements. The ARRA prepares a budget plan for two year budget cycles that essentially justifies expenditures for the program and requests increases in areas where needs have been identified. It appears that this is the only plan that is currently being used by management.

Recommendation #1
The 1990 strategic plan should be reviewed and updated with staff input to provide the ARRA with both short and long range goals for improvements in the program over at least the next two budget cycles (4–5 years).

COMMENT: Updating the plan would enable the ARRA to develop strategies on how to make desired changes and improvements. The staff should participate in the development of the strategic plan and the identification of areas where improvements or changes are needed. Without this "buy-in" by the staff, it will be difficult to implement changes without staff resentment over their lack of participation in the identification of agency goals.

Recommendation #2

CRITERIA: The ARRA program is supported for the most part by fees paid by licensees and registrants. These fees should be collected in the most efficient and cost effective manner to maximize their value to the program.

FINDINGS: All fees are billed and collected by the ARRA staff, which is a very time-consuming process. While the staff appear to handle this activity in an efficient manner, it requires a large number of staff hours that could be used for more productive purposes directly related to the protection of the public health. The clerical staff handles most of the renewals, but the technical staff is responsible for new registrants. In addition, the ARRA must follow rigid state accounting rules for handling the fees as they are paid which requires a substantial amount of staff time. The annual renewal process occurs each year during the months of September & October and all fees are due by January 1 of the following year. If the fees aren't paid by the due date, second, and if necessary, third notices are mailed out. While a registrant is technically out of business if they don't pay their registration fee, in most situations they continue to operate while the ARRA negotiates an agreement for the payment of the fee. At the time of this review, seven registrants had not paid their 1995 fees. This requires telephone calls to the owner/operator to determine when the fees might be paid. The agency cannot assess civil penalties at this time for non-payment of fees, but hopes to be able to do soon.

> Recommendation #2
>
> The ARRA should have another state agency, such as the Department of Administration, collect the fees and pursue the recalcitrant registrants and licensees.

COMMENT: Since all fees collected by the ARRA go into the state general fund, and the agency's budget is supported by appropriated funds, the agency does not realize any direct benefit from the time spent on the collection of fees. This will free up staff time for other activities more directly related to ARRA needs.

Recommendation #3

CRITERIA: Good communication between staff and management is necessary for an effective and efficient radiation protection program. Efforts need to be made to improve communication between staff and management of the ARRA.

FINDINGS: It was apparent from the comments made by a number of the staff members that there is a feeling that management does not want to listen to suggestions and recommendations on how to improve the ARRA program. In a similar vein, management believes the staff is unwilling to participate in efforts to upgrade the program because that is a "management responsibility". From these comments it is obvious there is a significant problem with communication between staff and management in the ARRA. This makes it very difficult for staff to "buy-in" to some of the changes being proposed by management to improve program operations.

Recommendation #3

Regularly scheduled staff meetings should be held. During these meetings, employees should be encouraged to report on significant activities and any problems that need resolving. Management should seek staff assistance in solving problems rather than rendering a top–down decision.

COMMENT: Staff seminars or workshops (away from the ARRA facility) conducted by facilitators might prove useful in bringing management and staff together in an environment where it would be more conducive to develop a team approach to problem solving. Annual planning meetings involving key members of the staff would also create more employee participation in the development of agency goals.

Recommendation #4

CRITERIA: Efforts should be made to improve the grade structure and salary for employees in the ARRA. The current system does not encourage employees to "grow" and take on new responsibilities. There needs to be substantial improvement in the process for rewarding employees for developing new skills which increases their value to the agency.

FINDINGS: Currently the career ladder for professional employees, and others, is extremely limited. For example, the ARRA has only two levels for the Radiation Regulatory Officer (RRO I and II) and under the state pay system, there is no provision for step increases based either on performance or longevity. This has a very negative impact on the morale of employees and was one of the most commonly heard complaints about working conditions. The ARRA now requires a newly hired RRO I to have a bachelors degree in a related field. However, the salary levels for the Radiation Regulatory Officer still lag behind other professional categories in the state civil service system such as engineering positions.

Recommendation #4

The ARRA should seek an expansion of the career ladder for employees, both in pay and responsibilities.

COMMENT: While the ARRA can set basic requirements for their staff positions, the state personnel office classifies the positions and establishes the pay schedules. The ARRA is currently seeking approval for the establishment of a Health Physicist position, but it is not clear if this will result in a higher salary for that position, if it is approved. The current system encourages employees to seek employment elsewhere which resulted in a high turnover rate in some parts of the agency, particularly the X-ray program.

Recommendation #5

CRITERIA: An effective radiation control program needs to keep its rules and regulations current and in conformance with federal standards and regulations. The agency should be able to promulgate new regulations or revisions to existing rules in a timely manner that will ensure protection of the public health.

FINDINGS: Recent revisions to the rule making process in the State of Arizona were supposed to streamline the promulgation and adoption of new regulations, but there is evidence that the opposite might have occurred. All proposed regulations must now be reviewed by the Governor's Regulation Review Council (GRDC) before they can go out for public comment and again after public hearings have been held. It appears that this process might take longer than the previous system. Under their agreement with the U.S. Nuclear Regulatory Commission, the ARRA has an obligation to timely update their regulations to be consistent with federal requirements. Also, the ARRA must amend their regulations each time they revise an inspection form or any other document established on the basis of an existing regulation. This requires a large amount of time from a small number of staff.

Recommendation #5

The ARRA should seek relief from the requirement to have changes in forms subject to the same process used for establishing new regulations.

COMMENT: There is very little the ARRA can do to change the rule making process in the State of Arizona since this is at the legislative level. A representative from the Governor's Office recognized the cumbersome process, but gave little hope that the overall process would be changed soon. However, there could perhaps be provisions made to eliminate the ARRA forms from having to be included in the system.

Recommendation #6

CRITERIA: Notwithstanding that a few large states, with substantial resources, have implemented successful radiation protection programs in different agencies, it is the formal position of the members of the Conference of Radiation Control Program Directors, Inc. that state government programs and activities established for the purpose of protecting the public from radiation exposure and protecting the environment from radiation pollution and contamination should be within a single agency and maintained as a unified entity for managing comprehensive radiation control programs. The state radiation control program should be under the administration, control, direction and management of an individual (Director) who possesses sufficient comprehensive knowledge for the consistent and uniform application of radiological health principles and practices for occupational and public health and safety and the protection of the environment, consonant with radiological activities conducted within each state.

FINDINGS: The ARRA is the single agency for the State of Arizona that has the responsibility to implement and maintain the radiation protection program for the state. The only exception identified was the involvement of the Department of Health for the certification of laboratories doing radiological analyses for drinking water. A recommendation was made in the Environmental Monitoring Program review above that addresses this issue.

Recommendation #6
The State of Arizona should continue to have the ARRA as the single agency responsible to implement and maintain a comprehensive radiation protection program for the state.

COMMENT: The statements made in the Criteria section above are from a recent resolution adopted by the CRCPD. It had thorough review and input from all states and is the position that has proven to be the most effective and efficient in the majority of cases. Memoranda of Understanding (MOU) must be developed between each agency which clearly identifies the responsibility of each if more than one agency is involved.

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Agency Response

Radiation Regulatory Hearing Board

Auditor General Note: The Radiation Regulatory Hearing Board was provided the opportunity to submit an Agency response but chose not to do so.