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

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MEMORANDUM FOR: Donald Lanham, Management Analyst
Document Control Branch

FROM: Cardelia H. Maupin
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SUBJECT: PLACEMENT OF DOCUMENTS IN THE PUBLIC DOCUMENT ROOM

As we discussed, I would like to place two documents in the NRC Public Document Room. These documents are State Agreements Program Internal Procedures B.7, "Criteria for Compatibility Determinations" and the June 1991 "Summary of the U.S. Nuclear Regulatory Commission's Agreement State Program." These documents are enclosed.

If you have any questions, I can be reached at 20312.

Attachments: As Stated

STATE AGREEMENTS PROGRAM
DIVISION I

Internal Procedures

B. Policy

B.7 - Criteria for Compatibility Determinations

I. Background

Section 274d.(2) of the Atomic Energy Act of 1954, as amended, requires that before entering into an agreement with any State, the Commission shall make a determination that the State's program is compatible with the Commission's program. Section 274g. authorizes and directs the Commission to cooperate with the States in the formulation of standards to assure that State and Commission programs will be coordinated and compatible. Section 274j(1) requires that the Commission periodically review such agreements and actions taken under the agreements to ensure compliance with Section 274. Sections 274d(2) and 274g. are the only sections of the Act that address the concept of compatibility. It should be noted that both sections refer to the compatibility of "programs." It is evident that Congress intended that the Commission address more than just regulations in its review, and since the earliest days of the State Agreements Program the Commission has used the term "compatibility" in relation to not only regulations, but also to such program areas as licensing and compliance. This procedure, however, will address compatibility only as it affects regulations.

The Commission has never formally defined compatibility or provided more than minimal guidance as to how the term should be interpreted. The basic objective has been to achieve uniformity among the various regulatory programs to the maximum extent practicable recognizing that the States must be allowed some flexibility to accommodate local conditions. With regard to regulations, it has been more or less understood that certain regulations such as 10 CFR Part 20 were considered to be "matters of compatibility" and that States were required to have regulations that had essentially identical language. With respect to other parts of the regulations it was less clear what requirements were considered "matters of compatibility" and why. In 1961, the Commission published criteria for the guidance of States and the Commission relating to the discontinuance of Commission authority under the terms of the agreement. The criteria require that "The State regulatory program shall adopt a set of standards for protection against radiation... It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by Part 20 of the [Commission] regulations based on officially approved radiation protection guides." However, questions remain as to how precisely State regulations must reflect NRC regulations.

In addition, NRC has always encouraged uniformity in regulations other than those listed above, but no specific guidance has been provided.

It should be noted that the Uranium Mill Tailings Radiation Control Act and the Nuclear Waste Policy Act require Agreement States as well as NRC to incorporate certain elements in their regulatory programs (e.g., environmental assessments, land ownership, financial assurances). These requirements have been appropriately included in the categorization.

In light of the above, this procedure establishes criteria for better defining compatibility and determining the degree to which States regulations must show uniformity with Commission regulations.

II. Rule Categorization

Historically, the notion of degrees of compatibility has always been implicit in compatibility determinations. This notion, however, has never been given substance in the form of policies or procedures. Under this procedure pertinent NRC rules are categorized according to the degree of uniformity necessary between NRC and Agreement State requirements. Four categories are established as follows:

Division 1 Rules

There are certain provisions in NRC regulations that States must adopt, essentially verbatim, into their regulations. These provisions include those that form the basic language of radiation protection essential for effective communication between regulatory agencies and the regulated community. These provisions have been formulated and agreed to by national and international organizations, from consensus standards followed by industry and government. They include technical definitions such as "curie," "dose," and "rad," radiation protection standards such as occupational exposure limits, effluent release limits, and legal definitions such as for "byproduct material," "restricted area" and "occupational dose." These provisions are so basic to the regulatory programs that their modification by a State would result in numerous and difficult problems including interference in interstate commerce. These provisions are collectively referred to as Division 1 rules and Agreement States are required to adopt essentially identical provisions.

Division 2 Rules

There are other provisions in NRC regulations that address basic principles of radiation safety and regulatory functions. Such principles include generally applicable safety requirements such as personnel monitoring and ALARA, and procedural requirements such as detailed in Part 19. While States must address such principles in their regulations, the States may adopt requirements more

restrictive than NRC rules. The use of language identical to that in NRC rules is not necessary provided the underlying principles are the same. For example, 10 CFR 19.11 addresses the posting of certain notices to workers. While we believe that it is important that Agreement State licensees be required to make available to workers certain documents, the manner, location and time constraints under which they are posted may differ somewhat from the corresponding NRC provisions. Local circumstances may dictate more stringent requirements than those of 19.11. Other rules that would be included in this category include basic procedural requirements necessary for licensing, inspection authority, incident reporting, and radiation safety requirements for industrial radiographers. Such provisions are designated Division 2 rules.

Division 3 Rules

There are a great number of provisions in NRC regulations which would be appropriate for Agreement States to adopt, but which do not require any degree of uniformity between NRC and States rules. For example, NRC has found group medical licensing to be an improved method of licensing the medical uses of radionuclides. States utilizing a different procedure in licensing medical uses of radionuclides would not be hindering interstate commerce or deviating in any manner from basic radiation protection standards or procedures. Such rules, some of which relate to areas which are strictly matters between the regulatory agency and the regulated community within its jurisdiction are designated Division 3 rules. Such rules include administrative requirements as well as technical criteria which the agency feels the licensee must address in order to meet the basic radiation standards. In all cases, States are encouraged to adopt the regulatory approach taken by NRC in such rules, but are not required to do so.

Division 4 Rules

There are certain regulatory functions which are reserved to NRC pursuant to the Atomic Energy Act and 10 CFR Part 150. Rules pertaining to these areas are designated Division 4 rules. Such rules include those concerning reactor regulation, distribution of consumer products, exports and imports, and high level waste disposal. State regulations should not address these areas.

III. Listing of Pertinent NRC Rules

Attached as Appendix A of this procedure is a listing of all pertinent NRC rules (Parts 19, 20, 30, 31, 32, 33, 34, 35, 40, 61, 70, 71, and 150) by compatibility type. The corresponding section of the Suggested State Regulations can be found in Internal Procedure A.2.

APPENDIX A

CATEGORIZATION OF NRC RULES BY COMPATIBILITY TYPE

Division 1 Rules

19.3	Definitions (Exceptions - Act, Commission, license)
20.3	Definitions (Exceptions - Act, Commission, Gov't Agency, license)
20.4	Units of radiation dose
20.5	Units of radioactivity
20.101	Dose limits
20.102	Prior dose
20.103	Concentrations in restricted areas
20.104	Exposure of minors
20.105	Levels in unrestricted areas
20.106	Radioactivity in effluents
20.203	Caution signs, etc., except (c)(6)&(7)
20.403	Notifications of Incidents
Part 20	Appendix B and Appendix C
30.4	Definitions (Exceptions - Act, Commission, Gov't Agency, license, production facility, utilization facility)
30.11	Specific exemptions
30.12	Contractor exemptions
30.14	Exempt concentration
30.15	Exempt items
30.16	Sc-46 resins exemption
30.18	Exempt quantities
30.19	Self-luminous products
30.20	Gas and aerosol detectors
30.70	Exempt concentrations schedule
30.71	Exempt quantities schedule
31.3	Certain devices and equipment
32.2	Definitions
40.4	Definitions (Exceptions - Act, Commission, Gov't Agency, Pharmacist, physician)
40.11	DOE & NRC contractor exemptions
40.13	Unimportant quantities
40.14	Specific exemptions
40.22	Small quantities of source material
61.2	Definitions (Exceptions - Commission, Director, Gov't Agency)
61.41	Protection of general population
61.55	Waste classification
70.4	Definitions (Exceptions - Act,Atomic Weapon, Commission, Common defense and security, Gov't Agency)
70.11	DOE & NRC contractor exemptions
70.14	Specific exemptions
71.4	Definitions (those relating to materials transportation)
71.5	Transportation of licensed material
71.10	Exemptions for low-level materials

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Part 71	Appendix A
150.3	Definitions (b), (c), (g), (i), and (j)
150.11	Critical mass
150.20	Reciprocity

Division 2 Rules

19.11	Posting of Notices
19.12	Instructions to Workers
19.13	Notifications
19.14	Presence of worker representatives
19.15	Consultation with workers
19.16	Requests for inspection
19.17	Inspection not warranted
20.1(c)	ALARA
20.108	Bioassay Services
20.201	Surveys
20.202	Personnel Monitoring
20.203	(c)(6) and (7) 500 rem/hr rule
20.205	Picking up, receiving, and opening packages
20.207	Storage & control in unrestricted areas
20.301	Waste Disposal - General Requirements
20.302	Approval of disposal procedures
20.303	Sewage disposal
20.311	Transfer for disposal
20.402	Reports of Theft or loss
20.405	Reports of overexposures
20.408	Monitoring Reports on termination
Part 20	Appendix A
30.3	Activities requiring license
30.13	Carrier Exemption
30.31	Types of Licenses
30.32	Application for specific license
30.33	General requirements
30.34	Terms & Conditions
30.41	Transfer of byproduct material
30.55	Tritium reports (to be deleted)
31.5	Certain measuring, gauging and controlling devices
31.6	Installation of GL gauges
31.7	Luminous safety devices for use in aircraft
32.11	Introduction of exempt concentrations
32.12	Material transfer reports
32.13	Prohibition of introduction
32.51	Manufacture of GL gauges
32.51a	Manufacture of GL gauges
32.52	Transfer reports - GL gauges
32.53	Manufacture of luminous safety devices
32.54	Labeling of luminous safety devices
32.55	QA - luminous safety devices
32.56	Transfer reports - luminous safety devices
32.57	Manufacture of Am-241 reference sources
32.58	Labeling of Am-241 sources
32.59	Leak testing of Am-241 sources
32.61	Manufacture of Sr-90 ice detection devices

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32.62	QA - ice detection devices
32.70	Manufacture of Medical GL material
32.71	Manufacture of in vitro kits
32.72	Manufacture of radiopharmaceuticals
32.73	Manufacture of generators and reagent kits
32.74	Manufacture of sources for medical use
32.101	Schedule B - tests for luminous safety devices
32.102	Schedule C - tests for Am-241 sources
32.103	Schedule D - tests for Sr-90 ice detection devices
32.110	Sampling procedures
34.2	Definition
34.11	Specific licenses for radiography
34.21	Levels of radiation
34.22	Locking of devices
34.23	Storage precautions
34.24	Survey Instruments
34.25	Leak testing, etc.
34.26	Quarterly inventory
34.27	Utilization logs
34.28	Inspection and maintenance
34.31	Training
34.32	Operating and emergency procedures
34.33	Personnel Monitoring
34.41	Security
34.43	Surveys
Part 34	Appendix A
40.2a	Inactive tailings sites
40.12	Carrier exemptions
40.20	Types of licenses
40.26	GL - possession & storage of tailings
40.31(f) & (h)	License for source material milling
40.32	General requirements
40.34	Manufacture of depleted uranium products for GL
40.35	Manufacture of depleted uranium products for GL
40.41	Terms and Conditions
40.51	Transfer of source material
40.65	Effluent monitoring
Part 40	Appendix A
61.3	License required
61.10	Content of application
61.11	General information
61.12	Specific Technical information
61.13	Technical analyses
61.14	Institutional information
61.15	Financial information
61.23	Standards for issuance
61.24	Conditions of licenses
61.27	Application for renewal or closure
61.28	Contents of application for closure
61.29	Post-closure observation
61.30	Transfer
61.31	Termination
61.40	General requirement

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61.42	Protection of individuals from intrusion
61.43	Protection of individuals during operations
61.44	Stability of site after closure
61.50	Site suitability requirements
61.51	Site design
61.52	Facility operation and site closure
61.53	Environmental monitoring
61.54	Alternative requirements
61.56	Waste characteristics
61.57	Labeling
61.59	Institutional requirements
61.61	Applicant qualifications
61.62	Funding for closure and stabilization
61.63	Financial assurances
61.81	Tests at disposal facilities
61.82	Commission inspections
70.12	Carrier exemption
70.18	Types of licenses
70.23(a)	Requirements for approval
70.39	Manufacture of Pu calibration sources
70.42	Transfer of SNM
71.12	GL for NRC approved packages
71.13	Previously approved Type B packages
71.14	GL: DOT containers
71.16	GL: foreign approved packages
71.81	Operating controls and procedures
71.85	Preliminary determinations
71.87	Routine determinations (except fissile related)
71.88	Air transport of Pu
71.89	Opening instructions
150.31	UMTRCA
150.32	UMTRCA

Division 3 Rules

19.1	Purpose
19.2	Scope
19.4	Interpretations
19.5	Communications
19.20	Employee protection
19.30	Violations
19.31	Applications for exemptions
19.32	Discrimination prohibited
20.1	(a) & (b) Purpose
20.2	Scope
20.6	Interpretations
20.7	Communications
20.107	Medical diagnosis & therapy
20.204	Posting exceptions
20.206	Instruction of personnel
20.305	Disposal by incineration
20.306	Biomedical waste rule
20.401	Records

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20.407	Personnel Monitoring reports
20.409	Notifications and Reports to Individuals
20.501	Applications for exemptions
20.502	Additional Requirements
20.601	Violations
30.1	Purpose & Scope
30.2	Resolution of conflict
30.5	Interpretations
30.6	Communications
30.7	Employee protection
30.36	Expiration of licenses
30.37	Applications for renewal
30.38	Applications for amendment
30.39	Commission Action to renew or amend
30.51	Records
30.52	Inspections
30.53	Tests
30.61	Modification and revocation of licenses
30.62	Withholding of byproduct material
30.63	Violations
31.1	Purpose and Scope
31.2	Terms and conditions
31.8	Am-241 reference sources
31.9	GL to own material
31.10	Sr-90 ice detection devices
31.11	In-vitro GL
32.1	Purpose and scope
33.1	Purpose and scope
33.11	Broad license requirements
33.12	Broad license requirements
33.13	Broad license requirements
33.14	Broad license requirements
33.15	Broad license requirements
33.16	Broad license requirements
33.17	Broad license requirements
33.100	Schedule A
34.1	Purpose and scope
34.3	Applications for specific licenses
34.29	Permanent radiographic installations
34.42	Posting
34.44	Supervision of radiographer's assistants
34.51	Applications for exemptions
35.1	Purpose and scope
35.2	Medical license requirement
35.3(a)	Definition of "Human Use"
35.3(b)	Definition of "physician"
35.4	Application form
35.11	Licenses for human use
35.12	Licenses for individual physician's
35.13	Human use of sources
35.14	Group medical licensing
35.21	Teletherapy calibrations
35.22	Teletherapy spot-checks
35.23	Instrument calibration

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35.24	Qualified expert
35.25	Teletherapy room monitor
35.26	5-year inspection and servicing
35.27	Records
35.31	Medical GL
35.41	Misadministration reporting
35.42	Misadministration reporting
35.43	Misadministration reporting
35.44	Misadministration reporting
35.45	Misadministration reporting
35.100	Medical Groups
40.1	Purpose
40.2	Scope
40.3	License requirements
40.5	Communications
40.6	Interpretations
40.7	Employee protection
40.21	GL- title to source material
40.25	GL- depleted uranium
40.31	(a)-(e), (g) applications for specific licenses
40.42	Expiration
40.43	Renewal of licenses
40.44	Amendment of licenses
40.45	Commission action to renew or amend
40.46	Inalienability
40.61	Records
40.62	Inspections
40.63	Tests
40.64	Reports
40.71	Modification, etc.
40.81	Violations
61.1	Purpose and scope
61.4	Communications
61.5	Interpretations
61.6	Exemptions
61.7	Concepts
61.9	Employee protection
61.20	Filing application
61.21	Repetition
61.22	Updating of application
61.25	Changes
61.26	Amendment of license
61.80	Maintenance of records
61.83	Violations
70.1	Purpose
70.2	Scope
70.3	License requirements
70.5	Communications
70.6	Interpretations
70.7	Employee protection
70.19	GL for plutonium reference source
70.20	GL to own SNM
70.21	Filing Applications
70.22	(a),(b),(c),(d),(e) Contents of applications

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70.31	Issuance of licenses
70.32	Conditions of licenses (Except statements strictly applicable to strategic quantities of SNM)
70.33	Renewal of licenses
70.34	Amendment of licenses
70.35	Commission Action to renew or amend
70.36	Inalienability
70.37	Disclaimer of warranties
70.41	Authorized use of SNM
70.55	Inspections
70.56	Tests
70.61	Modification and revocation
70.71	Violations
71.0	Purpose and scope
71.1	Communications
71.2	Interpretations
71.3	Requirement for license
71.7	Specific exemptions
71.9	Exemption of physicians
71.91	Records
71.93	Inspection and tests
71.95	Reports
71.99	Violations
71.101-71.137	QA
150.1	Purpose
150.2	Scope
150.4	Communications
150.5	Interpretations
150.30	Violations

Division 4 Rules

32.14	Manufacture of exempt items
32.15	QA - exempt items
32.16	Transfer reports - exempt items
32.17	Manufacture of Sc-46 resins
32.18	Manufacture of exempt quantities
32.19	Conditions of licenses - exempt quantities
32.20	Transfer reports - exempt quantities
32.22	Manufacture of self-luminous products
32.23	Safety criteria - self-luminous products
32.24	Table of organ doses - self-luminous products
32.25	Transfer reports - self-luminous products
32.26	Manufacture of gas and aerosol detectors
32.27	Safety criteria - gas and aerosol detectors
32.28	Table of organ doses - gas and aerosol detectors
32.29	Transfer reports - gas and aerosol detectors
32.40	Schedule A
61.8	Reporting: OMB approval
61.16	Other information
61.58	Alternative requirements
61.70	Scope
61.71	State and Tribal consultation
61.72	Filing of proposals

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61.73	Commission approval
70.13	DOD
70.13a	Foreign aircraft
70.20a	Strategic quantities of SNM
70.20b	Carriers of SNM
70.22	(f),(g),(h),(i),(j),(k) and (l)
70.23(b)	Requirements for approval - Pu processing
70.24	Criticality
70.44	Creditor regulations
70.51	Material balance, etc.
70.52	Reports of criticality
70.53	Material status reports
70.54	Transfer reports
70.57	Measurement control program
70.58	Nuclear material controls
70.59	Effluent monitoring
70.62	Suspension and operation in war
71.18 - 71.24	Fissile material
71.31 - 71.77	NRC package approvals
71.83	Assumptions -unknown properties
150.7	Persons in offshore waters
150.10	Persons exempt
150.14	Physical Protection
150.15	Persons not exempt
150.15a	Continued Commission authority
150.16	Material transfer reports
150.17	Material transfer reports
150.17a	US/IAEA Safeguards requirements
150.19	Tritium reports
150.21	SNM by aircraft

June 1991

SUMMARY OF
THE U.S NUCLEAR REGULATORY COMMISSION'S AGREEMENT STATE PROGRAM

Prior to enactment of the Atomic Energy Act of 1954, nuclear energy activities in the United States were largely confined to the Federal government. The Act made it possible for private commercial firms to enter the field for the first time. Because of the hazards associated with nuclear materials, Congress determined that these activities should be regulated under a Federal licensing system to protect the health and safety of workers in the nuclear industry and the public. The NRC is the Federal agency charged with this responsibility.

Although protection of the public health and safety has traditionally been a State responsibility, the Atomic Energy Act of 1954 did not specify such a role for the States in nuclear matters. This policy was changed in 1959 when Congress enacted Section 274 of the Atomic Energy Act. Section 274 spells out a State role and provided a statutory basis under which the Federal government can relinquish to the States portions of its regulatory authority. The 1959 amendment made it possible for the States to license and regulate byproduct material (radioisotopes)[1] source material (the raw materials of atomic energy), and small quantities of special nuclear material.[2] The Commission is required, however, to retain regulatory authority over the regulation of nuclear facilities vital to the national common defense and security and certain types of radioactive wastes. The Atomic Energy Act was amended in 1978 by the passage of the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978 which requires NRC Agreement States regulating uranium and thorium tailing resulting from recovery operations to adopt certain technical and procedural requirements. The 1978 amendment also requires NRC to periodically review Agreement State programs for adequacy and compatibility.

Section 274j of the Atomic Energy Act provides that the NRC may terminate its Agreement with a State if the Commission finds that such termination

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1 In 1978, Congress enacted the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) which, among other things, added to the category of byproduct material "tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content."

2. In 1981, the Commission amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an Amendment for the regulation of low-level radioactive waste as a separate category.

is necessary to protect the public health and safety. In 1980, Section 274j was amended to authorize the commission to temporarily suspend all or part of an Agreement with a State in the case of an emergency situation where the State failed to take necessary action. Such suspensions may remain in effect only for the duration of the emergency. A copy of Section 274 of the Act, as amended, is attached (Attachment 1).

The mechanism for the transfer of NRC authority to a State to regulate the radiological health and safety aspects of nuclear materials is an Agreement between the Governor of the State and the Commission. Criteria for such Agreements have been published by NRC as a Policy Statement in the Federal Register (Attachment 2). A copy of the most recent Agreement with Illinois is attached for illustration (Attachment 3). Before actually signing the document, the Commission, by statute, must determine that the State's radiation control program is compatible with the Commission's, meets the applicable parts of Section 274 and that it is adequate to protect the public health and safety. For its part, the State establishes its authority to enter such an Agreement by passing enabling legislation.

At present, 28 States have entered into such Agreements with NRC.[3] These States now regulate over 65% of the 24,000 licensees for byproduct, source material, and special nuclear material in the United States. In 1981 the Commission determined that qualified States may also enter into limited agreements for regulation of low-level waste in permanent disposal facilities.

Each Agreement provides that the State will use its best efforts to maintain continuing compatibility with the NRC's program. The NRC maintains a continuing relationship with each Agreement State to assure continued compatibility of the State's regulatory program and its adequacy to protect health and safety. This relationship includes: exchange of information on a current basis covering regulations, licensing, inspection and enforcement data; consultation on special licensing, inspection, enforcement and other regulatory problems; and an annual meeting of all Agreement States to consider regulatory matters of common interest. Special technical assistance is routinely provided to the States upon request.

As mandated by the Atomic Energy Act, NRC conducts onsite, in-depth program reviews periodically of each Agreement State in which

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3 Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, and Washington.

organizational, administrative, personnel, regulatory, licensing, compliance and enforcement program areas are reviewed. Selected Agreement State licensing and compliance casework is reviewed in detail. State inspectors are accompanied by NRC staff on selected inspections of State licensees. A copy of the guidelines used which NRC uses in conducting such reviews have been published in the Federal Register as a Commission Policy Statement (Attachment 4).

NRC provides a wide spectrum of training for Agreement State personnel. Examples are short-term courses in health physics, radiography radiation safety, nuclear medicine, licensing, inspection procedures, radiological engineering, well logging, transportation of nuclear materials and project management for the licensing of low-level waste disposal facilities. Travel costs and per diem for these training sessions are paid by NRC.

Although other Federal agencies, such as the Environmental Protection Agency, the Food and Drug Administration, and the Department of Transportation are also involved in the control of radiation hazards, NRC's Agreement State Program serves as a focal point for Federal-State cooperation in radiation control.

The NRC State Agreements Program is administered by State Programs in the Office of Governmental and Public Affairs. This Commission level office was established as part of an overall NRC reorganization which became effective April 12, 1987. The NRC Regional Offices participate in implementation of the State Agreements Program.

The staffs of the Office of Governmental and Public Affairs and the Regional Offices are ready to meet with Governors, State agencies, State legislative committees, State advisory groups, and others to explain fully the NRC Agreement States program. They can provide descriptive materials about these programs and model State acts for regulatory legislation and will also arrange meetings with other NRC staff members on specialized subjects, as appropriate.

What are the advantages for a State that takes over the Commission's regulatory authority as described? The principal advantages of Agreement State status are:

(a) NRC's authority does not include regulation of x-ray machines and other radiation producing equipment, accelerator-produced radioactive materials, or radium. Regulation of these sources for radiation is, and always has been, primarily the responsibility of the States. Many States now exercise surveillance over these sources of radiation

which in the aggregate, are responsible for over 75% of the public's exposure to radiation, other than from background. Thus, by assuming the authority which the NRC is authorized to relinquish, a State is able to have, as part of its public health system, a complete and comprehensive program for radiation safety.

(b) Many facilities, including medical institutions and physicians, use radioisotopes as well as x-ray machines and radium. A State regulatory system which covers all such radiation sources enables most users to deal with a single agency rather than with a Federal agency for a part and the State for the remainder.

(c) An Agreement with NRC enables a State to make its own licensing decisions and, in doing so, to take into account local conditions.

(d) The proximity of licensed users of radioactive materials to the regulating agency has been cited as having significant advantages for both the users and the agency.

(e) Entering into such an Agreement with NRC would be consistent with a serious interest of a State in being knowledgeable about all sources of radiation located within its boundaries.

(f) An Agreement with NRC develops and enhances the core of radiation professionals at the State level who can respond to inquiries and incidents.

(g) An Agreement with NRC enhances the core of knowledgeable people at the State level who can respond to inquiries and incidents.

Administrative costs that are incurred by a State becoming an Agreement State varies from State to State, depending , among other factors, upon whether or not the State already has a radiation control program covering sources of radiation not regulated by the NRC, i.e., x-ray machines, accelerator-produced radioactive materials and radium. Where this is the case, the incremental costs would be less than if the State previously had only a limited or voluntary radiation control program. As a rule of thumb, 1.0-1.5 staff-years per 100 licenses is needed to effectively administer the program assumed from the NRC. This is a rather general index and actual staffing needs will vary according to the particular circumstances in any given State. Further, those States having major licensed facilities in their State, such as low-level radioactive waste disposal facilities and uranium mills, will need additional resources. NRC staff can provide further guidance on staffing requirements for regulating in these areas.

NRC charges licensees licensing and inspection fees. Whether or not an Agreement State charges fees is a matter of choice for the State. NRC does not provide funding to States for routine program costs. Some Agreement States fund their programs out of general revenues and plan to continue doing so. The majority of the Agreement States, however, have authorized collection of user fees as a means of assuring an adequate funding base. As a result of these States' fees and those of NRC, over two-thirds of the licensees in the United States are licensed by agencies authorized to charge user fees. NRC has prepared model State legislation which includes authorization for a fee system. NRC staff can assist States in developing fee systems.

The Agreement State experience since 1962, the year of the first State Agreement, has been that the States generally conduct effective radiation control programs. When major program deficiencies are noted by NRC, technical advice, assistance and training are offered by NRC (with its resources). The main area of concern is maintaining adequate staffing levels, a reflection of State salary structures and funding. On the other hand, Agreement States typically excel in having highly trained staff and by conducting more frequent inspections than NRC.

Attachments:
1. Section 274 of the Act, as Amended
2. NRC Policy State for Criteria for Applicant Agreement States
3. Agreement with the State of Illinois
4. NRC Policy Statement for Review of Agreement State Programs

Section 274 of the
Atomic Energy Act, as amended

Cooperation With States

Cooperation with States.
42 U.S.C. sec. 2021.

"SEC. 274. COOPERATION WITH STATES.[203]—

"a. It is the purpose of this section—

"(1) to recognize the interests of the States in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this Act of the States and the Commission with respect to the regulation of byproduct, source, and special nuclear materials;

"(2) to recognize the need, and establish programs for cooperation between the States and the Commission with respect to control of radiation hazards associated with use of such materials;

"(3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;

"(4) to establish procedures and criteria for discontinuance of certain of the Commission's regulatory responsibilities with respect to byproduct, source, and special nuclear materials, and the assumption thereof by the States;

"(5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and

"(6) to recognize that, as the States improve their capabilities to regulate effectively such materials, additional legislation may be desirable.

Agreements with States.

"b. Except as provided in subsection c., the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under chapters 6, 7, and 8, and section 161 of this Act, with respect to any one or more of the following materials within the State—

"(1) by product materials as defined in section 11e. (1);[206]

"(2) byproduct materials as defined in section 11e. (2);[207]

"(3) source materials;

"(4) special nuclear materials in quantities not sufficient to form a critical mass.

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[203] Public Law 86-373 (73 Stat. 688) (1959), sec. 1, added sec. 274.

[206] Public Law 95-604 (92 Stat. 3036) (1978), sec. 204(a), amended sec. 274(b)(1) by adding "as defined in section 11e. (1)" after the words "byproduct materials".

[207] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(a), renumbered paragraphs (2) and (3) as paragraphs (3) and (4), and added a new paragraph (2).

Enclosure 1

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

"c. No agreement entered into pursuant to subsection b. shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of—

"(1) the construction and operation of any production or utilization facility;

"(2) the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

"(3) the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

"(4) the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission. The Commission shall also retain authority under any such agreement to make a determination that all applicable standards and requirments have been met prior to termination of a license for byproduct material, as defined in section 11e. (2).[20a] 42 U.S.C. 2014.

Notwithstanding any agreement between the Commission and any State pursuant to subsection b., the Commission is authorized by rule, regulation, or order to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission. Conditions

"d. The Commission shall enter into an agreement under subsection b. of this section with any State if—

"(1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and

"(2) the Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects[20b] compatible with the Commission's program for regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

"e. (1) Before any agreement under subsection b. is signed by the Commission, the terms of the proposed Publication in F.R.

[20a] Public Law 95-604 (92 Stat. 3038) (1978), sec. 204(f), added a new semicolon after paragraph (4).

[20b] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(b), amended sec. 274(d)(2) by inserting the words "in accordance with the requirements of subsection o. and in all other respects" before the word "compatible".

agreement and of proposed exemptions pursuant to subsection f. shall be published once each week for four consecutive weeks in the Federal Register; and such opportunity for comment by interested persons on the proposed agreement and exemptions shall be allowed as the Commission determines by regulation or order to be appropriate.

"(2) Each proposed agreement shall include the proposed effective date of such proposed agreement or exemptions. The agreement and exemptions shall be published in the Federal Register within thirty days after signature by the Commission and the Governor.

Licensing requirements. Exemptions.

"f. The Commission is authorized and directed, by regulation or order, to grant such exemptions from the licensing requirements contained in chapters 6, 7, and 8, and from its regulations applicable to licensees as the Commission finds necessary or appropriate to carry out any agreement entered into pursuant to subsection b. of this section.

"g. The Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

Federal Radiation Council.

"h. There is hereby established a Federal Radiation Council, consisting of the Secretary of Health, Education, and Welfare, the Chairman of the Atomic Energy Commission, the Secretary of Defense, the Secretary of Commerce, the Secretary of Labor, or their designees, and such other members as shall be appointed by the President. The Council shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. The Special Assistant to the President for Science and Technology, or his designee, is authorized to attend meetings, participate in the deliberations of, and to advise the Council. The Chairman of the Council shall be designated by the President, from time to time, from among the members of the Council. The Council shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. The Council shall also perform such other functions as the President may assign to it by Executive order.

Agreements.

"i. The Commission in carrying out its licensing and regulatory responsibilities under this Act is authorized to enter into agreements with any State, or group of States, to perform inspections or other functions on a cooperative basis as the Commission deems appropriate. The

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[1] Public Law 95-604 (92 Stat. 3037) (1978), sec. 104(b), amended sec. 274(f)(2) by inserting the words "in accordance with the requirements of subsection c. and in all other respects" before the word "inadequate".

Commission is also authorized to provide training, with or without charge, to employees of, and such other assistance to, any State or political subdivision thereof or group of States as the Commission deems appropriate. Any such provision or assistance by the Commission shall take into account the additional expenses that may be incurred by a State as a consequence of the State's entering into an agreement with the Commission pursuant to subsection b.

Termination of agreement.

"j. (1)[210] The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement under subsection b. has become effective, or upon request of the Governor of such State, may terminate or suspend all or part of[211] its agreement with the State and reassert the licensing and regulatory authority vested in it under this Act, if the Commission finds that (1)[212] such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to insure compliance with the provisions of this section.[213]

"(2) The Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission:

"(A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside of the State, and

"(B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose.

A temporary suspension under this paragraph shall remain in effect only for such time as the emergency situation exists and shall authorize the Commission to exercise its authority only to the extent necessary to contain or eliminate the danger."[214]

"k. Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.

Notice of hearing.

"l. With respect to each application for Commission license authorizing an activity as to which the Commission's authority is continued pursuant to subsection c., the Commission shall give prompt notice to the State or

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[210] Public Law 96-295 (94 Stat. 787) (1980), sec. 205, inserted "(1)" after "j.".

[211] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(d)(1), amended sec. 274j by adding the words "all or part of" after "suspend".

[212] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(d)(2), amended sec. 274j by inserting "(1)" after "finds that".

[213] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(d)(3), amended sec. 274j by adding at the end before the period ", or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to ensure compliance with the provisions of the section."

[214] Public Law 96-295 (94 Stat. 787) (1980), sec. 205 added new subsec. "j. (2)".

States in which the activity will be conducted of the filing of the license application; and shall afford reasonable opportunity for State representatives to offer evidence, interrogate witnesses, and advise the Commission as to the application without requiring such representatives to take a position for or against the granting of the application.

"m. No agreement entered into under subsection b., and no exemption granted pursuant to subsection f., shall affect the authority of the Commission under subsection 161 b. or i. to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material. For purposes of subsection 161 i., activities covered by exemptions granted pursuant to subsection f. shall be deemed to constitute activities authorized pursuant to this Act; and special nuclear material acquired by any person pursuant to such an exemption shall be deemed to have been acquired pursuant to section 53.

Definition

"n. As used in this section, the term 'State' means any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia.

"Agreement"

As used in this section, the term 'agreement' includes any amendment to any agreement.[215]

"o. In the licensing and regulation of byproduct material, as defined in section 11 e. (2) of this Act, or of any activity which results in the pr[illegible]tion of byproduct material as so defined under an a[illegible]ent entered into pursuant to subsection b., a State sha[illegible]equire—

"(1) compliance with the requirements of subsection b. of section 83 (respecting ownership of byproduct material and land), and

"(2) compliance with standards which shall be adopted by the State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose, including requirements and standards promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to sections 83, 84, and 275, and

Amend. p. 2013
Post. p. 3014

"(3) procedures which—

"(A) in the case of licenses, provide procedures under State law which include—

"(i) an opportunity, after public notice, for written comments and a public hearing, with a transcript,

"(ii) an opportunity for cross examination, and

"(iii) a written determination which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;

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[215] Public Law 95-604 (92 Stat. 3037) (1978), sec. 304(c), added last sentence to sec. 274o.

"(B) in the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;

"(C) require for each license which has a significant impact on the human environment a written analysis (which shall be available to the public before the commencement of any such proceedings) of the impact of such license, including any activities conducted pursuant thereto, on the environment, which analysis shall include—

"(i) an assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such license;

"(ii) an assessment of any impact on any waterway and groundwater resulting from such activites;

"(iii) consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and

"(iv) consideration of the long-term impacts, including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined by section 11 e. (2); and

"(D) prohibit any major construction activity with respect to such material prior to complying with the provisions of subparagraph (C).

If any State under such agreement imposes upon any licensee any requirement for the payment of funds to such State for the reclamation or long-term maintenance and monitoring of such material, and if transfer to the United States of such material is required in accordance with section 83 b. of this Act, such agreement shall be amended by the Commission to provide that such State shall transfer to the United States upon termination of the license issued to such licensee the total amount collected by such State from such licensee for such purpose. If such payments are required, they must be sufficient to ensure compliance with the standards established by the Commission pursuant to section 161 x. of this Act. No State shall be required under paragraph (3) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission.[21a]

above, p. 2033

42 U.S.C. 2201.

"In adopting requirements pursuant to paragraph (2) of this subsection with respect to sites at which ores are processed primarily for their source material content or which are used for the disposal of byproduct material as defined in section 11 e. (2), the State may adopt alternatives (including, where appropriate, site-specific alternatives) to the requirements adopted and enforced by the

42 U.S.C. 2014.

[21a] Public Law 95-604 (92 Stat. 3037) (1978), sec. 204(c), added a new subsec. e.

Commission for the same purpose if, after notice and opportunity for public hearing, the Commission determines that such alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with such sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by standards and requirements adopted and enforced by the Commission for the same purpose and any final standards promulgated by the Administrator of the Environmental Protection Agency in accordance with section 275. Such alternative State requirements may take into account local or regional conditions, including geology, topography, hydrology and meteorology."[21]

42 U.S.C. 2022

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[20] Public Law 95-604 (92 Stat. 3077) (1978), sec. 207(c), added a new subsec. a.
[21] Public Law 97-415 (96 Stat. 2067) (1983), sec. 10 added the paragraph

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Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Statement of Policy.

SUMMARY: The Nuclear Regulatory Commission has revised its statement of policy regarding criteria for guidance of States and NRC in discontinuance of NRC regulatory authority and assumption of regulatory authority by States through agreement. This action is necessary to make editorial changes to update the policy statement, to allow States to enter into agreements for low-level waste only, and to incorporate the provisions and requirements of the Uranium Mill Tailings Radiation Control Act of 1978. Adoption of this policy will allow interested States to enter into agreements with the NRC and regulate low-level waste sites only. Additionally, those States that meet the criteria for the regulation of uranium mills and tailings may exercise regulatory authority over these sources as provided by the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

The revised statement of policy reflects the following principal changes:

1. Modification of Criterion 27 to allow a State to seek an agreement for the regulation of low-level waste as a separate category.

2. Inclusion of additional criteria for States wishing to continue regulating uranium and thorium processors and mill tailings after November 8, 1981.

3. Editorial and clarifying changes to make the statement current.

DATES: This policy statement is effective January 23, 1981.

FOR FURTHER INFORMATION CONTACT: John F. Kinsig, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: 301-492-7767.

SUPPLEMENTARY INFORMATION:

1. These criteria were developed to implement a program, authorized by Pub. L. 86-373 which was enacted in the form of a new section to the Atomic Energy Act (Section 274) and approved by the President on September 23, 1959 and amended by Pub. L. 95-601 approved November 8, 1978. These criteria are intended to indicate factors which the Commission intends to consider in approving new or amended agreements. They are not intended to limit Commission discretion in viewing individual agreements or amendments. In accordance with these statutory provisions, when an agreement between a State and the NRC is effected, the Commission will discontinue its regulatory authority within that State over one or more of the following materials: byproduct material as defined in Section 11e(1) of the Act (radioisotopes), byproduct material as defined in Section 11e(2) of the Act (mill tailings or wastes), source material (uranium and thorium), special nuclear material (uranium 233, uranium 235 and plutonium) in quantities not sufficient to form a critical mass and permanent disposal of low-level waste containing one or more of the materials stated above but not including mill tailings.

2. An agreement may be effected between a State and NRC: (1) upon certification by the Governor that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement and the State desires to assume regulatory responsibility for such materials; and (2) after a finding by the Commission that the State program is in accordance with the requirements of subsection o of section 274 and in all other respects compatible with the Commission's program for the regulation of such materials, and is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement. It is also necessary that the State have enabling legislation authorizing its Governor to enter into such an agreement.

3. The original criteria were published on March 24, 1961 (26 FR 2537) after discussions with various State officials and other State representatives, to provide guidance and assistance to the States and the AEC (now NRC) in developing a regulatory program which would be compatible with that of the NRC. The criteria were circulated among States, Federal agencies, labor and industry, and other interested groups for comment.

4. The criteria require that the State authority consider the total accumulated occupational radiation exposure of individuals. To facilitate such an approach, it is the view of the NRC that an overall radiation protection program is desirable. The maximum scope of

each State's radiation protection program is not, however, a necessary or appropriate subject for coverage in the criteria. Consequently, the criteria are silent on the question of whether a State should have a total regulatory program covering all sources of radiation, including those not subject to control by the NRC under the Atomic Energy Act, such as x-rays, radium, accelerators, etc.

1. These revised criteria provide for entering into an agreement for a separate category of materials, namely, low-level waste material in permanent disposal facilities. They also provide new criteria for States wishing to continue regulating uranium and thorium processing and the wastes resulting therefrom under the provisions of the Uranium Mill Tailings Radiation Control Act of 1978 (Pub. L. 95-604) after November 8, 1981. The revised criteria also contain a number of editorial changes such as changing AEC to NRC where appropriate to conform to present practice and law.

8. Inquiries about details of the criteria or other aspects of the NRC Federal-State Relations Program should be addressed to the Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Criteria [1]

Objectives

1. *Protection.* A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.

Radiation Protection Standards [2]

2. *Standards.* The State regulatory program shall adopt a set of standards for protection against radiation, which shall apply to by-product, source and special nuclear materials in quantities not sufficient to form a critical mass.

3. *Uniformity in Radiation Standards.* It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by Part 20 of the NRC regulations based on officially approved radiation protection guides.

4. *Total Occupational Radiation Exposure.* The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.

5. *Surveys, Monitoring.* Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.

6. *Labels, Signs, Symbols.* It is desirable to achieve uniformity in labels, signs and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.

7. *Instruction.* Persons working in or frequenting restricted areas [3] shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19, section 19.16 and to be represented during inspections as specified in section 19.14 of 10 CFR 19.

8. *Storage.* Licensed radioactive material in storage shall be secured against unauthorized removal.

9. *Waste Disposal.* The standards for the disposal of radioactive materials into the air, water, and sewers, and burial in the soil shall be in accordance with Part 20. Holders of radioactive material desiring to release or dispose of quantities in excess of the prescribed limits shall be required to obtain special permission from the appropriate regulatory authority.

10. *Regulations Governing Shipment of Radioactive Materials.* The State shall to the extent of its jurisdiction promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR Part 71.

11. *Records and Reports.* The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

12. *Additional Requirements and Exemptions.* Consistent with the overall criteria here enumerated and to accommodate special cases or circumstances, the State regulatory authority shall be authorized to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.

Prior Evaluation of Uses of Radioactive Materials

13. *Prior Evaluation of Hazards and Uses, Exceptions.* In the present state of knowledge, it is necessary in regulating the possession and use of by-product, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards and the capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the possessor and user. These categories fall into two groups—those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating each specific use.

14. *Evaluation Criteria.* In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities

[1] The criteria were first adopted in February 1961 (26 FR 2537, March 24, 1961) and amended in November 1965 (30 FR 13844, December 4, 1965). Minor editorial changes were made in June 1968 to reflect the authority of the U.S. Department of Transportation and Organization changes in NCRP.

[2] Suggested State regulations and State legislation will give consideration to all criteria enumerated.

[3] "Restricted area" means any area access to which is controlled by the licensee for the purpose of radiation protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any area used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

and safety equipment, training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants; this guidance should be consistent with NRC licensing and regulatory guides for various categories of licensed activities.

18. *Human Use.* The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

Inspection

19. *Purpose, Frequency.* The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests as required by the regulatory authority. Inspection and testing is conducted to determine, and to assist in obtaining compliance with regulatory requirements.

Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance.

17. *Inspections Compulsory.* Licensees shall be under obligation by law to provide access to inspectors.

18. *Notification of Results of Inspection.* Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.

Enforcement

19. *Enforcement.* Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials, the obtaining of injunctive relief, and the imposing of civil or criminal penalties.

Personnel

20. *Qualifications of Regulatory and Inspection Personnel.* The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspection of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments—their selection, use and calibration—laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various types of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training-radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These persons should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions but also for emergency cases.

Special Nuclear Material, Source Material and Tritium

21. *Conditions Applicable to Special Nuclear Material, Source Material and Tritium.* Licensing in the State's regulatory program shall not interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms (1) transfers of special nuclear material, source material and tritium, and (2) periodic inventory data.

22. *Special Nuclear Material Defined.* Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235, uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula. For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of

such ratios for all of the kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(This definition is subject to change by future Commission rule or regulation.)

[illegible]ation

23. State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:

a. Formulation of rules of general applicability.

b. Approving or denying applications for licenses or authorization to possess and use radioactive materials, and

c. Taking disciplinary actions against licensees.

Arrangements For Discontinuing NRC Jurisdiction

24. *State Agency Designation.* The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.

25. *Existing NRC Licenses and Pending Applications.* In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with, interruption of licensed activities or the processing of license applications, by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.

26. *Relations With Federal Government and Other States.* There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.

27. *Coverage. Amendments. Reciprocity.* An agreement providing for discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State may relate to any one or more of the following categories of materials within the State, as contemplated by Public Law 86-373 and Public Law 95-604:

a. Byproduct materials as defined in section 11e(1) of the Act.

b. Byproduct materials as defined in section 11e(2) of the Act.

c. Source materials.

d. Special nuclear materials in quantities not sufficient to form a critical mass.

e. Low-level wastes in permanent disposal facilities, as defined by statute or Commission rules or regulations containing one or more of the materials stated in a, c, and d above but not including byproduct material as defined in Section 11e(2) of the Act;

but must relate to the whole of such category or categories and not to a part of any category.* Unless less than the five categories are included in any discontinuance of jurisdiction, discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State of the others may be accomplished subsequently by an amendment or by a later agreement.

The agreement may incorporate by reference provisions of other documents, including these criteria, and the agreement shall be deemed to incorporate without specific reference the provisions of Pub. L. 86-373 and Pub. L. 95-604 and the related provisions of the Atomic Energy Act.

Arrangements should be made for the reciprocal recognition of State licenses and Federal licenses in connection with out-of-the-jurisdiction operations by a State or Federal licensee.

28. *NRC and Department of Energy Contractors.* The State should provide exemptions for NRC and DOE contractors which are substantially equivalent to the following exemptions:

a. Prime contractors performing work for the DOE at U.S. Government-owned or controlled sites;

b. Prime contractors performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

c. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of DOE or NRC when the State and the NRC jointly determine (i) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and (ii) that the exemption of such contractor or subcontractor is authorized by law.

Additional Criteria for States Regulating Uranium or Thorium Processors and Wastes Resulting Therefrom After November 8, 1981

Statutes

29. State statutes or duly promulgated regulations should be enacted, if not already in place, to make clear State authority to carry out the requirements of Public Law 95-604, Uranium Mill Tailings Radiation Control Act (UMTRCA) as follows:

a. Authority to regulate the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

b. That an adequate surety (under terms established by regulation) will be provided by the licensee to assure the completion of all requirements established by the (cite appropriate State agency) for the decontamination, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with the generation or disposal of such byproduct material.

c. If in the States' licensing and regulation of byproduct material or of any activity which produces byproduct material, the State collects funds from the licensee or its surety for long-term surveillance and maintenance of such material, the total amount of the funds collected by the State shall be transferred to the U.S. If custody of the byproduct material and its disposal site is transferred to the Federal Government upon termination of the State license. (See 10 CFR 150.32.) If no default has occurred and the reclamation or other bonded activity has been performed, funds for the purpose

*A State which does not wish to continue regulation of uranium and thorium processors and byproduct material, as defined in Section 11e(2) of the Atomic Energy Act as amended, after November 8, 1981 pursuant to Pub. L. 95-604 may obtain authority over all source material licenses within the State except for uranium or thorium processors.

are not to be transferred to the Federal Government. The funds collected by the State shall be sufficient to ensure compliance with the regulations the Commission establishes pursuant to Section 161X of the Atomic Energy Act.

d. In the issuances of licenses, an opportunity for written comments, public hearing (with transcript) and cross examination is required.

e. In the issuances of licenses, a written determination of the action to be taken based upon evidence presented during the public comment period and which is subject to judicial review is required.

f. A ban on major construction prior to completion of the aforementioned stipulations.

g. An opportunity shall be provided for public participation through written comments, public hearings, and judicial review of rules.

30. In the enactment of any supporting legislation, the State should take into account the reservations of authority to the U.S. in UMTRCA as stated in 10 CFR 150.15e and summarized by the following:

a. The establishment of minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of the byproduct material.

b. The determination that prior to the termination of a license, the licensee has complied with decontamination, decommissioning and reclamation standards, and ownership requirements for sites at which byproduct material is present.

c. The requirement that prior to termination of any license for byproduct material as defined in Section 11a.(2), of the Atomic Energy Act or for any activity that results in the production of such material, title to such byproduct material and the disposal site be transferred to the Federal Government or State at the option of the State, provided such option is exercised prior to termination of the license.

d. The authority to require such monitoring, maintenance, and emergency measures after the license is terminated as necessary to protect the public health and safety for those materials and property for which the State has assumed custody pursuant to Pub. L. 95-604.

e. The authority to permit use of the surface or subsurface estate, or both of the land transferred to the United States or State pursuant under provision of the Uranium Mill Radiation Tailings Control Act.

f. The authority to exempt land ownership transfer requirements of Section 83(b)(1)(A).

31. It is preferable that State statutes contain the provisions of Section 8 of the Model Act. But the following may be accomplished by adoption of either procedures by regulation or technical criteria. In any case, authority for their implementation should be adequately supported by statute, regulation or case law as determined by the State Attorney General.

In the licensing and regulation of ores processed primarily for their source material content and for the disposal of byproduct material, procedures shall be established which provide a written analysis of the impact on the environment of the licensing activity. This analysis shall be available to the public before commencement of hearings and shall include:[4]

a. An assessment of the radiological and nonradiological public health impacts;

b. An assessment of any impact on any body of water or groundwater;

c. Consideration of alternatives to the licensed activities; and

d. Consideration of long-term impacts of licensed activities (see Item 86b.(1).

Regulations

32. State regulations should be reviewed for regulatory requirements, and where necessary incorporate regulatory language which is equivalent to the extent practicable or more stringent than regulations and standards adopted and enforced by the Commission, as required by Section 274o (see 10 CFR 40 and 10 CFR 150.31(b)).

Organizational Relationships Within the States

33. Organizational relationships should be established which will provide for an effective regulatory program for uranium mills and mill tailings.

a. Charts should be developed which show the management organization and lines of authority. This chart should define the specific lines of supervision from program management within the radiation control group and any other department within the State responsible for contributing to the regulation of uranium processing and disposal of tailings. When other State agencies or regional offices are utilized, the lines of communication and administrative control between the agencies and/or regions and the Program Director should be clearly drawn.

b. Those States that will utilize personnel from other State Departments or Federal agencies in preparing the environmental assessment should designate a lead agency for supervising and coordinating preparation of this environmental assessment. It is normally expected that the radiation control agency in Agreement States will be the lead agency. The basic premise is that the lead agency is required to prepare the environmental assessment. Utilization of an applicant's environmental report in lieu of a lead agency assessment of the proposed project is not adequate or appropriate. However, the lead agency may prepare an environmental assessment based upon an applicant's environmental report. Other credible information may be utilized by the State as long as such information is verified and documented by the State.

c. When a lead agency is designated, that agency should coordinate preparation of the statement. The other agencies involved should provide assistance with respect to their areas of jurisdiction and expertise. Factors relevant in obtaining assistance from other agencies include the applicable statutory authority, the time sequence in which the agencies become involved, the magnitude of their involvement and relative expertise with respect to the project's environmental effects.

In order to bring an environmental assessment to a satisfactory conclusion, it is highly recommended that an initial scoping document be developed which clearly delineates the area and scope of work to be performed by each agency within a given time constraint.

d. For those areas in the environmental assessment where the State cannot identify a State agency having sufficient expertise to adequately evaluate the proposal or prepare an assessment, the State should have provisions for obtaining outside consulting services. In those instances where non-governmental consultants are utilized, procedures should be established to avoid conflict of interest consistent with State law and administrative procedures.

Medical consultants recognized for their expertise in emergency medical matters, such as the Oak Ridge and Hanford National Laboratories, relating to the intake of uranium and its diagnosis thereof associated with uranium mining and milling should be identified and available to the State for advice and direct assistance.

During the budget preparation, the State should allow for funding costs incurred by the use of consultants. In addition, consultants should be available for any emergencies which

[4] It is strongly recommended that a 30-day period be provided for public review.

may occur and for which their expertise would be needed immediately.

Personnel

34. Personnel needed in the processing of the license application can be identified or grouped according to the following skills: Technical, Administrative, and Support.

a. Administrative personnel are those persons who will provide internal guidance, policy memoranda, reviews and [illegible] services necessary to assure completion of the licensing action. Support personnel are those persons who provide secretarial, clerical support, legal, and laboratory services. Technical personnel are those individuals who have the training and experience in radiation protection necessary to evaluate the engineering and radiological safety aspects of a uranium concentrator. Current indications are that 2 to 2.75 total professional person years' effort is needed to process a new conventional mill license, in situ license, or major renewal, to meet the requirements of UMTRCA. This number includes the effort for the environmental assessment and the in-plant safety review. It also includes the use of consultants. Heap leach applications may take less time and is expected to take 1.0 to 1.5 professional staff years' effort, depending on the circumstances encountered. Current indications are that the person years effort for support and legal services should be one secretary for approximately 2 conventional mills and ½ staff years for legal services for each noncontested mill case. The impact on environmental monitoring laboratory support services is difficult to estimate but should be added into the personnel requirements.

In addition, consideration should be given to various miscellaneous post-licensing ongoing activities including the issuance of minor amendments, inspections, and environmental surveillance. It is estimated that these activities may require about 0.5 to 1 person years effort per licensed facility per year, the latter being the case for a major facility. These figures do not include manpower for Title I activities of UMTRCA.

b. In evaluating license applications the State shall have access to necessary specialties, e.g., radiological safety, hydrology, geology and dam construction and operation.

In addition to the personnel qualifications listed in the "Guide for Evaluation of State Radiation Control Programs," Revision 3, February 1, 1980, the regulatory staff involved in the regulatory process (Radiation) should have additional training in Uranium Mill Health Physics and Environmental Assessments.

c. Personnel in agencies other than the lead agency are included in these total person year numbers. If other agencies are counted in these numbers then it shall be demonstrated that these personnel will be available on a routine and continuing basis to a degree claimed as necessary to successfully comply with the requirements of UMTRCA and these criteria. The arrangements for making such resources available shall be documented, such as an interagency memorandum of understanding and confirmed by budgetary cost centers.

Functions To Be Covered

35. The States should develop procedures for licensing, inspection, and preparation of environmental assessments.

a. *Licensing*

(1) Licensing evaluations or assessments should include in-plant radiological safety aspects in occupational or restricted areas and environmental impacts to populations in unrestricted areas from the plant.

(2) It is expected that the State will review, evaluate and provide documentation of these evaluations. Items which should be evaluated are:

(a) Proposed activities;
(b) Scope of proposed action;
(c) Specific activities to be conducted;
(d) Administrative procedures;
(e) Facility organization and radiological safety responsibilities, authorities, and personnel qualifications;
(f) Licensee audits and inspections;
(g) Radiation safety training programs for workers;
(h) Radiation safety program, control and monitoring;
(i) Restricted area markings and access control;
(j) At existing mills, review of monitoring data, exposure records, licensee audit and inspection records, and other records applicable to existing mills;
(k) Environmental monitoring;
(l) Emergency procedures, radiological;
(m) Product transportation; and
(n) Site and physical decommissioning procedures, other than tailings.
(o) Employee exposure data and bioassay programs.

b. *Environmental Assessment*

(1) The environmental evaluation should consist of a detailed and documented evaluation of the following items:

(a) Topography;
(b) Geology;
(c) Hydrology and water quality;
(d) Meteorology;
(e) Background radiation;
(f) Tailings retention system;
(g) Interim stabilization, reclamation, and Site Decommissioning Program;
(h) Radiological Dose Assessment;
(1) Source terms
(2) Exposure pathway
(3) Dose commitment to individuals
(4) Dose commitment to populations
(5) Evaluation of radiological impacts to the public to include a determination of compliance with State and Federal regulations and comparisons with background values
(6) Occupational dose
(7) Radiological impact to biota other than man
(8) Radiological monitoring programs, pre-occupational and operational
(i) Impacts to surface and groundwater, both quality and quantity;
(j) Environmental effects of accidents; and
(k) Evaluation of tailings management alternatives in terms of regulations.

(2) The States are encouraged to examine the need to expand the scope of the assessment into other areas such as:

(a) Ecology;
(b) Environmental effects of site preparation and facility construction on environment and biota;
(c) Environmental effects of use and discharge of chemicals and fuels, and
(d) Economic and social effects.

c. *Inspections*

(1) As a minimum, items which should be inspected or included during the inspection of a uranium mill should adhere to the items evaluated in the in-plant safety review. The principal items recommended for inspection are:

(a) Administration;
(b) Mill circuit, including any additions, deletions, or circuit changes;
(c) Accidents/incidents;
(d) Part 19 or equivalent requirements of the State;
(e) Action taken on previous findings;
(f) A mill tour to determine compliance with regulations and license conditions;
(g) Tailings waste management in accordance with regulations and license conditions (see NRC Reg. Guide 3.11.1);
(h) Records;
(i) Respiratory protection in accordance with license conditions or 10 CFR Part 20.
(j) Effluent and environmental monitoring;
(k) Training programs;
(l) Transportation and shipping;
(m) Internal review and audit by management.

(n) Exit interview; and

(o) Final written report documenting the results of the inspection and findings on each item.

(f) In addition, the inspector should perform the following:

(a) Independent surveys and sampling.

(3) Additional guidance is contained in appropriate NRC regulatory and inspection guides. A *complete* inspection should be performed at least once per year.

d. *Operational Data Review*

(1) In addition to the reporting requirements required by the regulations or license conditions, the licensee will submit in writing to the regulatory agency within 60 days after January 1 and July 1 of each year, reports specifying the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous six months of operation. This data shall be reported in a manner that will permit the regulatory agency to confirm the potential annual radiation doses to the public.

(2) All data from the radiological and non-radiological environmental monitoring program will also be submitted for the same time periods and frequency. The data will be reported in a manner that will allow the regulatory agency to conform the dose to receptors.

Instrumentation

36. The State should have available both field and laboratory instrumentation sufficient to ensure the licensee's control of materials and to validate the licensee's measurements.

a. The State will submit its list of instrumentation to the NRC for review. Arrangements should be made for calibrating such equipment.

b. Laboratory-type instrumentation should be available in a State agency or through a commercial service which has the capability for quantitative and qualitative analysis of radionuclides associated with natural uranium and its decay chain, primarily: U-238, Ra-226, Th-320, Pb-210, and Rn-222, in a variety of sample media such as will be encountered from an environmental sampling program.

Analysis and data reduction from laboratory analytical facilities should be available to the licensing and inspection authorities in a timely manner. Normally, the data should be available within 30 days of submittal. State acceptability of quality assurance (QA) programs should also be established for the analytical laboratories.

c. Arrangements should also be completed so that a large number of samples in a variety of sample media resulting from a major accident can be analyzed in a time frame that will allow timely decisions to be made regarding public health and safety.

d. Arrangements should be made to participate in the Environmental Protection Agency quality assurance program for laboratory performance.

46 FR 38069
Published 7/16/81

Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement; Statement of Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Revision of Criterion 29f.

SUMMARY: In a Federal Register document published on January 23, 1981 (46 FR 7540–7548, FR Doc. 81–2428), the NRC published Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement. As published at 46 FR 7544, Col. 1, Criterion 29f, which states "bas on major construction prior to completion of the aforementioned stipulations," is inaccurate. This document corrects the text of Criterion 29 by revising paragraph f. to read as follows:

"f. A bas on major construction prior to completin of the written environmental analysis stipulated in Criterion 21."

FOR FURTHER INFORMATION CONTACT: John F. Kendig, Office of State Programs, Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 492-9897.

Dated at Washington, D.C. this 10th day of July 1981.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

48 FR 32376
Published 7/21/83

Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement; Criteria for Guidance of States and NRC

AGENCY: Nuclear Regulatory Commission.

ACTION: Statement of policy; Revision.

SUMMARY: Criterion 8 of the NRC's Policy for Discontinuance of Authority (stated January 23, 1961 appearing at 46 FR 7540–7546, deals with waste disposal. It states that the standards for disposal into air, water and sewer, and burial in soil shall be in accordance with 10 CFR Part 20. The Commission's regulation 10 CFR Part 61, which became effective December 27, 1982, provides licensing procedures, performance objectives, technical requirements and financial assurance requirements for the issuance of licenses by NRC for the land disposal of most wastes that are commonly referred to as low-level waste. In addition, the Nuclear Waste Policy Act of 1982 requires that the NRC and the Agreement States provide and approve certain stated financial arrangements prior to issuance of a license for low-level radioactive waste disposal or in the case of licenses in effect, prior to termination of such licenses. The financial arrangements are to cover completion of all requirements for the decontamination, decommissioning, site closure and reclamation of sites, structures and equipment used in conjunction with low-level waste disposal.

The Commission believes that States seeking an agreement pursuant to Section 274b of the Atomic Energy Act of 1954, as amended, to regulate land disposal of radioactive waste should establish standards for disposal which are in accord with the applicable technical definitions, performance objectives, technical requirements, and financial assurance requirements of 10 CFR Part 61 and the waste transfer and manifest system prescribed in 10 CFR Part 20. For the waste manifest system to function effecively on a national basis, it is necessary for all licensees, both NRC and Agreement State, to follow the same system. Thus, the Agreement States are expected to adopt and implement this system for their licensees.

Therefore, the NRC is revising Criterion 8 to include reference to the performance objectives, technical requirements and financial assurance requirements contained in Part 61 and the waste transfer and manifest system contained in Part 20. The revision also satisfies the provisions of the Nuclear Waste Policy Act of 1982. Criterion 8 will be used in judging the adequacy and compatibility of that aspect of a State's regulatory program for regulating land disposal of low-level radioactive waste. No additional revisions to the criteria are considered necessary at this time to enter into an agreement with a State which includes authority to regulate low-level radioactive waste disposal.

For Agreement States currently regulating operating burial sites, NRC has been and will continue to work with the States to implement Part 61 provisions on a case-by-case basis, to the extent practicable. The waste transfer and manifest system, 10 CFR 20.311 becomes effective December 27, 1983. On an interim basis, arrangements are being made with the Agreement States regulating the existing burial sites to implement the waste classification system and waste transfer and manifest system through the burial site licenses.

FOR FURTHER INFORMATION CONTACT: Kathleen N. Schneider, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301–492–0623.

SUPPLEMENTARY INFORMATION: Criterion 8 is revised to read as follows:

* * * * *

8. Radioactive Waste Disposal.

(a) Waste disposal by material users. The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR Part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority.

Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR 20.

The waste disposal standards shall include a waste classification scheme and provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR Part 61.

(b) Land disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal

of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR Part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (section 151(a)(2), Pub. L. 97-425).

Commissioner Roberts, in disapproving, stated "Given the states' and the public's interest in all aspects of our waste disposal regulations and guidance, this revision should go out for public comments."

AGREEMENT
BETWEEN THE
UNITED STATES NUCLEAR REGULATORY COMMISSION
AND THE
STATE OF ILLINOIS
FOR
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND
RESPONSIBILITY WITHIN THE STATE P[illegible]SUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF [illegible]4, AS AMENDED

WHEREAS, the United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, the Governor of the State of Illinois is authorized under Illinois Revised Statutes, 1985, ch. 111 ½, par. 216b and ch. 111 ½, par. 241-19, to enter into this Agreement with the Commission; and,

WHEREAS, the Governor of the State of Illinois certified on October 2, 1986, that the State of Illinois (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

WHEREAS, the Commission found on May 13, 1987 that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and,

Enclosure 3

WHEREAS, the State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, the Commission and the State recognize the desirability of reciprocal recognition of licenses and exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, this Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, IT IS HEREBY AGREED between the Commission and the Governor of the State, acting in behalf of the State, as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following:

A. Byproduct material as defined in Section 11e.(1) of the Act;

B. Source materials;

C. Special nuclear materials in quantities not sufficient to form a critical mass; and,

D. The land disposal of source, byproduct and special nuclear material received from other persons.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source or special nuclear material, or of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission; and,

E. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

ARTICLE III

This Agreement may be amended, upon application by the State and approval by the Commission, to include the additional area specified in Article II, paragraph E, whereby the State can exert regulatory control over the materials stated therein.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will use its best efforts to cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the

regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

ARTICLE VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any Agreement State. Accordingly, the Commission and the State agree to use their best efforts to develop appropriate rules, regulations and procedures by which such reciprocity will be accorded.

ARTICLE VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all o part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this Agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act.

ARTICLE IX

This Agreement shall become effective on June 1, 1987 and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Washington, D.C., in triplicate, this 14th day of May, 1987.

FOR THE UNITED STATES
NUCLEAR REGULATORY COMMISSION

Lando W. Zech Jr.

Lando W. Zech, Jr., Chairman

Done at Springfield, Illinois, in triplicate, this 18th day of May, 1987.

FOR THE STATE OF ILLINOIS

James R. Thompson, Governor

NUCLEAR REGULATORY COMMISSION

Evaluation of Agreement State Radiation Control Programs; Final General Statement of Policy

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final general statement of policy.

SUMMARY: The Nuclear Regulatory Commission is adopting as a general statement of policy the recently revised "Guidelines for NRC Review of Agreement State Radiation Control Programs." This statement of policy is being issued to inform the States and the public of the criteria and guidelines which the Commission intends to use in its periodic evaluations of Agreement State programs.

FOR FURTHER INFORMATION CONTACT: Donald A. Nussbaumer, State, Local and Indian Tribe Programs, Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7767.

SUPPLEMENTARY INFORMATION: On November 13, 1986 the NRC published in the Federal Register proposed minor revisions to its General Statement of Policy, "Guidelines for NRC Review of Agreement State Radiation Control Programs" (51 FR 41172). Interested persons were invited to submit written comments on the proposed revised policy statement which expired January 12, 1987. Seven written comments were received. After review and evaluation of the comments, the Commission has concluded the revisions can be published as proposed as a final general statement of policy. Minor editorial corrections have been made to the text for clarification.

Six letters offered comments on the proposed revision to the Policy Statement.

One comment letter was received from a public citizen, one from a utility health physicist, three from Agreement State radiation control program directors and one from a non-Agreement State radiation control program director. A seventh comment letter, from a nuclear utility, commented on the Federal Register notice of the Commission's interest in the feasibility of developing a set of objective performance indicators for the various materials licenses regulated by the NRC and the Agreement States. The Commission plans to further explore this possibility and will seek opportunities to do so together with the Agreement States and, when appropriate, with additional opportunity for public input.

One comment was specific to a State (Pennsylvania) which recently entered a Memorandum of Understanding (MOU) with NRC (51 FR 43487). The MOU was viewed by the commentor as circumventing this Policy Statement. The referenced agreement is authorized by section 247i of the Atomic Energy Act as amendmed. State activities under it will not include regulatory functions that could be conducted pursuant to a Section 274b Agreement (which this Policy Statement covers).

One comment recommended elevating staffing level to Category I and another recommended elevating all the Indicators under Personnel to Category I. Commission staff, when developing the proposed revision, solicited Agreement State and regional staff views on moving staffing level to Category I. Supporting arguments were that staffing level deficiencies were frequently a major contributing cause of significant Category I deficiencies in State programs, e.g., lack of staff leads to inspection backlogs, and elevating the Indicator to Category I would help focus State attention on the underlying causes, e.g., inadequate funds for positions and low salaries. On the other hand, NRC staff routinely couple comments on staff deficiencies with comments on Category I problems, when linkage exists, in the comment letters to the State Health Officers. NRC staff will also comment on staffing deficiencies in the absence of Category I deficiencies if the staff believes the staffing deficiencies, if uncorrected, will lead to problems in Category I areas. Category I Indicators, as explained in the Policy Statement, have a direct bearing on health and safety and Category II Indicators address essential technical and administrative support which if not maintained may lead to Category I problems. As an example of a Category II Indicator the Policy Statement cites staffing level. Maintaining staffing level and other Personnel Indicators as Category II will be consistent with the

Policy's intended distinctions between Categories I and II.

One comment from a non-Agreement State recommended maintaining the separation of Status of Regulation and Compatibility of Regulations (as in the present Policy Statement). As explained in the November 13, 1986 Federal Register notice confusion has arisen over the distinctions between the two indicators. The proposal to combine them received no negative comments from the 28 Agreement States. Allied with this comment, was another recommending that draft language for State regulations should be provided to the States to enable them to meet the guidelines for maintaining compatible regulations within 3 years of adoption by NRC. Agreement States are routinely notified of NRC regulatory amendments that must be adopted to maintain compatibility. In many cases simple redrafting of the NRC requirement to meet State codification standards can be done easily by the States. When major NRC amendments are issued, such as the waste manifest rules contained in 10 CFR 20.311, NRC staff will prepare and make available to the States draft suggested State regulation language that incorporate NRC amendments. The Conference of Radiation Control Program Directors, Inc. with NRC and other Federal Agency assistance maintains model Suggested State Regulations (SSR) through a formal adoption process. Experience has shown that when State delays in adopting amendments are encountered, they have been as much related to inadequate staff resources that are needed to prepare amendments and the complex State administrative procedures for adopting regulations as they have been to the availability of timely issued SSR's. The Conference has not always adopted revisions within 3 years of NRC amendments; however, these other NRC measures provide adequate alternatives by which Agreement States can initiate actions to adopt conforming amendments to State regulations.

One comment from a non-Agreement State suggested that the guidelines should establish criteria for determining if a State's program is inadequate because of common defense and security (CD&S) considerations. As noted in the Federal Register notice on the proposed agreement with the State of Illinois (52 FR 2309), the Commission is considering the question of continued NRC regulation of a specific licensee in that State in the interest of the common defense and security of the United States. This CD&S issue emanates from the Commission's statutory obligations to protect the common defense and security as set forth in section 274m of the Act, as amended. That section makes clear that this obligation is separate from determining that the State's program is adequate to protect the public health and safety as required by section 274o.

One comment received from a non-Agreement State suggested that in adding to the guidelines, NRC should compare Agreement State programs to the Regional NRC materials programs. The implication of the comment is that the NRC regulatory program for materials should be reviewed in light of the same guidelines for the Agreement States. The Policy Statement has been developed specifically for the review of Agreement State programs as required by section 247j of the Act, as amended, which provides that NRC "shall periodically review such agreements and actions taken by the States under the agreements to insure compliance with the provisions of this section." Thus, the guidelines are not totally applicable to NRC programs. However, the periodic appraisal or assessments which NRC makes of its own materials regulatory program utilize comparable principles to those used in evaluating Agreement State programs.

One comment recommended development of guidelines for staff for Agreement State programs responsible for regulation of low-level waste disposal. Guidance in assessing staff technical capability needs and overall staffing requirements for States seeking low-level waste regulatory authority is available from NRC staff under NRC's Low-Level Waste Technical Assistance Program (51 FR 3866). NRC staff plans to prepare a supplementary Policy Statement addressing guidelines which are specific to Agreement State regulatory programs in this area.

Additional comments were received that addressed typographical errors by the Federal Register and offered minor editorial corrections. The latter have been incorporated.

Guidelines for NRC Review of Agreement State Radiation Control Programs, 1987

(Prepared by Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, DC 20555)

Introduction

Section 274 of the Atomic Energy Act was enacted by the Congress in 1959 to recognize the interests of the States in atomic energy, to clarify the respective responsibilities of State and Federal Governments, and to provide a mechanism for States to enter into formal agreements with the Atomic Energy Commission (AEC), and later the Nuclear Regulatory Commission (NRC), under which the States assume regulatory authority over byproduct, source, and small quantities of special nuclear materials, collectively referred to as agreement materials. The mechanism by which the NRC discontinues and the States assume regulatory authority over agreement materials is an agreement between the Governor of a State and the Commission. Before entering into an Agreement, the Governor is required to certify that the State has a regulatory program that is adequate to protect the public health and safety. In addition, the Commission must perform an independent evaluation and make a finding that the State's program is adequate from the health and safety standpoint and compatible with the Commission's regulatory program.

Current Guidelines

In 1981, the Commission published a major revision of the guide for review of Agreement State programs (two earlier revisions reflected primarily minor and editorial changes). These Guidelines constitute Commission policy in the form of a document entitled "Guidelines for NRC Review of Agreement State Radiation Control Programs." This document provides guidance for evaluation of operating Agreement State programs based on over 20 years of combined AEC–NRC experience in administering the Agreement State program. In 1985, Commission staff initiated minor updating, clarifying and editoral changes reflecting the experience gained with the 1981 policy statement. The revised document will be used by the NRC in its continuing program of evaluating Agreement State programs.

The "Guidelines" contain six sections, each dealing with one of the essential elements of a radiation control program (RCP) which are: Legislation and Regulations, Organization, Management and Administration, Personnel, Licensing, and Compliance. Each section contains (a) a summary of the general significance of the program elements, (b) indicators which address specific functions within the program element, (c) categories which denote the relative importance of each indicator, and (d) guidelines which delineate specific objectives or operational goals.

Categories of Indicators

The indicators listed in this document cover a wide range of program functions, both technical and administrative. It should be recognized that the indicators, and the guidelines under each indicator, are not of equal importance in terms of the fundamental goal of a radiation control program, i.e., protection of the public health and safety. Therefore, the indicators are categorized in terms of their importance to the fundamental goal of protecting the public health and safety. Two categories are used.

Category I—Direct Bearing on Health and Safety. Category I indicators are:

- Legal Authority.
- Status and Compatibility of Regulations.
- Quality of Emergency Planning.
- Technical Quality of Licensing Actions.
- Adequacy of Product Evaluations.
- Status of Inspection Program.
- Inspection Frequency.
- Inspectors' Performance and Capability.
- Response to Actual and Alleged Incidents.
- Enforcement Procedures.

These indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in one or more Category I indicator areas, then the need for improvements may be critical. Legislation and regulations together form the foundation for the entire program establishing the framework for the licensing and compliance programs. The technical review of license applications is the initial step in the regulatory process. The evaluation of applicant qualifications, facilities, equipment, and procedures by the regulatory agency is essential to assure protection of the public from radiation hazards associated with the proposed activities. Assuring that licensees fulfill the commitments made in their applications and that they observe the requirements set forth in the regulations is the objective of the compliance program. The essential elements of an adequate compliance program are (1) the conduct of onsite inspections of licensee activities, (2) the performance of these inspections by competent staff, and (3) the taking of appropriate enforcement actions. Another very important factor is the ability to plan for, respond effectively to, and investigate radiation incidents.

Category II—Essential Technical and Administrative Support. Category II Indicators are:

- Location of Radiation Control Program Within State Organization.
- Internal Organization of Radiation Control Program.
- Legal Assistance.
- Technical Advisory Committees.
- Budget.
- Laboratory Support.
- Administrative Procedures.
- Management.
- Office Equipment and Support Services.
- Public Information.
- Qualifications of Technical Staff.
- Staffing Level.
- Staff Supervision.
- Training.
- Staff Continuity.
- Licensing Procedures.
- Inspection Procedures.
- Inspection Reports.
- Confirmatory Measurements.

These indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e. those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need of improvement in particular program areas is critical. The NRC would request an immediate response. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with section 274j of the Act.

Category II comments concern functions and activities which support the State program and therefore would not be critical to the State's ability to protect the public. The State will be asked to respond to these comments and the State's actions will be evaluated during the next regular program review.

It should be recognized that the categorization pertains to the significance of the overall indicator and not to each of the guidelines within that indicator. For example, "Technical Quality of Licensing Actions" is a Category I indicator. The review of license applications for the purpose of evaluating the applicant's qualifications, facilities, equipment, and procedures is essential to assuring that the public health and safety is being protected. One of the guidelines under this indicator concerns prelicensing visits. The need for such visits depends on the nature of the specific case and is a matter of judgment on the part of the licensing staff. The success of a State program in meeting the overall objective of the indicator does not depend on literal adherence to each recommended guideline.

The "Guidelines for NRC Review of Agreement State Radiation Control Progams" will be used by the NRC staff during its onsite reviews of Agreement State programs. Such reviews are conducted at approximately 18 month intervals, or less if deemed necessary. If there are no significnat Category I comments, the staff may extend the interval between reviews to approximately 24 months.

In making a finding of adequacy, the NRC considers areas of the State program which are critical to its primary function, i.e., protection of the public health and safety. For example, a State that is not carrying out its inspection program, or fails to respond to significant radiological incidents would not be considered to have a program adequate to protect the public health

nd safety. Basic radiation protection standards, such as exposure limits, also directly affect the States' ability to protect public health and safety. The NRC feels that it is important to strive for a high degree of uniformity in technical definitions and terminology, particularly as related to units of measurement and radiation dose. Maximum permissible doses and levels of radiation and concentrations of radioactivity in unrestricted areas as specified in 10 CFR Part 20 are considered to be important enough to require States to be essentially equivalent in this area in order to protect public health and safety. Certain procedures, such as those involving the licensing of products containing radioactive material intended for interstate commerce, also require a high degree of uniformity. If no serious performance problems are found in an Agreement State program and if its standards and program procedures are compatible with the NRC program, a finding of adequacy and compatibility is made.

Program Element: Legislation and Regulations

The effectiveness of any State radiation control program (RCP) is dependent upon the underlying authority granted the RCP in State legislation, and implemented in the State regulations. Regulations provide the foundation upon which licensing, inspection, and enforcement decisions are made. Regulations also provide the standards and rules within which the regulated must operate. Periodic revisions are necessary to reflect changing technology, improved knowledge, current recommendations by technical advisory groups, and consistency with NRC regulations. Procedures for providing input to the NRC on proposed changes to NRC regulations are necessary to assure consideration of the State's interests and requirements. The public and, in particular, affected classes of licensees should be granted the opportunity and time to comment on rule changes.

Indicators and Guidelines

Legal Authority (Category I)

- Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement.
- States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA.

Status and Compatibility of Regulations (Category I)

- The State must have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards, effluent limits, waste manifest rule and certain other parts), Part 61 (technical definitions and requirements, performance objectives, financial assurances) and those required by UMTRCA, as implemented by Part 40.
- The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.
- For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than 3 years.
- The RCP has established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC.
- Opportunity should be provided for the public to comment on proposed regulation changes (Required by UMTRCA for uranium mill regulation.)
- Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

Program Element: Organization

The effectiveness of any State RCP may be dependent upon its location within the overall State organizational structure. The RCP should be in a position to compete effectively with other health and safety programs for budget and staff. Program management must have access to individuals or groups which establish health and safety program priorities. The RCP should be organized to achieve a high degree of efficiency in supervision, work functions, and communications.

Indicators and Guidelines

Location of Radiation Control Program Within State Organization (Category II)

- The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.
- Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Internal Organization of Radiation Control Program (Category II)

- The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy.
- Where regional offices or other government agencies are utilized, the lines of communication and administrative control between these offices and the central office (Program Director) should be clearly drawn to provide uniformity in licensing and inspection policies, procedures and supervision.

Legal Assistance (Category II)

- Legal staff should be assigned to assist the RCP or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program, statutes, and regulations.

Technical Advisory Committees (Category II)

- Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems.
- A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans.
- Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Program Element: Management and Administration

State RCP management must be able to meet program goals through strong, direct leadership at all levels of supervision. Administrative procedures are necessary to assure uniform and appropriate treatment of all regulated parties. Procedures for receiving information on radiological incidents, emergency response, and providing information to the public are necessary. Procedures to provide feedback to supervision on status and activities of the RCP are necessary. Adequate facilities, equipment and support

services are needed for optimum utilization of personnel resources. Laboratory support services should be administered by the RCP or be readily available through established administrative procedures.

In order to meet program goals, a State RCP must have adequate budgetary support. The total RCP budget must provide adequate funds for salaries, travel costs associated with the compliance program, laboratory and survey instrumentation and other equipment, and other administrative costs. The program budget must reflect annual changes in the number and complexity of applications and licenses, and the increase in costs due to normal inflation.

Indicators and Guidelines

Quality of Emergency Planning (Category I)

- The State RCP should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.
- The Plan should define the responsibilities and actions to be taken by State agencies. The Plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup.
- Emergency communication procedures should be adequately established with appropriate local, county and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the Plan while in draft form.
- The plan should be reviewed annually by Program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Budget (Category II)

- Operating funds should be sufficient to support program needs such as staff travel necessary to the conduct of an effective compliance program, including routine inspections, follow-up or special inspections (including pre-licensing visits), and responses to incidents and other emergencies, instrumentation and other equipment to support the RCP, administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence office equipment, hearing costs, etc. as appropriate.
- Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Laboratory Support (Category II)

- The RCP should have laboratory support capability inhouse, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc. on a priority established by the RCP.

Administrative Procedures (Category II)

- The RCP should establish written internal policy and administrative procedures to assure that program functions are carried out as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange-of-information and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing and inspection and enforcement.

Management (Category II)

- Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquires, regulation revisions).
- RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services and fundings.
- Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, large scope-Type A Broad, potential for significant releases to environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports and enforcement actions should also be performed.
- When regional offices or other government agencies are utilized, program management should conduct periodic audits of these offices.

Office Equipment and Support Services (Category II)

- The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (greater than 300–400 licenses) programs. Similar services should be available to regional offices, if utilized.
- Professional staff should not be used for fee collection and other clerical duties.

Public Information (Category II)

- Inspection and licensing files should be available to the public consistent with State administrative procedures. It is desirable, however, that there be provisions for protecting from public disclosure proprietary information and information of a clear personal nature.
- Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws.

Program Element: Personnel

The RCP must be staffed with a sufficient number of trained personnel. The evaluation of license applications and the conduct of inspections require staff with in-depth training and experience in radiation protection and related subjects. The staff must be adequate in number to assure licensing, inspection, and enforcement actions of appropriate quality to assure protection of the public health and safety. Periodic training of existing staff is necessary to maintain capabilities in a rapidly changing technological environment. Program management personnel must be qualified to exercise adequate supervision in all aspects of a State radiation control program.

Indicators and Guidelines

Qualifications of Technical Staff (Category II)

- Professional staff should have bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel including the director of the radiation protection program should be commensurate with the type of licenses issued and inspected by the State.
- Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Staffing Level (Category II)

- Professional staffing level should be approximately 1–1.5 person-year per 100 licenses in effect. RCP must not have less than two professionals available with training and experience to operate RCP in a way which provides continuous coverage and continuity.
- For States regulating uranium mills tailings, current indications are that 2–

5 professional person-years' of effort, cluding consultants, are needed to ocess a new mill license (including in n mills) or major renewal, to meet quirements of Uranium Mill Tailings diation Control Act of 1978. This fort must include expertise in diological matters, hydrology, geology, d structural engineering.[1]

aff Supervisor (Category II)

- Supervisory personnel should be dequate to provide guidance and view the work of senior and junior rsonnel.
- Senior personnel should review pplications and inspect licenses dependently, monitor work of junior rsonnel, and participate in the tablishment of policy.
- Junior personnel should be initially xited to reviewing license applications d inspecting small programs under ose supervision.

raining (Category II)

- Senior personnel should have ttended NRC core courses in licensing rientation, inspection procedures, edical practices and industrial diography practices. (For mill States, ill training should also be included.)
- The RCP should have a program to tilize specific short courses and orkshops to maintain appropriate level f staff technical competence in areas of hanging technology.

taff Continuity (Category II)

- Staff turnover should be minimized y combinations of opportunities for raining promotions, and competitive alaries.
- Salary levels should be adequate to ecruit and retain persons of appropriate rofessional qualifications. Salaries hould be comparable to similar mployment in the geographical area.
- The RCP organization structure ould be such that staff turnover is inimized and program continuity naintained through opportunities for romotion. Promotion opportunities hould exist from junior level to senior evel or supervisory positions. There lso should be opportunity for periodic alary increases compatible with xperience and responsibility.

Program Element: Licensing

It is necessary in licensing byproduct, source, and special nuclear materials that the State regulatory agency obtain information about the proposed use of nuclear materials, facilities and equipment, training and experience of personnel, and operating procedures appropriate for determining that the applicant can operate safely and in compliance with the regulations and license conditions. An acceptable licensing program includes: preparation and use of internal licensing guides and policy memoranda to assure technical quality in the licensing program (when appropriate, such as in small programs, NRC Guides may be used); prelicensing inspection of complex facilities; and the implementation of administrative procedures to assure documentation and maintenance of adequate files and records.

Indicators and Guidelines

Technical Quality of Licensing Actions (Category I)

- The RCP should assure that essential elements of applications have been submitted to the agency, and that these elements meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions.
- Prelicensing visits should be made for complex and major licensing actions.
- Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorizes uses, and permissive or restrictive conditions.
- The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Adequacy of Product Evalautions (Category I)

- RCP evalautions of manufacture's or distributor's data on sealed sources and devices outlined in NRC, State or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users.
- The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.
- Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Licensing Procedures (Category II)

- The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.
- License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions.
- The present compliance status of licensees should be considered in licensing actions.
- Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees should be submitted to NRC on a timely basis.
- Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process
- Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Program Element: Compliance

Periodic inspections of licensed operations are essential to assure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections depends on the amount and the kind of material, the type of operation licensed, and the results of previous inspections. The capability of maintaining and retrieving statistical data on the status of the compliance program is necessary. The regulatory agency must have the necessary legal authority for prompt enforcement of its regulations. This may includes, as appropriate, administrative remedies, orders requiring corrective action, suspension or revocation of licenses, the impounding of materials, and the imposing of civil or criminal penalties.

Indicators and Guidelines

Status of Inspection Program (Category I)

- State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions.
- The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.
- At least semiannual inspection planning for number of inspections to be performed, assignments to senior vs.

[1] Additional guidance is provided in the Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement (46 FR 7540, 7560 and 46 FR 33376).

junior staff, assignments to regions, identification of special needs and periodic status reports. When backlogs occur, the program should develop and implement a plan to reduce the backlog. The plan should identify priorities for inspections and establish target dates and milestones for assessing progress.

Inspection Frequencey (Category I)

- The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, and industrial radiographers should be inspected approximately annually-smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency including for initial inspections should be no less than the NRC system.

Inspectors' Performance and Capability (Category I)

- Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections.
- The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Response to Actual and Alleged Incidents (Category I)

- Inquiries should be promptly made to evaluate the need for onsite investigations.
- Onsite investigations should be promptly made of incidents requiring reporting to the Agency in less that 30 days. (10 CFR 20.403 types.)
- For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection.
- Onsite investigations should be promptly made of non-reportable incidents which may be of sifgnificant public interest and concern, e.g., transportation accidents.
- Investigations should include indepth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate.
- State licensees and the NRC be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operation procedures).
- Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency.
- The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Enforcement Procedures (Category I)

- Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended.
- Enforcement Procedures should be issued within 30 days following inspection and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated.
- Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent re-occurrence (normally 20–30 days). The inspector and compliance supervisor should review licensee responses.
- Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items.
- Written procedures should exist for handling escalated enforcement cases of varying degrees.
- Impounding of material should be in accordance with State administrative procedures.
- Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Inspection Procedures (Category II)

- Inspection guides consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs. NRC Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc.
- Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, interviewing workers and observing operations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems.
- Procedures should be established for maintaining licensees' compliance histories.
- Oral briefing of supervisors or the senior inspector should be performed upon return from nonroutine inspections.
- For States with separate licensing and inspection staffs procedures should be established for feedback information to license reviewers.

Inspection Reports (Category II)

- Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of license's programs, and indicating the substance of discussions with license management and licensee's response.
- Reports should uniformly and adequately document the result of inspections including confirmatory measurements, status of previous noncompliance and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should show the status of previous noncompliance and the results of confirmatory measurements made by the inspector.

Confirmatory Measurements (Category II)

- Confirmatory Measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements.
- RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samples, lab counting equipment for smears, identification of isotopes, etc).
- RCP instrumentation should include the following types: GM Survey Meter, 0–50 mr/hr; Ion Chamber Survey Meter, several r/hr; micro-R-Survey meter; Neutron Survey Meter, Fast and Thermal; Alpha Survey Meter, 0–1000,000 c/m; Air Samples, Hi and Lo Volume; Lab Counters, Detect 0.001 uc/wipe; Velometers; Smoke Tubes; Lapel Air samplers.
- Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service

contact. Exceptions for other State Agencies, e.g., a State University, may be made.

• Agency instruments used for surveys and confirmatory measurements should be calibrated within the same time interval as required of the licensee being inspected.

Dated at Washington, DC this 27 day of May 1987.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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