

TOPICAL DISCUSSION

OF THE

NRC / AGREEMENT STATE PROGRAM

October 1994

Prepared by

Organization of Agreement States

Published by

Illinois Department of Nuclear Safety

PREFACE

The evolvement of the NRC/Agreement State Program covers a span of some 35 years. It has been, and continues to be, unique in the arena of federal-state programs.

At the 1993 meeting of the Organization of Agreement States (OAS), a suggestion was made that the collective body of Agreement States and the U.S. Nuclear Regulatory Commission were losing the historical perspective of this unique program and that some effort might be made to assure the retention of this perspective. Therefore, the Executive Committee of the OAS appointed an ad hoc committee to document the important aspects of the development of the program. The committee decided to adopt a topical approach rather than a strict historical or chronological approach. This was because there is no formal documentation readily available to the OAS that would support the latter approach, nor are the resources available to OAS to prepare a more complete document. The committee recognizes that there may be gaps in its report due to the lack of records and documentation or due to our failing memories.

We hope that this document will benefit those Agreement State program directors and staff members and the NRC staff who will succeed the current generation. It should provide an institutional record, albeit modest, and therefore be useful in considering future actions that may affect Agreement State programs.

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ACKNOWLEDGEMENTS

The committee appreciates the contributions of many Agreement State representatives in the preparation of this report. In addition, the assistance of NRC staff is appreciated, particularly Lloyd Bolling who provided copies of some of the records utilized in this effort. The committee sought the comments of the following individuals on the draft:

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The assistance of the IDNS in preparing the report for publication is greatly appreciated.

- * The Conference of Radiation Control Program Directors (CRCPD) is an incorporated organization of the representatives of 49 state radiation control programs plus several local radiation programs. Its activities are much broader in scope than those of the Organization of Agreement States, and there is no organizational relationship between the two entities.

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TOPICAL DISCUSSION OF THE NRC/AGREEMENT STATE PROGRAM

"States are not mere political subdivisions of the United States. State governments are neither regional offices nor administrative agencies of the Federal Government. The positions occupied by state officials appear nowhere on the Federal Government's most detailed organizational chart. The Constitution instead 'leaves to the several States a residuary and inviolable sovereignty,' the Federalist No. 39, p. 245 (C. Rossiter ed. 1961), reserved explicitly to the States by the Tenth Amendment." Cited in decision of the Supreme Court of the United States, Nos. 91-543, 91-558, and 91-563, June 19, 1992.

I. Introduction

The NRC/Agreement State program has been in existence for more than 30 years. Its genesis actually began several years before the first state entered the program in 1962. The states were showing signs of restlessness as early as 1954 over their role in the regulation of nuclear materials and facilities. The resulting 1959 amendment to the Atomic Energy Act of 1954 established the statutory framework for what has become known as the Agreement State program.

The program was initially developed and administered by the regulatory arm of the U.S. Atomic Energy Commission (AEC). These functions were transferred to the U.S. Nuclear Regulatory Commission (NRC) on Jan. 19, 1975 when the AEC was abolished and the NRC was created by the enactment of the Energy Reorganization Act of 1974.¹ This change came about after several years of concern that there was an inherent conflict of interest in having the AEC be the promoter of uses of atomic energy and its nuclear weapons development program while also being the regulator of some of those activities. Interestingly, the state of Arizona established an Atomic Energy Commission in its initial stage following the AEC pattern. This agency was abolished in 1980 for conflict of interest reasons after a serious incident (the American Atomics incident, see p. 10). A few other states initially had development agencies also, which will be discussed in Section III.

The program established by the 1959 amendment to the Atomic Energy Act was unique in that it involved a discontinuance of regulatory authority by the AEC and assumption of that authority by the states. The federal government had exercised this authority in an area where authority was traditionally exercised by state and/or local governments. Further, the legislation did not establish a delegated program as was the case for federal programs in some other areas. Thus, the program was a reversal of the traditional solution to such issues. The traditional approach to emerging issues was that the federal government only stepped in when an issue became national in scope that might justify some federal action. As Roy Parker, former program director in Louisiana, frequently reminded us, the federal government was only involved

¹ The terms AEC and NRC are used interchangeably in this document, particularly where the dates of certain events are not known.

because of the development of atomic energy during World War II. Absent that traumatic event, there might well have never been an Agreement State program.

This report will focus on a number of significant areas in the development and implementation of the NRC/Agreement State program. These areas include legislative initiatives as well as programmatic functions, organizational aspects and technical issues. The report is thus organized in a topical fashion as opposed to an historical approach. The report should provide some perspective to future state and federal officials on key developments in the program.

II. Section 274 of the Atomic Energy Act

Section 274 was added to the Atomic Energy Act of 1954 (AEA) on Sept. 23, 1959. This was the culmination of much effort by the U.S. Congress and many state and federal officials and organizations. The most comprehensive background on circumstances leading up to this amendment are found in references 1 and 2. Section 271 of the AEA of 1946 and of 1954 had some references to state functions, but it was not clear that this extended to the areas of health and safety.

The AEC's Director of Regulation (or equivalent) formed an Advisory Committee of State Officials in late 1955 that first met in February 1956. The committee served to advise the AEC during the consideration of the federal/state relations issue and for a period of time after enactment of section 274. We are unaware of when the advisory committee was disbanded, but believe it was in the mid-to-late 1960s. The New England Governor's Conference Committee on Atomic Energy recommended a model state bill in 1955. The state of New Hampshire, in August 1955, passed an act that established a state policy, authorized studies related to atomic industrial development, provided for coordination of studies and development activities, and provided the modest sum of \$1,000 for certain related expenses. A suggested state radiation protection act and suggested regulations were published as early as December 9, 1955.²

Other states followed with legislation, some of which related to development and others to regulatory programs. Many of these followed the style and content of model legislation published by the Council of State Governments (COSG) in 1957. The COSG also published model legislation in 1961 addressing the subjects of coordination of atomic energy activities, enabling authority to enter into regulatory agreements with the AEC, and providing three options for administrative organizations covering development, coordination and regulatory functions. It included a provision to "permit maximum utilization of sources of ionizing radiation consistent with the health and safety of the public." Several states used this model legislation in developing their legislation. A few states, notably Mississippi and Michigan, through the opinion of their Attorneys General, determined that special enabling legisla-

² See Appendices A and B, National Bureau of Standards Handbook 61, that incorporates recommendations of the National Committee on Radiation Protection. The Preface to this handbook is of particular interest, indicating NCRP studies on this issue began in early 1953.

tion was not needed for their states. Another notable provision of the model legislation was that it was not limited to agreement materials. Rather, it covered all sources of ionizing radiation, and thereby established a basis for a comprehensive radiation control program for any state that followed the model legislation.

In 1983 the COSG published a new version of the Suggested State Legislation at the recommendation of the NRC. It included new specific provisions related to the regulation of low-level radioactive waste and of uranium/thorium processing facilities. It also deleted some of the developmental aspects of the previous model legislation.

By mid-1958, 13 states had authorized the establishment of an Office of Coordinator for Atomic Energy Activities or a similar position (Reference 1, page 154, footnote 1). There appeared to be a conscious effort by the states to avoid imposing any requirements that might hamper the development of atomic energy.

The Joint Committee on Atomic Energy of the U.S. Congress (JCAE) collected a large volume of materials related to federal-state cooperation in the field of atomic energy (reference 1). On Feb. 11, 1959, the JCAE wrote a letter to the governors of each state announcing a hearing to be held in May 1959 to consider legislative proposals in this area. The letter invited the states to participate in the hearings. Prior to this the AEC had proposed a bill in 1957 that would have permitted dual regulation of what has become known as agreement materials (source, byproduct and small quantities of special nuclear material).

The lead-off witness at the May 19, 1959 hearing was Professor G. Hoyt Whipple of the University of Michigan School of Public Health. One particularly interesting statement Dr. Whipple made was, "I believe that today the sum total of the greatest exposure to people in the United States comes from the medical uses of x-ray." (Reference 2, p. 10). Seems like deja vu in the 1990s. Numerous witnesses appeared at the hearings, including several from the AEC, state officials and their organizational representatives, organized labor and representatives of industry or other users of radioactive material. The testimony was far-ranging, covering subjects such as AEC operations, waste disposal, training, inspections, reactor hazards and of course, states' rights. Commissioner Graham of the AEC testified that "it would be desirable to enact legislation to clarify the role of the States at an early date." (Reference 2, p. 289). Organized labor generally opposed the bill being considered by the committee which would give the states a regulatory role over agreement materials. Labor felt it was a federal responsibility to control radiation hazards. Mr. Leo Goodman, of the United Auto Workers (UAW), recommended it be rejected in toto since it would dilute the AEC's responsibility. However, Goodman stated that the UAW supported the development of this science. Organized labor also seemed to feel the states were not capable of regulating these materials. The hearings continued on May 20, 21, and 22, 1959.

A final day of hearings was held on Aug. 26, 1959, with several witnesses from the AEC led by Chairman McCone. The JCAE received specific comments on both Senate and House bills regarding a new section 274 on Cooperation with States. The AEC generally supported the bills but had reservations regarding the establishment of a Federal Radiation Council, which was also opposed by

the Bureau of the Budget. A letter submitted later on the same day of the hearing by the AEC's General Manager stated the AEC "did not intend to leave any room for the exercise of concurrent jurisdiction by the States..." (Reference 2, p. 500). The JCAE reported out both bills on Aug. 31, 1959, and the legislation was signed into law on Sept. 23, 1959. Although the act provided for training and other assistance to states without charge, the JCAE made it clear that cash grants were not to be provided.

The 1959 amendment stood unchanged for nearly 20 years when the Uranium Mill Tailings Radiation Control Act of 1978 was passed. This act imposed certain additional requirements on states that wished to continue regulating uranium or thorium mills and tailings (paragraph o of section 274). This came about because of questionable authority of AEC over tailings at closed mills and problems associated with the environmental impact of these tailings. Further, section 274j was amended at this time to require the NRC to periodically review agreements and actions taken by the states under the agreements to ensure compliance with the provisions of section 274 of the Act.

Section 274 also was amended in 1980 by the modification of paragraph j regarding temporary suspensions of agreements in emergency situations. This was a result of the 1979 American Atomic incident in Arizona noted in Section I. As a result, Congressman Udall of Arizona held hearings on the Agreement State Program on July 19, 1979. The temporary suspension amendment is commonly referred to as the DeConcini amendment. DeConcini is a senator from Arizona who sponsored the legislation. The only other amendment to section 274 was made in 1983 when the last paragraph of section 274o was added.

Section 274 provides for discontinuance of regulatory authority by the NRC for source material, byproduct material (two kinds) and small quantities of special nuclear material. Naturally occurring and accelerator produced materials (NARM) are not subject to the Atomic Energy Act. This is presumably because of a reluctance by Congress to provide the AEC with any authority over radioactive materials beyond those associated with the atomic energy program, such as certain naturally occurring radioactive material, and a reluctance to intrude on what was presumably already subject to state jurisdiction through general public health responsibilities. The preemption provisions of the act only applied to the materials specified and, of course, over major nuclear facilities such as reactors. In addition, at the time of the 1959 amendment, the states might have been opposed to AEC regulation of NARM. This will be discussed further in Section VIII.

One other unique feature of section 274 is that the program provided in paragraph (b) is a discontinuance of authority by the NRC and the assumption or exercise of authority by the state on the effective date of an agreement. This can be contrasted with many federal-state programs that provide for delegated authority and, in many cases, include federal monies for the state. Many today seem to lose sight of this feature, and in the view of some it appears that the NRC currently searches for some way to impose uniformity on the Agreement States even in the absence of a good health and safety reason. Most Agreement States feel that adequacy of their programs is the only test required by section 274j after agreements are in place. Further, they feel that in the absence of operating funds provided by the NRC, they should have the freedom to manage their programs with considerable flexibility.

III. Unique Features of Agreement State Programs

A. Criteria, Conditions Fostering Agreements, and Agreement Forms

To implement the new law, one of the AEC's first chores was to develop criteria to evaluate the applications of states desiring to achieve agreement status. After consulting with a number of groups of state officials, including the AEC's Advisory Committee of State Officials, other state organizations and individual states, industry, labor and several other federal agencies, the draft criteria were published for public comment in early 1960. In April 1960, President Eisenhower solicited comments from the governors on the draft criteria. In early 1961 the AEC staff provided revised criteria to the Commission, and final criteria were published in the *Federal Register* on March 24, 1961. The criteria covered areas such as radiation protection standards, prior evaluation of uses, inspections, enforcement, personnel qualifications, conditions applicable to special nuclear material (particularly the formula for small quantities that Agreement States could regulate), administration, arrangements for discontinuing AEC jurisdiction and reciprocity. The criteria were modified on Jan. 23, 1981 to include requirements for uranium/thorium processing Agreement States, and on July 21, 1983 with additional provisions related to disposal of radioactive waste. The final criteria in 1961 deleted the proposed requirement that state standards be "no more and no less" than AEC standards (Reference 5, p. 297) that were included in the draft criteria. Further, the criteria were intended to be used as guidelines for the factors that the AEC would consider in evaluating a state's proposal (46 FR 7540, Jan. 23, 1981).

Soon after enactment of section 274, several states began active preparations to assume this new regulatory authority. Agreements could not be consummated immediately, however, since each state would have to achieve several actions. They needed to enact enabling legislation, draft and promulgate rules, hire and train staff, obtain the necessary funds to support staff and buy equipment, and negotiate the details of the agreement package with the AEC. The AEC initially had a State Relations Branch in its Regulatory Division of Radiation Standards that handled the negotiations with assistance from other AEC offices, including the General Counsel.

A beneficial side effect of states preparing for agreement status was that it usually enhanced their program for regulation of non-agreement material and x-ray machines. Some had little or no regulatory program for those sources. By obtaining gubernatorial and legislative support for the agreement program, the states frequently obtained the support necessary for a more comprehensive radiation control program, which was felt to be a significant advantage to becoming an Agreement State. In some cases, additional support was given by the U.S. Public Health Service (PHS) by the placement of assignees in the states. Sometimes they worked in x-ray and sometimes in radioactive materials. In any event, it was a useful supplement to the state and in turn, provided field experience for the PHS staff. The activities of the Southern Interstate Nuclear Board (SINB) and Western Interstate Nuclear Board (WINB) also helped generate interest in the program among high-level state officials (governors and legislators), which might not have been possible otherwise. Many of the early Agreement States were from the South and West where states' rights attitudes were strong. Thus, this program appealed to those states.

As indicated earlier, the AEC could not provide operating cash grants to states but did provide valuable training and technical assistance. Likewise, the PHS provided some more limited training. Further, the U.S. Department of Health and Welfare (or equivalent) originally provided category grants to state programs. In 1969, it shifted to a block grant approach, and state radiation control programs may have indirectly received money through this mechanism. In the 1970s and 1980s, the AEC did consider "seed money" for trying to obtain new Agreement States, but was unsuccessful. Some AEC staff felt this effort would not have been successful in any event. (One provision for giving grants will be discussed in Section VIII.D.) One more exotic idea advanced by some AEC staff was the walk-away proposal whereby AEC would simply quit regulating in the materials area and leave it up to the states by default. This would, of course, have required legislation. Although discussed as an option from time to time, it was considered unrealistic. In 1994, NRC again considered seed money in a response to a request from the State of Oklahoma. The result of this reconsideration was that NRC again determined that it did not have explicit legal authority and that it was a consistent and long-standing Commission policy not to provide seed money grants to support preparations of an Agreement State program. Also in light of the 100% fee support of the NRC by its licensees, there is an equity issue with the NRC licensees supporting such a program.

The agreements entered into with each state followed a reasonably standardized pattern. They all contained several "Whereas" statements of purpose and findings followed by several articles on the authority being transferred, the authority reserved to the AEC, authority for the AEC to reserve additional functions in the future, reservations to the AEC of common defense and security and safeguards functions, a best efforts article to maintain coordinated and compatible programs, a reciprocity article, a termination article and an effective date article. A significant change was made in the best efforts article with the fourth state, New York. The first three agreements placed emphasis on the state using its best efforts to maintain compatibility with the AEC. At the request of New York, the article was changed in its agreement pledging both New York and the AEC to use their respective best efforts to maintain compatible programs with the AEC and other Agreement States (Reference 6, attachment, p. 7). This change was included in all subsequent agreements. However, even this did not lay to rest the issue of continuing compatibility, which in 1994 is still an issue between the NRC and the Agreement States.

The agreements were generally signed by the AEC Chairman or delegated Commissioner and the Governor of the state. Some states had joint formal signing ceremonies in their capital city and other agreements were signed by correspondence without a ceremony. Appendix A shows a list of Agreement States with their effective dates and a list by year of the agreement.

Many of the early radiation programs were organizationally a part of a State Health Department. Later, several were in environmental departments, and two were free-standing cabinet level agencies (Arizona and Illinois). The program directors frequently were engineers with training in radiation or other environmental aspects. However, the following initial directors were physicians:

New York Department of Labor
Florida
North Carolina
Oregon
Tennessee

Morris Kleinfeld, M.D.
Ed Williams, M.D.
William Wilson, M.D.
Oscar Schneider, M.D.
Curtiss McCammon, M.D.

To our knowledge, no subsequent directors have been physicians.

B. Features of Individual Agreement State Programs

As indicated previously, the state radiation control programs were not identical organizationally in terms of their parent agency or style. Discussion of some of the unique aspects of several Agreement State programs and circumstances regarding negotiation of their agreements follows.

The first state we examine is Kentucky, which became the first Agreement State on March 26, 1962. Attorney General John Breckinridge was a key individual in negotiating the agreement with the AEC. Kentucky had established an Atomic Energy and Space Authority that conducted promotional activities, of which Breckinridge was the chairman. However, the regulatory program was organizationally located in the Health Department. During consideration of the application submitted by Kentucky, controversy arose over whether the state should regulate land disposal of radioactive wastes and whether the state should regulate the manufacture and distribution of products containing radioactive material (Reference 5, pp. 299 and 300). The AEC apparently questioned the ability of the state on the waste issue and was concerned about uniformity in evaluation and distribution of products in interstate commerce. Regarding the waste issue, one AEC official was quoted as saying, "if states assume jurisdiction in this matter, each state would want a burial site within its borders" (Reference 5, p. 299) - a view that can be contrasted with the prevailing attitude of states in 1994. After consideration of the issues, the Kentucky agreement was consummated and allowed the state to regulate low-level waste disposal on land and to regulate devices containing radioactive material except for those in consumer products (these products came to be known as exempt distribution products). A picture of the signing of the Kentucky agreement is shown in Fig. 1. Three days after the signing, Chairman Seaborg addressed a joint session of the Kentucky legislature. The state indeed licensed a land-disposal facility located near Morehead, Kentucky in 1963. The common feeling among Kentucky officials was that this action would encourage other nuclear facilities, including power plants, to locate in the area. This, of course, soon was shown to be a false hope. Further, as noted in Section VIII.E., this site experienced technical operating problems in the mid-1970s.

The next state to enter the agreement program with unique features was California on Sept. 1, 1962. The California program was unique in that other state agencies and local agencies carried out some inspections for the centralized Health Department program. These included the state's Division of Industrial Safety, Los Angeles County Health Department and Orange County Health Department, and were known as contract agencies. They did not have licensing authority. The second unique aspect of the California program was



Fig. 1. Signing of Kentucky Agreement, Feb. 8, 1962 in Washington, D.C.
L. to R.: James Neel, Kent. Coordinator of Atomic Energy Activities; Dr. Russell Teague, Commissioner of Health;
Attorney General John Breckinridge; Governor Bert Combs; AEC Chairman Glenn Seaborg. Photo courtesy of Wide World Photos.

the establishment of fees. The fee system was based on the form of material (sealed or unsealed) and the curie quantity. Later, most fee systems adopted by the NRC and other Agreement States were based on the category of licensee and the type of program they conducted (e.g., radiography, medical, academic, etc.). The California fee program generated considerable discussion and concern within the AEC as to whether it would be compatible with the AEC program without fees.³ The finding of the Commission was "How a state finances its regulation of materials under an agreement should not be a concern of the Commission."⁴ One non-regulatory Division Director of the AEC was very concerned over the decision since he felt it might curtail the use of radioisotopes. AEC still had a heavy promotional bent at that time.

In addition to the aforementioned change to the best efforts article of the agreement, there were other unique aspects of the New York program. New York's program included three separate agencies, each of which issued rules, licensed material users, inspected licensees and took enforcement actions against licensees. These agencies were the New York State Department of Labor, New York State Department of Health and New York City Department of Health.⁵ Labor regulated industrial concerns throughout the state including New York City; State Health regulated academic and medical licensees outside of New York City; and City Health regulated academic and medical users within New York City. Originally, the Health Departments regulated the environmental release aspects of Labor Department licensees. The agencies operated independently, but a coordinating group called the Committee on Licensing (COL) was established in the state's Office of Atomic and Space Development. Although the word "Development" was part of the agency's title, in actuality it mostly did planning and inter-agency coordination. This office was organizationally located in the governor's office. The principal contact for the COL was Robert Vessels in the early years and the COL coordinated regulatory functions of the affected agencies. A significant technical difference from the AEC in the New York program was a variation in occupational dose limits. New York had based its limits regarding quarterly doses on guidance from the Federal Radiation Council and the National Committee on Radiation Protection and Measurements (Reference 6, attachment, p. 16). New York allowed 13-week exposures of 3 rem, whereas AEC only allowed 1¼ rem per quarter unless an occupational history was maintained and accumulated doses could not exceed 5(N-18) where N was the age in years. The AEC finally concluded that the regulations were compatible. The New York negotiations were consummated at a late date. Vessels handled the logistics for New York State. It is our recollection that the AEC Commissioners approved the agreement on Oct. 14, 1962 and it was signed by Chairman Seaborg. Vessels returned to Albany late that day and obtained Governor Rockefeller's signature so the agreement would be effective on October 15. Vessels sent a telegram to Ben Harless, Chief of the AEC's State Agreements Branch that evening that said, "The pony is in the barn."

³ AEC's first fee program for materials licensees was established Oct. 1, 1968, but did not cover all categories of materials licensees at that time.

⁴ Letter dated June 20, 1994 from J. Vaden to W. Kerr.

⁵ The Bureau of Radiation Control in the New York State Department of Environmental Conservation was established July 1, 1970 to handle environmental issues and low-level waste.

The New Hampshire agreement became effective May 16, 1966. The unique feature of this agreement was that it was signed by six individuals for the state. The agreement was signed by Governor John King and co-signed by the five members of the Governor's Executive Council, which was a statutory requirement of the state.

The Louisiana agreement became effective May 1, 1967. Louisiana established a Board of Nuclear Energy with two components: the Atomic Energy Development Agency and the Division of Radiation Control. Although the two groups shared offices, they functioned independently. In 1973, the Division of Radiation Control was merged into the Division of Natural Resources. The Board of Nuclear Energy was abolished and the development activities gradually faded away. The negotiations with Louisiana were probably the most difficult of any Agreement State. The main issue of contention involved the regulation of Louisiana licensees (and other jurisdiction's licensees operating under reciprocity) in disputed areas of off-shore coastal areas. At the time of the agreement negotiations, the state of Louisiana and the United States of America were involved in a cause pending before the U.S. Supreme Court. At stake were vast sums of money that would accrue to either party from offshore oil and gas drilling operations, depending on the outcome of the case. One other consideration was that it affected only persons operating in the disputed area or seaward thereof and that were on or in the seabed or structures affixed thereto (primarily drilling rigs). The AEC acknowledged the existing practice of the Agreement States having authority to regulate their citizens on the high seas, i.e., unattached vessels. The negotiations on behalf of AEC were elevated to the level of Eber Price, Director, Division of State and Licensee Relations and Howard Shapar, Associate General Counsel. This dilemma was solved by the development of two documents in addition to the standard agreement. The first was a Memorandum of Understanding that was basically a disclaimer of any effects on the pending Supreme Court case. The second additional document was a section 274i inspection agreement. The agreement permitted the state to perform, without charge, inspections of AEC licensees, for and on behalf of the AEC, in the areas subject to the litigation. These inspections were to be performed subject to AEC supervision and to certain restrictions regarding enforcement. The three documents were signed at a ceremony in Baton Rouge, Louisiana, on April 17, 1967. Commissioner Wilfrid Johnson signed on behalf of the AEC and Lieutenant Governor Aycok on behalf of Governor McKeithen. This is believed to be the only case where the Lieutenant Governor signed for a state. Dr. Roy Parker, Director of the Louisiana Division of Radiation Control, co-signed the Section 274i agreement.

The Arizona agreement became effective May 15, 1967. As noted in Section I of this report, the state established the Arizona Atomic Energy Commission (AAEC) following the pattern of the U.S. AEC. The agency was a cabinet-level agency that had both promotional and regulatory functions. After a serious incident at an industrial licensee's facility in Tucson in 1979, which resulted in extremely large releases of tritium to the surrounding neighborhood, the Arizona AEC was abolished and a new cabinet-level Radiation Regulatory Agency was established July 31, 1980. An obvious conflict of interest situation came to the forefront during the course of the incident and was addressed by the governor and state legislature. Among other things, the sitting Chairman of the AAEC at the time of the incident was a top executive of the licensee involved.

The next state that faced a unique situation in achieving agreement status was Rhode Island. Rhode Island was a state with a very small program (about 50 licensees) and was negotiating in the aftermath of the Arizona incident and the July 1979 Udall hearing. The NRC's Office of Nuclear Materials Safety and Safeguards raised concerns about the Rhode Island staffs' capability.⁶ In addition, the NRC's Commissioner Gilinsky, who testified for the NRC at the Udall hearing, was pushing for more rigorous standards by which to judge Agreement States. Jim Hickey, Director of the Rhode Island program, and Dante Ionata of the governor's office appeared before the Commission in late 1979 to present the state's case. In sum, they stated that if Rhode Island's application was turned down on anything other than health and safety grounds, the state would pursue other actions. The Commission approved the Rhode Island agreement, which became effective Jan. 1, 1980. The approval was by split vote (3-2) with Commissioners Gilinsky and Bradford opposed. This is the only state of which we are aware where the state appeared before the Commission or where the decision was by split vote.

The New Mexico agreement became effective May 1, 1974. Upon passage of the Uranium Mill Tailings Radiation Control Act of 1978 on Nov. 8, 1978 (UMTRCA), Agreement States that wished to continue regulating uranium mills had three years to upgrade their programs (see Section VIII.D). This period was later extended and although New Mexico did considerable work to try and achieve an amended agreement, it was unsuccessful. The main reason was the opposition by the uranium milling industry to the proposed regulations, which, of course, pursuant to UMTRCA, were closely patterned after those of NRC. Thus, Governor Anaya of New Mexico requested that the NRC reassert authority over uranium milling in New Mexico and the NRC did so effective June 1, 1986. The basis for the request was the inability to adopt regulations and a lack of resources. Ironically, the industry then became subject to almost identical regulations of the NRC although objected to when proposed by New Mexico.

The Illinois agreement became effective June 1, 1987. The question of transfer of authority of one source material license became an issue in this case. Allied Chemical Corp. operates a UF₆ conversion plant for uranium (source material) at Metropolis, Ill. It is one of two such conversion plants in the United States, the other being in a non-Agreement State. Ordinarily, the authority over this licensee would transfer to the state on the effective date of the agreement. The NRC, after receiving advice from the U.S. Department of Energy, decided to retain jurisdiction over this licensee in order to protect the common defense and security. Commissioner Asselstine opposed the decision. Chairman Zech's letter to Governor Thompson informed him of the approval of the agreement and of the decision on Allied Chemical but stressed that the decision was not reflective of Illinois' ability to regulate the licensee for health and safety purposes. This is the only case we know of where a single license was not transferred because of common defense and security considerations.

⁶Judging a small state's capability was always difficult because the total effort required to conduct the program was probably less than a full person-year. NRC generally followed the practice of requiring a state to have at least two qualified professionals on staff even though they might spend part of their time on such other duties as x-ray or environmental programs.

Idaho became an Agreement State on Oct. 1, 1968. On April 26, 1991, Idaho voluntarily relinquished its agreement authority. The state had chronic funding and staffing problems and was unable to obtain the necessary support from its legislature. The NRC never formally moved to revoke this agreement, but rather put pressure on Idaho to either get the program in shape or relinquish its authority. The matter was discussed at the Synar hearing on Aug. 2, 1993 and is discussed in the next section.

IV. Routine Relations of NRC and Individual Agreement States

A. Individual Agreement State Relations

In the early phase of the NRC/Agreement State program, the AEC instituted meetings with each individual Agreement State on a periodic basis. In fact, these early meetings were usually done by invitation of the state. They were intended to implement the best efforts articles of each agreement. These were labeled, "Exchange of Information" meetings, and a typical agenda for such a meeting is shown in Appendix D. The emphasis was clearly on a two-way exchange of information. Each party relayed information regarding incidents or events, regulation changes, inspection information and general information on regulatory matters. Typically, the AEC was represented by one or two staff members of the State Agreements Branch and one from the AEC region, frequently the regional director or the materials branch chief. The state was normally represented by the program director and most of the materials staff. The meetings usually lasted one to two days, and contacts were not usually made with senior state management officials. There was no organized aspect of review and evaluation by the AEC staff, however, they sometimes offered suggestions and were certainly willing to offer the benefit of their experience to the state officials.

Before long, however, the AEC staff began developing a list of questions in their own area of expertise to guide themselves in developing an opinion as to how the state was managing its agreement materials program. A major change in the direction of the program came about in May 1965. The U.S. Department of Labor (DOL) was proposing to impose regulatory requirements duplicative of those imposed by the AEC and Agreement States on their respective licensees. The DOL was using the authority of the Walsh-Healey Public Contracts Act. It is believed that there were Congressional hearings on the matter with strong objection by the states and the AEC. The AEC negotiated the issue with the DOL, and the quid pro quo arrangement was that the AEC would make an annual formal redetermination of compatibility for all Agreement States and DOL would not impose dual regulation on these licensees. This recognition of the AEC's determination was later incorporated into the Occupational Safety and Health Act, which superseded the Walsh-Healey Act. Another notable event in this regard was that in 1965 the Commission chose not to go forward with proposed legislation that would have given AEC the authority to terminate agreements based on incompatibility. Even earlier, in 1963, the AEC determined that "'unilateral power to require compatibility would appear to be inconsistent with both the nature of the program established and the underlying philosophy of the statute'." (Reference 6, attachment, pp. 8 and 10.) The first formal redetermination of compatibility by the Commission was made on Jan. 5, 1966.

This approach was abandoned in 1982 when it was realized the redeterminations for many states were up to two years old, and it would be more useful for the NRC staff to meet periodically with the DOL staff to discuss areas of mutual interest and to provide the DOL with information when significant concern arose. In any event, the 1965 change in policy required the AEC staff to take an evaluative approach to the individual Agreement State programs. Appendix E shows an early letter to a state following the review of its program after this new evaluation process was implemented.

In 1973, the AEC staff formalized the guidance that they had been using for several years in evaluating Agreement State programs. The staff published a "Guide for Evaluation of State Radiation Control Programs Under Agreement" that did not have the stature of the later and more formal 1981 policy statement of the NRC on this subject. Nevertheless, the 1973 guide contained many of the same elements of review that appeared in the 1981 and subsequent policy statements. Essentially, these documents covered the major categories of legislation and regulations, organization, management and administration, personnel, licensing and compliance. Although the meetings with individual Agreement States continued to include an element of information exchange, they became longer and were structured differently. [One former state program director continued to call them Exchange of Information (EOI) meetings long after the change had taken place.] The NRC staff began to review license files, including the backup material, inspection and enforcement actions, response to incidents, laboratory support, and staffing and personnel activities. One other practice that was instituted was the accompaniment of Agreement State inspectors. Initially, these were carried out by regional AEC staff members who had materials inspection experience. As the State Agreements Branch added staff with licensing and inspection experience, the AEC regions stopped participating in the review meetings and no longer performed accompaniments. This came as a result of a recommendation by John Davis, then Director of the AEC's Region II office in Atlanta, Ga. Davis had been particularly helpful in assisting states in that region and in helping the State Agreements Branch. Within the AEC, he no doubt had the best understanding of the agreement state program outside of the Division of State and Licensee Relations.

Another important aspect of the AEC review process was that the criteria, and more particularly the internal procedures of the AEC, were intended to be used as guidance by AEC staff. As noted above, the earlier documents were titled as guides and the Agreement States were furnished copies of them so they knew what elements were included in the reviews. Their use was to be tempered with good judgement by people knowledgeable about radiation regulatory programs. They were not intended to be used by "bean counters" - a contemporary term that has been applied to certain aspects of reviews and their results. The results of these more formal reviews were discussed with state management officials at the conclusion of their review visit. The NRC's conclusions and recommendations were then sent to the senior state management official (e.g., State Health Officer), and in most cases with a request for a response on the recommendations. However, the State Agreements Officers in the regions conducted many of the reviews (See Section VI).

The review process continued along these lines for many years. NRC's Office of State Programs did supplement its reviewers with staff from other NRC offices on an ad hoc basis in such areas as uranium mill regulation, low-level radioactive waste disposal, and sealed source and device reviews. In

the late 1980s, NRC made another change in its review process. It began to organize team reviews, in some cases quite large, for the review of the larger Agreement State programs. Usually the lead reviewer and team coordinator was the Regional State Agreements Officer for the region in which the particular state was located. The team could consist of staff with various specialties from NRC's Office of Nuclear Material Safety and Safeguards, occasionally the Office of Nuclear Reactor Regulation, other regions and occasionally some other office. Of course, the use of out-of-region personnel negated one of the advantages of having a State Agreements Officer in each region, namely cost savings accrued by reduced travel expenses. Smaller Agreement State programs continued to be reviewed by the regional State Agreements Officer.

Aside from the periodic review meetings with individual Agreement States, the NRC's post-agreement program contained other elements. All of these were intended to carry out the best efforts articles for coordination and cooperation. It also was deemed necessary to carry out the provision of section 274a.(3) to "promote an orderly regulatory pattern between the Commission and state governments...".

One of the other key parts of the program was technical assistance to the Agreement States. This assistance took several forms. The most frequent was oral advice given by the staff of the Office of State Programs (OSP) or other NRC staff on a large variety of technical and regulatory matters. Another way of obtaining such assistance was for the Agreement State to submit a written request to the NRC and to receive a written response. These requests were normally coordinated by OSP, which obtained the necessary information from appropriate NRC offices. This coordination was particularly useful to the Agreement States so as to avoid having to locate the appropriate staff member(s) in other NRC offices to provide the information. Less frequently, technical assistance was made available to the Agreement State at its offices for very specialized issues and for assistance on complex inspections.

Another key part of the NRC's assistance program was, and is currently, its training program. Starting with the earliest Agreement States, the AEC recognized the need to provide some specialized training to states preparing to become Agreement States or after their agreements became effective. The first course was a three-week orientation course on regulatory practices (covering both licensing and inspection functions). It was recognized that state officials had basic knowledge in radiation safety and in some cases, experience in x-ray regulation or NARM control. However, the AEC's regulatory program was somewhat unique, so courses were tailored to that aspect of regulation. The time progression for the various courses is not known; however, courses were developed in basic health physics, radiation protection engineering, licensing procedures, inspection procedures, transportation, medical uses, well logging, industrial radiography, uranium mill regulation, waste disposal, and other areas. Many of these are still offered today and are extremely valuable to the Agreement States.

A fourth element of the NRC's post agreement program is the exchange of information program. This covers the distribution of regulatory information necessary for the NRC and Agreement States to carry out their respective programs in an efficient and orderly fashion. The type of information to be distributed by the NRC and to be sent to the NRC by Agreement States was ordinarily covered in an exchange of letters with each new Agreement State. The information typically covered regulatory guides, sealed source and device

evaluation sheets, statistical data on licensing and inspections, exempt distribution licenses, all licenses issued by the state, incident information, draft regulation changes, NRC bulletins and information notices, NUREG documents and various other regulatory documents of general interest. Much of this exchange continues today, although some is requested in conjunction with the review meetings. Appendix F shows an April 3, 1992 letter to Maine establishing such an exchange.

The fifth principal element of the post-agreement program is of more recent vintage. Beginning in the late 1980s, the NRC has hosted a number of workshops to address specific regulatory issues. Workshops have been held on low-level waste regulation, uranium/thorium mill regulation, industrial radiographer certification, regulation of medical uses, megacurie irradiation facilities, and evaluation of sealed sources and devices. The Agreement States have, in general, found these to be very useful. They provide an opportunity to discuss each participant's views on an issue and sometimes come to a consensus on a given regulatory approach. In some cases, the Agreement States have been able to persuade the NRC to make significant changes in regulatory approaches - most notably in industrial radiography certification and medical use of radioactive materials.

B. Reviews by the U.S. General Accounting Office (GAO)

GAO is an arm of the U.S. Congress and generally conducts reviews and audits of federal agencies on its own initiative or at the specific request of Congress. The first comprehensive review of the AEC's management and oversight of the Agreement State program was conducted about 1972. The Committee does not have access to the GAO report resulting from that review, but it is recalled that relatively modest recommendations were made. The formalization of the 1973 review guide referenced in IV.A. above may have resulted from the GAO recommendations. Also, there were likely follow-up reviews to that initial comprehensive review.

GAO has performed a number of other reviews of NRC activities over the years. Several of these have been related to low-level waste disposal and the NRC's materials regulatory program. Frequently these reports have covered certain aspects related to Agreement States, since they conduct independent but integral parts of these functional areas.

In April 1993, GAO issued a report titled, "Better Criteria and Data Would Help Ensure Safety of Nuclear Materials," GAO/RCED-93-90. This report was prepared in response to a request from Congressman Mike Synar, Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on Government Operations. The purpose of the review was stated to be (1) the review of the comparability of NRC's programs for Agreement States and NRC-regulated states, including assessments of the effectiveness of both programs, and (2) follow-up on previous recommendations in a 1988 report (not related to the Agreement State program). The 1993 report recommended (1) that the NRC establish common performance indicators to evaluate the Agreement State programs and NRC's regulatory program, and (2) that specific criteria and procedures for suspending or revoking an Agreement State program be developed. The GAO spent very little time during its review with Agreement State officials and never discussed its findings with any of the Agreement States prior to publication. Congressman Synar held a lengthy hearing on Aug. 2, 1993 at which GAO, OAS and NRC testified. At that hearing, GAO stated that it never

found an Agreement State program inadequate, but that it was questionable if the public is being adequately protected by the state-regulated or NRC-regulated programs. NRC was questioned extensively on its oversight program with particular emphasis on so-called problem Agreement States. These were states where NRC had withheld findings of adequacy and/or compatibility for lengthy periods, or were unable to make findings as a result of its reviews. As this document is being written, NRC is wrestling with what changes should be made, both in its relationship to Agreement States and in the NRC oversight program.

The Synar hearing followed on the heels of a May 6, 1993 hearing by Senator John Glenn, Chairman, Senate Committee on Governmental Affairs, on the regulation of medical uses of radiation. This hearing was a result of a series of articles that appeared in the *Cleveland Plain Dealer* in December 1992. The articles covered a number of medical-related radiation incidents involving agreement materials, x-ray machines and linear accelerators in both Agreement and non-Agreement States. Aubrey Godwin, Past Chairman, CRCPD, testified at that hearing. As a result of that hearing and because of an extremely serious incident that occurred on Nov. 16, 1992 in Pennsylvania, a non-Agreement State, the NRC is making a number of changes in its program for regulation of nuclear materials used in the medical area. Some of these changes could well affect how Agreement States regulate medical uses.

V. Annual Meetings of All Agreement States

The AEC began holding joint meetings with all Agreement States, apparently in 1964. A list of these meetings is shown in Appendix B. This was another effort to keep the Agreement States informed of significant regulatory developments at the AEC. The Agreement States were requested to submit topics they wanted discussed at the meeting. The AEC tried to select topics that would be of broad interest, rather than an issue relating to only 1 or 2 states. Most of the early meetings were held in the Washington, D.C. area. Frequently, an AEC Commissioner or the Director of Regulation (the Executive Director for Operations in NRC) would present opening remarks. Appendix G shows the agenda for the Dec. 14-15, 1964 meeting.

One advantage of holding the meeting in the Washington, D.C. area was that if individual state officials needed to meet with other AEC staff, such meetings could be arranged. Secondly, staff from other AEC offices were readily available to discuss topics without costly travel. In the early meetings, most of the topics were presented by AEC staff, although there was ample opportunity for dialogue between the state officials and the AEC staff. Officials from the FDA and EPA and the federal representatives to the Southern and Western Interstate Nuclear Boards usually were invited to the meetings.

The Agreement State representatives were never shy about expressing their opinions to the AEC staff. At one early meeting, there was a presentation by the AEC's Harold Kneeland on its attempt to initiate a program for the retention of personnel monitoring records and the reporting of certain data from selected groups of licensees to the AEC to be maintained in a central

repository.⁷ This is the provision of AEC/NRC regulations currently contained in Section 10 CFR 20.2206 (formerly 20.407). The AEC wanted the Agreement States to participate in this program and would, to the best of our recollection, provide some monies to Agreement States to do so. This proposal prompted a heated discussion by the Agreement State representatives and the AEC staff. It was perhaps a portent of things to come several years later on issues such as certification of industrial radiographers, medical misadministration rules, compatibility and others. The state officials' primary concern was that personnel monitoring records were not that reliable because of the imprecision of doses recorded on film badges. This, of course, predated the requirement for personnel dosimeters to be processed and accredited by processors accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).⁸ The Agreement States were generally opposed to being forced to participate in this program and to implementing similar regulations. We believe few, if any, Agreement States ever participated.

This particular discussion had both a serious aspect and a humorous twist. Sometime during the heat of the discussion, Mr. Jon Anderson of New York left the meeting to visit Mr. Harold Price, Director of Regulation. He informed Mr. Price that the Agreement States were adamantly opposed to any such requirements being imposed on them or their licensees, and it would be wise for the AEC to back off from their position. The AEC followed this wise counsel, and Agreement States were not required to adopt similar regulations. In NRC's Internal Procedure B.7, "*Criteria for Compatibility Determinations*," this rule is listed in the Division 3 category, which Agreement States have the choice to adopt or not. This rule is not included in the current version of the CRCPD's Suggested State Regulations for Control of Radiation, but will be included as an optional provision in the next version. Mr. Eber Price, Director, Division of State and Licensee Relations, had chaired the meeting. In a post-mortem discussion of the meeting with his staff, Price remarked that Dr. Curtiss McCammon of Tennessee made a slip of the tongue when he referred to the futility of placing these records of little value in a radiation records suppository. The staff informed Mr. Eber Price that they believed Dr. McCammon had stated precisely what he intended.

The agendas for these early meetings show that topics typically covered medical uses of radioactive materials, industrial radiography, problems with generally licensed devices, waste disposal, transportation of radioactive materials and many others. Many of these subjects continue to be discussed in the more recent meetings. The early meetings were heavily dominated by AEC staff presentations, although the discussions were frequently active and frank. Beginning perhaps in the mid-1970s, more presentations were made by state officials, although few states volunteered. Usually NRC staff recruited state staff to discuss various topics. However, in some cases, Agreement State requests to speak were denied. Also, starting about 1980, the agenda frequently included panel discussions on given topics. These were chaired by NRC or Agreement State officials with panel participants from both groups. In more recent years, the ratio of the number of NRC speakers to Agreement State

⁷ Kneeland was substituting for Charles Eason, who had formerly been Assistant Director of AEC's Division of State and Licensee Relations.

⁸ See 10 CFR 20.1501(c).

speakers has been about two to one, but most of the panels have been chaired by Agreement State officials.

During the early years, AEC staff took notes and prepared internal reports of the meetings. Since about the mid-1970s, the NRC has used a court reporter. Few, if any, of these reports have been furnished to the Agreement States.

The AEC normally has invited non-Agreement States that are actively negotiating an agreement to send one official to these meetings. These range from one to four non-Agreement States each year.

Beginning in 1971, the Agreement States began meeting for a half-day amongst themselves with no federal officials present. This allowed the states to discuss issues common amongst themselves, issues relating to Agreement State/NRC relations, and to prepare suggestions and recommendations for NRC consideration. The closed atmosphere of this meeting allowed for very frank and open discussions. In order to conduct this meeting the Agreement States for several years elected a chairman whose main tasks were to organize an agenda for the meeting, preside over the meeting, and send a letter with recommendations to NRC, which were normally addressed to the Director, Office of State Programs.⁹ Beginning with the 1989 meeting, these letters have been addressed to the Chairman of the NRC. The states expect the NRC to reply to each of their comments, which generally happens, although not always to the satisfaction of the states.

On occasion, the NRC would consult with the chairman of the OAS on some particular issue, and sometimes ask for suggestions for persons from Agreement States who might serve on an ad hoc committee being established by the NRC.¹⁰ At the October 1985 meeting, the Agreement States elected both a chairman and chairman-elect. This continued until the October 1991 meeting when the Agreement States established a more formal structure. The OAS established an Executive Committee composed of a chairperson, past-chairperson and chairperson-elect with some modest operating guidelines provided to the Executive Committee. The chairperson was designated as the principal point of contact for the OAS.

In 1989, the NRC staff requested they be allowed to sit in on the OAS meeting as observers. This was denied, but the NRC made the request again at the 1991 meeting. At the beginning of the 1991 OAS meeting, the Agreement States debated the issue. After a vote, it was decided to allow the NRC staff to be present as observers. This practice has continued to date, but the states reserve the right to close portions of the meeting if deemed appropriate. A copy of the agenda for the 1993 annual meeting is shown in Appendix H. One might compare the topics discussed with those shown in Appendix G for the 1964 meeting.

⁹ A list of the chairpersons of the OAS is shown in Appendix C.

¹⁰ Note that this arrangement preceded the more recent brouhaha over complications arising from considerations under the Federal Advisory Committee Act (FACA). The recent position of the NRC is that state officials cannot become active partners in such working groups or committees. This is an issue the Agreement States continue to feel needs a more satisfactory resolution.

VI. AEC/NRC Officials and Organization

The initial AEC organization charged with developing the Agreement State program, including negotiation of agreements and post-agreement cooperative work, was the State Relations Branch in the Division of Radiation Protection Standards of the AEC's regulatory arm. In 1964, the AEC's Director of Regulation established the Division of State and Licensee Relations (SLR). The director of the division was Eber Price and the assistant director was Charles Eason. The division included the State Relations Branch (SRB), the State Agreements Branch (SAB) and two other unrelated branches. When the AEC initiated its licensee fee program in the late 1960's, this function also was placed in SLR. The SRB was headed by George W. (Bill) Morgan, and a key staff member who served many years in that branch was John Vaden (currently of Nevada). The SRB provided developmental assistance to prospective Agreement States and an extensive training program for state officials. In the early days of the program, the SRB and the PHS jointly manned exhibits at various meetings that described the program and other aspects related to the use of sources of ionizing radiation.

The SAB was headed by Ben Harless. This branch actually negotiated the agreements and conducted the post-agreement program of information exchange, technical assistance and program reviews. One major policy change instituted by Price was that the AEC would not take a heavy promotional approach toward obtaining new Agreement States. Rather, the SLR staff would provide extensive advice and assistance to any state when the state decided to pursue seriously an agreement. Price remained the SLR division director until 1971 and was succeeded by Lyall Johnson, who served as director until 1972. In the years following passage of the National Environmental Policy Act of 1969, the AEC's regulatory arm underwent a major expansion and reorganization. In 1972, SLR was abolished and an Agreements and Exports Branch (AEB) was relegated to the lowest organizational level in what was the equivalent of today's Office of Nuclear Material Safety and Safeguards (NMSS) in the NRC. The AEB carried out all state-related functions as well as export licensing.

Gene Blanc, a former Director of AEC's Region V office, was named chief of the AEB in 1972. Blanc continued in this position until late 1974, when Wayne Kerr was named chief of the AEB. Kerr recruited Joel Lubenau, Lloyd Bolling, and Kathleen Schneider, among others, into the state agreements portion of the AEB operation. These three individuals are to this day key officials in the NRC regulatory program.

In June 1976, the NRC reinvented the wheel and created the Office of State Programs (OSP) as a staff office reporting to the Executive Director for Operations. The Commission felt that the states' activities were of such importance that they should be centralized and not be buried deep in the organization, and recognized the importance of state relationships in a number of areas of common interest. The director of OSP was Robert Ryan, who was recruited from the U.S. Environmental Protection Agency. OSP consisted of three organizational components. Kerr was named Assistant Director for State Agreements and carried out the functions of the AEB minus export licensing, which was placed in the Office of International Programs. Sheldon Schwartz was named Assistant Director for State Liaison, which carried out general liaison activities with state and local governments and their organizations.

These liaison functions covered aspects related to transportation, power plant licensing and liaison with the Conference of Radiation Control Program Directors (CRCPD). Harold (Doc) Collins was named Assistant Director for Emergency Preparedness. This unit reviewed states' plans for responding to emergencies at nuclear power plants. It also arranged emergency response training for state and local government staff, primarily the Radiological Emergency Response Operations (RERO) course conducted at Las Vegas, Nevada.

The OSP organization remained unchanged until late 1979. In the aftermath of the March 1979 incident at the Three Mile Island nuclear power station at Middletown, Pennsylvania, many changes were made in the federal government's response planning for emergencies at large nuclear facilities, primarily power plants. These changes also had significant impact on state and local governments. Messrs. Ryan, Schwartz, Collins and a few others involved in emergency preparedness were detailed to the Federal Emergency Management Agency (FEMA) for several months to work in this program. The remaining NRC emergency preparedness functions were placed in the NRC's Office of Inspection and Enforcement (IE).

After serving as acting director for several months, Kerr succeeded Ryan as Director, OSP in September 1980. OSP then had two organizational components, Assistant Director for State Agreements (ADSA) and Assistant Director for State Liaison (ADSL). Kerr recruited Don Nussbaumer from NMSS to fill the ADSA slot. Nussbaumer had extensive experience in the NRC's fuel cycle and materials licensing program. Schwartz returned briefly to the ADSL position, and when he left, Kerr created a slot titled Assistant Director for State and Licensee Relations (ADSLR). The position was filled with Jerome Saltzman from the Office of Nuclear Reactor Regulation. Frank Young headed the section dealing with state relations. In addition to liaison functions, the ADSLR also was assigned the duties of administering NRC's Price-Anderson indemnity program, review of licensee financial qualifications and nuclear insurance programs.

In 1981, the NRC decided to place a state agreements officer in each region. The perceived advantage was to have these officers located geographically closer to the states they served on a daily basis and that they reviewed periodically. Presumably, they would develop a more in-depth knowledge of the states in their region. There also was a presumed saving of travel expenses, since the officers were located in the geographic area of the Agreement States in that region. State agreement officers were placed in NRC Regions I, II and IV in 1981, in Region V in 1982, and in Region III in 1987.

Kerr retired as Director, OSP in March 1987 and was succeeded by Carlton Kammerer, previously Director of NRC's Office of Congressional Affairs. OSP was renamed the State, Local and Indian Tribe Programs (SLITP), a component of a new Office of Government and Public Affairs (GPA) reporting to the Commission. GPA was headed by Harold Denton of Three Mile Island fame. Schwartz became the Deputy Director of SLITP. In late 1988, Don Nussbaumer retired as ADSA and Vandy Miller, a branch chief in NMSS, replaced Nussbaumer.

Miller took another position in the NRC in June 1993, and was replaced on an acting basis by John Surmeier. In the aftermath of the Synar hearing on Aug. 2, 1993, Kammerer was replaced as Director of OSP by Richard Bangart, formerly Director of the Division of Low-Level Waste Management and Decommissioning in NMSS. Schwartz retired in February 1994. Paul Lohaus, who served

in management positions in NMSS, and was previously an OSP staff member, became the Deputy Director, OSP. Lohaus had worked for the State of New York's coordinating office in the early 1970s.

Various organizational changes of the NRC programs concerning state relations have been noted above. However, there were other attempts to restructure the functions, some of which failed. These attempts may have reflected a poor understanding of these functions by senior NRC management and a lack of appreciation for their importance, have been used to address some perceived organizational problem, or resulted from some personality differences among officials.

The abolishment of the Division of State and Licensee Relations in 1972 appears to have been instituted to address severe personnel shortages as a result of coping with the National Environmental Policy Act (NEPA) legislation. Since the agreement state program performed some functions similar to those of NMSS, the branch was located in NMSS. However, the then Director of Regulation, L. Manning Muntzing, retained an active interest in the Agreement States. He made opening remarks at the annual joint meetings, and sometimes was present at the close when the Agreement States made recommendations to the NRC.

When the Office of State Programs (OSP) was established in June 1976, a better understanding of the importance of state relations in the framework of the NRC's total program was reflected. In addition to the state agreements program, states had significant concerns and legitimate roles in emergency preparedness for the NRC-regulated facilities, high-level waste disposal, low-level waste disposal, transportation of radioactive materials, siting of nuclear facilities, and granting water quality permits, to name a few. It is notable that the newly created Nuclear Regulatory Commission had been in place about 18 months when the decision to create OSP was made. Further, at least one of the then sitting Commissioners, Richard Kennedy, had a keen interest in the issue and was always a strong supporter of the OSP, its activities and its staff.

In June 1980, shortly before Kennedy's term expired, a fledgling attempt was made to abolish OSP and to again relocate the state agreements program in NMSS. It is not clear who instigated the proposal, but Commissioner Kennedy was incensed when he heard of the plan, which had not been sent officially to the Commission. It appears the proposal was at least partially related to the actions discussed in Section III.B. above concerning Rhode Island. The incongruity of the Rhode Island situation was shown by an NRC action in 1990. On July 30, 1990, Chairman Kenneth M. Carr sent a letter of commendation to the Honorable Edward DiPrete, Governor of Rhode Island, acknowledging the state's outstanding Agreement State Program, sustained over 10 years.¹¹ Thus, the dire predictions about Rhode Island's capability raised by NMSS in 1979 were apparently unfounded.

Even after the issue of the abortive reorganization attempt was settled in 1980, Commissioner Gilinsky expressed his belief that evaluations of each Agreement State's capabilities would be improved if a major technical line

¹¹ NRC Annual Report for 1990, p. 108.

office such as NMSS or IE supervised these activities.¹² The irony of the situation was that the then Director of NMSS (a technical line office) had a non-technical degree. When the states learned of the proposed reorganization, many wrote strongly worded letters to the NRC opposing it. They felt the functions of OSP were important enough to have some status in the organization. These letters came from Agreement State officials, state management officials, members of Congress, and from governor-appointed State Liaison Officers (SLO).¹³

Another action occurred in June 1980 when the unofficial reorganization plan surfaced. Marshall Parrott of Oregon and chairman of CRCPD, Dave Lacker of Texas and past chairman of CRCPD, and Charles Tedford of Georgia and chairman of OAS requested an opportunity to meet with the Commission. They did so, and urged the Commission not to downgrade the Office of State Programs in general and not to relocate the state agreements program to NMSS. The states felt their needs were better served by having a dedicated NRC staff to which they could turn for information and assistance. These officials also stated that they would usually come to talk to the Commission if they had problems with the agency's relations with them, but in this case they stated that things were already operating smoothly. After considering these factors, the abortive plan was not pursued. The strong position and support of the states influenced the then Executive Director for Operations for NRC, William Dircks, but the message was apparently lost on the next EDO, Victor Stello, who tried again to abolish OSP by splitting up its units.

In late 1986, the NRC again proposed to abolish OSP by locating the state agreements program in NMSS and placing the liaison section in the new Office of Government and Public Affairs (GPA) under Harold Denton. The states again became aware of the plan and wrote numerous letters to NRC opposing the plan. In this case, the NRC plan backfired and the Office of State Programs was moved to Denton's new GPA office with the functions intact except that the Price-Anderson indemnity program, financial reviews and nuclear insurance program were returned to the Office of Nuclear Reactor Regulation. The new GPA office reported to the Commission, so the result was that the Office of State Programs was elevated to a position above the EDO.

¹² Personal correspondence from Commissioner Gilinsky to G. Wayne Kerr dated July 17, 1980.

¹³ The NRC established the SLO program in 1976 based on a recommendation of the National Governors' Association. Initially, the principal purpose was to have the governor of each state designate a liaison officer to the NRC who could coordinate several state agency interests and responses. This included NRC requests for information on issues such as granting state permits for nuclear power plants and other nuclear-related issues. They did not serve as an interface on Agreement State matters. The SLOs also could serve as a contact point for the NRC on generic issues by presumably having sufficient stature to gain access to the governor, if necessary. The NRC began having periodic national or regional meetings with the SLOs. The appointees ranged from Agreement State program directors to agency heads to policy advisors in the governors' offices. Due to the lack of new power plant licensing actions in recent years, the current SLO program is more in the nature of a general information exchange.

The last major organizational change occurred in the fall of 1991 when SLITP was placed under Hugh Thompson, Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support as the Office of State Programs. The stated purpose of this move was to locate the program organizationally closer to NMSS who carried out similar functions for its licensees as did the Agreement States for their licensees. Of course, the same argument did not prevail for some of the state liaison activities, which frequently dealt with NRC offices other than NMSS. Another result was the removal of a nominal reporting relation of the Directors of Public Affairs and Congressional Affairs to Denton as head of GPA. This series of actions left Denton as managing only the Office of International Programs.

VII. Active Phase of Organization of Agreement States

The 1989 All Agreement States Meeting was held Oct. 11 - 13 in Overland Park, Kansas. The tone for this meeting started to develop at the 1988 meeting. The states had not received a response to their letter to the NRC following the 1987 all Agreement States Meeting before the 1988 meeting began. It was not until six weeks (Nov. 15, 1988) after the 1988 meeting that a response from the SLITP for the 1987 meeting was mailed to Donald Hughes, chairman of the Agreement States Committee. A quick response by the SLITP was made to the written comments made by the states at the 1988 meeting. However, of the seven comments, the response to six of these followed the pattern, "we will forward your concerns to the appropriate NRC staff and/or we will keep you advised." Because the states had not been kept advised, the agenda for the "States Only Meeting" prepared in advance of the 1989 meeting included a discussion topic entitled "1988 All Agreement States Comments with NRC Responses, Discussion of Unresolved/Ongoing Items." As a result of the discussion, the Agreement States requested in their 1989 letter updates or the current status on six of the seven items raised in 1988.

The Director of the SLITP opened the technical program with a talk titled "The Agreement States Program's Accomplishments and Challenges." This presentation was serious and low-key. In presenting the accomplishments, the tone of the presentation emphasized failures by drawing attention to the 36 state program reviews during the seven-year period of 1981 through 1988 in which the programs were found to be neither compatible nor adequate. The delivery de-emphasized the 127 reviews during the same time period when the states' programs were found adequate, including the 97 reviews when findings of adequacy and compatibility were issued. For those states where a finding of compatibility was withheld, the predominate reason was failure to adopt NRC rules within three years. Where findings of adequacy were withheld, the predominate reasons were inspection backlogs and lack of inspector adequacy.

In presenting the challenges, the periodic state program reviews would emphasize compatibility. To help address the problems of adequacy, the Office of State Programs would seek increased budget for training and use less expensive training facilities to maximize the availability of training for state personnel. The speaker then returned to the compatibility issue. In hindsight, what was probably an attempt to offer assistance to State Program Directors experiencing difficulty in promulgating rules, the speaker stated that the NRC was willing to talk to Program Directors, Office Directors,

Commissioners or the Governor to address compatibility issues. The message was received almost, if not universally, as a threat by the attendees. The speaker had misjudged his audience.

The next topic on the agenda was titled "Training and Operations Discussions." Two presentations were made concerning training and operations. The tone of the remarks by the first presenter can be conveyed best by quoting from Greta Dicus' letter to Chairman Carr dated Nov. 16, 1989. "We also take special note this year of the keynote address by Dr. John Montgomery, Deputy Administrator, NRC Region IV. His most positive remarks about the partnership type relationship which exist between the states and the U.S. NRC are consistent with our concept of how we must relate with each other." The next presentation under this agenda item was by the Assistant Director for State Agreements Program and focused on operational items. The item that received everyone's attention was a proposal for state recognition. Those states that met the "Performance Indicators for State Recognition" or accomplished some other notable action would receive a "GOLD STAR" award and see the "inspector" less often. Note: INSPECTOR, not program reviewer or agreement states officer. Needless to say, this proposal received many negative comments from the Agreement State representatives.

Before lunch on the opening day of the 1989 all Agreement States Meeting, the stage had been set for the future working relationship between the Agreement States and the NRC. The states received a threat, then a talk that they could endorse and then a condescending proposal for recognition. Confusion reigned. The states arrived at the meeting concerned that the NRC was not responsive to states' needs and issues, and before lunch were presented with proof positive that their concerns were not unfounded. This only added to the states' concerns about their relations with the NRC, prompted by individual remarks attributed to senior NRC staff. Such comments as "Don't worry about the Agreement States, they'll do what we tell them." and "This is the compatibility regulation of the year." were not conducive to a good relationship.

During the states-only meeting, the members responded to their concern about the lack of responsiveness to their letters and the "stick and carrot" message received during the opening session by directing the chairperson to address all future correspondence to the Chairman of the Commission, not directly to the Director of the Office of State Programs. The Nov. 16, 1989 letter to Chairman Carr marked the first correspondence directly to the Chairman from the Organization of Agreement States.

Frequently, NRC invited U.S. Air Force and U.S. Navy representatives to attend the Agreement State meetings. The NRC had requested to attend the OAS states-only meeting in 1989. The OAS declined this request, but did allow representatives of the Air Force and Navy to attend as observers. Even though these persons represented NRC broad licensees, one of them remarked to an ad hoc committee member that their problems with the NRC were not unlike those that the Agreement States experienced.

Although some progress had been made by the October 1990 meeting, it was not deemed totally sufficient by the Agreement States. Chairperson Dicus' letter of Dec. 7, 1990 to NRC Chairman Carr noted that a separate letter on compatibility would be forthcoming. Such a letter was sent by the next OAS Chairman, Tom Hill, on Jan. 24, 1991, presenting some detailed preliminary

thoughts on the compatibility issue and announcing the formation of an OAS Task Force on Compatibility. This action generated sufficient attention by the NRC's own interoffice compatibility task force to request a meeting with the OAS task force. Hill submitted the report of the task force to Chairman Carr by letter dated March 13, 1991. The actions of the Agreement States in 1989, 1990 and 1991 placed the issue of compatibility squarely on the NRC's plate. Absent those actions, the NRC would not likely ever have recognized the deep concerns of the Agreement States. However, one NRC manager expressed the view that Dicus' letters were not helpful! It also should be noted that the OAS Task Force on Compatibility was the first formal group ever established by the OAS to set forth consolidated views on a subject.

At the Commission's request, the Executive Committee met with the Commission in the summer of 1991. The OAS representatives generally discussed the issue of compatibility and other aspects of OAS/NRC mutual relations. The Executive Committee, together with representatives of four other Agreement States, met with the Commission in January 1993. This discussion focused primarily on medical issues, since this meeting followed shortly after the articles that appeared in the *Cleveland Plain Dealer* in December 1992. The chairman of the OAS met with the Commission on Feb. 8, 1994, in what is now planned to be an annual briefing.

The chairman of the OAS represented the Executive Committee of the OAS and the Executive Board of the Conference of Radiation Control Program Directors at the Aug. 2, 1993 hearing on the Agreement State program convened by the Subcommittee on Environment, Energy and Natural Resources of the House Committee on Government Operations. This hearing was at least in part a result of the GAO report on the program that was released in April 1993.

It appears the OAS will continue to be actively involved in developing issues concerning the regulation of agreement materials. The chairperson has, at various times, been asked to speak at such meetings as those of the American Society for Non-Destructive Testing and to participate in the NRC's residual radioactivity rulemaking public meetings.

VIII. Perspectives on Selected Technical Issues

The ad hoc committee felt there were a number of areas regulated by the NRC and Agreement States that have been of concern for many years. Most continue to this day to be frequent topics of discussion among the NRC and the Agreement States, and with their respective licensees in many cases. Therefore, it was deemed appropriate to include some historical and regulatory perspective on six technical subjects.

A. Regulation of Medical Uses of Radioactive Material

The regulation of medical uses of radioactive material in the 1960s, when the Agreement State program began, was drastically different than the program in 1994. This section will focus heavily on the activities of the Agreement States (and sometimes with AEC/NRC input) in this area, particularly as the program has developed through the CRCPD's Committees on Suggested State Regulations For Control of Radiation (SSRCR).

The AEC/NRC regulated these uses from 1946 forward. At one time or another, the AEC program covered nearly every aspect of nuclear medicine, including efficacy determinations as well as radiation safety considerations. These broad aspects, particularly efficacy determinations, occurred between 1962 and 1975. During those years, the FDA exempted radiopharmaceuticals regulated by the AEC and Agreement States from the FDA's requirements for new drugs.

In 1975, the FDA withdrew that exemption for radiopharmaceuticals and the NRC withdrew from regulating drug safety and efficacy. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended the FDA's authority to medical devices containing radioactive material. Prior to the FDA withdrawal, however, the AEC and Agreement States evaluated proposals for investigational new drugs with the assistance of their respective Medical Advisory Committees. Such investigative and research proposals were supported by protocols describing the proposed studies that were evaluated by these committees. Physician's training and experience also were evaluated by the committees. When enough data was accumulated to establish the efficacy of a new drug, the AEC Advisory Committee approved it for routine use, and this list of approved uses was furnished to the Agreement States for their guidance (known as the routine use list).

On Feb. 9, 1979, the NRC published a statement of general policy on the regulation of medical uses of radioisotopes (44 FR 8242). It established the NRC's role of principally regulating radiation safety aspects, minimization of intrusion into judgements affecting the practice of medicine, and regulating the safety of patients only in limited circumstances. This statement of policy remains in place today; however, the NRC is undertaking a major review of the regulation of medical uses in the aftermath of the serious incident at the Indiana Regional Cancer Center in Indiana, Pennsylvania in November 1992, a series of articles in the *Cleveland Plain Dealer* in late 1992, and a hearing by the Senate Committee on Governmental Affairs in May 1993. A significant step in this review is a two-year study being performed by the National Academy of Sciences covering such issues as risk, policy guidance and institutional relations.

Earliest records relating to the development of SSRCR on medical use reference a meeting held in Kansas City in May 1977 in which the new Part "L" Committee, chaired by Gerald Allen of Kansas, was to look at the need for drafting regulations for nuclear medicine. The task force reviewed notes of a recent meeting of the Part "K" Task Force (on radiopharmaceuticals) and a public hearing held by the NRC on May 6, 1977 in Silver Spring, Maryland. Most of the time was spent reviewing existing regulations such as the Medical Device Amendments of 1976, those of the FDA and the NRC, and the Joint Commission on Accreditation of Hospitals. Allen was to make a report on behalf of the committee at the annual CRCPD meeting in Seattle. Members of the committee were Donald Hamilton, BRH; Goldie Watkins, New York; Steve Collins, then of Louisiana; and Gerald Allen, Kansas.

In March 1978 another meeting of the committee was held in Kansas City. In addition to those listed above, Dan Hightower, D.V.M., and Gerald Johnson, D.V.M., were in attendance, and the discussion centered on the use of radiopharmaceuticals in veterinary medicine. The committee concluded that the "use of radiopharmaceuticals in veterinary medicine was not well enough understood

to deal with effectively." The committee decided to produce a draft of Part L, nuclear medicine, for the SSRCRs.

The committee met in Harrisburg, Pennsylvania at the 1978 annual meeting of the CRCPD. At this meeting Collins provided a first draft to which Watkins, Hamilton, Collins and Allen made minor suggestions and created a new draft. At this meeting Watkins asked to be removed from the committee so that she could concentrate on newly added responsibilities as Chairperson of Task Force II, "Public Health Impact of Nuclear Medicine." In 1979 a revised draft of Part L with accompanying rationale was sent to a selected group of individuals for preliminary review and comment.

While this work was being done by the CRCPD committee, a move was underway by the NRC to incorporate the vast number of license conditions and regulatory guide requirements placed on nuclear medicine licenses into the regulations. The thought was that if the conditions and guides had the effect of being rules, they should be codified. In the early 1980s, the NRC proposed to revise 10 CFR 35. With the understanding that the NRC's revision of Part 35 would substantially change existing rules for nuclear medicine, the work of the Part L committee was put on hold pending further action by the NRC.

The states had expressed a desire to be a party to the early rulemaking process and were invited by the NRC to be early participants. At the 1984 meeting of the Agreement States, an ad hoc committee was appointed to review the proposed changes to Part 35. The committee was chaired by Mary Lou Blazek of Oregon with Carol Connell of Georgia and Kirk Whatley of Alabama (new Chairman of the CRCPD Part L committee) as members.

The CRCPD also appointed an ad hoc committee to review the changes to Part 35. This committee was chaired by Blazek and included the other members of the Agreement States committee. This committee was not the same as the Part L committee.

At the 1984 Agreement State meeting, the state representatives discussed the possibility of writing nuclear medicine rules for states and not waiting on the NRC. However, no request was made to the Part L committee to proceed. The chairman of the Part L committee requested clarification from the CRCPD Chairman, Chuck Tedford of Arizona, and was advised to proceed with continuing the development of nuclear medicine rules for the SSRCRs.

With its charge clarified, the Part L committee met in Milwaukee during the annual CRCPD meeting in May 1985 to discuss the charge to the committee and to make plans for writing nuclear medicine rules for the SSRCRs. Mary Lou Blazek, Paul Eastvold of Illinois, Steve Collins, Kathy Schneider (NRC, standing in for Lloyd Bolling of the NRC), and Kirk Whatley attended this meeting. The committee agreed to use the latest revision to 10 CFR 35 as a basis from which to proceed. Kathy Schneider volunteered to put the NRC version into the SSRCR standard format for review by the committee. The Part L committee was invited to an NRC briefing on the plans for the revision to 10 CFR 35. The proposed changes were drastically different from what the State representatives had envisioned.

A Federal Register Notice stated that since the field of nuclear medicine had become so stable and because few significant changes were expected to take

place over several years, basically all regulatory control should be removed. The NRC proposed that all nuclear medicine should be generally licensed. The

concept was that a nuclear medicine applicant would use a check-off form stating that requirements were understood and that the applicant met requirements for the use of radioactive material. The applicant also was to use a check-off sheet as proof of training, both for diagnostic and therapeutic uses.

Instead of experienced NRC license reviewers performing reviews of applications, the applications would be checked by clerical staff to assure that all items of the forms had been addressed. If the forms were complete the clerical staff would type out the "standard license" on the spot. No procedures were to be submitted. No documentation of training was to be submitted. No review was to be made. Such a system would avoid delays in processing applications and the time in which a license could be written, which at times was substantial since the NRC's medical licensing staff consisted of two individuals. The members of the Part L committee and the ad hoc committee members expressed their concern and disagreement with this radical departure from current licensing practices. Many representatives of the states expressed disagreement with the NRC's proposed changes.

The NRC held a hearing on the subject of the nuclear medicine rule changes and invited representatives of the states to offer comments before the Commission. William Spell of Louisiana addressed the concerns and objections of the states.

One needs to understand the intensity of the debate that occurred on this matter. Many states were strongly opposed to the concept and openly expressed those concerns. Many of the NRC employees also were extremely opposed to the concept. In fact, the NRC's entire nuclear medicine licensing staff took annual leave to appear before the Commission in opposition to the concept. Over a period of time, and in face of the opposition, a new approach to licensing nuclear medicine was developed by the NRC.

The NRC's next proposal was to continue basically the licensing process as it had been done in the past except that the applicant would not have to submit any written radiation safety procedures for review with the application. The idea was that the applicant was capable of, and would in fact, develop written procedures and that the procedures would be adequate. Instead of reviewing the procedures during the licensing review, the procedures would be reviewed during inspections. The licensee also would have the flexibility to change the procedures without review or concurrence by the NRC prior to implementing the changes.

Again, many states expressed disagreement and concern over this new concept. Concern was again expressed by the NRC staff. The NRC's Region III Administrator wrote on March 11, 1986, "we do wish to point out that your statement, 'with the exception of the Agreement States, the flexibility provision was widely endorsed', is not totally accurate. We still prefer that the regulation not permit medical programs the freedom of modifying their procedures, since some of them may not have the ability to perform the required internal review and approval process."

The NRC's Region I Administrator expressed concern over another change by stating, "We believe that the final revision to 10 CFR 35 represents a major policy change regarding the level of supervision to be exercised by the authorized user. We are concerned that the lack of specificity regarding the expected duties of the supervisory physician makes enforcement of the authorized user condition meaningless if not impossible."

Reverting back in time for a moment, the phrase, "radioactive material shall be used by (named physician)", had been interpreted by NRC, in writing, to mean the following:

The licensed nuclear medicine physician (named on the license) must:

1. Select each patient to receive radioactive material by either examining the patient himself/herself; reviewing the patient's chart; or consulting with the referring physician,
2. Prescribe the isotope and dose to be administered and
3. Interpret the results of the study.

These responsibilities could not be delegated to other physicians who were not licensed to practice nuclear medicine. This concept was changed to permit any physician to order diagnostic nuclear medicine procedures on patients and to enable any physician to interpret the results of the studies. Questions were raised regarding the necessity of diagnostic nuclear medicine training requirements if any physician (with no nuclear medicine training) could select patients and interpret results of studies. Despite several letters of concern, Part 35 was published without specifically requiring the authorized user to interpret the results of the study.

This led to even greater confusion regarding who is allowed to interpret results. A March 30, 1990 letter to all Agreement States (SP-90-63) stated that "The interpretation of patient images or data is considered to be within the practice of medicine and outside the scope of NRC regulations." Almost exactly one year later, a March 1, 1991 letter to all Agreement States (SP-91-28) stated that "it is the licensee's responsibility to ensure that at least one interpretation of nuclear medicine scans is performed by an authorized user or a physician under the supervision of an authorized user" and failure to do so might result in a violation of 10 CFR 35.13(a) for failure to supervise and 10 CFR 35.13(b) for use of radioactive material by an unauthorized individual.

The concept of revising 10 CFR 35 was supported by the Agreement States and the NRC staff from the standpoint of incorporating license conditions and regulatory guides into the rules. Differences of opinion that created heated opposition were raised over proposed significant changes to the licensing process that had evolved over the years.

During the development of revisions to 10 CFR 35, the CRCPD Part L committee expanded its efforts in reviewing and commenting on the proposed changes and attempting to keep the Agreement States apprised of significant new proposals and problems. The membership of the committee changed as Blazek and Connell changed jobs. Paul Eastvold and Terry Frazee, Washington, were

added as members. Steve Collins (now from Illinois) also provided much assistance to the committee. The work and effort of Lloyd Bolling of the NRC was especially helpful.

The NRC's newly revised 10 CFR 35 was published in the *Federal Register* on Thursday, Oct. 16, 1986, with an effective date of April 1, 1987. The final version, although not totally endorsed by the Part L committee, was one that significantly improved the old Part 35 and could be used by the states with minor revisions.

In early 1987 the Executive Board of the Conference combined the SSRCR Committees for Part "G" (Use of Sealed Radioactive Sources in the Healing Arts) and Part "L" (Nuclear Medicine). The resulting SSRCR "G/L" Committee prepared a "new" Part "G" based on the final 10 CFR 35 rule. The new Part "G" was sent to the Technical Review Committee of the Conference, which required many style changes. Due to the lack of a "style manual" for the SSRCRs, Part "G" had been drafted using one of several styles found in the SSRCR at the time.

In March 1988 the final draft Part "G" was sent to the states for review, and in August 1989 was sent for federal concurrence. Additional changes were required to gain NRC concurrence, but the new Part "G" was ready in early 1990 for Executive Board approval and was issued in the 8th Edition of the SSRCR.

In the meantime, the SSRCR "G/L" Committee became known as the SSR Group 6, "Use of Radioactive Material in the Healing Arts" (SR-6). In January 1990, Terry Frazee assumed the role of chair of SR-6. It was also at this time that the first non-state regulator became an advisor to the committee. A number of the new associate members of CRCPD became advisors in the ensuing years, bringing with them the perspective of the regulated community. Their insight into such issues as the ACNP/SNM petition, the NRC basic quality assurance program, and use of Positron Emission Tomography (PET) helped move SR-6 toward favoring less prescriptive regulation.

The NRC proposed changes to Part 35 that included misadministration reporting and a requirement that licensees develop and submit a Quality Management Plan (QMP). The purpose of the QMP was to reduce the number of errors in administration of radiopharmaceuticals, although medical professionals argued that the rate of error was already quite low, considering the number of administrations performed each year. A QMP development timeline is shown in Table 1.

The SR-6 committee generally believed that the NRC's basic quality assurance program would most likely fail to attain the NRC's goal of preventing errors, since most misadministrations seemed to be caused by "human error" rather than a system problem. However, members of SR-6 were actively involved in the NRC's series of workshops involving Agreement States and the public in 1990 and 1991 from which emerged the renamed Quality Management program. At the end of the Quality Management Workshop in San Mateo, California in February 1991, the Agreement State representatives, including several SR-6 members, advised NRC: **1)** to republish the quality management rule because of the substantial changes that had occurred since the public and regulated community had last seen it; **2)** to not make the quality management rule a matter of compatibility since it dealt heavily with the practice of medicine, a state's right to regulate; and **3)** if compatibility had to be addressed, to

place the rule in Division 3 to allow the states to develop, or in some cases to continue using, alternative paths to achieve the same goal.

Table 1. Quality Management Program Timeline

Dec. 1989	Draft Regulatory Guide, "Basic Quality Assurance Program for Medical Use."
Jan. 16, 1990	Proposed rule published in <u>Federal Register</u> .
Jan. 1990	Letters sent from Brookhaven National Laboratory to licensees requesting participation in Pilot Program.
March 14, 1990	NRC held public workshop.
July 23, 1990	NRC workshop with ACNP and SNM to compare QMP and JCAHO standards.
Dec. 18-19, 1990	NRC held public workshop (Irving, TX).
Feb. 7-8, 1991	NRC held public workshop (San Mateo, CA).
July 25, 1991	Final rule published in <u>Federal Register</u> , with an effective date of January 27, 1992.
Oct. 19, 1991	Reg. Guide 8.33 "Quality Management Program"
Jan. 25, 1992	Letter from James B. MacRae, Jr., OMB's Acting Administrator for the Office of Information and Regulatory Affairs to James Taylor, NRC's EDO, questioning NRC's need for the QM rule and its burden on licensees.
Jan. 27, 1992	QMP rule effective.
Feb. 5, 1992	ACNP and SNM filed a brief in their lawsuit against NRC which challenges the medical quality management rule.
May 12, 1992	Oral arguments in lawsuit.
June 26, 1992	OMB informed NRC that OMB was disapproving the information collection request for the QMP rule. This meant NRC could not enforce the information collection requirements of the rule (including reporting of misadministrations) after this date. However, licensees would still be required to collect and report for the period of time Jan. 27 - June 26, 1992.
Aug. 14, 1992	NRC Commissioners override OMB. This keeps the rule effective for three years. AAS letter (SP-92-136) indicates that "if the Commission finds this rule, in whole or in part, to be overly burdensome or ineffective, it will consider modifying or deleting portions of the rule."
Jan. 21, 1994	Compatibility deadline (as per SP-92-136).
Jan. 25, 1995	Compatibility deadline (as per Fed. Reg. Vol. 56, No. 143, p. 34118).

The SR-6 committee met in May 1991 at the Wichita, Kansas annual meeting of the CRCPD. Major topics of discussion were NRC's quality management rule and changes in the misadministration rule, the use of PET and the need to coordinate with SR-3 in evaluating the regulation of PET. Because of a short comment period for the NRC's proposed changes to the misadministration rule, the committee prepared comments and submitted them on CRCPD letterhead while at the annual meeting. This led to the development of committee letterhead for all committees and a procedure for gaining approval of the Executive Board for any use of the CRCPD letterhead.

In September 1991, SR-6 held a joint meeting with SR-3 in Tampa, Florida. The meeting was developed around a visit to an operating PET facility and a public hearing designed to educate committee members on all aspects of PET. SR-6 members gained a greater appreciation for the similarities to conventional nuclear medicine, and appropriate changes to Part "G" were drafted. As a side note, interest on the part of the regulated community was kindled in the CRCPD which resulted in many new associate members.

The next meeting of SR-6 was in Orlando, Florida in May 1992 when more changes to Part "G" were proposed. The patient release criteria, dose calibrator requirements, "moly breakthrough" frequency and other requirements were modified to reflect more of a performance (and less of a prescriptive) requirement. Also, the training and experience requirements for authorized users were evaluated in light of the states' role in regulating the practice of medicine. It was felt that the radiation control programs should regulate the handling of radioactive material and leave judgements concerning who is qualified to select patients and interpret results to the states' board of medicine and the professional associations. The committee also discussed the emerging issue of the NRC regulation of nuclear pharmacies. In July 1992 several members of SR-6 attended the NRC's Workshop on Medical Issues in Atlanta, Georgia, where nuclear pharmacy, doses to the public, and patient release criteria were discussed.

The latest draft revision of Part "G", covering PET, authorized user qualifications, the misadministration rule change and quality management was sent for peer review in October 1992. The Regulation Oversight Committee (ROC) received the updated version in April 1993. Delays in the ROC review helped prompt a change to the SSRCR review process. At one point the quality management rule was removed from the proposed revision because of the belief that a lawsuit against it and political pressure would negate the rule, and the committee did not want to put something in place only to have to remove it. In early 1994, the Executive Board specifically asked for the quality management rule to be included so that model regulations would be in place by the NRC's compatibility deadline. The proposed revision of Part "G" was sent to all radiation control programs in April 1994.

In recent years, SR-6 has been of the opinion that some NRC requirements intrude upon the practice of medicine, and this usurps the states' right and primary responsibility to regulate the public health and welfare. The committee believes the concept behind many of these requirements may have some validity, but the actual rules tend to be too prescriptive. In effect, prescriptive rules remove a sense of responsibility from the regulated community as well as restrict innovation. The committee believes performance-based rules make the licensee think through procedures and actions, and

makes both licensee and regulator operate on health physics rather than "bureaucratic" principles.

It appears that issues relating to medical uses will continue to require significant attention for the foreseeable future, particularly in view of actions being taken by the NRC as discussed previously in this section.

In light of the 1992 and 1993 events, one might consider how the NRC would view the medical situation today if the earlier proposal to generally license most medical uses had gone into effect. It appears the work of the states and some NRC staff had a salutary effect on this process.

B. Regulation of Industrial Radiography

Industrial radiography, a subset of non-destructive testing (NDT), has been performed for many years. In fact, early experimenters with x-ray radiographed persons' hands and other body parts and could arguably have been performing non-destructive testing.

Industrial radiography utilizing x-ray and sealed radium sources has been performed since the 1930s, but sealed sources of by-product material have been used commercially since shortly after passage of the Atomic Energy Act of 1954, when the AEC released by-product radionuclides for civilian use. Early methods of use would be considered somewhat primitive by today's standards. The "fishpole" technique is probably as rare today as some of the flying reptiles of days past. However, the persons who perform these tasks under less than ideal conditions have not changed drastically.

This industry has experienced a significant number of serious overexposures, frequently to the extremities of the individual doing the work. The first industrial radiography training manuals were produced in the late 1950s by a professor at Louisiana State University under contract with the AEC. This manual covered not only radiation safety but also the methods of performing industrial radiography. Many state and federal personnel have been trained utilizing these manuals. In 1982, the NRC produced a safety manual for gamma radiography, NUREG/BR-0024, which contained graphic pictures of the effects of large radiation doses to the fingers and hands and other parts of the body. This book is widely used in training courses around the nation and helps document what has happened, as well as to demonstrate what can happen if safety procedures are not followed. It is significant to note that considerable expertise exists in the states to evaluate these types of exposure, especially in the major oil and gas producing states where radiography is widely utilized. In addition, the Oak Ridge REAC/TS facility is available to assist in assessing the medical impacts to accident victims.

Horror stories of unsafe practices and attempts (usually successful) to thwart regulations abound. However, regulators persisted in attempting to make the practice safer, and several innovative methods and modifications to equipment to make devices "fail-safe" have come about over the years. Some of the regulators' experience with industrial radiography have spilled over into other areas and can be readily identified, e.g., certification of industrial radiographers, oil and gas well-logging regulations, and National Voluntary Laboratory Accreditation Program (NVLAP) approval for personnel dosimetry. These initiatives had their origins, at least in part, with the Agreement States, sometimes with the support of federal regulators.

In addition to relatively few fixed location devices around the country for industrial radiography, most devices are self-contained and portable, leading to problems unique to this type of NDT. Large quantities of very penetrating sources of radiation are generally used in relatively lightweight, shielded devices. The shielding itself has improved over the years, changing from lead shielding to depleted uranium shielding. This allowed more portability of devices containing radiation sources with higher activities. More source strength equated to shorter exposure time, which equated to increased production and (possibly) greater profits. Hence, the pressure to do the job quickly.

Of note in this regard is the variety of working conditions in which most industrial radiography is practiced, from the swamps of south Louisiana and Texas and backwoods in other locations, to offshore oil and gas exploration platforms and so-called "lay barges" in the Gulf of Mexico where pipelines are being placed on the floor of the Gulf. At the height of oil and gas exploration, radiographers were often required to work long hours in very unfavorable conditions consisting of bad weather, mud, and cold in the wintertime. Offshore, problems of close working quarters, high winds, choppy seas, and transfer from one location to another by personnel baskets or knotted ropes occasionally resulted in mishaps, including the accidental loss of equipment into deep water with little hope of being retrieved. In addition, in the early days, because of labor-management disputes, equipment was deliberately thrown overboard. Fortunately, this usually resulted in little or no danger to anyone, now or in the future.

Working conditions on lay barges, where both x-ray and sealed source radiography are performed, were a bit better as far as creature comforts were concerned, but the close quarters and proximity of sleeping quarters to the radiography stations raised questions of potential excessive exposure to personnel. In the late 1960s to early 1970s, Louisiana conducted a study of several lay barges and made recommendations regarding the addition of shielding to increase the protection of workers. In addition, this pointed up the need for close coordination in a program for the two modalities of NDT which are used.

Over the years, efforts to improve the safety of radiographic operations have revolved around safer devices, better training, adherence to regulations, and insistence on the proper use of survey meters. Virtually every investigation of an industrial radiography incident has led to the inescapable conclusion that if an operable survey meter had been properly used, there would have been no accidental over-exposure.

Since it was obvious that without more extensive enforcement, proper use of survey meters by everyone was not going to be accomplished in the regulators' lifetimes, efforts to improve the safety of radiography also included improvements in personnel training and the design of so-called "fail-safe" devices. Whether or not such a device can ever be designed is a matter only time can tell. No true fail-safe equipment exists today. The proper use of the survey meter remains the most reliable device. It may be that the quality of radiographic personnel is slowly improving to the point where accidents will be reduced significantly.

In the beginning, when AEC licenses were converted to agreement state licenses, it became apparent that there were too many in-house training

courses, especially in smaller companies. Some states rescinded the authorization and required observation by state inspectors of those which were continued.

Regarding personnel improvements, Louisiana noticed that most of the radiation accidents which occurred at temporary jobsites in industrial radiography involved persons who were not trained to be radiographers but who were either "assistant radiographers" or "helpers," the latter having even less training than assistant radiographers. In 1980, Louisiana began to require that two radiographers be present at a temporary jobsite and that only radiographers with several years of experience and a good safety record be allowed to train others to become radiographers. This helped to assure that only fully trained persons actually made radiographic exposures at temporary jobsites. A requirement for two qualified workers at temporary jobsites is currently proposed by the NRC for the first time. In addition, training courses were monitored by the state's regulators, and only certain individuals who demonstrated competence were allowed to train others. These were included as license conditions and formalized in regulations. Some states have followed suit, and a number of others are considering it. Additional training for radiographer assistants is now included in the NRC's proposed rules.

Improvements in survey meters and personnel monitoring have also followed. Survey meters have become more rugged and more accurate, as well as smaller, and they may now include alarms. Personnel monitoring is almost exclusively of the thermoluminescent variety instead of the early film badges.

One problem observed by the states was that one never knew if the exposure reported by the personnel dosimetry supplier was accurate. In fact, two badges from different companies, worn in the same location on several radiographers in Louisiana, were observed to differ in exposure by as much as an order of magnitude! Other states, including Montana (a non-Agreement State), had similar concerns. This finding was reported at a workshop at an annual meeting of the Conference of Radiation Control Program Directors in the early 1970s and a task force was formed to study the problem and make recommendations. The ultimate outcome was the NVLAP certification program many years later and ultimate adoption of regulations requiring the use of NVLAP-certified suppliers.

Another spin-off of industrial radiography which was initiated by the states was the development of regulations for the well-logging industry. In the mid-1960s, Louisiana worked out abandonment procedures for well-logging sources lodged down-hole. This included instructions for sealing the source in place, placarding the wellhead, and notifying the state oil and gas regulatory agency.

In addition, NRC and the states sought to regulate well-logging much the same as industrial radiography. With the seemingly bad reputation of industrial radiography haunting the well-logging industry, they felt that regulations pertinent to their industry were needed. The states agreed, and representatives from Texas and Louisiana met in Austin. They took those parts of the industrial radiography regulations which were felt to be generic enough to warrant retention, added some regulations which were specific to the well-logging industry, and presented the package to the industry. After a year or two of discussion with several state representatives, several federal agencies, and industry representatives, the regulations became part of the

Suggested State Regulations for the Control of Radiation. Later, the NRC adopted most of these regulations with a few minor changes.

In the late 1960s, Louisiana attempted to gain support for the establishment of a testing program for industrial radiographers by proposing such a program at an Agreement States meeting. The concepts advanced included individual responsibility and regulation of radiographers, a nationwide registry of qualified radiographers, and a method of verifying training of such individuals. This did not materialize until many years later. Again, in the mid-1970s, the Louisiana program took a close look at the regulations for industrial radiography to evaluate the need for change. Meetings between Texas and Louisiana were held to discuss possible changes to the radiography regulations. In the late 1970s, Louisiana promulgated regulations which, among other things, removed the assistant radiographer classification, required two-man crews at temporary jobsites, and gave the program the authority to begin testing radiographers. Small companies that wanted to provide in-house training were authorized by a license condition in which a specific instructor was named, and if that instructor left the company, the authorization was no longer valid. A representative of Louisiana's program attended the training courses to evaluate the training program before issuing an amendment to the license.

The Louisiana program began testing radiographers on a limited basis in 1980 but soon learned that it was difficult to develop an adequate test and began to encourage the NRC to help in this area. In the early 1980s, the NRC provided funds to the State of Texas to develop a test which could be used by other states.

The idea of nationwide testing of industrial radiographers did not gain widespread support until the 1980s, when the state of Texas developed an extensive bank of test questions to administer to prospective industrial radiographers. The effort received support and funding from the NRC. Later, NRC expanded this third-party independent testing to a certification concept. Since the state of Texas wanted to ensure that the test was not compromised by having copies getting out of their control, the Conference of Radiation Control Program Directors, Inc., now brokers the test to other states for the state of Texas. It has gained widespread support as a mechanism to assure adequate formal safety training in the industry. Prior to this time, the only nationwide testing program was administered by the American Society for Non-Destructive Testing (ASNT). This resulted in confusion, since an individual had to be a "radiographer" before he or she could apply for certification by ASNT. States deemed it inadequate for their needs, since the ASNT Level I, II, and III certifications focused on competency to do the job, not radiation safety. Now, ASNT offers the Texas examination in their safety certification programs.

In addition to changes in regulations, the Louisiana program made industrial radiography field inspections the number one priority and began inspecting radiography companies several times a year in the field, in addition to an annual office inspection. In fact, an effort was made to inspect every company once a quarter and every field crew at least once a year. This type of concentrated effort is difficult to sustain. In addition, Agreement State personnel, most notably from Louisiana and Texas, have participated in many industry and NRC-sponsored safety seminars and training courses.

Louisiana began tracking reported overexposures in the 1970s but did not keep a computerized database until 1990. Other states may be doing the same, but the experience in Louisiana has shown a steady and significant decrease in overexposures in industrial radiography. Reported overexposures in Louisiana have declined from 17 in 1990 to 11 in 1993. Equipment has not changed significantly during the period (e.g., no alarming rate meters, automatic locking devices, etc.).

The apparent improvement in safety is due, in part, to: clients having more concern for quality in every area (including safety) since quality produces more acceptable results; greater concern on the part of managers and firms that the job be done right; client companies insisting that radiographers working at their facilities have as much safety training as is feasible; and regulators cracking down on training requirements by issuing civil penalties for the use of unqualified radiographic personnel. In the late 1970s, the State of Louisiana assessed its first civil penalty in the amount of \$5,000 to a company for using an unqualified radiographer. It was later reduced to \$2,500, but it did succeed in attracting the attention of the radiography community.

Another contributing factor may be that there has been a slump in oil and gas exploration in recent years, providing these firms an opportunity to retain only the better employees. Some think that the largest contributing factor is that radiographers appear to be taking more responsibility for their own actions. The impetus for this is being provided by movement toward certification cards, diligent inspection efforts, stiffer enforcement by regulatory agencies, and an increasing potential for the employee to be individually cited for violations and, perhaps, even fined.

There appears to be evidence, nationwide, that the number of excessive exposures to operating personnel has, indeed, decreased over the past few years. It is probably impossible to identify a single reason for this trend, but most likely, it is due to a combination of all of the above efforts being made on the part of many individuals, firms, and agencies.

To a casual observer, it would appear that state efforts have largely concentrated on improvements in training radiography personnel, improvements in regulations, more inspections, and proper use of survey meters, whereas the NRC efforts seem to be more concentrated on equipment design and performance, including fail-safe devices, alarming rate meters, improved connectors (based on requirements developed by Texas in the mid 1980s), etc. The incorporation of an American National Standards Institute (ANSI) standard into the NRC's 10 CFR 34 has resulted in the most significant change regarding equipment design and performance. The cognizant ANSI committee consists mainly of industry representatives from Agreement States.

The above is not to say that either group has excluded other efforts, however. The result has been a noticeable improvement in the radiography industry over the years, although it is doubtful that such improvements will ever completely preclude the type of excessive exposures that seem to plague the radiography industry, but this should not hinder further efforts for improvement.

C. Generally Licensed Devices

General licenses are those licenses issued to an identifiable group of persons for the use of radioactive material that does not require a specific license, yet the use is not exempt from regulatory control. Specifically, the degree of regulatory control is between that required of a specific license and an exemption. Some general licensees are typically identified by the device manufacturer providing regulatory agencies with the names of persons to whom they have shipped the device. General licensees are not authorized to manufacture, distribute or repair devices or products. The actual general license (GL) is incorporated into the regulations, and everyone in the identified group has the "general license." The degree of regulatory control varies with each GL, and any restrictive conditions are contained in the regulation for that GL. It is important to note that a general licensee can be inspected and, if in non-compliance, is subject to all of the enforcement actions applicable to a specific licensee. The following sections identify each GL currently in effect as a federal regulation and by Agreement States with equivalent regulations.

1. 10 CFR 31.3. Certain Devices and Equipment

This general license authorizes the use of static elimination devices and ion-generating tubes. The GL limits the use to those devices and tubes which are specifically manufactured for this GL. The GL is extended to anyone who uses such devices. The general licensee may not transfer the radioactive material to persons exempt, must maintain labels, must confine use to the manufacturer's instructions, must file incident reports and transfers must be to a specific licensee or to a general licensee. Possession is limited to 500 microcuries of polonium-210 per static eliminator device or ion-generator tube, and 50 millicuries of hydrogen-3 per ion-generator tube. North Carolina feels there are some problems with this GL, since the identity of users is not known automatically.

2. 10 CFR 31.5. Certain Measuring, Gauging or Controlling Devices

The original version of this GL was implemented by the AEC in the early 1960s. This general license is currently the one most utilized. The devices may be used by commercial and industrial firms, research, educational and medical institutions, individuals in the conduct of their business and agencies at all levels of government. The GL does not limit the amount of radioactive material that may be in a device. The quantity and isotope of radioactive material is limited by the specific manufacturing license. Devices have been licensed for up to four curies of cesium-137 and 20 curies of tritium. The GL requires the user to follow the labeled instructions and the manufacturer's instructions. Leak tests are required for non-gas sources as well as off-on tests, if such is a part of the device. Transfer may be only to a specific licensee, or if in a fixed facility, to a successor facility owner. Disposal is through a specific licensee unless sufficient decay has occurred. The manufacturer/distributor is required to report the transfer of all devices quarterly to all regulators. Some Agreement States also require the general licensee to report the receipt of such devices within 10 to 30 days of receipt. Records of receipt, transfer, area surveys and incidents are required. All labels must be maintained in legible condition.

The state of North Carolina always has had an active program for 31.5 type devices. If the devices are authorized to be possessed under the states' equivalent general license, the licensee may choose to possess them under an existing specific license, but all the conditions of that specific license apply to the GL devices. If this option is chosen, the licensee is inspected at the same frequency as the rest of the license requires. Licensees possessing devices under the GL are inspected at four-year intervals unless they have a large number of devices (about 25), when they are inspected at three-year intervals. The North Carolina system involves billing the general licensee for a fee on an annual basis, thereby aiding in the accountability of the devices. Many other Agreement States also charge fees.

3. 10 CFR 31.6. General License to Install Devices Generally Licensed in § 31.5

As an administrative convenience, this GL allows one regulatory jurisdiction to recognize a licensing document of another like jurisdiction for specific uses. The recognized uses are to install devices authorized by § 31.5.

4. 10 CFR 31.7. Luminous Safety Devices for Use in Aircraft

Aircraft pass through many regulatory jurisdictions, and as an administrative convenience as well as for safety considerations, a GL is the effective way to control the use of these devices. This GL authorizes the possession and use of luminous "EXIT" signs on aircraft. As with all other GLs, the devices must be manufactured pursuant to a specific license. The maximum authorization limits under this GL are 10 curies of hydrogen-3 and 300 millicuries of promethium-147 per device. The general licensee is to report incidents and maintain the records specified for the GL in § 31.4.

5. 10 CFR 31.8. Americium 241 in the Form of Calibration Reference Sources

Anyone who has a specific license is expected to perform calibration of radiation detectors or to standardize other sources. This GL automatically provides for such sources without an additional application. This GL is available only to specific license holders. The GL is limited to five microcuries of americium-241. The states have added radium-226 to this GL.

6. 10 CFR 31.9. General License to Own Byproduct (Radioactive)¹⁴ Material

This GL allows anyone to own byproduct (radioactive) material. It does not authorize manufacture, receipt, transfer, production, possession, use, import or export of radioactive material.

7. 10 CFR 31.10. General License for Strontium-90 in Ice Detection Devices

This GL is for anyone to possess, use, receive or transfer ice detectors containing strontium 90. The maximum amount of radioactive material allowed is 50 microcuries per device. Retention of labels and reporting of incidents are the requirements for this GL.

¹⁴ The word 'radioactive' is included here since Agreement States apply this GL to all radioactive material.

8. 10 CFR 31.11. General License for Use of Byproduct (Radioactive) Material
for Certain In-Vitro Clinical or Laboratory Testing

Any physician, veterinarian, hospital or clinical laboratory may use iodine-131, iodine-125, carbon-14, hydrogen-3, iron-59, selenium-75, and mock iodine-125 for clinical testing. The GL requires registration with the regulatory agency and limits the total possession to 200 microcuries. Further, pursuant to the GL, the material must be stored in the original shipping packages or their equivalent, and all transfers must be in unopened containers to a specific licensee or someone authorized to utilize this GL.

9. **NOTE:** 10 CFR 40.13. is an exemption even though it has regulatory requirements. The requirements generally relate to concentrations of source material in various products or the type of product in which it is contained.

10. 10 CFR 40.21. General License to Receive Title to Source or Byproduct
Material

See 10 CFR 31.9 above.

11. 10 CFR 40.22. Small Quantities of Source Material

This general license is issued to the same persons as listed in 10 CFR 31.5. above. It authorizes 15 pounds of source material to be transferred at a time to the general licensee with not more than 150 pounds to be transferred in a year. The GL does not permit the use of the source material on or in humans. There are no reporting requirements for this GL.

12. 10 CFR 40.23. General License for Carriers of Transient Shipments
of Natural Uranium Other Than in the Form of Ore
or Ore Residue

This GL implements the federal control of imports and exports; therefore, it does not appear in the Agreement States regulations. The GL is set to assure the physical safeguarding of large shipments of natural uranium.

13. 10 CFR 40.25. General License for Use of Certain Industrial Products or
Devices

This GL is for source material for shielding or weights and is issued to anyone. The GL is required to register with the regulatory agency. No changes to the source material may be made by the GL. Transfers may be made to either general or specific licensees if a copy of the GL and registration form also are provided.

14. 10 CFR 40.26. General License for Possession and Storage of Byproduct
Material as Defined in Part 40

This GL allows the mill tailings and solution wastes to be stored without amending a specific license. There is no quantity limit other than the specific license limit. The GL allows storage and necessary transport in authorized containment areas. The GL terminates with the expiration or termination of the specific license or when the specific license is renewed with financial assurances.

15. 10 CFR 40.27. General License for Custody and Long-Term Care of Residual Radioactive Material Disposal Sites

This GL is for any site for which the NRC has accepted a long term surveillance plan for a disposal site under Title I of UMTRCA. This is to allow for the orderly transfer from a Title I site to a long-term care provider (DOE).

16. 10 CFR 40.28. General License for Custody and Long-Term Care of Uranium or Thorium Byproduct Materials Disposal Sites

Similar to 10 CFR 40.27 for Title II UMTRCA sites, although a state may be the provider of long-term care.

17. 10 CFR 150.20. Recognition of Agreement State Licenses

This general license is supportive of interstate commerce and administratively allows the recognition of another agency's license. The GL requires prior notice to the jurisdiction receiving the material and the possession by the GL of a specific license that does not limit the location of use of radioactive material. The licensee must also maintain radiation-related records in the jurisdiction that issued the specific license being recognized.

18. Problems Associated with General Licenses

A number of concerns have been raised by the Agreement States and others over the years, particularly as related to the 31.5 GL. Most problems associated with radioactive materials possessed and used under a general license have been identified with this particular GL.

Some of the problems identified were:

- a. Improper transfers from one general licensee to another general licensee.
- b. Failure of the manufacturer/distributor to provide a contact name for the general licensee.
- c. Some concern that all transfers were not being reported.
- d. The sale of a facility to another company with no accountability for the devices.
- e. Failure to maintain labels and perform function and leak tests. This is particularly a problem in industries in which corrosive atmospheres are present.
- f. Concern over generally licensed devices (sources) appearing in scrap metal.

As a result of these identified problems, some changes were made in 1984 to the general license. These were:

- a. Authorization for general licensee to general licensee transfers for some devices.

- b. Requirement that the name of a contact be included in the reports provided to the regulatory agencies, and the requirement for a negative report when no devices were transferred.
- c. Specific authorization for the transfer to the new owners of a manufacturing plant of any fixed devices.

At approximately the same time, several states (Texas, South Carolina, North Carolina, Florida) began to identify other possible problems. These were:

- a. Inadequate awareness of general licensees that they possessed radioactive material.
- b. The use of large (>500 millicuries) gamma sources such as cesium-137 in GL devices.
- c. The installation of alpha-emitting devices in severe environments.
- d. The failure to provide copies of the GL to the recipients.
- e. The failure of the manufacturer to notify the regulatory agencies of design changes.

The NRC also identified the severe environment problem when several 3M Company devices were found to be leaking. The manufacturer had modified the sources without the approval of the NRC.

South Carolina and Florida had reported questions regarding the use of static eliminators on food production lines, and Florida raised questions regarding their use in the phosphate industry. Texas and Florida raised questions regarding the use of large gamma sources. These sources were being used on large vessels where maintenance personnel were working. Concern was expressed about the adequacy of the safety programs at facilities that might never have been inspected. During the late 1980s, the NRC attempted to contact a group of GLs. A significant number could not be located or indicated that they were unaware they possessed a radioactive source. Several states, including Alabama and Florida, also inspected their GLs. The results varied with the degree of regulatory involvement. Awareness by the GL was higher in a state that required the reporting by the GL within 10 days of receiving the radioactive material. The longer a source was possessed by a GL, the less likely that management was aware they possessed the radioactive material.

A recent problem identified by Tennessee was the mounting of a GL device on a barge. The barge worked in several states, then was scrapped; the scrap ended up in Tennessee. Louisiana and Alabama also were involved. Alabama also has identified at least one truck-mounted GL device that has worked in several jurisdictions. The mobile use of this GL has raised many questions of the legitimacy of the practice. After Illinois became an agreement state, it discovered that the NRC database of GL's was not current. A series of mail-out survey questionnaires resulted in elimination of more than two-thirds of the GLs. There is no reasonable way of determining what happened to the radioactive material formerly possessed by these GLs.

Suggestions to improve this GL include:

- a. Telephone or mail contact with the GL at least once every five years.
- b. Inspecting at least ten percent of the GLs that do not also have a specific license.
- c. Placing more responsibility on the manufacturer for accountability of devices.

There has been some discussion within the NRC that the exemptions and GLs in 10 CFR 40 (source material) need a comprehensive revision and possible modifications. In October 1992, the NRC published NUREG/CR-5881 titled, "An Examination of Source Material Requirements Contained in 10 CFR Part 40." That document presents some of the major issues to be considered in any such revision. On Oct. 28, 1992, the NRC published an Advance Notice of Proposed Rulemaking on this subject.

D. Uranium/Thorium Mill Regulation

The regulation of uranium and thorium mills originally came under the umbrella of source material licenses. Thus, when any state entered into a section 274 agreement with the AEC, the state assumed authority over these facilities along with other source material licenses of more limited scope. No specific regulations addressed mills as a class, although the AEC had a few modest guides and had one engineer on staff who evaluated the structural aspects of tailings impoundments.

Even though some states, notably Colorado, had raised concerns about potential hazards from mill tailings and, indeed, Congressional hearings had been held on the subject, the issue did not receive high priority at the federal level until the late 1970s.¹⁵ The AEC position was that, although the AEC could exert control over all aspects of the mill during operations, no regulatory control could be exerted over tailings after termination of a license. This was because the principal hazard came from radium, which was a naturally occurring radioactive material and not subject to the Atomic Energy Act, and the concentration of source material (uranium) in the tailings was less than 0.05 percent by weight, which was the cutoff for licensing.

Due to increasing concern about the environmental impacts and pressure from environmental groups (particularly the Natural Resources Defense Council), Congress enacted the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA, P.L. 95-604) that established a number of new requirements for these facilities. The U.S. Department of Energy (DOE) had submitted the proposed legislation in April 1978. Title I of UMTRCA included provisions for reclamation of non-commercial facilities that were to be carried out by the DOE. Title II of the Act gave the NRC regulatory authority over mill tailings in the commercial sector. The NRC interpreted UMTRCA's definition of byproduct material to include above-ground wastes from in-situ extraction operations and

¹⁵ By letter dated July 27, 1970 from the U.S. Surgeon General to Dr. R. L. Cleere, Colorado Department of Health, exposure guidelines applicable to cleanup of homes constructed with or on uranium mill tailings were provided to the state.

uranium and thorium tailings. The new requirements of UMTRCA would not take effect in Agreement States until 1981. In the interim, the NRC issued general licenses in these states to licensees that were involved in activities that generated byproduct material. These licenses were valid until Nov. 8, 1981, three years after the effective date of UMTRCA. The National Environmental Policy Act of 1969 (NEPA) was the standard the NRC used when reviewing milling licenses. This required federal agencies to prepare an environmental impact statement (EIS) considering environmental consequences of any major action that could have a significant effect on the environment.

The NRC prepared a Generic Environmental Impact Statement (GEIS) addressing the issue. The purpose of the GEIS was to assess the nature and extent of the environmental impacts of conventional uranium milling in the United States, provide information that would support new regulatory requirements for this industry and support any rule change that might be deemed necessary. The Agreement States with mills could continue regulating them until Nov. 8, 1981 (a date which was later extended), but had to adopt the new regulatory requirements and generally upgrade their programs by adding more staff, obtaining new equipment and adopting new procedures. The NRC published new criteria for those states desiring to enter into amended agreements for mill and tailings regulation on Jan. 23, 1981. The NRC provided assistance to Agreement States in performing environmental reviews for proposed mill licensing actions until 1981. UMTRCA required that after 1981 the Agreement State must perform environmental impact analyses that must include impacts to public health and safety, impacts to waterways and ground water and consider any long-term impacts such as decommissioning, decontamination and reclamation.

Prior to UMTRCA, there were no requirements pertaining to site ownership. UMTRCA states that before terminating any license, title to the land used for the disposal of tailings shall be transferred to the United States or to the state in which the land is located. This requirement could be waived if the NRC determines, prior to license termination, that the transfer is not necessary to protect public health and safety. The ultimate custodian of the property shall maintain the land in such a manner as to protect public health and safety as well as the environment.

UMTRCA also added section 275 to the Atomic Energy Act. This section granted authority to the Environmental Protection Agency (EPA) to establish standards (40 CFR 190 and 192) of "general application," covering both radiological and other hazards from mill tailings located at active mill sites. The NRC or Agreement State was responsible for enforcing these standards.

In Part 190, promulgated in January 1977, the EPA established a dose limit of 25 millirem per year to the general public from active uranium fuel-cycle operations. Part 192, adopted in October 1983, required stabilization of tailings so that associated health hazards could be controlled, preferably for 1,000 years and, in any case, for 200 years. It required that disposal piles be designed to limit radon releases to 20 picocuries per square meter per second, averaged over the surface of the disposed tailings. Part 192 required that measures be taken to limit the release of hazardous material, including radioactive material, from tailings into ground and surface water. These measures included liner installation in new impoundments and corrective actions to restore contaminated ground water.

In response to the Clean Air Act, the EPA promulgated additional standards in 40 CFR 61 to ensure that tailings piles would be closed in a timely manner. It requires that once a tailings pile or impoundment ceases to be operational, it must be closed and brought into compliance with the standard within two years of the effective date of the standard (by Dec. 15, 1991) or within two years after it ceases to be operational, whichever is later. It also requires submission of a tailings closure plan and a final test of the barrier at a facility to determine compliance with radon flux emission limits. This rule became effective Jan. 14, 1994.

When UMTRCA was passed in 1978, there were four Agreement States regulating mills - Colorado, New Mexico, Texas and Washington. However, there was the potential for milling activities in other Agreement States such as Arizona, California and Oregon. Section 207 of UMTRCA provided \$500,000 in grant money to assist the Agreement States in upgrading their regulatory programs. The larger grants were given to Colorado, New Mexico, Texas and Washington, but modest grants were provided to several other Agreement States. Eventually Washington, Texas and Colorado entered into amended agreements with the NRC on Feb. 19, 1982, March 24, 1982 and April 20, 1982 respectively. As noted earlier in this report, New Mexico relinquished this authority back to the NRC on June 1, 1986.

No other Agreement State pursued an amended agreement to a final stage except Illinois. The only commercial thorium facility in the United States was located in West Chicago, Illinois. Although the facility ceased operations in 1973, it has not yet been closed out. Even though the NRC recognized that the on-site material was section 11.e(2) byproduct material (tailings), it never regulated this material in the same manner as similar facilities in the western United States. Illinois obtained an amended agreement on Nov. 1, 1990 to regulate mill tailings facilities. As this report is being written, the facility currently has a pending application with Illinois to decommission and close out the facility. Initial shipments of material to Envirocare began on Sept. 9, 1994.¹⁶

The remainder of the discussion in this section is primarily a description of the Texas program for regulation of milling activities. Texas had a large number of underground solution mining operations in addition to a few conventional mills. The solution mining operations do not generate large quantities of tailings (wastes) above ground, so some aspects of the Texas program are unique to that type of operation. Nevertheless, this discussion should be helpful in understanding the regulatory aspects of this industry. Table 2 may be of particular interest since it lists some unique features of pre-UMTRCA and post-UMTRCA regulatory programs.

1. Uranium Mining and Milling in Texas

Uranium was first mined in Texas in 1959. In 1961, Susquehanna Western, Inc. built a mill near Deweesville, Texas and began processing ore that had already been mined. In 1968, a second mining area was started by Susquehanna

¹⁶ On Nov. 19, 1993, the NRC issued a license to Envirocare of Utah, Inc., authorizing the receipt, storage, and disposal of section 11e.(2) byproduct material at a site near Clive, Utah. This is the first and only license issued to date that authorizes such activities on a commercial basis.

Western near Three Rivers, Texas. A number of other operations were developed from 1968 - 1981.

Table 2. Uranium Facility Regulation and UMTRCA

Pre-UMTRCA

1. Specific rules pertaining to licensing and operation of uranium recovery operations did not exist.
2. Financial surety was not required.
3. Pre-licensing environmental assessments were not required.
4. Specific impoundment design requirements did not exist.
5. Long-term care and ultimate land disposition was unclear.
6. Radon emanation from tailings was not addressed.
7. Specific inspection criteria and interval not established.

Post-UMTRCA

1. Specific rules regarding licensing and operation of uranium recovery facilities were adopted.
2. Title transfer of tailings impoundment property was established.
3. Pre-licensing environmental assessment became mandatory.
4. Financial surety was required to ensure proper decontamination and reclamation of uranium recovery facilities, and for long-term surveillance.
5. Mandatory submission of closure plan and estimated timetable for reclamation were required.
6. Environmental monitoring of air emissions (including radon) and groundwater was required.
7. Specific impoundment construction criteria were established that required liner placement and limited erosion.
8. Worker bioassays were required and limits established.
9. Six-month inspection interval established. Responsibility of inspection transferred to the state.
10. State environmental monitoring programs around impoundment facilities were established.

Solution (in-situ) mining was begun in Duval and Live Oak counties about 1968. This employed a new technology that was less environmentally damaging and lowered doses to both workers and the general public.

As of Oct. 1, 1981, the Bureau of Radiation Control had 19 active licenses for uranium recovery operations and four new applications under review. The Susquehanna Western site near Deweesville was named as one of the processing sites in Title I, section 102 of UMTRCA. In 1992, the Bureau of Radiation Control had eight in-situ facility licenses for 16 sites and three licenses for conventionally mined ore processing and tailings impoundments.

2. Environmental Surveillance at Texas Uranium Facilities

In 1981 the Bureau of Radiation Control established formal environmental surveillance programs at 18 facilities. One full-time employee performed surveillance activities. Prior to that date, inspectors did limited sampling at these sites as part of their inspection procedure. The original surveillance activities around the conventional uranium facilities were quite modest.

During 1987 and 1988, programs were established that greatly expanded the monitoring programs, increasing monitoring frequency and including media such as soil, vegetation, groundwater and use of TLD monitors.

In 1987, the bureau performed surveillance activities at 28 sites. This list included the three original conventional mill facilities as well as the Exxon-Ray Point impoundment and three in-situ facilities.

3. Texas Regulations for the Control of Radiation

The Texas Regulations for Control of Radiation (TRCR) were adopted by the State Board of Health in accordance with the Texas Radiation Control Act. They became effective on March 1, 1963 and have been amended several times to be kept compatible with NRC regulations. These regulations, as well as individual license conditions, are the basis for any facility inspection.

Part 43 of the TRCR, "Licensing of Uranium Recovery Facilities" was adopted in October 1981. This part addresses license application, general requirements for license issuance, financial security requirements, long-term care/maintenance requirements, license renewal, technical requirements for impoundments, transfer of material and land ownership. Among other things, these rules were necessary to include in the state's request for an amended agreement with the NRC.

There have been a number of other changes to the Texas regulations covering such items as fees, notification of bankruptcy, submission of closure plans, environmental monitoring requirements and the role of the Texas Department of Water Resources. Table 3 is a chronology of significant events in the development of the Texas program.

4. Inspection of Texas Uranium Facilities

In 1961, the state of Texas enacted the Radiation Control Act. This law established the state's authority to license and regulate the possession and use of radioactive material. Texas became the fifth Agreement State on March 1, 1963. It assumed regulatory authority over approximately 500 licenses issued by the AEC, which included one uranium facility. The law

Table 3. Significant Events in Uranium Regulation in Texas

<u>Date</u>	<u>Event</u>
April 17, 1961	Texas Radiation Control Act
January 10, 1963	Texas/USAEC Agreement signed
March 1, 1963	Agreement became effective
June 6, 1963	First uranium mill licensed
1963	Tailings disposal areas required to be lined
1963	Use of tailings in construction of tailings dams prohibited
August 15, 1968	First in-situ solution mining pilot project licensed
March 11, 1970	First Texas conventional uranium mill licensed
September 1972	Uranium mining was made a generally licensed activity
February 1973	First tailings pond restoration standards issued
May 7, 1973	First standards for the abandonment of uranium mines established
December 17, 1975	First in-situ mining project licensed
February 1976	First soil contamination guidelines established
August 1978	Amendment to all uranium licenses with dryers requiring bioassay
May 21, 1979	First environmental assessment issued
April 1980	Letter issued outlining UMTRCA requirements
April 1 & May 22, 1981	Texas Radiation Control Act amended to include UMTRCA provisions
October 1981	Part 43 "Licensing of Uranium Recovery Facilities" adopted
March 24, 1982	Amended agreement with NRC regarding mills
1982	Financial security requirements set
1982	Reclamation cost estimates set by TDH
September 1993	Authority to regulate uranium recovery operations transferred to Texas Natural Resource Conservation Commission

designated the Texas State Department of Health (TDH), now known as the Texas Department of Health, as the Texas radiation control agency. At the time, the Radiation Control Branch was within the department's Division of Occupational Health and Radiation Control. This branch was responsible for developing and implementing a program for licensing and regulating radioactive materials.

In 1981, the Texas Radiation Control Act was amended to include all the provisions of law required by UMTRCA. The Radiation Control Branch became the Bureau of Radiation Control. This bureau consisted of three divisions and an administrative support office. In addition, three attorneys from the TDH's Legal Division and five chemists from TDH's Bureau of Laboratories assisted with uranium facility regulation efforts.

The Division of Compliance and Inspection, part of the Bureau of Radiation Control, had the responsibility for inspecting uranium recovery operations. Within this division is the incident investigation program. This program investigated any reports of employee overexposure. Bioassay results of greater than 30 micrograms per liter of uranium required immediate bureau notification. This action level, suggested by the NRC, was based on uranium toxicity, not radiological hazard. This bioassay requirement was incorporated into all uranium facility licenses that had a dryer. The incident investigation program also would examine any reports of significant fluid release from any of the uranium recovery facilities.

Inspections of uranium facilities prior to 1979 were performed using a general inspection guide developed by the Bureau of Radiation Control. This form used a "check box" format and allowed little room for additional inspector comments or observations. Inspections were done on an annual interval. In 1981 the inspection interval was changed to every six months. A narrative format for the inspection report was utilized. The inspection guide became more specific for uranium facilities and in 1990 guides were developed for each specific license. These guides included specific requirements documented in the license, application and TRCR and allowed for a "tailor-made" inspection of a facility and a specific narrative report of the inspection.

Three other state agencies are involved in regulating the uranium industry in Texas. The Texas Railroad Commission regulates surface mining. The Texas Air Control Board regulates air emissions, excluding radionuclides, from these facilities. The Texas Department of Water Resources regulates the release of pollutants into groundwater and permits injection and disposal wells.

In September 1993, Senate Bill 1043 transferred regulatory jurisdiction for all uranium recovery facilities to the Texas Water Commission, formerly the Texas Department of Water Resources, now called the Texas Natural Resource Conservation Commission. The Texas Air Control Board is also part of this organization.

E. Regulation of Low-Level Waste Disposal

In 1960 the AEC announced that it would support the development of low-level radioactive waste disposal sites throughout the country to be operated by the commercial sector for the fast-developing nuclear industry and nuclear power plants. This was a new concept since most disposals were allowed only at federal facilities. It was prompted in part by the AEC's moratorium placed

on sea disposal of wastes and its plans to close burial grounds at Oak Ridge, Tennessee and the National Reactor Test Site in Idaho to commercial waste, once adequate capacity was established at new sites in the private sector.

The Agreement States played a major role in the development of regulatory licensing and oversight of these commercial facilities, since five of them were located in Agreement States. One was located in Illinois, which at that time was not an Agreement State. The states have the authority to license and regulate byproduct, source material and limited quantities of special nuclear materials (SNM). The NRC also is involved to a lesser degree in regulating these sites for large quantities of SNM. At the time of this writing, only one of the original sites is open to waste from throughout the country from qualifying states and compacts, and one to waste from only its compact and another compact with which it has a contract. A seventh site has been opened in Utah¹⁷, but it has not been subjected to the same regulatory requirements as the others, because it is only allowed to accept small concentrations of by-product material and small concentrations of naturally occurring radioactive materials (NORM).

Since the opening of commercial disposal sites there have been many dramatic changes in regulations, disposal technologies, waste forms and political forces. Much of this was brought about by problems experienced at the burial sites in the late 1970s, the increased concentrations of radionuclides in the waste forms, problems with waste packaging in transportation and at the burial sites, and the public perception of waste disposal. Some of these changes had a sound health and safety basis, whereas others were politically motivated. The Low Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA) has had the most profound effect. It provided a series of milestones and penalties for the states and compacts to meet.

The low-level waste regulatory program directly affected the six states where original sites were located and later those that were developing sites under the compact system. However, the indirect effect was on thousands of generators located in all 50 states plus citizens of all states which could be affected by the transportation of these wastes.

It should be noted that, of the initial six sites, all but the Hanford site were located on state-owned land (Hanford was on federal land leased to the state). Thus, these five host states could exert ownership leverage on the operators of these sites. In addition, the six original sites were developed as a private-sector oriented market venture compared to the quasi-governmental venture resulting from the LLRWPA. The original system was rather successful from a distributional aspect, but less than successful from a technical and management perspective.

1. Sequence of Facility Openings, Problems and Closings

- a. The Beatty, Nevada site was the first commercial site to open in 1962. The site is located on an 80-acre tract of arid Amargosa Desert land approximately ten miles from the small town of Beatty and 100 miles northwest of Las Vegas. The site is approximately 2800 feet above sea level with a groundwater table depth of 300 feet. There is no appre-

¹⁷ Same company and location as noted in footnote 16.

ciable surface water for 10 miles. Rainfall averages two to five inches per year with a much higher evaporation rate. Technically, these conditions are excellent for shallow land disposal. There is also a hazardous waste disposal site adjacent to the Beatty facility.

The site was originally operated by Nuclear Engineering Company (NECO), which later changed its name to US Ecology. It incorporated the shallow land disposal technology with a final trench cover of 10 feet. Technically the site has had no problems, but has been somewhat mismanaged. Employees were allowed to remove certain tools and building materials that may or may not have been contaminated, and waste was found disposed outside of the fenced area. In the late 1970s, some of the shipments arriving at the facility were found to have significant violations of transportation regulations. After one event when a truck caught fire due to improper packaging of waste, the site was closed by the Nevada regulatory officials until assurances were made by each state, generator and the federal government that all health and safety and transportation regulations would be adhered to and enforced.

Following passage of the LLRWPA, the Beatty site was chosen as the regional facility for the Rocky Mountain Waste Compact, and as such, the site was subsequently closed in December 1992 as authorized by the act. The state of Colorado was selected as the next host state, but since then the Rocky Mountain Compact has contracted with the Northwest Compact to accept its waste at the Richland (Hanford), Washington site.

- b. NECO, now US Ecology, also operated the Maxey Flats, Kentucky site. The site opened in January 1963 and was to provide disposal service to the fast-growing nuclear industry in the middle Atlantic states, Southeast and some of the Northeast. This site is located near Morehead, Kentucky, approximately 65 miles northeast of Lexington, Kentucky. In December 1977 the site was closed after it was determined that radionuclides from one trench were seeping into an adjacent trench.

The main problems encountered at the Maxey Flats site are attributable to the shale and sandstone bed that was approximately 25 feet below the disposal trenches. Significant amounts of water would accumulate in the trenches since the infiltration rate into the trenches was much greater than the out-flow through the soil. This is commonly called the "bathtub effect." This led to considerable migration of radionuclides, especially tritium.

The state of Kentucky decided to take control of the site and initiate remedial action. The program first involved pumping contaminated water and treating by various methods to remove radioactivity. In addition, a synthetic membrane was installed over the trenches to reduce the amount of water percolating into the trenches. This proved very beneficial. The site was closed on Dec. 27, 1977. Following negotiations with the site operator, Kentucky signed an agreement with NECO in May 1978 whereby the lease rights to the site were bought back by the State.

By the mid-1980s the environmental sampling at the site indicated that radionuclides could potentially migrate from the site, and this caused concern from a health and safety standpoint. Therefore, the Commonwealth of Kentucky requested that the EPA place the site on the Superfund list in order to receive funds for remediation and designate entities that had disposed of waste there as potentially responsible parties. They would be responsible for reimbursement to the Superfund. More than 800 parties were named by the EPA. Immediately thereafter, the EPA began a process to have all the contaminated liquids that were being stored in tanks solidified into concrete blocks and placed in a new trench specially constructed for that purpose. Remediation continues at this site to date.

- c. In 1963 Nuclear Fuel Services opened the West Valley, New York commercial low-level waste site at its Nuclear Service Center approximately 30 miles southeast of Buffalo, New York. The 22-acre site operated under a lease agreement with the state of New York until March 1975. At that time the site was closed from further disposal operations when water overflowed or seeped upward through the covers of several of the disposal trenches. Percolation of above-normal rainfall over a period of time through the trench covers contributed significantly to the accumulation of water in the trenches. It also was discovered that a subsurface sand and gravel area near the disposal trenches may have acted as a conduit and directed large quantities of groundwater into the trenches.

A trench cap rehabilitation program was undertaken by the New York Energy Authority, but water continued to infiltrate the disposal trenches. Recent indications, however, show that water continues to infiltrate some of the trenches despite pumping efforts previously carried out and cap remedial action. Plans presently call for the removal and treatment of water in one of the trenches with the most significant accumulation.

The West Valley site continues to be shut down from all disposal operations and there are no plans to reopen it. However, there have been discussions to locate another disposal facility for only New York State generated waste at the West Valley location.

- d. The Richland, Washington commercial low-level waste disposal site was licensed in 1965 and was operated by California Nuclear, Inc., but was later transferred to Nuclear Engineering Company (NECO), subsequently renamed US Ecology, Inc. The site is located on the DOE Hanford Reservation about 25 miles northwest of Richland, Washington in the southeastern part of the state. The site is approximately 100 acres and is leased from DOE by the state of Washington.

The Richland site is unique in that it is situated on sediments that were fed by glaciers in a semiarid area about 200 feet deep. Below this is another 1,200 feet of sedimentary material above a bedrock of basalt. Surficial silt and sand cover the site and are susceptible to movement by wind. The depth to the water table is approximately 350 feet. The closest surface water is the Columbia River, which flows about six miles from the site. There is an annual precipitation of about six inches per year with a 55-inch-per-year evaporation rate.

This site is ideal for low-level waste disposal due to the arid conditions. Problems associated with silt-sand cover can be rectified with a proper cap. Despite this, however, the site was closed to out-of-region waste in 1992, but continues to accept NORM nationally on a limited basis.

With the exception of some soil contamination problems associated with underground tanks used to hold liquids and resins in earlier years of operation, the site has had very few problems from an operational and environmental standpoint. However, the site was closed in 1979 for two months, as was the Beatty site, when transportation and packaging violations were found. It was reopened once the state of Washington was assured that the federal government (NRC) would take adequate enforcement action against its licensees. Like Nevada and South Carolina, Washington established a formal transportation inspection and enforcement program that contributed substantially to compliance with applicable federal and state shipping regulations. These enhanced requirements came about in part as a result of visits to the NRC Chairman and other federal officials and members of Congress by Governors Riley, Ray, and List (see Section VIII.E.4. below). The three Governors expressed the need for new inspection and enforcement practices for waste generators in a joint letter to NRC Chairman Hendrie dated July 10, 1979. Chairman Hendrie replied positively to the Governors' proposals by letter dated July 18, 1979.

- e. The Sheffield, Illinois site is located in Bureau County, approximately 120 miles west of Chicago, and was opened in 1966 by California Nuclear, Inc. The license was later transferred to NECO, now U.S. Ecology, Inc. The site was closed in April 1976 when it reached its planned capacity. The site was licensed by the NRC until June 1987 when the State of Illinois became an Agreement State, and it assumed responsibility.

There are also two hazardous chemical waste disposal areas located approximately 150 feet from the low-level radioactive waste site. These have since been closed as well. The site is approximately 20 acres and is situated on a glaciated terrain, which consists of lake deposits of silt and clay, and a sandy soil cover. The site is underlain by both shallow and deep aquifers. A 450-foot bedrock area separates the two groundwater units. A small lake (Trout Lake) also is located near the disposal site. The climate is relatively humid and the site receives approximately 35 inches of rain annually. Waste was buried in 21 trenches typically 500 feet long, 60 feet wide and 25 feet deep. During its operations, it received approximately 3 million cubic feet of waste.

In 1976, tritium was detected migrating toward Trout Lake northeast of the site. Other samples taken indicated tritium was migrating from Trench 11, and that groundwater movement exceeded initial estimates. The U.S. Geological Survey (USGS) conducted extensive studies at the site and determined greater groundwater movement than expected of 10 to 20 feet per year, due to subsurface sand and coarse materials. A new water management program was initiated at the site to direct precipitation runoff away from trenches and minimize infiltration.

In order to extend the capacity of the site in 1975, NECO requested the NRC to approve new compact-filled trenches. Although the NRC approved construction of the trenches, it never authorized disposal of waste in them. This caused the demise of any further site operations. In 1978, the site operator attempted to absolve itself of any further responsibility for the site and to have its license terminated. The state of Illinois sued the company since there was a contractual agreement with the state. A settlement was negotiated, and US Ecology was required to establish a long-term maintenance fund, complete all site improvements, conduct an environmental surveillance program and maintain the site for 10 years. In 1989, a new clay cap constructed over the entire site was completed to help prevent infiltration of rain water, thus minimizing further migration of radionuclides.

- f. In August 1969, Chem-Nuclear Systems, Inc., (CNSI), submitted a license application to the South Carolina Board of Health for the disposal of commercial low-level radioactive waste on property they had acquired near Barnwell, South Carolina. This property is adjacent to the Savannah River site and the Allied General Nuclear Fuel Services (AGNS) processing facility that was under construction at that time. AGNS was decommissioned before it began operations. The site is approximately 70 miles southwest of Columbia, South Carolina.

Although there were other commercial sites operating throughout the country, South Carolina initially supported a commercial facility in the state, since it was becoming heavily involved in the commercial nuclear industry. It was perceived from an economic standpoint that this site would serve the state and surrounding states in the Southeast that were also developing commercial nuclear power. Little did the state know at that time that Barnwell would become the nation's largest commercial disposal facility due to the closure of other sites. This prompted numerous political actions such as the LLWPA of 1980 and the LLWPAA of 1985 requiring all states to assume the responsibility for low-level waste management and disposal.

An initial license was issued to CNSI on Nov. 6, 1969. However, this license restricted CNSI to receipt and possession of prepackaged waste for transfer to other authorized disposal facilities throughout the country. Twenty months later, following a lengthy review process by many state agencies and commissions, the AEC and the U.S. Geological Survey, exchange of numerous documents and information in support of land disposal, and one public hearing held March 4, 1971, an amended license was issued to CNSI on April 13, 1971, authorizing disposal of waste at the Barnwell site. Also in April of that year, the land acquired by CNSI was deeded to the state and subsequently leased back to CNSI. The original perpetual maintenance fee was eight cents per cubic foot, later raised to 16 cents, and is currently \$2.80 per cubic foot. There is more than \$60 million in this interest bearing account to provide long-term care and maintenance for the site. In addition, a decommissioning trust fund has been established with an \$8 million requirement for funding. This will be used to decommission the site and install a final enhanced cap.

Since operations began, the Barnwell site has received approximately 34 million cubic feet of low-level waste. This contained more than

300 million curies of radionuclides, which, when decayed to date yields an inventory of 2.1 million curies, 3000 kilograms of special nuclear material and 2.9 million pounds of source material.

The site encompasses more than 300 acres. Of that, 107 acres were designed for disposal of which 76 acres have been used with 31 acres remaining. This equates to approximately 10 more years of operation at a rate of 800,000 cubic feet per year, although 1.2 million cubic feet is authorized annually.

The site was scheduled to close Dec. 31, 1992, but was granted an extension until Jan. 1, 1996. However, since July 1994 it is allowed to receive waste only from Southeast Compact States. The extension was to give the state of North Carolina additional time to develop the next site as the new host state for the Southeast Compact.

This extension also prompted the state regulatory agency to require improvements in the site operations that will enhance performance and long-term stability. Therefore, all Class B and C waste must be disposed of in concrete overpacks, which are equivalent to below-grade vaults. All irradiated reactor core components must also be disposed in reinforced concrete-lined slit trenches with fitted concrete covers. Other improvements in waste forms and administrative procedures were also required.

Like the Beatty, Nevada and Richland, Washington sites, Barnwell also experienced considerable problems with the waste shippers complying with transportation and packaging regulations and waste acceptance requirements. Although the Barnwell site was not closed like the other two sites, significant legislation was passed to require compliance. This was a unique step for a state and it challenged interstate commerce considerations. The law was designed to put the responsibility on the generator of the waste rather than on the transporters.

On July 1, 1980, the South Carolina Low-Level Waste Transportation and Disposal Act was enacted. This legislation was somewhat controversial to waste generators. For the first time in regulatory history, persons having waste transported were required to secure a transport permit, provide financial liability and give 3-day advance notice of their shipments. This legislation also subjected them to enforcement sanctions by the state in the form of civil penalties and permit suspensions for noncompliance with federal and state regulations. In an effort to minimize the impact on waste generators, the state devised a permitting and notification system that was reasonable and somewhat simplified. This program has been extremely effective in the management of low-level waste and regulatory compliance. Nevada and Washington took similar action and required site use permits. The South Carolina Department of Health and Environmental Control (DHEC) has collected well over one-half million dollars in regulatory fines and suspended permits on numerous occasions. Occurrences of noncompliance with federal and state transportation regulations and site criteria are now very seldom found.

The Barnwell site has experienced few operational problems. However, in 1992 it was determined that tritium was migrating from some of the

earlier trenches at a rate greater than had been anticipated. This was due mainly to the poor construction technique of the trenches, the large quantities of tritium placed in them, interlinking subsurface sand lenses and above normal rainfall. The tritium plume with concentrations that exceed EPA drinking water standards (which are not applicable) is still confined to the facility operator's property, but has moved past the burial site boundary. However, no public or private drinking water supplies are affected.

A very expensive and elaborate study was required by DHEC to determine the extent of the tritium plume. This study continues to date, and extraordinary information has been gathered concerning groundwater movement in this particular geological location that may be useful for other facilities. In addition, remedial action was required in the form of an enhanced cap over the affected trench area. This cap includes impermeable and semi-permeable synthetic materials, and drainage layers that direct rainfall away from the site. Preliminary indications show reduced tritium concentrations in the groundwater wells adjacent to the trenches, and it is anticipated that in time, the tritium plume will no longer be supplied with a source from the trenches.

2. Regulatory and Technical Changes

In 1978, the Barnwell, Beatty and Richland sites were the only facilities open to commercial disposal of low-level radioactive waste. Federal standards and regulations for shallow land disposal to this point were virtually nonexistent except for minimal technical criteria. Essentially, the Agreement States were responsible for regulating these disposal sites and developed the standards and regulations through specific license conditions. Each site had its own unique requirements. The evolution of low-level radioactive waste from minimally contaminated materials to high activity metal components and ion exchange resins required the Agreement State regulatory agencies to establish higher standards and complex requirements for disposal.

In the earlier years of operation, the facilities received waste with low to moderate concentrations of radionuclides. The original submittal for a license at Barnwell specified radiation levels from waste containers not to exceed 100 millirems per hour on contact. Today, stainless steel liners containing irradiated components have measured 50,000 rems per hour on contact. Radiation levels are restricted to the shielding capacity of the transportation casks and operational limits imposed by the facility operator.

Low-level waste received at these sites has evolved over the years from barely detectable activity in dry active waste, evaporator concentrates, ion exchange resins and filter media to much higher activity waste. As the operational lifetime of the commercial reactors increased, the waste stream loadings began to increase in radionuclide concentrations. Replacement of metal reactor components, power level monitors, poison curtains and other metal fixtures contributed to a new waste stream of high activity radionuclides with extremely high radiation levels, such as cobalt-60. Due to these increased concentrations and high activity components, new restrictions were required to provide enhanced protection of the burial environment from migration of radionuclides, and protection of site workers and transport workers. Some of these restrictions were administrative in nature for better

management controls, but others required innovative measures on the part of waste generators and their contractors to meet these new regulatory requirements. For the most part, generators had the ability to comply with the requirements. Some took longer than others to effect changes in their waste programs. Eventually, all generators complied. However, the Agreement State agencies worked very closely with the burial facility operators, the waste generators and the NRC to formulate these requirements. 10 CFR 61 reflects many of these restrictions, which were vanguarded by the states of South Carolina, Nevada, and Washington.

Until October 1974, the burial sites received bulk shipments of liquids for on-site solidification prior to disposal. This allowance was made due to the poor design of evaporators at most of the reactor sites. Many waste generators did not have the capability to solidify large volumes of water that were slightly contaminated. Therefore, they were allowed to ship these liquids in large tankers for storage and processing at the burial sites. This concept became quite controversial from a transportation standpoint and would have had severe repercussions if an accident occurred and large quantities of liquids were released. This practice was reviewed and determined not to be in the best interest of the states from a public health standpoint. Thus, the requirement was initiated to solidify liquids at the point of origin.

The reactor sites objected to this decision. However, mobile solidification units were designed and put into operation at the reactors and permanent solidification units eventually were built. The generators were able to comply with this restriction through the use of contractors, although it was expensive. Urea formaldehyde was selected as one of the solidification media of choice, but was eventually disallowed as a solidification media due to its extensive hazardous and corrosive properties.

Following the accident at Three Mile Island (TMI) in 1979, a public statement was made that said, in effect, "any waste resulting from the accident would probably be disposed at commercial sites." This invoked a public and political outcry. Little was known at that time about the amounts of waste, what the waste would contain and the concentrations. Therefore, an immediate ban was imposed in South Carolina to prevent any waste from the TMI facility from being disposed at Barnwell. This decision was later supported by the analysis of certain waste that contained large concentrations of fission products and transuranics. This action also caused a rethinking of low-level waste, and a realization that stricter requirements would be necessary. Eventually, some waste was allowed into Barnwell and the other sites, but the bulk of high-activity waste was transferred to DOE facilities in Idaho.

Also in 1979, a ban on organic liquids such as scintillation fluids containing hazardous chemicals was imposed at Barnwell to avoid environmental consequences from the liquids' chemical properties and mobility. Hanford and Beatty continued to receive these wastes, but eventually phased them out as well. Clearly, scintillation fluids with slight quantities of hydrogen-3 and carbon-14 were overwhelmingly chemically hazardous. This proved to be a sound decision, because mixed wastes under the provisions of the Resource Conservation and Recovery Act (RCRA) were later prohibited. However, new regulations were promulgated that allowed the disposal of nonhazardous fluids and recycling of the hazardous "cocktail" mixtures. This had a short but profound

effect on research until the NRC established regulations to allow deregulation of these wastes from the radiological standpoint.

Through inspection efforts at the disposal sites, it was determined that many waste forms arriving at the burial facilities contained large quantities of freestanding liquids, and occasionally these liquids were found to be corrosive to the carbon steel waste containers. Not only did this cause concern for the potential of radionuclide migration, it also presented a problem during transportation due to leaking containers. Therefore, a freestanding liquid restriction of no more than 0.5 percent non-corrosive liquids by waste volume was imposed. Further, due to the increased concentrations of radionuclides in ion-exchange resins and other filter media, all waste containing radionuclides with half-lives greater than five years having a specific activity of one microcurie per cubic centimeter or greater required stabilization by an approved solidification media. Prior to this, ion-exchange resins were allowed to be "dewatered"; however, this earlier process left large amounts of residual liquids in the containers.

These new restrictions caused considerable controversy throughout the nuclear industry, and the Agreement State regulatory agencies were besieged with concerns over the ability of generators to meet these new sanctions. Even the NRC expressed its concerns. These objections were considered, and a phase-in schedule allowed the generators time to comply and acquire the equipment and/or services to meet these new requirements. Those utilities that failed to make progress were prohibited from shipping their waste. The results of these restrictions were quite significant, but went a long way to provide credibility for shallow land disposal. By Jan. 1, 1981, these restrictions were fully implemented.

By November 1979 it was becoming increasingly evident that the Barnwell site had become the major commercial low-level waste site in the nation, accepting more than 75 percent of waste transferred for disposal (not generated). This was viewed by the political leaders of the state as an unacceptable situation. Therefore, Governor Riley requested DHEC to impose a volume limitation on Barnwell. This decision was twofold; not only was there concern about the public's health from the impact of increased transportation, but the disposal capacity for South Carolina-generated waste was being jeopardized.

Earlier, in January 1978, a volume restriction had been imposed not to exceed 2.4 million cubic feet per year. The November 1979 restriction established a declining schedule that limited the site to no more than 189,000 cubic feet per month, and by October 1981 the site could receive only 100,000 cubic feet per month. This is now the current restriction of 1.2 million cubic feet per year.

This plan also required a prior notification condition and an allocation scheme to insure that South Carolina interests were preserved and disposal of its waste given priority. CNSI was responsible for administering the allocation program based on the historical waste disposals made by all the generators, and was closely monitored by the South Carolina radiation control program.

The volume limit restrictions had a considerable impact on the nuclear industry and almost created a panic situation, more so than the eventuality that the Barnwell site would close at the end of 1992. However, waste

generators again took innovative measures to solve the problem confronting them. Better waste management practices were devised such as segregation and compaction. Advancements were made in waste processing such as extrusion, evaporation and solidification. Ion exchange resins were regenerated and loadings became heavier. However, there were some negative consequences to this. Waste became higher in quantity of radionuclides and therefore more hazardous from a handling, transportation and disposal standpoint. This required further restrictions concerning containment of waste, as well as improvements in handling techniques during disposal operations.

3. Impact of 10 CFR Part 61

Until 1983, there were no specific regulations at the federal or state level that established requirements for shallow land disposal of low-level radioactive waste. There were general requirements in regulations that primarily required a review of the geohydrological conditions before authorizing disposal of low-level waste with at least six feet of ground cover. Regulatory requirements were mainly specified in the specific radioactive material licenses issued by the Agreement States. Many of these license conditions were later promulgated in the Part 61 regulations.

In December 1983, 10 CFR Part 61 requirements were implemented fully at all the burial sites. Prior to the implementation of Part 61, all waste streams were required to be properly quantified and qualified, and required an accurate account of the radionuclide concentrations. Therefore, the generators had established databases and formalized their process control programs to assure proper classification. Many generators were assisted by vendors who developed elaborate computer codes. The impact of 10 CFR 61 on burial facility operations was somewhat minimal due to the fact that many of the restrictions had been previously implemented by the states in phases, and it was not a tremendous problem for the generators to comply with the new restrictions.

The new regulations established, for the first time, waste classifications based on radionuclide concentrations with specific half-lives and waste form requirements. They also required the higher concentration waste, Classes B and C, which had to meet structural stability requirements, to be segregated from Class A waste with lower concentration, which did not have to be structurally stable, in order to provide stable trenches. Specific criteria also were established in the regulations which included performance assessments, site characteristics and selection, and performance objectives for the site. The most important requirement, however, was the establishment of the protection of the population from releases of radioactivity in the general environment with an annual dose limit of 25 millirem (0.25 mSv) to the whole body, 75 millirems (0.75 mSv) to the thyroid and 25 millirems (0.25 mSv) to any other organ. Other important performance objectives also were established, such as protection of inadvertent intruders by the use of engineered barriers, protection of individuals during operations, and stability of the disposal site after closure.

4. Impact of the LLWPA of 1980 (P.L. 96-573) and the Low-Level Waste Policy Amendments Act of 1985 (P.L. 99-240)

The LLWPA of 1980 was a very simple act establishing authority for states to enter into compacts, establishing a federal government policy that each

state was responsible for disposal capacity and that LLW could be most safely and efficiently managed on a regional basis. The initiative for this act came from a number of sources, including Governors Riley of South Carolina, Ray of Washington, and List of Nevada, who were host to the then three operating sites. In addition, on Feb. 12, 1980, President Carter established a State Planning Council by Executive Order. The council provided recommendations on several waste management issues and endorsed the principles established by the LLWPA of 1980. Other organizations such as the National Governor's Association and the National Conference of State Legislatures supported this approach. Due to the lack of progress under this law, partly because of the lack of incentives for developing new sites, Congress passed the LLWPAA of 1985. Neither of these acts provided any new health and safety regulatory authority to states; rather, they were designed to establish institutional mechanisms for the development of new waste disposal capacity.

Congress enacted this legislation in an effort to have each state share the responsibility of managing and disposing of radioactive waste generated within its borders, and to relieve the states of Nevada, South Carolina and Washington from this continuing burden.¹⁸ The legislation set forth the requirements to establish regional compacts with a designated host state and set a schedule of milestones the states were required to meet in order to have continued access to the operating burial facilities. The law also established substantial penalties to be paid to the three host states, and allowed surcharges to be collected for use by the states with operating facilities for whatever purpose they wanted.

As a result of this law, several compacts and unaffiliated states were established. These entities are listed in Table 4 as they exist today. The law also allowed the three sites to cease operating in December 1992. The Beatty, Nevada site was closed and the Richland (Hanford), Washington site limited access to states in the Northwest and Rocky Mountain compacts. The Barnwell, South Carolina site operating time was extended by the South Carolina General Assembly until June 30, 1994 for waste throughout the country, and until December 1995 for Southeast compact states only. However, the Barnwell site could remain open to South Carolina-generated waste only beyond 1995.

The legislation also requires that each party state:

1. Establish the capability to regulate, license and ensure the maintenance and extended care of any LLW facility within its borders.
2. Establish the capability to enforce any applicable federal or state laws and regulations pertaining to the packaging and transportation of waste generated within or passing through its borders.

¹⁸ During the crisis time of 1979, some observers suggested that the federal government take responsibility for disposal of low-level wastes by shipping it to DOE sites. When DOE pointed out that if such were done, the wastes would likely go to Savannah River (South Carolina), Hanford (Washington) and the Nevada Test Site (Nevada) and it was likely those three states would object to continuing to be host states, albeit on federal government installations.

Table 4. Compact Members and Unaffiliated States

Appalachian	Midwest	Northeast	Unaffiliated States¹⁹
Delaware	Indiana	*Connecticut	Dist. of Columbia
Maryland	Iowa	*New Jersey	Maine
*Pennsylvania	Minnesota		Massachusetts
West Virginia	Missouri	Southeast	Michigan
	*Ohio	Alabama	New Hampshire
Central	Wisconsin	Florida	New York
Arkansas		Georgia	Puerto Rico
Kansas	Northwest	Mississippi	Rhode Island
Louisiana	Alaska	*North Carolina	Texas
*Nebraska	Hawaii	South Carolina	Vermont
Oklahoma	Idaho	Tennessee	
	Montana	Virginia	
Central Midwest	Oregon		
*Illinois	Utah	Southwestern	
Kentucky	*Washington	Arizona	
	Wyoming	*California	
Rocky Mountain		North Dakota	
Colorado		South Dakota	
Nevada			
New Mexico			
*Designated			
Host State			

¹⁹ At the time this document was written, a bill had been introduced in the U.S. Congress to approve the Texas LLRW Disposal Compact comprised of Texas, Maine and Vermont with Texas designated as the host state.

3. To the extent authorized by federal law, require generators within its borders to use the best waste management technologies and practices available to minimize the volumes of waste requiring disposal.

The act also has had a rather significant effect on not only the regulatory and management aspects of low-level radioactive waste, but waste technology as well. Most of the proposed facilities will incorporate above- or below-grade vaults for containment of waste packaged in concrete. This will substantially drive up the cost of low-level waste disposal from conventional shallow land burial.

5. Conclusion

Regulation and management of low-level radioactive waste has evolved significantly over the past 20 years from an obscure issue to one of the more controversial and important matters facing the states, radioactive material users and utilities today.

The Agreement States have played a vital role in the development of regulations, criteria and standards for the safe disposal and isolation of low-level radioactive waste. The future of this issue also will be in the hands of the states, and it is unfortunate that politics, not technology, is delaying schedules for site development. It is also ironic that some of the political leaders who were responsible for the development and passage of the LLWPAA are also the ones who now are trying to undo the process. If this is not resolved soon, the nation will surely be in a dilemma with low-level radioactive waste management and storage at the site of generation, which will have profound health and safety repercussions. All states, not only Agreement States, will have to face this issue with a lack of support from elected officials and the public.

F. Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)

NARM have the same type radiation emissions as the radioactive materials identified in the Atomic Energy Act and pose similar threats to the public health and safety, and the environment.

Approximately 25 years ago, Jim Miller of FDA quoted Jane Addams who said, "Progress is not automatic. The world grows better because people wish that it should and take the right steps to make it better. If things are ever to move forward, somebody must be willing to take the first steps and assume the risk."

Almost every state that entered into an agreement with the AEC/NRC included a program for regulation of NARM sources. This reflected the states' recognition that ionizing radiation presented the same kinds of potential hazards regardless of its source. The Mississippi actions regarding NARM are illustrative.

In early 1961, A. L. Gray, M.D., Executive Officer, Mississippi Board of Health, noted that although the Atomic Energy Commission regulated radioactive materials under its jurisdiction and the state regulated x-ray, there was a void in that radium and other naturally occurring radioactive materials were not under the jurisdiction of any regulatory agency in so far as licensure was

concerned. A plan was implemented in Mississippi whereby radium users would be required to apply for and receive a license for the possession and use of radium identical to that required by the Atomic Energy Commission for the materials under its control. This plan included an agreement with radium distributing companies throughout the country and elsewhere whereby the company would not lease or sell radium to anyone within the state that did not possess a license for that material. The public health significance of this move was quite obvious. Why should a license be required for one millicurie of iodine-131 with a half-life of eight days and not for 100 millicuries of radium-226 with a half-life of over 1600 years? The timing of the radium licensing program was intentional, since it was felt the publicity of the expected AEC-Mississippi transfer of authority would make this new regulatory program more palatable, especially to those who had never before been required to have a license. The state immediately began receiving requests for applications for a radium license. This move did not prove to be premature, since subsequent inspections indicated that 30 percent of the radium sources inspected exhibited considerable leakage and contamination.

On Nov. 21, 1966, the Atomic Energy Commission (AEC) appointed a panel to review the Commission's regulatory program for byproduct material. The panel submitted a report, the Trowbridge Report, to the Commission on Sept. 5, 1967. One conclusion it made was that the Atomic Energy Act provides authority for the regulation of only a relatively small percentage of the sources of potential radiation hazard. The panel firmly believed that regulation of all sources of ionizing radiation should be conducted according to uniform standards and procedures and under the aegis of a single federal agency.

To quote from a paper titled, "Health Physics Problems in Oil and Gas Well Logging," which was presented at the annual meeting of Agreement States and AEC in November 1966, "...because of the widespread use of radium and lack of previous government regulations concerning its use, careless handling methods evolved. State inspectors have noted direct handling of 300 milligram radium-beryllium neutron sources with gamma exposure rates of 50 roentgens per hour at the surface of the source. To emphasize a misunderstanding of the problem, one company's operating procedures warned its personnel never to handle a sealed radium-beryllium source with the bare hands but always to wear a pair of cotton gloves."

In 1970, the Interstate Relations Committee of the Conference of Radiation Control Program Directors (CRCPD) identified five areas where it felt action was needed (see reference 14, p. 325). The first area of concern was the licensing of non-agreement material specifically related to radium distributors. This would be the licensing of non-agreement materials in non-licensing states. This was a new term that had been suggested rather than non-agreement states, since there were two radium licensing states that were non-agreement states.

One of 12 resolutions approved by the Agreement States in October 1972 addresses a uniform program of control and licensure for both agreement materials and non-agreement materials. "All radioactive materials should receive the same degree of control in all states. At the federal level, uniform and effective control can best be provided by a single agency; therefore, the General Accounting Office should recommend to the Joint Committee on Atomic Energy that the Atomic Energy Act of 1954 be amended to

extend the authority and responsibility of the U.S. Atomic Energy Commission to include all radioactive material."

Excerpts from page 65 of the 1972 GAO Report, B-155352, to the Joint Committee on Atomic Energy, Congress of the United States, from the Comptroller General of the United States, indicate that "the states expressed concern about the lack of comprehensive federal controls - or uniform and compatible state control - over NARM. No federal agency has comprehensive jurisdiction over users of such materials, even though the hazards are similar to those of reactor-produced radioactive materials. In fact, according to the AEC and the Department of Health, Education and Welfare (HEW), radium is more hazardous than most man-made radioactive materials."

At the 1974 All Agreement States Meeting, the Agreement States recommended strongly that the AEC or its successor agency move immediately to bring accelerator-produced and naturally occurring radioactive material under its jurisdiction.

On May 8, 1975, the Executive Committee of the Conference of Radiation Control Program Directors met with the NRC Commissioners and strongly urged the NRC to consider taking appropriate actions to place this type of material under the same control as is now applied to materials falling under the Atomic Energy Act. In response, the NRC established a task force in January 1976 to review the matter of regulation of these materials.

NUREG-0301, Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials, was published in July 1977 by the NRC. It was recommended by the task force that the NRC seek legislative authority to regulate NARM because these materials present significant radiation exposure potential and existing controls were fragmentary and non-uniform at both the state and federal level.

In 1975, the Executive Committee of the Conference of Radiation Control Program Directors established a task force consisting of representatives from several state radiation control programs with resource persons from the EPA to assess contamination by naturally occurring radionuclides. The Task Force Report on Natural Radioactivity Contamination Problems was published by CRCPD in June 1977 and was later published by the EPA in February 1978 as Natural Radioactivity Contamination Problem, EPA-520/4-77-015. Natural Radioactivity Contamination Problem, Report No. 2, was published by CRCPD in August 1981.

On Feb. 24, 1977, a symposium on Radioactivity in Consumer Products was held in Atlanta, Georgia. Papers were presented on products containing NARM and on the laws, regulations, standards and guides (see reference 12). In July 1977, the CRCPD published the NARM Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials, FDA publication 77-8025.

At the 1982 All Agreement States Meeting, the Agreement States again discussed the problems associated with the non-regulation of NARM in non-agreement states and non-licensing states. The Agreement States strongly suggested that the NRC petition Congress to amend the Atomic Energy Act to authorize the regulation of NARM. A letter reflecting their concerns was written to the National Governor's Association to be included in their Agreement States program assessment. The NRC response dated Dec. 9, 1982 stated that, "we expect the subject of NARM regulation to be brought to the

Commission's attention in connection with the consideration of the recommendation of the NGA study, one of which we understand will deal with NARM." The National Governor's Association in its publication, *The Agreement State Program: A State Perspective* dated January 1983, states "The Atomic Energy Act should be amended to authorize the regulation of radioactive materials not presently affected by the Act, that is, NARM." (Reference 4, p. 5.)

The licensing state concept for the regulation of NARM conceived in 1976 by CRCPD was finally developed and implemented in 1983. At present, there are 15 states identified as "Licensing States." Each of the 15 states is an Agreement State. This program is one where CRCPD has determined that a state has an effective program for regulation of NARM regardless of whether or not the state is an Agreement State.²⁰

At the 1984 All Agreement States Meeting, the states adopted a resolution on NARM supporting the concept that the NRC should seek legislation to regulate discrete sources of NARM. The resolution stated, "That the States which have signed Agreements with the U.S. Nuclear Regulatory Commission, declare that it is in the best interest of the citizens of the United States, that naturally occurring or accelerator-produced radioactive material that is used or produced for its radioactive properties, or radioactive material produced incidental to such production, should be regulated by the U.S. Nuclear Regulatory Commission in an equal manner with Byproduct, Source and Special Nuclear Material." The NRC's response dated Dec. 4, 1984 stated, "In October 1984 we published NUREG-0976, an update of the original NARM study. Most of the original findings pointing to the need for uniform control were confirmed in the update survey. Also, there is the possibility of dual regulation of low-level waste disposal by NRC and EPA, due to potential EPA regulations of NARM disposal."

The CRCPD at its 17th Annual Meeting adopted a formal position relative to the need for amending the Atomic Energy Act to authorize the NRC to regulate NARM. This was forwarded by letter dated June 6, 1985, to Nunzio Palladino, Chairman, NRC. Enclosed with the letter were suggested amendments for the Atomic Energy Act of 1954 and CRCPD's position paper on NRC Regulatory Control of NARM.

At the 1986 All Agreement States Meeting, the Agreement States once again urged the NRC to work toward getting the Atomic Energy Act amended to include all radioactive materials. Some states had investigated occurrences of radioactive contamination associated with scale from tubing and other equipment that had been used in the production and processing of oil and natural gas. The states felt strongly that the appropriate entity to regulate all radioactive materials was the NRC. The NRC responded in a letter dated Dec. 16, 1986, that "... absent Commission directives to do so, the NRC staff has no current plans to request congressional action to gain control of NARM or NORM. NRC has published two detailed reports on the regulation of these materials, NUREGs 0301 and 0976. Also, the Conference's program of 'Licensing

²⁰ In practice, this program only covers programs for regulation of discrete sources of NARM.

States' should help alleviate the NARM problem, if taken advantage of by the States."

At the 1987 All Agreement States Meeting, encouraged by NRC Chairman Zech's commitment to take charge, the Agreement States again requested the NRC to regulate NARM and NORM. The states also requested the opportunity to review the NRC staff paper on this subject and to be allowed to appear before the Commission regarding the NARM/NORM issues.

At the 1988 All Agreement States Meeting, it was expressed that the Agreement States have traditionally and appropriately recommended to the NRC that NARM should be regulated by the NRC. It remains impractical and illogical that NARM not have a home in a single federal agency. The NRC's response letter dated Dec. 22, 1988, stated, "We acknowledge the comments of the Agreement States on NARM issues. As you know, NRC referred this question to the Science Advisor to the President and the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) has agreed to review it and to work with the CRCPD."

In the CIRRPC Fourth Annual Report dated June 30, 1984, it is reported that the CIRRPC chairman, Alvin L. Young, met with the NRC to discuss a potential CIRRPC review of the NRC report, "Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review." In CIRRPC's Eighth Annual Report dated December 1992, it is reported that a CIRRPC working group was created in response to a request from the Chairman of the NRC to the Director of the Office of Science and Technology Policy (OSTP) to examine the need for federal regulation of "discrete" sources of NARM. This request stemmed from the earlier requests by state radiation control program directors for the NRC to seek legislative authority to regulate NARM. The CIRRPC working group drafted a report that addressed the regulation of discrete NARM and noted that there are existing federal authorities to support any future need for such regulation. The working groups did not identify risks due to NARM that would warrant expanded federal authority. CIRRPC stated that existing federal and state legislative authorities provide adequate public health protection for any likely risks from NARM. The CIRRPC Executive Committee informed the NRC and OSTP of its agreement with the working group's conclusion.

The chairman of the OAS recommended that all discrete sources of NARM be brought under the federal regulatory scheme when he testified before the Synar subcommittee on Aug. 2, 1993. More than 30 years have passed, and most Agreement State radiation control programs are regulating NARM as they do other types of radioactive materials. Notwithstanding all the efforts from individuals, states, groups, organizations, and state and federal agencies - federal standards and regulations are non-existent for NARM even though CIRRPC stated that sufficient federal authorities existed to support regulation.²¹

It would appear that no one at the federal level has taken seriously the numerous concerns and recommendations made by the states. The longstanding feeling of the federal agencies that naturally occurring radiation (God's radiation) need not be regulated seems archaic. And when they put their mind

²¹ This is presumably based on the EPA's general authority.

to it, as in the case of uranium mill tailings (see section VIII.D above), the federal government did decide it was worth regulating by enacting the UMTRCA.

Four states, Arkansas, Louisiana, Mississippi and Texas, have specific regulations addressing the licensing of NORM. Litigation regarding NORM in one state, Mississippi, is causing tension for the Radiological Health staff. As this document is being prepared, concerned citizens are requesting Mississippi legislative committees to investigate the NORM issue.

IX. Current Issues

A. Medical

Many of the current developments in the medical area have been covered in Section VIII.A. However, a few other points are worth mentioning.

When 10 CFR 35 was adopted by the NRC, it did not truly address quality assurance in nuclear medicine departments. The issue was addressed in a separate rulemaking that had the effect of reducing the reporting level for misadministrations of radiopharmaceuticals. The original 10 CFR 35 required misadministration reports to be filed both for diagnostic and therapeutic misadministrations. The medical quality control amendments removed virtually all diagnostic misadministrations from the reporting requirements. Unfortunately, in most of the public discussions during Congressional hearings, the impression was left that the data reported by the original requirements was inadequate, since it was not in accord with the newest regulation.

When 10 CFR 35 was being prepared for final publication, the Agreement States became alarmed that the NRC staff was not sensitive to the existing requirements in use in many states for nuclear medicine. Specific concerns were that the duties of the authorized user were changed, the licensee could revise his procedures without notice to the licensing agency, and physicians not specifically trained in nuclear medicine could order nuclear medicine procedures.

The series of articles in the *Cleveland Plain Dealer* in late 1992 raised a number of concerns about both state and federal programs for regulating uses of ionizing radiation. The articles covered occurrences involving both radiation machines and radioactive materials. The resulting U.S. Senate hearing in May 1993 focused on these issues. As noted earlier, the NRC is involved in a major reevaluation of its medical regulatory program, which will in turn affect the Agreement State programs.

It appears this subject will receive increased attention by the NRC and the Agreement States in the next few years.

B. Compatibility

This issue was covered in some detail in Section VII.

The agreements with the NRC require that both the Commission and the respective state use their best efforts to keep their programs compatible with each other. Further, the language of the Atomic Energy Act is that a state must have a program that is "adequate to protect the public health and safety"

and compatible with the NRC before an agreement may be entered into by the state and the NRC. Once the agreement is signed, the Atomic Energy Act requires the state to maintain an adequate program, but does not say that the program must be compatible. This vagueness and differing interpretation by the NRC began to cause concerns in that some federal requirements were not being implemented by the Agreement States.²² A new emphasis on compatibility quickly indicated that a definition was needed, as well as a full understanding of what Congress intended with the Agreement States program.

The NRC has been working on a compatibility policy for some time, which hopefully will establish a good foundation for our mutual efforts in this regard.²³ However, the differing interpretations of the compatibility provisions of section 274 may never be settled absent some court ruling.

C. Imports

Several incidents involving the importation of products containing radioactive material indicate a need to improve the ability to detect and control such imports. This would help preclude the need for extensive investigations by state and federal officials after the products have been widely distributed.

D. Decommissioning

Two efforts are required for this issue. One is the establishment of levels, i.e., concentrations, contamination levels, or exposures, to which a contaminated piece of property must be cleaned in order to be released for use by the general public. Second is how to estimate the amount of money to be held available by the licensee for use in decontaminating the piece of property, including real estate. Some proposals by the NRC were inadequate to meet state regulatory requirements.

For many years, states had asked the AEC/NRC to set clean-up standards for soil in particular. The conventional response from the NRC was that they deferred to the EPA to set a generic standard. The EPA's standard response was that this was a low priority task for them. The earliest record of discussions at the Agreement State meetings on this issue was at the 1974 meeting.

The NRC finally attempted to set such a standard by issuance of its Below Regulatory Concern (BRC) policy on June 27, 1990. This was in response to section 10 of the LLRWPA of 1985. State reaction was mixed, but many wanted the ability to set more stringent standards than those being proposed by NRC. After the U.S. Congress interceded, the NRC announced deferral of the BRC policy on July 30, 1991, and that it would initiate a consensus-building process on the issue. The NRC's initial attempt at this failed, and then it

²² The NRC's Office of General Counsel has stated in various fora that the NRC has the authority to revoke an agreement because of a lack of continued compatibility (e.g., see page 80 of reference 13).

²³ The NRC published a draft adequacy and compatibility policy for comment on July 21, 1994 at 59 Federal Register 37269-37274.

began a process with significant public participation in late 1992. This involved a series of workshops to discuss the issues and obtain views of the interested participants. States, industry, public interest and environmental groups participated in these workshops. The NRC's efforts are currently in the early rulemaking stage. Ironically, in 1993, the EPA began a rulemaking effort somewhat in parallel with the NRC work. The states' concerns now are that the two agencies may develop inconsistent rules, notwithstanding the pledges of the two federal agencies to work together to avoid duplication.

E. Integrated Materials Performance Evaluation Program (IMPEP)

As a result of the 1993 GAO report on the NRC/Agreement State program and the August 1993 Synar hearing, the NRC has been developing a program for evaluating Agreement State and NRC regional materials regulatory programs on a common basis.²⁴ The NRC presented a program for discussion at the October 1993 meeting of the Agreement States. The Agreement States' reaction to the proposal was negative, and concluded it needed extensive revision in both concept and details. A numerical grading system, which the states felt was not appropriate for this cooperative regulatory program, was of particular concern, and they felt that such indicators could be misused or misunderstood by persons not familiar with the elements needed to carry out effective radiation control programs. A March 1994 version of the proposal received by the Agreement States is much improved, and appears responsive to many of the concerns of the states. Further, the numerical ratings have been removed. The program is being implemented on a pilot basis initially. The pilot program involves the NRC's Regions I and II and the states of Utah, Illinois and New Hampshire.

F. Federal Advisory Committee Act (FACA)

Although some indication of problems with the application of FACA to joint NRC/Agreement State efforts appeared earlier, the issue came to a head in September 1993. Prior to this, the NRC had sometimes formed a working group or task force to address a regulatory issue, and Agreement States provided members to such groups.

Two Agreement State representatives (Sharp of Texas and K. Allen of Illinois) were members of an NRC task force created in 1992 to develop a NUREG document titled, "Management of Radioactive Material Safety Programs at Medical Facilities." In September 1993, Allen was informed (Sharp then was retired from Texas) that her participation on the task force would be limited and, in particular, she would not be allowed to participate in reaching consensus positions by exercise of a vote. This was a result of internal NRC discussions on the applicability of FACA to such task forces. The OAS proposed a solution to this issue at the August 1993 Synar hearing and directly to the NRC. There was little response to this matter by the NRC until a staff briefing of the Commission in early January 1994, when the Commission requested its staff to work on it. The Office of the General Counsel submitted a report to the Commission on Feb. 4, 1994, which reflected the first serious thought given to the issue by the NRC. On Feb. 8, 1994,

²⁴ Prior to 1993, on several occasions, the Agreement States had suggested that the NRC materials regulatory program be subjected to a review similar to that for the agreement states.

when the Chairman of the OAS briefed the Commission, the matter was also discussed and the Commission seemed receptive to trying to resolve this matter. The Executive Committee of the OAS and the Chairman of the CRCPD met with NRC officials on June 14, 1994 to discuss this issue.

X. Epilogue

We know not what the future holds. Of one thing we are certain - there will be change.

One purpose of studying historical events is to learn from them. After all, historical events, whether in our professional lives or our personal lives, are what shape us and develop our character. The information discussed in this report can be used as a reference when future actions are considered.

All of us have seen many changes in the use and regulation of nuclear materials over the years. We are very much aware of the fragile nature of our environment and the efforts exerted today by regulators and regulatees to correct past mistakes and prevent future ones. We should not fault our predecessors for conditions that, in retrospect, appear to have been handled inappropriately. They acted in good conscience with the knowledge and technical understanding of the time. Likewise, we expect our successors to do a better job, having the benefit of the experience we provide, because their knowledge will have been expanded and because their technical capabilities will have been improved.

Thus, changes should be expected. We would hope that they are based on a reasoned approach, pure motives, and an expectation of substantial benefit to all concerned.

REFERENCES

1. Selected Materials on Federal-State Cooperation in the Atomic Energy Field, Joint Committee on Atomic Energy, Congress of the United States, March 1959.
2. Hearings Before the Joint Committee on Atomic Energy, Congress of the United States, Eighty-Sixth Congress, May 19, 20, 21, 22 and August 26, 1959, Committee Report.
3. Final Task Force Report on the Agreement States Program, U.S. Nuclear Regulatory Commission, NUREG-0388, December 1977.
4. The Agreement State Program: A State Perspective, National Governors' Association, January 1983.
5. Controlling the Atom, The Beginnings of Nuclear Regulation, 1946-1962, George T. Mazuzan and J. Samuel Walker, University of California Press, 1984.
6. U.S. Nuclear Regulatory Commission, Policy Issue (Information) Paper, SECY-91-039, February 12, 1991.
7. April 1993 GAO Report, GAO/RCED 93-90, Better Criteria and Data Would Help Ensure Safety of Nuclear Materials.
8. Regulation of the Barnwell Low-Level Radioactive Waste Disposal Facility, V. R. Autry, July 1993.
9. 1990 Update, Summary of Low-Level Radioactive Waste Disposal Facility Siting Laws, University of Tennessee, January 1991.
10. Directions in Low-Level Radioactive Waste Management: A Brief History of Commercial Low-Level Radioactive Waste Disposal, U.S. Department of Energy, October 1990.
11. NUREG/CR-1759, Vol. 1., Data Base For Radioactive Waste Management, Review of Low-Level Radioactive Waste Disposal History, November 1981.
12. NUREG/CP-0001, Radioactivity in Consumer Products, August 1978.
13. Committee on Government Operations, U.S. Congress, Report on Aug. 2, 1993 Hearing on the NRC's Agreement States Program.
14. Proceedings of 2nd Annual Conference, Conference of Radiation Control Program Directors, April 26-29, 1970.

APPENDIX A

LIST OF AGREEMENT STATES

<u>State</u>	<u>Effective Date of Agreement</u>
Alabama	October 1, 1966
Arizona	May 15, 1967
Arkansas	July 1, 1963
California	September 1, 1962
Colorado	February 1, 1968
	Amended April 20, 1982 for Mills
Florida	July 1, 1964
Georgia	December 15, 1969
Idaho	October 1, 1968 NRC reasserted April 26, 1991
Illinois	June 1, 1987 Amended November 1, 1990 for Mills
Iowa	January 1, 1986
Kansas	January 1, 1965
Kentucky	March 26, 1962
Louisiana	May 1, 1967
Maine	April 1, 1992
Maryland	January 1, 1971
Mississippi	July 1, 1962
Nebraska	October 1, 1966
Nevada	July 1, 1972
New Hampshire	May 16, 1966

APPENDIX A, con't.

<u>State</u>	<u>Effective Date of Agreement</u>
New Mexico	May 1, 1974 NRC reasserted on Mills, June 1, 1986
New York	October 15, 1962
North Carolina	August 1, 1964
North Dakota	September 1, 1969
Oregon	July 1, 1965
Rhode Island	January 1, 1980
South Carolina	September 15, 1969
Tennessee	September 1, 1965
Texas	March 1, 1963 Amended March 24, 1982 for Mills
Utah	April 1, 1984 Amended May 9, 1990 for LLW
Washington	December 31, 1966 Amended February 19, 1982 for Mills

APPENDIX A, con't.

AGREEMENT STATES

By Year of Agreement

1962	Kentucky, Mississippi, California, New York
1963	Texas, Arkansas
1964	Florida, North Carolina
1965	Kansas, Oregon, Tennessee
1966	New Hampshire, Nebraska, Alabama, Washington
1967	Louisiana, Arizona
1968	Colorado, Idaho (NRC reasserted Idaho in 1991)
1969	North Dakota, South Carolina, Georgia
1971	Maryland
1972	Nevada
1974	New Mexico
1980	Rhode Island
1984	Utah
1986	Iowa
1987	Illinois
1992	Maine

APPENDIX B

LIST OF ANNUAL JOINT MEETINGS

	1962	
	1963	
December 14-15,	1964	Washington, D.C.
November 17-18,	1965	Washington, D.C.
November 16-18,	1966	Washington, D.C.
November 15-16,	1967	Bethesda, Md.
October 21-22,	1968	Bethesda, Md.
October 20-21,	1969	Bethesda, Md.
October 19-20,	1970	Bethesda, Md.
October 18-19,	1971	Bethesda, Md.
October 16-18,	1972	Bethesda, Md.
October 16-18,	1973	Bethesda, Md.
October 8-10,	1974	Bethesda, Md.
October 7-9,	1975	Bethesda, Md.
October 5-7,	1976	Bethesda, Md.
	1977	
October 3-5,	1978	Silver Spring, Md.
October 2-4	1979	
October 7-9,	1980	Atlanta, Ga.
October 20-22,	1981	Arlington, Tex.
October 27	1982	Gaithersburg, Md.
September 27-29,	1983	Arlington, Va.
October 2-4,	1984	King of Prussia, Pa.
October 8-10,	1985	Bethesda, Md.
October 7-9,	1986	San Francisco, Calif.
October 7-9,	1987	Louisville, Ky.
October 5-7,	1988	Potomac, Md.
October 11-13,	1989	Overland Park, Kans.
Oct. 30 - Nov. 1,	1990	Reno, Nev.
October 28-29,	1991	Sacramento, Calif.
October 26-28,	1992	Towson, Md.
October 24-27,	1993	Tempe, Ariz.
October 23-26,	1994	Portland, Maine

APPENDIX C

CHAIRPERSONS

ORGANIZATION OF AGREEMENT STATES

1962	
1963	
1964	
1965	
1966	John Heslep, California *
1967	
1968	
1969	
1970	
1971	B. Jim Porter, Louisiana
1972	
1973	
1974	
1975	Aubrey Godwin (then of Alabama)
1976	Al Hazle, Colorado
1977	Ellis Simmons, Nebraska
1978	Eddie Fuente, Mississippi
1979	Ted Wolff, New Mexico
1980	Charles Tedford (then of Georgia)
1981	John Vaden, Nevada
1982	Diane Tefft, New Hampshire
1983	Bill Spell, Louisiana
1984	Mike Mobley, Tennessee
1985	Joe Ward, California

APPENDIX C (con't.)

1986	Ed Bailey (then of Texas)
1987	Frank Bradley, New York Department of Labor
1988	Larry Anderson, Utah
1989	Don Hughes, Kentucky **
1990	Greta Dicus, Arkansas
1991	Tom Hill, Georgia
1992	Tom Hill, Georgia ***
1993	Wayne Kerr, Illinois
1994	Bob Kulikowski, New York City Health Department

* There appears to have been a special meeting convened in this year to discuss topics such as x-ray regulation.

** Chair-Elect Dicus presided over the 1989 meeting in Hughes' absence.

*** The Chair-Elect, Don Flater of Iowa, was unable to serve and Tom Hill was elected to a second term.

Historical Note: Eddie Fuente, Director, Division of Radiological Health, Mississippi Department of Health, was absent from the 1993 All Agreement States meeting for the first time in 30 years. This is a record unmatched by any other program director.

**United States
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545**

March 3, 1964

Mr. Charles R. Barden
Director, Radiation Control Program
Texas State Department of Health
1100 West 49 Street
Austin 5, Texas 78700

Dear Charles:

This is to confirm Bill Sims telephone conversation of February 24 concerning an exchange-of-information meeting at your office on Monday, March 23. If this date is still convenient with you, we would like to have him meet with you at 9:00 a.m.

Among other things, we would anticipate covering the following items:

1. Specific variations or exemptions from Texas regulations that have been granted.
2. Problems encountered in reciprocal recognition of licenses.
3. The number of agreement materials licenses inspected according to categories, including pre-licensing inspections or visits.
4. Inspection work load, number of re-inspections conducted, etc.
5. New procedures for evaluating license applications, new conditions of use that have been included on Texas licenses, and new or unusual uses that have been licensed or evaluated.
6. Use of medical consultation in evaluating applications for medical use of radioactive materials.
7. Incidents and overexposures.
8. State experience in licensing naturally occurring and accelerator-produced materials.

Mr. Charles R. Barden
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9. Enforcement actions taken against licensees.
10. Personnel changes and present number of personnel regulating agreement materials. Additional training, if any, received by radiological health personnel.
11. Specific types of information or assistance needed from the AEC.
12. Acquisitions of new facilities or equipment.

A copy of a suggested agenda is attached. We will appreciate your comments on the agenda as well as the appropriateness of the suggested date at your earliest convenience. If you have any particular questions which may involve advance preparation on our part, please let us know.

Sincerely yours,

/s/

B. L.

Harless, Chief
Agreements Branch

State

Division of Radiation Protection
Standards

Attachment:
Suggested Agenda

SUGGESTED AGENDA FOR TEXAS-AEC**EXCHANGE-OF-INFORMATION MEETING**

Austin, Texas
 March 23, 1964

9:00 - 9:05 a.m.	Opening Remarks - Texas
9:05 - 9:10 a.m.	Opening Remarks - USAEC
9:10 - 9:45 a.m.	Discussion of contemplated changes in USAEC regulations
9:45 - 10:15 a.m.	Discussion of contemplated changes in Texas regulations *
10:15 - 10:30 a.m.	Break
10:30 - 11:15 a.m.	Current AEC licensing activities
11:15 - 12:00 p.m.	Current Texas licensing activities
12:00 - 1:30 p.m.	Lunch
1:30 - 2:00 p.m.	AEC experience in Compliance matters
2:00 - 2:30 p.m.	Texas experience in Compliance matters
2:30 - 4:00 p.m.	Exchange of Information - AEC and Texas
4:00 - 4:30 p.m.	Presentation by AEC representatives of suggested changes to Texas regulations **
4:30 - 5:00 p.m.	Tour of Texas Radiological Health Facilities

* This item may or may not be appropriate, depending on whether Texas proposes any modification of its existing regulations.

** Prior to the meeting, AEC representatives will prepare a list of any modifications that have been made in AEC regulations which Texas may wish to consider incorporating in order to maintain our regulatory programs on a current basis.

United States
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

December 13, 1965

Mr. Charles R. Barden, P.E., Director
Division of Occupational Health and
Radiation Control
Texas State Department of Health
Austin, Texas 78756

Dear Charlie:

As discussed in my letter of July 15, 1965, to all Agreement States, and as Ben Harless mentioned during the October 26-27 meeting in Austin, we plan to furnish each Agreement State with our comments or suggestions concerning the State's program subsequent to each review meeting. The purpose of this letter is to supply our comments concerning the Texas program based on the October meeting and the information which we continuously exchange with you during the interval between meetings.

I would like to convey to you the very favorable impression gained by our staff with respect to the constructive and cooperative attitude exhibited by you and your staff in our mutual efforts to fulfill the purpose of the agreement. Although our review disclosed no significant deficiencies in your program, we would like to pass along to you the following comments which we feel may be helpful.

We noted that in most cases inspection reports are not prepared other than as recorded on your inspection findings form, which specifies the name of the licensee, licenses inspected, date of inspection, items of noncompliance found, and name of inspector. We understand that more extensive reports are prepared for incident investigations or in cases where major items of noncompliance are encountered. Although we realize that in most cases Agreement States do not need to prepare inspection reports in the same detail that is necessary under AEC procedures, you may wish to consider whether it would be useful to your program to include in inspector's reports additional detail as necessary to support items of noncompliance and findings with respect to the adequacy of the conduct of licensees' operations to protect health and safety. We feel such information is important in the event formal enforcement action needs to be taken and as a reference for future inspections and licensing actions. In most cases, it may suffice to summarize the inspector's notes and retain these summaries in the inspection files for future use.

Mr. Charles R. Barden
December 13, 1965
Page 2

We also understand that results of inspections are usually discussed at the time of the inspection with the person immediately responsible for safety of the program, such as the radiation safety officer, and that letters of noncompliance are usually directed to the same person. We have found it useful to discuss inspection results with a member of licensee management, who is in a position to assure that corrective measures are taken. Similarly, letters setting forth items of noncompliance have been addressed to the head of the licensee's organization. This practice has resulted, in part, from our experience which indicates that the heads of such organizations were often not aware of violations or unsafe practices and, therefore, were not in a position to take corrective action. You may wish to consider whether a similar practice would be useful in the administration of your program since we understand you have, in a few instances, experienced some delays on the part of licensees in taking appropriate corrective measures.

I hope that the foregoing comments will be useful to you in the administration of your radiation control program. If you have any questions about them, please let us know. I would like to thank you again for the courtesies extended to our representatives at the meeting.

Sincerely yours,

/s/

Eber R. Price, Director
Division of State & Licensee
Relations

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

April 3, 1992

Mr. W. Clough Toppan, Manager
Radiological Health Program
State House, Station 10
Augusta, ME 04333

Dear Mr. Toppan:

Under section 274g. of the Atomic Energy Act of 1954, as amended, the Commission is authorized and directed to cooperate with Agreement States to assure that the Nuclear Regulatory Commission (NRC) and Agreement State programs for protection against the hazards of radiation will be coordinated and compatible. As a part of our mutual "best efforts" program to achieve these objectives, the NRC and the Agreement States have agreed to exchange certain information on a periodic schedule.

I would like to inform you of the information currently being exchanged between the Commission and the Agreement States and request that the State of Maine supply us with the same type of information which the other Agreement States are now forwarding to us. The NRC will provide Maine with the following:

1. NRC regulatory guides pertinent to agreement materials.
2. NRC regulations (10 CFR), including proposed and effective amendments.
3. NRC and Agreement State sealed source and device registration catalog.
4. NRC and Agreement State licensing statistics and data on inspections and other selected aspects of Agreement State programs.
5. Selected data on incidents in Agreement States.
6. Selected information related to escalated enforcement proceedings.
7. Copies of regulations published in the Federal Register by other Federal agencies, as appropriate.
8. NRC bulletins and information notices.
9. Responses to specific requests for procedural, technical, and regulatory information concerning the Commission's regulatory program.
10. NUREG reports of interest.

Mr. W. Clough Toppan

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APR 3 1992

The Commission also will supply, from time to time, additional information which we feel will be of interest to the Agreement States.

We would like the State of Maine to provide the NRC Office of State Programs with the following information:

1. One copy of all licenses and amendments issued by the State (monthly).
2. Selected annual program information including statistical data on licensing and Inspection activities per the All Agreement States Letter SP-92-038 (enclosed).
3. Updated statistical data and other programmatic Information which will be requested in connection with the conduct of our periodic reviews of the Maine program.
4. Copy of each order or equivalent document issued in enforcement proceedings.
5. Draft proposed and effective regulations (2 copies, 2nd copy to Region I). Draft regulations should be furnished to us with at least a 60-day period for us to review and comment.
6. Copies of sealed sources and devices registrations issued by the State.
7. State Issued licensing guides and similar regulatory documents which may be prepared from time to time and which may be of interest to NRC and all Agreement States.
8. Abnormal Occurrence Reports.
9. Miscellaneous Information as way be requested.
10. Information on significant incidents occurring in Maine involving licensed material.

I would appreciate confirmation that such information will be provided to NRC.

I appreciate your cooperation and that of your staff during our pre-agreement negotiations and wish to assure you of our commitment to be of assistance as necessary in the future. Please call Mr. Vandy L. Miller at (301) 504-2326 if you have any questions.

Sincerely,

Original signed by:
Carlton Kammerer

Carlton Kammerer, Director
Office of State Programs

Enclosure:
As stated

Agenda
U.S. A.E.C.
1717 H. St. N.W.
Washington, D.C.
Room 1146
Dec. 14-15, 1964

December 14

Opening

Meeting of Agreement State Representatives with Principal Staff

Regulation of Medical Uses of Isotopes

 General Licensing of Diagnostic Uses

 FDA-AEC-Agreement State Interfaces

 Exchange of Information from Medical Advisory Committee

Contamination Levels for Facilities and Equipment Released for

 Unrestricted Use

Waste Disposal

 Status of Sea Disposal of LLW

 Regulatory Problems Associated with Land Burial

December 15

Transportation of Radioactive Material

 Guides and Regulations

 Status of Regulations of Other Federal Agencies

 Part 71

 Part 72

General Discussion

 Exchange of Licensing and Enforcement Data

 Establishment of Film Calibration Lab

 Report by Committee regarding Compliance Visits with State Inspectors

 Evaluation of Agreement State Programs

 Universal Label for Products

 Sealed Source Device and Testing Program

 Plans for Next AEC/Agreement State General Meeting

APPENDIX H

Tuesday, October 26, 1993

8:00 - 9:30	Materials Regulation Panel	R. Kulikowski, Chair
	Medical Misadministration and Patient Followup	C. Paperiello, NRC R. Kulikowski, N.Y.C.
	Scaled Source and Device Evaluations	C. Paperiello, NRC
	Generally licensed Devices	F. Combs, NRC
	Food & Drug Administration/NRC Memorandum of Understanding (MOU)	S. Schwartz, NRC
9:30 - 10:00	Break	
10:00 - 11.30	Contaminated Sites Issues	S. Collins, IL, Chair
	NRC SDMP Program Status	J. Austin, NRR
	Agreement State Program Status	S. Collins, IL
	Sewerage System Contamination	J. Austin, NRR R. Owen, Ohio
	Site Decommissioning Funding	Charles Pierson Assistant Attorney General, AZ
11:30 - 12:30	Lunch	
12:30 - 2:30	NRC/EPA Interface Issues	A. Godwin, Chair
	Subpart I - Clean Air Act	R. Bangart, NRC
	Subpart T - Uranium Mill	D. Sollenberger, NRC
	Residual Contamination Standards	D. Cool, NRC
2:30 - 3:00	Break	

APPENDIX H

3:00 - 4:00	Legal issues NRC Authority in Agreement States (1) Program Revocation (2) Investigatory Legal and Policy Considerations of Early State Involvement in the Development of NRC Rules and Policies	M. Malsch, NRC
4:00	Agreement States Meeting	

Wednesday, October 27, 1993

	General Session	
8:30 - 9:30	Radioactive Waste Panel	William Sinclair, Chair
	Land ownership Issue	W. Sinclair, Utah
	Compact Revisions	
9:30 - 10:00	Break	
10:00 - 11:30	Operational Events Panel	P. Merges, Chair
	Gamma Knife Misadministration	R. Quillin, CO
	Source in Steel Mills	P. Merges, NYS DEC
	Abnormal Occurrence Reporting & National Materials Events Database	S. Pertijohn, AEOD
11:30 - 12:00	Meeting Summary Remarks	G. Wayne Kerr, IL
12:00	Meeting Adjourns - Staff Meeting	