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PROPOSED RULE: PR-MISC. 90-2 OPEN ITEM (Y/N) N RULE NAME: EVALUATION OF AGREEMENT STATE RADIATION CONTROL PR OGRAMS: PROPOSED GENERAL STATEMENT OF POLICY PROPOSED RULE FED REG CITE: 55FR10851 PROPOSED RULE PUBLICATION DATE: 03/23/90 NUMBER OF COMMENTS: 16 ORIGINAL DATE FOR COMMENTS: 05/22/90 EXTENSION DATE: / / FINAL RULE FED. REG. CITE: 57FR22495 FINAL RULE PUBLICATION DATE: 05/28/92 NOTES ON FILE LOCATED ON P1. STATUS -. DF RULE TO FIND THE STAFF CONTACT OR VIEW THE RULEMAKING HISTORY PRESS PAGE DOWN KEY

HISTORY OF THE RULE

PART AFFECTED: PR-MI	8C. 90-2		
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PROPOSED RULE	PROPOSED RULE	DATE PROPOSED RULE	03/19/90
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In the Matter of

EVALUATION OF AGREEMENT STATE RADIATION CONTROL PR OGRAMS: PROPOSED GENERAL STATEMENT OF POLICY

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	DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
	03/21/90	03/19/90	FEDERAL REGISTER NOTICE - PROPOSED RULE
	04/13/90	04/09/90	COMMENT OF ARIZONA RADIATION REGULATORY AGENCY (CHARLES F. TEDEORD, DIRECTOR) (1)
	05/04/90	05/01/90	COMMENT OF DEPARTMENT OF PUBLIC HEALTH (LEE E. JAGER. P.E., CHIEF) (2)
	05/14/90	05/09/90	COMMENT OF DEPARTMENT OF HUMAN RESOURCES (JOHN VADEN, MANAGER) (3)
	05/17/90	05/10/90	COMMENT OF GARY ROBERTSON, HEAD (4)
	05/22/90	05/21/90	COMMENT OF YANKEE ATOMIC ELECTRIC COMPANY (D. W. EDWARDS) (5)
)	05/24/90	05/22/90	COMMENT OF NUCLEAR INFORMATION & RESOURCE SERVICE (DIANE D'ARINGO) (6)
	05/25/90	05/16/90	COMMENT OF COMMONWEALTH EDISON COMPANY (T.J. KOVACH) (7)
	05/30/90	05/22/90	COMMENT OF DEPT. OF HEALTH SERVICES (DON J. WOMELDORF) (8)
	06/05/90	05/22/90	COMMENT OF AR DEPT. OF HEALTH (GRETA J. GICUS) (9)
	06/06/90	06/05/90	COMMENT OF ILLINOIS DEPARTMENT OF NUCLEAR SAFETY (PAUL D. EASTVOLD) (10)
	06/06/90	06/01/90	COMMENT OF ENVIRON. COALITION ON NUCLEAR POWER (JUDITH H. JOHNSRUD, DIRECTOR) (11)
	06/06/90	06/01/90	COMMENT OF SIERRA CLUB (J. H. JOHNSRUD, CO-CHAIRPERSON) (12)
	06/08/90	05/22/90	COMMENT OF THE COMMONWEALTH OF MASSACHUSETTS (CAROL C. AMICK, EXECUTIVE DIRECTOR) (13)

DOCKET NO. PR-MISC. 90-2 (55FR10851)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT	
06/08/90	06/01/90	COMMENT OF COLORADO DEPARTMENT OF HEALTH (ROBERT M. QUILLIN) (14)	
06/12/90	06/07/90	COMMENT OF BUREAU OF RADIATION CONTROL (DAVID K. LACKER) (15)	
06/12/90	06/05/90	COMMENT OF ILLINOIS DEPARTMENT OF NUCLEAR SAFETY (PAUL D. EASTVOLD) (16)	
05/26/92	05/21/92	NRC REVIEW OF AGREEMENT STATE RADIATION CONTROL PROGRAMS: FINAL GENERAL STATEMENT OF POLICY	

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(55 FR 10851)

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Nuclear Regulatory Commission 92 MAY 26 P5:12 NRC Review of Agreement State Radiation Control Programs: Final General Statement of Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final general statement of policy.

SUMMARY: The Nuclear Regulatory Commission is revising its general statement of policy on "Guidelines for NRC Review of Agreement State Radiation Control Programs." This statement of policy informs the States and the public of the criteria and guidelines that the Commission intends to use in its periodic evaluations of Agreement State programs. Most of the revisions are related to regulation of low-level radioactive waste management and disposal. EFFECTIVE DATE: (Upon publication in the <u>Federal Register</u>). FOR FURTHER INFORMATION CONTACT: Kathleen N. Schneider, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: 301-504-2320.

SUPPLEMENTARY INFORMATION: On March 23, 1990 (55 FR 10851) the NRC published in the Federal Register proposed revisions to its General Statement of Policy, "Guidelines for NRC Review of Agreement State Radiation Control Programs." Interested persons were invited to submit written comments on the proposed revised policy statement. The comment period expired May 22, 1990. Fifteen written comments were received. After review and evaluation of the comments, the Commission has concluded the revisions can be published as a final general statement of policy.

Pub. 5/28/192 57 FR 22-195

The NRC revision to its General Statement of Policy "Guidelines for NRC Review of Agreement State Radiation Control Programs" specifically addresses the review of State programs which regulate the disposal of low-level radioactive waste in permanent disposal facilities. The revision also addresses packaging, treatment, storage, processing, and transportation of low-level radioactive waste. The final guidance takes into account the regulatory requirements of 10 CFR Part 61 and the experience of States with low-level radioactive waste regulatory programs. The guidance is considered to be flexible enough to be used in the review of low-level radioactive waste disposal control programs which predated 10 CFR/Part 61.

Eight comments were received from Agreement States, two from non-Agreement States, two from utilities and three comments from public interest groups. A copy of the comments and an NRC staff summary and analysis of comments are available in the NRC Public Document Room.

Commenters on the Status and Compatibility of Regulations indicator stated the view that compatibility should be interpreted to allow States to establish more restrictive standards. The Commission is considering this issue as a separate matter. This revision of the guidelines supplements and strengthens the current guidelines, and although two States opposed the revisions, the U.S. NUCLEAN SECURITY COMMISSION are needed now. Additional changes, as of the commission concludes that they are needed now. Additional changes, as appropriate, will be made to the guidelines once the Commission makes a final Document States of compatibility.

Postmark Date Copies Received

Addi Copies Reproduced 3Commenters raised the issue of the authority Agreement States have at the site Miller, PDN, RTM of waste generation by persons in the State who are not Agreement State

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Commenters raised the issue of the authority Agreement States have at the site of waste generation by persons in the State who are not Agreement State licensees. This issue is adequately addressed in other criteria and in 10 CFR

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Part 150. Except as they relate to conflict of interest issues, activities stemming from the State's role as site developer, host State, compact member, or land owner are outside the scope of this policy statement. These guidelines deal only with the State's regulatory program under section 274 of the Atomic Energy Act.

Many of the comments suggested additional flexibility or level of detail. With respect to flexibility, the guidelines are just that, and judgement is to be used in their implementation. Further, many of the indicators are expressed in terms of "should" to emphasize flexibility. It is always a challenge to achieve the proper mix between performance objectives and details in any such document and the decision is, in the final analysis, a judgement call. With respect to specific flexibility concerns raised by the commenters and suggestions offered but not adopted as too prescriptive, procedural, or outside the scope of the State's authority or responsibility as an Agreement State, see the detailed staff analysis, which is available in the NRC Public Document Room.

Three commenters addressed the proposed indicator for Quality of Emergency Planning. Illinois suggested the present indicator had the flexibility necessary and the proposed revision created ambiguity. The Commission agrees and has dropped the proposed March 23, 1990 revision.

One State suggested deleting the proposed addition to the Budget indicator on maintaining adequate support for the RCP throughout the life cycle of the LLW disposal facility as unnecessary. The Commission disagrees based on experience where funding levels based on waste volumes resulted in unjustified loss of funding and staff. For the Management indicator, a suggestion to add

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"health physics" as a discipline for the Project Manager was adopted but a suggestion to delete the Project Manager was not because the lack of a designated project manager would hinder timely licensing action.

Illinois commented that the indicator for Office Equipment and Support Services be broadened to include a management system to organize and control the documents associated with the licensing of all radioactive material and not just low-level radioactive waste. The Commission agrees with this comment.

A comment advocating deletion of the recommendation that States provide the opportunity for hearings for major LLW disposal site licensing actions was not adopted. Public involvement is important. The Commission notes that the nature of such hearings would be dictated by State administrative procedures.

A common concern among many commenters was the extent to which staff resources must be RCP staff and when they may be outside the RCP. A parenthetical addition to the Qualifications of Technical Staff and the existing language in the Contractual Support indicator should help clarify that there is extensive flexibility so long as the resources and expertise are available.

The Staffing Level indicator was one of the more controversial. Two States expressed the view that the nature of the operations and the site could result in an adequate lesser staffing level than the baseline of 3 to 4 professional technical person-years proposed. The Commission agrees that there may be such cases and has added language to consider site activities on a case-specific basis. The Commission also agrees with commenters that more than a baseline of 3 to 4 may be needed in some cases, but views the language as sufficiently flexible to address higher levels. A parenthetical addition also responds to commenters questions by clarifying that the 3 to 4 person-year level for LLW disposal site regulation does not include the baseline staff for the basic RCP. The proposed explanatory text referring to the staffing levels that would be needed for review as an example of a peak activity period has been deleted, consistent with other decisions on level of detail.

Three comments were received regarding the Training indicator. Illinois recommended broadening the indicator to state that Radiation Control Program staff should be afforded opportunities for training that is consistent with the need of the program. The Commission also agrees with this recommendation.

Minor word changes made include deleting "timely" from the Contractual Assistance indicator, replacement of the phrase "current regulatory guidance" with the phrase "State licensing requirements" in the Technical Quality of Licensing Actions indicator, and deletion of "minimum approval standards" from the Licensing Procedures.

The Commission directed the staff to evaluate NRC's LLW program against the proposed revisions. Although no changes in the guidelines were recommended by the task force which conducted the evaluation, the Commission concludes that the task force findings show the need to amend the guidelines in one area in order to provide the States with the same flexibility the staff plans for itself. The text for the indicators Laboratory Support and Confirmatory Measurements have been modified to provide additional flexibility for access to nonradiological testing.

In addition, the Commission added a clarifying sentence to the indicator for

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staffing level to indicate that the RCP should have at least two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. These two professionals available to operate the RCP should not be supervisory or management personnel.

> Guidelines for NRC Review of Agreement State Radiation Control Programs, 1992

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 by-product, 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

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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 editorial changes reflecting the experience gained with the 1981 policy statement. Those changes were promulgated in June 1987.

In 1988, the Commission staff initiated revisions to the Review Guidelines to improve reviews of State regulatory programs for the disposal of low-level radioactive waste. The revised document will be used by NRC in its review of those State programs which regulate the disposal of low-level radioactive waste in permanent disposal facilities. It will also be used to strengthen the review of State programs which regulate other aspects of radioactive waste management, such as packaging, treatment, storage and transportation.

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 element, (b) indicators which address specific functions within the program element, (c) guidelines which delineate specific objectives or operational goals under each indicator.

<u>Categories of Indicators</u>

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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 (and the Program Elements of which they are a part) are:

- o Legal Authority (Legislation and Regulations)
- Status and Compatibility of Regulations (Legislation and Regulations)
- Quality of Emergency Planning (Management and Administration)
- o Technical Quality of Licensing Actions (Licensing)
- o Adequacy of Product Evaluations (Licensing)
- o Status of Inspection Program (Compliance)
- o Inspection Frequency (Compliance)
- o Inspectors' Performance and Capability (Compliance)
- o Response to Actual and Alleged Incidents (Compliance)
- o Enforcement Procedures (Compliance)

These indicators address primary 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

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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 are the objectives 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 (and the Program Elements of which they are a part) are:

- Location of Radiation Control Program Within State
 Organization. (Organization)
- Internal Organization of Radiation Control Program.
 (Organization)
- o Legal Assistance. (Organization)
- o Technical Advisory Committees. (Organization)
- o Contractual Assistance. (Organization)
- o Budget. (Management and Administration)
- o Laboratory Support. (Management and Administration)
- o Administrative Procedures. (Management and Administration)
- o Management. (Management and Administration)

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	Administration)
J,	Public Information. (Management and Administration)
0	Qualifications of Technical Staff. (Personnel)
0	Staffing Level. (Personnel)
0	Staff Supervision. (Personnel)
0	Training. (Personnel)
0	Staff Continuity. (Personnel)
0	Licensing Procedures. (Licensing)
0	Inspection Procedures. (Compliance) .
0	Inspection Reports. (Compliance)

o Confirmatory Measurements. (Compliance)

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 primary program functions, 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

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(Management and

Office Equipment and Support Services.

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protect the public health and safety and that the need for 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. 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. 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.

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

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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 Programs" will be used by the NRC staff during its onsite reviews of Agreement State programs. At least once each year, there will be onsite communication between the NRC staff and each State either as a result of a routine review or a review site visit. A routine review is a total assessment of each Agreement State program and is conducted at least biennially. A review visit is a trip to the Agreement State to assess the status of the State program and to address any special concerns within the State program. Additional contacts may also be made through special or follow-up reviews.

In making a finding of adequacy, the NRC considers areas of the State program which are critical to 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 and 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

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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.

It should be noted that the categories of indicators, and the significance thereof, apply equally to the regulation of uranium and thorium recovery and associated wastes; low-level radioactive waste management; as well as the overall radiation control program. Any differences in the guidelines for review of uranium mill tailings programs or low-level waste programs are specified within the individual program elements.

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 by which the licensee 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)

o Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement.

o 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.

o States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level waste management and disposal. The statutes should also provide regulatory program authority and provide for a system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur.¹

Status and Compatibility of Regulations (Category I)

¹The level of separation (e.g., separate agencies) should be determined for each State individually.

o 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.

o The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.

o 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.

o The RCP has established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC.

o Opportunity should be provided for the public to comment on proposed regulation changes (Required by UMTRCA for uranium mill regulation.)

o 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)

o 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.

o 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)

o 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.

o 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)

o 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)

o Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems.

o 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.

o 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.

Contractual Assistance (Category II)

o Because of the diversity and complexity of low-level radioactive waste disposal licensing and regulation, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for acquisition of technical and vendor services necessary to support these functions that are not otherwise available within the RCP.

o The RCP should avoid the selection of contractors which have been selected to provide services associated with the LLW facility development or operations.

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, contract services, 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)

o The State RCP should have a written plan in response to incidents at licensee facilities which takes into account such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

o 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.

o 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.

o 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)

o 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. States regulating the disposal of low-level radioactive waste facilities should have adequate budgetary resources to allow for changes in funding needs during the LLW facility life cycle. After appropriations, the sources of program funding should be stable and protected from competition from or invasion by other State programs.

o 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)

o The RCP should have laboratory support capability in house, 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.

o In addition, States regulating the disposal of low-level radioactive waste facilities in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level waste disposal, including soils testing, testing of environmental media, testing of engineering properties of waste packages and waste forms, and testing of other engineering materials used in the disposal of low-level radioactive waste. Access to laboratory support should be available on an "as needed" basis for nonradiological analyses to confirm licensees' and applicants' programs and conditions for nonradiological testing should be prescribed in plans or procedures.

Administrative Procedures (Category II)

o 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)

o Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, regulation revisions).

o RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to

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forecast needs for increased staff, equipment, services and funding.

o Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, low-level radioactive waste disposal facilities, large scope-Type A Broad, potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports and enforcement actions should also be performed.

o For the implementation of very complex licensing actions, such as initial license review, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the technical reviews which the Project Manager will be coordinating such as health physics, engineering, earth science or environmental science.

o 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)

o 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

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services should be available to regional offices, if utilized.

o States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials.

o Professional licensing, inspection, and enforcement staff should not be used for fee collection and other clerical duties.

Public Information (Category II)

o 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 clearly personal nature.

o Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws during the process of major licensing actions associated with UMTRCA and low-level radioactive waste in permanent disposal facilities.

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. In addition, in States regulating low-level radioactive waste facilities, the RCP should be staffed with individuals with training and experience in engineering, earth science, and environmental science. 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)

o 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. For States regulating uranium mills and mill tailings, staff training and experience should also include hydrology, geology, and structural engineering.² For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or

mechanical engineering, geology, hydrology, and other earth science, and environmental science. In both types of materials, staff training and experience guidelines apply to available contractors and resources in State agencies other than the RCP.

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² 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, 36969 and 48 FR 33376).

o Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Staffing Level (Category II)

o Professional staffing level should be approximately 1-1.5 personyears per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

o For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years of effort, including consultants, are needed to process a new mill license (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978.

o States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow a baseline RCP staff effort of 3-4 professional technical person-years (in addition to the two professionals for the basic RCP indicated in the first bullet of this indicator). However, in some cases, the level of site activity may be such that a lower level is adequate, particularly if contractor support is on call. In any event, staff resources should be adequate to conduct inspections on a routine basis during operations of the LLW facility, including inspection of incoming shipments and licensee site activities and to respond to emergencies associated with the site. During periods of peak activity additional staff or specialty consultants should be available on a timely basis.

Staff Supervision (Category II)

o Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel.

o Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy.

o Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Training (Category II)

o Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices.

o The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology.

o The RCP staff should be afforded opportunities for training that is consistent with the needs of the program.

Staff Continuity (Category II)

o Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries.

o Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area.

o The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

PROGRAM ELEMENT: LICENSING

It is necessary in licensing by-product, 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); consultation and prelicensing inspection of complex facilities (e.g., waste disposal sites, mills, irradiators, etc.); 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)

0 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 guantities to be used, gualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet State licensing requirements for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process.

o Prelicensing visits should be made for complex and major licensing actions.

o Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions.

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o 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 Evaluations (Category I)

o RCP evaluations of manufacturer'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.

o The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.

o 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.

o Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Licensing Procedures (Category II)

o The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.

o In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans and procedures for license review and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process.

o License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions.

o The present compliance status of licensees should be considered in licensing actions.

o 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.

o Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process.

o 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 include, 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)

o State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. The inspection program in all States should provide for the inspection of licensee's waste generation activities under the State's jurisdiction.

o In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for preoperational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the LLW facility, including inspection of incoming shipments and licensee site activities.

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o 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.

o At least semiannual inspection planning should be done for the number of inspections to be performed, assignments to senior vs. 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 Frequency (Category I)

o 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 initial inspections, should be no less than the NRC system.

Inspectors' Performance and Capability (Category I)

o 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.

o For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment.

o 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)

o Inquiries should be promptly made to evaluate the need for onsite investigations.

o Onsite investigations should be promptly made of incidents requiring reporting to the Agency in less than 30 days. (10 CFR 20.403 types.)

o For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection.

o Onsite investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern, e.g., transportation accidents.

o Investigations should include in-depth 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.

o State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures).

o 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.

o 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)

o 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.

o Enforcement procedure letters should be issued within 30 days following inspections 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.

o Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses.

o Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items.

o Written procedures should exist for handling escalated enforcement cases of varying degrees.

o Impounding of material should be in accordance with State administrative procedures.

o Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Inspection Procedures (Category II)

o 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. o 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.

o Procedures should be established for maintaining licensees'
compliance histories.

o Oral briefing of supervisors or the senior inspector should be performed upon return from non-routine inspections.

o For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Inspection Reports (Category II)

o 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 the licensees' programs, and indicating the substance of discussions with licensee management and licensee's response.

o 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)

o Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, access to testing should be available on an "as needed" basis for confirming licensees' and applicants' programs for measurements related to nonradiological aspects of facility operations such as soils and materials testing and environmental sampling and analysis to demonstrate compliance with 10 CFR Part 61 or compatible Agreement State regulations and ensure facility performance. Conditions for nonradiological testing should be prescribed in plans or procedures.

o RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samples, lab counting equipment for smears, identification of isotopes, etc).

o 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 Samplers, Hi and Lo Volume; Lab Counters, Detect 0.001 uC/wipe; Velometers; Smoke Tubes; Lapel Air samplers.

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

o 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 Rockville, Maryland, This 7 Day of Maryland, 1992.

For the U.S. Nuclear Regulatory Commission

Secretary of the Commission

DOCKET NUMBER MISC. BOPOSED RULE PN MISC (55 F.R. 10851)

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STATE OF ILLINOIS DEPARTMENT OF NUCLEAR SAFETY **1035 OUTER PARK DRIVE** SPRINGFIELD, IL 62704 (217) 785-9900

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

THOMAS W. ORTCIGER DIRECTOR

June 5, 1990

JAMES R. THOMPSON

GOVERNOR

Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Attn: Docketing and Service Branch

Re: "Evaluation of Agreement State Radiation Control Programs; Proposed General Statement of Policy," 55 Fed. Reg. 10851-10861 (March 23, 1990)

The Illinois Department of Nuclear Safety (IDNS) hereby submits its comments on the above-identified proposed revisions to the Guidelines concerning review of Agreement State Radiation Control Programs as they relate to the regulation of low-level radioactive waste (LLW) disposal. Illinois is an Agreement State and IDNS is the lead agency in Illinois for all radiation control activities, including the regulation of low-level radioactive waste disposal.

On January 6, 1989, IDNS submitted comments on a draft version of this document. Although a few of the concerns identified in IDNS' comments on the draft version have been addressed, many of IDNS' concerns remain unresolved. The Department's primary criticism of the proposed policy statement is that NRC has not made a persuasive case for some of the specific quidelines to address low-level radioactive waste regulation. The evaluation of Agreement State programs should be based on the overall activities of the program. In addition, the proposed Guidelines are deficient because the revised indicators are often repetitive and unnecessary. Furthermore, many of the indicators included in the proposed Guidelines are drafted so that they only apply to state radiation control programs (RCPs) with regulatory responsibility over the disposal of low-level radioactive waste LLW, even though it would be more appropriate to apply the indicators to all state radiation control programs. Also, some of the indicators are ambiguous and should be redrafted. Our specific comments are as follows:

Under the indicator "Legislation and Regulations," we believe that the 1. third Guideline should be revised as follows:

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> "States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulation for low-level waste management and disposal. The statutes should also provide regulatory program authority and <u>provide for a</u> system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur."

This language more accurately reflects NRC's stated purpose for the Guideline, to require that Agreement States have in place adequate safeguards to assure "avoidance of conflict of interest and, ultimately, to protect the public health and safety" (page 10852), while at the same time giving each Agreement States more discretion in determining what safeguards should be incorporated into the RCP.

2. In the description of the proposed revisions, NRC suggests that a new category, "Contractual Assistance," be added. While this indicator appears to be new in its entirety, in the notice the last paragraph of the indicator is not designated as new language. The indicator is inappropriate since it is limited specifically to LLW disposal and licensing and regulation. As IDNS noted in its previous comments, Agreement States are responsible for regulating licensees other than LLW disposal facilities that are at least as complicated as, if not more complicated than, LLW disposal facilities. Should not all Agreement States have procedures and mechanisms in place for timely acquisition of technical and vendor services necessary to perform those functions not otherwise available with the radiation control program? Why should this indicator not apply to Tennessee, an Agreement State that does not regulate LLW disposal but that does license major LLW treatment facilities?

Furthermore, the restriction in the last paragraph does not reflect the reality facing state programs. There are few firms in the United States that have the expertise to provide professional services in a manner that will allow all states, simultaneously, to meet federally mandated milestones for providing LLW disposal capacity. While it is understandable that contractors that have provided assistance in a specific aspect of facility development should not be allowed to provide assistance in regulatory evaluation of that aspect, such contractors should not be precluded from providing assistance in evaluation of other aspects of licensing that are not related to the development services they provided previously. Therefore, if the last paragraph of this indicator is retained, it should be revised as follows:

"When seeking technical and vendor services to support regulatory functions, the Radiation Control Program (RCP) should avoid selection of contractors who have provided related developmental or operational services."

3. The proposed addition to the indicator "Quality of Emergency Planning" is ill-advised. The proposal would add a sentence that provides, "(p)lans for States regulating the disposal of low-level radioactive waste in permanent disposal facilities should include response to emergencies associated with the disposal of low-level radioactive waste." (55 Fed. Reg. 10857) This addition is redundant since the indicator already provides that state RCPs should have a written plan for responding to incidents at licensee facilities. The

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proposed revision to this indicator adds no new requirements. It is disconcerting, however, because it implies that emergencies involving disposal of LLW are either more likely to occur or more serious than emergencies at other licensed facilities. This is not the case and, in fact, emergencies at disposal facilities may be less complex than those at a major radiopharmaceutical manufacturer, for example.

In support of this proposed change, NRC states that "(t)he diversity of activities associated with the transportation, handling, storage, and disposal of LLW suggests the potential for both radiological and non-radiological emergencies or unusual [sic (word missing)] which should be covered in the State RCP radiological emergency response plan." (55 Fed. Reg. 10653) Although the explanation notes that the potential for emergencies is "suggested" by transportation, handling, storage, and disposal activities, the revised indicator would only apply in states where disposal activities are conducted. It would not be applied to states, like Tennessee and Florida, that regulate waste treatment facilities, but not waste disposal facilities. Evaluation of the emergency response plans in such states is already covered by the existing language. The proposed modification to this indicator would not add any substantive criteria; to the contrary, the proposed revision would create ambiguity about the need for state emergency plans for licensed waste management facilities other than disposal facilities.

4. The proposed revision of the "Budget" indicator should be deleted. The existing indicator, which already states that "(p)rincipal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc.," applies to all aspects of the Agreement State program and sufficiently covers this matter.

5. One of the new Guidelines under "Management" indicates that the Project Manager should have training or experience in one of the main disciplines, such as engineering, earth science, or environmental science. (55 Fed. Reg. 10858) The other key discipline, Health Physics, should be added to this list.

6. Under the category "Office Equipment and Support Services," the proposed revised Guidelines would add a new indicator, which provides that:

"States regulating the disposal of low-level radioactive waste in permanent disposal facilities should develop and implement a license document management system commensurate with the volume and diversity of materials associated with a low-level waste disposal facility license." (55 <u>Fed. Reg.</u> 10858)

This indicator should be broadened. Every Agreement State program should have a management system to organize and control the documents associated with licensing radioactive materials. While IDNS agrees that it would be difficult to regulate a LLW disposal facility without a document control system, this indicator is equally applicable to all licenses. Therefore, the indicator should be rewritten as follows:

> "States should have a license document management system that is capable of organizing the volume and diversity of

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materials associated with inspection and licensing of radioactive materials."

7. Under the program element "Personnel," NRC has proposed adding the following new sentence:

"In addition, in States regulating low-level radioactive waste facilities, the RCP should be staffed with individuals with training and experience in engineering, earth science, and environmental science." (55 Fed. Reg. 10858)

The Department believes that this criterion should apply to states that regulate storage or treatment of LLW or other complex facilities and that the indicators "Qualifications of Technical Staff," "Staffing Level," and "Training" should be revised accordingly. We suggest the sentence be reworded as follows:

"In addition, in States regulating complex operations, such as low-level radioactive waste storage or treatment facilities and large manufacturing operations, the RCP should either be staffed with individuals who have training and experience in engineering, earth science, environmental science or other disciplines as appropriate, or be capable of contracting for such expertise."

8. The Guideline pertaining to staff training should be broadened. The desirability of affording to program staff training that is consistent with the needs of the regulatory program is not limited to radiation control programs that are responsible for licensing LLW disposal facilities or uranium mills. All radiation control programs would benefit from staff training that is "consistent with the needs of those programs." (55 Fed. Reg. 10859) For this reason, IDNS recommends that this indicator be revised to read as follows:

"RCP staff should be afforded opportunities for training that is consistent with the needs of the RCP."

9. Under the indicator labeled "Technical Quality of Licensing Actions," the following new sentences are being proposed:

"Additionally, in States which regulate the disposal of lowlevel radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet current regulatory guidance for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process." (55 Fed. Reg. 10859) Secretary of the Commission Page 5 June 5, 1990

This indicator should be revised by replacing the phrase "current regulatory guidance" with the words "State licensing regulations." Conformance with regulatory guidance, such as NUREG reports and CR reports, is not a requirement for obtaining a license and should not be the basis for a decision to issue a license.

10. Under the "Licensing Procedures" indicator, a new paragraph specific to states that regulate disposal of LLW has been added. That paragraph provides that such states should have program specific licensing guides, plans, and procedures for license review, as well as minimum approval standards. IDNS recommends that this paragraph be deleted. The minimum standards for approval of an application are established in the rules pertaining to licensure of LLW disposal facilities. If the standards codified in these rules are vague, the rules should be amended to incorporate more specific standards. It is not appropriate to establish "minimum approval standards" in guides, plans, or procedures. If NRC persists in retaining this indicator, the indicator should be rewritten to apply only if the need for such documents has been indicated. The Agreement States should not be required to prepare licensing guidance documents, plans, and procedures if a need for such documents has not been determined.

11. On page 10860, under the indicator "Inspectors' Performance and Capability," a new Guideline has been added which states that a "multidisciplinary team approach" for inspection of complex licensed activities "is desirable to assure a complete compliance assessment." The new Guideline, however, does not define, or in any way describe, what is meant by "multidisciplinary team approach." In the notice that precedes the Guidelines, NRC says that "many of the inspections associated with a LLW facility will be nonradiological in nature, concerned instead with construction practices, performance of engineering systems, and verification of system performance." (55 Fed. Reg. 10854) If this is the basis for the Guideline, the new language should specify this and should provide examples of the types of disciplines that would be appropriately included in a multidisciplinary inspection. We would also note that while a team approach may be desirable for many inspections, it may not be the only satisfactory approach. For example, a series of partial inspections may suffice.

12. Under the indicator "Confirmatory Measurements," NRC is proposing to modify the first Guideline by adding the following sentence:

the disposal of low-level "In States regulate which permanent radioactive waste in disposal facilities. shou1d measurements also be adequate to confirm nonradiological aspects of facility operations such as soils and materials testing and environmental sampling and analysis to demonstrate compliance with 10 CFR Part 61 and assure facility performance." (55 Fed. Reg. 10861)

In support of this modification, NRC states in the introductory material that, "(b)ecause of the importance of soils and engineering materials in overall facility performance, the RCP should have the capability of confirming performance of the materials." (55 <u>Fed. Reg.</u> 10854) Since the objective of this Guideline can be fulfilled through the use of laboratories under contract, and since most RCPs will not have the necessary laboratory Secretary of the Commission Page 6 June 5, 1990

capability in-house, the Guideline should be revised to indicate that the necessary capability may be obtained by contracting with laboratories.

13. The Department also notes that the "Summary" section of the notice states that "the proposed revision to the guidelines was prepared by the NRC to incorporate changes specifically related to the regulation of low-level radioactive waste disposal in permanent disposal facilities. . . The Commission considers that these revisions are necessary given the present and potential low-level waste regulatory responsibility in Agreement States." (55 Fed. Reg. 10851-10852) Under the indicator labeled "Qualifications of Technical Staff," however, NRC has proposed adding a sentence pertaining to technical staff requirements for regulation of uranium mills and mill tailings. Since this is not at all relevant to LLW management, the final version of the notice for the Guidelines should explain that the revisions are intended to address aspects of regulatory control programs other than those related to the regulation of low-level radioactive waste disposal. This change would also be necessary if NRC adopts IDNS' recommendations to broaden certain specific indicators.

As indicated by the Department's specific comments enumerated above, the proposed revisions to the Guidelines are seriously flawed. The Illinois Department of Nuclear Safety strongly recommends that the Nuclear Regulatory Commission refrain from making the revisions currently being proposed. The Department is concerned that many of the proposed revisions are inappropriate.

The Department appreciates the opportunity to comment on the proposed revision to the Policy Statement regarding evaluation of Agreement State programs. We hope that these comments will be incorporated into any further action on these revisions. If there are any questions regarding IDNS' comments, we would be happy to discuss them with NRC representatives.

Sincerely,

Paul D. Eastword

Paul D. Eastvold, Manager Office of Radiation Safety

PDE/vh

cc: Carlton C. Kammerer, Director State Programs Office of Governmental and Public Affairs

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Texas Department of Health

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June 7, 1990

Radiation Control (512) 835-7000

The Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dear Sirs:

Staff members of the Bureau of Radiation Control have reviewed the proposed revisions to the statement of policy entitled "Guidelines for NRC Review of Agreement State Radiation Control Programs," and offer the following comments for consideration.

- 1. Page 13 The NUREG documents prepared by the Nuclear Regulatory Commission (NRC) are valuable technical instruments that can be utilized during the low-level waste license application review process. However, it would be beneficial to Bureau staff members if the NRC could develop appropriate regulatory guides in the areas not specifically addressed in NUREGs. The regulatory guides could address such topics as packaging, treatment, storage, processing, and transportation of low-level radioactive wastes specific to a low-level waste disposal facility.
- 2. Page 25 It would be helpful if the NRC would encourage Agreement State Programs to develop specific topics to address during a review site visit. A topical outline provided prior to the visit would allow the appropriate technical staff to be in attendance during the visit and discuss current issues on a face-to-face basis with NRC personnel.
- Page 32 In the first paragraph on this page, the term "timely acquisition" should be clarified.
- 4. Page 35 It is unclear whether the state program is responsible for conducting independent tests of engineering materials used in low-level waste disposal, such as the concrete used in canisters. The NRC should specify whether the state program is responsible for such testing, which would require additional laboratory support. Otherwise, the NRC should specify that contracting an outside laboratory to do package testing, soils engineering testing, and testing of engineering materials used in the disposal of low-level waste is acceptable.
- 5. Page 37 In the last paragraph on this page, the term "periodic audits" should be more specific.

Thank you for the opportunity to comment on the proposed revisions. If you have any questions, please contact me.

Yours truly,

David K. Lacker, Chief Bureau of Radiation Control

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Acknowledged by card

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COLORADO DEPARTMENT OF HEALTH

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USNRC

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OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

June 1, 1990

Vandy L. Miller, Assistant Director State Programs Office of Govermental and Public Affairs Mail Stop 3D23 U.S. Nuclear Regulatory Commission Washington, DC 20555

Subject: Guidelines for NRC Review of Agreement State Radiation Control Programs

- NRC identifies many specific criteria for low-level radioactive (LLW) facilities. In most cases, the existing criteria permit adequate evaluation of a state program without additional specific items being added.
- 2. Colorado supports the separation of the regulatory functions from the developmental and operational functions for a LLW disposal facility. We do believe, however, that if a state contracted for the development and/or operation of a LLW facility, sufficient separation of functions would exist.
- 3. The proposed guideline for "Quality of Emergency Planning", which will require response to emergencies associated with the disposal of low-level radioactive waste, including non-radiological emergencies or occurrences, should not be limited to states which have LLW disposal sites. Transportation accidents involving these materials can happen in any state.
- 4. Under the indicators "Laboratory Support" and "Adequacy of Product Evaluations," each host state should not have to perform its own evaluation of waste packages and waste forms. Because the same package types and waste forms will likely be common to all disposal sites, a single entity, such as the NRC, should assume the responsibility of assuring these evaluations are performed.



Roy Romer Governor

Thomas M. Vernon, M.D. Executive Director

FEB 1 2 1991

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Vandy L. Miller State Programs Page 2

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- 5. Within the indicator "Status of Inspection Program," there should be a requirement that a state inspector be present at all times when a disposal trench is being constructed or closed.
- The NRC has not justified the need for compatibility of regulations under Part 61. Unless demonstrated otherwise, "equivalent" should be the standard for review.
- Colorado strongly supports the Category I indicator Status of Inspection Program requiring an inpsection program for waste generation activities.

If you require further clarification of any of these issues, please contact this Division.

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Robert M. Quillin, Director Radiation Control Division

RMQ:WJ:rmcm



MICHAEL S. DUKAKIS GOVERNOR

JOHN A. MAYER, JR. CHAIRMAN

CAROL C. AMICK EXECUTIVE DIRECTOR

May 22, 1990

The Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555 Attn: Docketing and Service Branch

Dear Sir or Madam:

Enclosed are the comments of the Massachusetts Low-Level Radioactive Waste Management Board on the proposed revisions to the guidelines for NRC review of Agreement State Radiation Control Programs.

A copy of these comments are also being sent to you via the U.S. mail.

Sincerely,

Carol C. Amick

Executive Director

Enclosure

CCA:smh

MSC. 90-2

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PROPOSED RULE

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THE COMMONWEALTH OF MASSACHUSETTS LOW-LEVEL RADIOACTIVE WASTE MANAGEMENT BOARD

xxxxxxxxxxxx 100 Cambridge Street, room 903 Boston, MA 02202 (617) 727-6018

MICHAEL S. DUKAKIS GOVERNOR

JOHN A. MAYER, JR CHAIRMAN

CAROL C. AMICK EXECUTIVE DIRECTOR

May 21, 1990 Comments of the Massachusetts Low-Level Radioactive Waste Management Board on the proposed Revision to Guidelines for NRC Review of Agreement State Radiation Control Programs

The Massachusetts Low-Level Radioactive Waste Management Board is responsible for planning and effecting the management of lowlevel radioactive waste in the Commonwealth. The Board was created by the passage of M.G.L. c.111H, which also assigned critical regulatory responsibilities to the Department of Public Health's Radiation Control Program.

Under M.G.L. c.111H, the Radiation Control Program establishes and implements regulations for LLW source and volume minimization and storage for decay programs; and regulations for facility licensing, development, operation, closure, post-closure observation and maintenance, and institutional control.

At the same time c.111H was approved, the Governor also signed into law amendments to the Radiation Control Program's statutory authority. These amendments enable the state to take the actions necessary to become an Agreement State under section 274 of the Atomic Energy Act of 1954.

Because Agreement State status is an essential component of full implementation of c.111H, the Management Board submits these comments regarding the Nuclear Regulatory Commission's proposed revisions of it guidelines for reviewing Agreement State Radiation Control Programs.

The Management Board is in agreement with the concept embodied in the proposed guideline revision which separates the regulatory authority from the low-level waste management and facility development authority. This policy, which has been in effect in Massachusetts since the passage of M.G.L. c.111H, is crucial to ensure the proper separation between the agency charged with managing LLW and the one responsible for regulating radioactive materials users and any disposal facility.

The Management Board has no difficulty with the proposed guideline revision to bring NRC staff on-site every year for an Agreement State review and every two years for a "total assessment" of the Agreement State Program.

The Management Board is also supportive of the NRC's proposed expansion of the indicator, Technical Quality of Licensing Actions, to include such guidelines as:

(1) waste product and volume

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- (2) facility personnel qualifications
- (3) facilities and equipment
- (4) operating and emergency procedures
- (5) operator's financial qualifications
- (6) closure and decommissioning procedures
- (7) institutional arrangements with other institutions

Each of these guidelines is an important component in the licensing activity, and with the exception of (7) above, M.G.L. c.111H requires their inclusion in the Massachusetts siting process.

The Management Board is also pleased that the NRC revision proposes to retain earlier language:

"The success of a state program in meeting the overall objective of the indicator does not depend on literal adherence to each recommended guideline." (p.24)

and

"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." (p.26)

We urge you to retain that language in the final revision.

In addition, the Management Board finds no difficulty with the remaining proposed changes in the Agreement State evaluation guideline, with one exception. That exception is the recommendation under Staffing Level (Category II) which would require Radiation Control Program staff of 3-4 technical personyears to regulate a LLW disposal facility during its operation. The Board urges NRC to clarify the requirement for this additional staff in the context of the language, contained in the same "indicator," that further staff or consultants should be available at peak periods during all phases of the facility. It is not clear to the Management Board whether these two separate "additional" staff references represent one set of new staff, or two.

The Management Board recommends a clarification which allows each state the flexibility to assign additional staff necessary during each phase of the facility, based upon the facility size, type of technology employed, number of months of operation each year, etc. The Board urges you to replace the 3-4 technical person-years provision with language which sets a higher level of staff for a state regulated facility, but assumes the NRC and the state will negotiate on the specific staff needs once the specifics of the facility are established.

CCA/050890



Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

RE: 7590-01

Dear Madame or Sir:

The enclosed comments are submitted on behalf of the Pennsylvania Chapter of Sierra Club; they respond to the Commission's Draft Revision of "Evaluation of Agreement State Radiation Control Programs: Proposed General Statement of Policy" (7590-01, Federal Register, March 23, 1990).

I have just returned from some two months of travel abroad and, opening the accumulated mail, I find the NRC's announcement of this proposed revision that had been sent out after my departure. I have spoken with an NRC staff person in the Office of State Programs concerning acceptance of comments received after the May 22 deadline prescribed in the notice and have been assured that, under the circumstance, our comments will be considered. I trust that this commitment will be honored.

Sincerely,

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J.H. Johnsrud, Co-Chairperson Committee on Radiation in the Environment Pennsylvania Chapter of Sierra Club

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COMMENTS FOR THE PENNSYLVANIA CHAPTER OF SIERRA CLUB ON THE NRC DRAFT REVISION OF EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAMS: PROPOSED GENERAL STATEMENT OF POLICY

Interest of the Commenter: The Pennsylvania Chapter of Sierra Club, with 18,000 members throughout the Commonwealth, has been concerned with issues of nuclear energy and radioactive waste since its inception. Since Pennsylvania has been designated as Host State for the Appalachian States Compact LLRW disposal facility, the Chapter is closely involved with the siting and design decisions and with regulation of radioactive wastes that will affect Sierra Club members. The Chapter is represented on Pennsylvania's legislativelymandated State Advisory Committee on Low-Level [Radioactive] Waste ("LLRW").

1. State radiation regulatory programs over byproduct, source, and small quantities of special nuclear materials ("agreement materials") and over their generators, brokers, treatment and disposal facilities and operators must, in our opinion, both meet and be permitted to exceed the minimum Federal radiation protection standards and regulations established by the Nuclear Regulatory Commission, Environmental Protection Agency, Department of Energy, or Department of Transportation. We are pleased to support the Policy Statement to the extent that this Proposed Policy Statement (a) accomplishes the goal of public health and safety and environmental protection from radiation exposures, all of which may be harmful, and (b) assures to Agreement States the flexibility to provide radiation regulation more stringent or restrictive than that of the Federal agencies.

2. In the section "<u>Categories of Indicators</u>, Category I," we recommend adding, as another essential element of a compliance program, the State's ability to supervise and accomplish prompt decontamination, remediation, and recovery from any radiation accident or other contamination of a site or offsite area.

3. No Category I Indicator or Program Element rule or standard of a Federal agency should restrict or prohibit the right of any State to set more restrictive or prohibitive regulations and procedures deemed by the authorized, responsible State agency to be required in order to assure health and safety protection for the citizens of that State. In this matter, it must be recognized that certain sites, situations, prior events, or other conditions within a given State may require a higher standard of radiation protection and control than is provided for in the more generalized nationally applicable regulations set at the Federal level. But in no instance should the States be permitted to regulate to a lesser degree than Federal agencies.

4. To the extent that Category II Indicators and Program Elements are essential for carrying out the Category I requirements, the State radiation control program must meet Category I "quality assurance." 5. We concur that a State's regulation of maximum permissible radiation doses and levels of radiation and concentrations of radioactivity in unrestricted areas must meet that prescribed in 10 CFR Part 20 and in the EPA's 40 CFR Part 190, but, in addition, we emphasize that a State must also be able to exceed those standards as may be determined to be necessary by the State regulatory agency in order to assure protection of health and safety of its residents in unrestricted areas. Just as one State may impose a higher standard for certain foods or other consumer products and activities (Pennsylvania and Califorfinia Department of Agriculture standards, sales of fireworks, liquor control, divorce laws, and driver age come readily to mind), so the ability to do so for radiation control should reside with the individual States. In other words, we strongly support a baseline Federal standard and regulation beyond which a State may apply the level of control that it deems essential to accomplish the goal of protection from radiation hazards.

6. The NRC states that it is essential for low-level radioactive waste Host States to revisit their enabling legislation and effect changes if necessary. For States that have already put in place strong regulatory procedures and control, "effecting changes" may not be appropriate, unless such changes strengthen and broaden further the State's ability to assure successful long-term isolation of the wastes.

7. We concur with the NRC's emphasis on separation of functions and responsibilities of the governmental agencies, and also of the private companies involved in all aspects of waste management, in order to assure avoidance of conflicts of interest; we urge that this requirement be strongly stated in the Policy Statement. We suggest that NRC add a suggestion, or a regulation, that State regulators disallow the use of contractors that are involved or affiliated with other aspects of management of other kinds of waste. An example of the potential conflict of interest would be a consulting firm that assists in developing the disposal regulations but is also associated with remediation activities at sites where the regulatory process has failed, or where the regulations or their enforcement were inadequate to prevent an operator from causing contamination.

8. With respect to the Indicator "Budget," NRC's Policy Statement must take into account the fact the radioactive hazards associated with a waste site will not end at the conclusion of the active life of the facility. Nor will the responsibility of the political unit, most probably the State, cease at closure. Therefore, the budget process must look to long-term financial capability for both remediation and compensation beyond the operational life of the facility. The Policy Statement should reflect this obligation.

We hope to submit additional comments shortly.

ENVIRONMENTAL COALITION ON NUCLEAR POWER (55 FR 10851)

Headquarters: 433 Orlando Avenue, State College, Pa. 16803

DOCKETED USNRC

'90 JUN -6 P2:46

Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

RE: 7590-01

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

FEB 1 2 1991

Acknowledged by card

Dear Madam or Sir:

The Environmental Coalition on Nuclear Power, based in Pennsylvania, joins with the comments of the Pennsylvania Chapter of Sierra Club on the Draft Proposed Revision to the General Statement of Policy on Agreement State Radiation Control Programs.

PROPOSED RULE PR MISC. 90-2

We particularly note that States which undertake responsibility for the regulation of nuclear facilities, remediation actions, and radioactive waste disposal must have the authority, commensurate with their responsibility under Federal law, to set standards, regulations, and rules as restrictive as they may deem necessary to carry out their obligations to protect public health and safety and environmental quality.

Sincerely, Judith H. Johnsrud

Judith H. Johnsrud, Director

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Secretary of the Commission Page 2 June 5, 1090

> "States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulation for low-level waste management and disposal. The statutes should also provide regulatory program authority and <u>provide for a</u> system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur."

This language more accurately reflects NRC's stated purpose for the Guideline, to require that Agreement States have in place adequate safeguards to assure "avoidance of conflict of interest and, ultimately, to protect the public health and suffaty" (page 10852), while at the same time giving each Agreement States more discretion in determining what safeguards should be incorporated into the PCP.

In the description of the proposed revisions, NRC suggests that a new intenery, "Contractual Assistance," be added. While this indicator appears to object in its entirety, in the notice the last paragraph of the indicator is not designated as new language. The indicator is inappropriate since it is limited specifically to LLW disposal and licensing and regulation. As IDNS noted in its previous comments, Agreement States are responsible for regulating licensees other than LLW disposal facilities that are at least as complicated as, if not more complicated than, LLW disposal facilities. Should not all Agreement States have procedures and mechanisms in place for timely acquisition of technical and vendor services necessary to perform those functions not otherwise available with the radiation control program? Why should this indicator not apply to Tennessee, an Agreement State that does not receivate LLW disposal but that does license major LLW treatment facilities? For thermore, the restriction in the last paragraph does not reflect the charles being state programs. There are few firms in the United States that the 1-expertise to provide professional services in a manner that will crow all states, simultaneously, to meet federally mandated milestones for providing LLW disposal capacity. While it is understandable that concractors that here provided assistance in a specific aspect of facility development should not be allowed to provide assistance in regulatory evaluation of that evaluation of other aspects of licensing that are not related to the development services they provided previously. Therefore, if the last paragraph of this indicator is retained, it should be revised as follows:

> "When seeking technical and vendor services to support regulatory functions, the Radiation Control Program (KCP) should avoid selection of contractors who have provided related developmental or operational services."

3. The proposed addition to the indicator "Quality of Emergency Planning" is ill-advised. The proposal would add a sentence that provides, "(p)lans for States regulating the disposal of low-level radioactive waste in permanent disposal facilities should include response to emergencies associated with the disposal of low-level radioactive waste." (55 Fed. Reg. 10857) This addition is redundant since the indicator already provides that state RCPs should have a written plan for responding to incidents at licensee facilities. The Secretary of the Commission Page 3 June 3, 1990

proposed revision to this indicator adds no new requirements. It is disconcerting, however, because it implies that emergencies involving disposal of LLW are either more likely to occur or more serious than emergencies at other licensed facilities. This is not the case and, in fact, emergencies at disposal facilities may be less complex than those at a major radiopharmaceutical manufacturer, for example.

In support of this proposed change, NRC states that "(t)he diversity of activities associated with the transportation, handling, storage, and disposal of LLW suggests the potential for both radiological and non-radiological emergencies or unusual [sic (word missing)] which should be covered in the State RCP radiological emergency response plan." (55 Fed. Reg. 10653) Fithough the explanation notes that the potential for emergencies is "tugnested" by transportation, handling, storage, and disposal activities, the revised indicator would only apply in states where disposal activities are traducted. It would not be applied to states, like Tennessee and Florida, the existing language. The proposed modification to this indicator would not be applied to states is already covered by the existing language. The proposed modification to this indicator would not use and for state emergency the proposed revision would create ambiguity about the need for state emergency plans for licensed waste imanagement facilities other than disposal facilities.

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4. The proposed revision of the "Budget" indicator should be deleted. The existing indicator, which already states that "(p)rincipal operating Funds should be from sources which provide continuity and reliability, i.e., general wax, incense fees, etc.," applies to all aspects of the Agreement State program and sufficiently covers this matter.

Use of the new Guidelines under "Management" indicates that the Project Manager should have training or experience in one of the main disciplines, that is engineering, earth science, or environmental science. (55 Fed. Reg. 1993) The other key discipline, Health Physics, should be added to this Hat.

b. Ender the category "Office Equipment and Support Services," the proposed revised Suidelines would add a new indicator, which provides that:

"States regulating the disposal of low-level radioactive waste in permanent disposal facilities should develop and implement a license document management system commensurate with the volume and diversity of materials associated with a low-level waste disposal facility license." (55 <u>Fed. Reg.</u> 10858)

This indicator should be broadened. Every Agreement State program should have a management system to organize and control the documents associated with licensing radioactive materials. While IDNS agrees that it would be difficult to regulate a LLW disposal facility without a document control system, this indicator is equally applicable to all licenses. Therefore, the indicator should be rewritten as follows:

"States should have a license document management system that is capable of organizing the volume and diversity of Secretary of the Louission Page 4

June 5, 1990

materials associated with inspection and licensing of radioactive materials."

7. Under the program element "Personnel," NRC has proposed adding the following new sentence:

"In addition, in States regulating low-level radioactive waste facilities, the RCP should be staffed with individuals with training and experience in engineering, earth science, and environmental science." (55 Fed. Reg. 10858)

The Department believes that this criterion should apply to states that regulate storage or treatment of LLW or other complex facilities and that the indicators "Qualifications of Technical Staff," "Staffing Level," and "Training" should be revised accordingly. We suggest the sentence be reworded is follows: and the second second second second

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"In addition, in States regulating complex operations, such as low-level radioactive waste storage or treatment facilities and large manufacturing operations, the RCP should either be staffed with individuals who have training and experience in engineering, earth science, environmental science or other disciplines as appropriate, or be capable of contracting for such expertise."

8. The Guideline pertaining to staff training should be broadened. The destrability of affording to program staff training that is consistent with the needs of the regulatory program is not limited to radiation control programs that are responsible for licensing LLW disposal facilities or uranium minic. All radiation control programs would benefit from staff training that is "consistent with the needs of those programs." (55 Fed. Reg. 10859) for thus reason, IDNS recommends that this indicator be revised to read as follows:

"RCP staff should be afforded opportunities for training that is consistent with the needs of the RCP."

9. Under the indicator labeled "Technical Quality of Licensing Actions," the following new sentences are being proposed:

"Additionally, in States which regulate the disposal of lowlevel radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet current regulatory guidance for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures. Financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process." (55 Fed. Reg. 10859) Secretary of the Commission Page 3 June 5, 1990

This indicator should be revised by replacing the phrase "current regulatory guidance" with the words "State licensing regulations." Conformance with regulatory guidance, such as NUREG reports and fR reports, is not a requirement for obtaining a license and should not be the basis for a decision to issue a license.

10. Under the "Licensing Procedures" indicator, a new paragraph specific to states that regulate disposal of LLW has been added. That paragraph provides that such states should have program specific licensing guides, plans, and procedures for license review, as well as minimum approval standards. IDNS recommends that this paragraph be deleted. The minimum standards for approval of an antification are established in the rules pertaining to licensure of LLW disporal facilities. If the standards codified in these rules are vague, the transmitted to establish "minimum approval standards." It is not received. If NRC persists in retaining this indicator, the indicator should be indicator should not be required to prepare licensing outdance documents, plans, and procedures if a need for such documents has been indicator.

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12. Under the indicator "Confirmatory Measurements," NRC is proposing to modify the first Guideline by adding the following sentence:

> "In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, measurements should also be adequate to confirm nonradiological aspects of facility operations such as sulls and materials testing and environmental sampling and analysis to demonstrate compliance with 10 CFR Part Si and assure facility performance." (55 Fed. Reg. 10861)

(n Support of this modification, NRC states in the introductory material that, "(b)ecause of the importance of soils and engineering materials in overall facility performance, the RCP should have the capability of confirming performance of the materials." (55 Fed. Reg. 10854) Since the objective of this Guideline can be fulfilled through the use of laboratories under contract, and since most RCPs will not have the necessary laboratory

Secretary of the Commission Page 6

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Carlton C. Kammerer, Director State Programs Office of Governmental and Public Softa S


(55 FR 10851) Arkansas DEPARTMENT OF HEALTH

PROPOSED RULE PR MISC. 90-2

4815 WEST MARKHAM STREET • LITTLE ROCK, ARKANSAS 72205

M. JOYCELYN ELDERS, M.D. DIRECTOR **'90 JUN -5** P4:20

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

May 22, 1990

Carlton Kammerer, Director State Programs Office of Governmental and Public Affairs U.S. Nuclear Regulatory Commission Washington, DC 20555

Dear Carlton:

Regarding your notice (SP-90-47) of the NRC's proposed revision to its general statement of policy on "Guidelines for NRC Review of Agreement State Radiation Control Programs", be advised that we have reviewed the document but as Arkansas is not tasked with the regulation of a permanent disposal facility, we have chosen not to comment on the proposed language. I have put a message on the system regarding same, asking for state comments and suggesting Agreement States review the proposed revision.

Hope you had a productive and enjoyable trip to Europe.

Sincerely,

Greta J. Dicus, Director Division of Radiation Control and Emergency Management

GJD:wrj

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DEPARTMENT OF HEALTH SERVICES

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55 FR 10851



USNRC

'90 MAY 30 P3:31 May 22, 1990

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

The Secretary of the Commission U. S. Nuclear Regulatory Commission Attention: Docketing and Service Branch Washington, DC 20555

Dear Secretary:

After reviewing the Nuclear Regulatory Commission (NRC) Proposed General Statement of Policy related to "Guidelines for NRC Review of Agreement State Radiation Control Programs," the Department generally supports the new quidelines.

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PROPOSED RULE

Two areas of concern exist. Under the heading of "Personnel," the first point lists the minimum staff qualifications for a low-level radioactive waste program. There should be some explanation of training and experience in earth science and environmental science. As stated, the disciplines listed are exclusive of one another and each of the listed sciences seems to call for a position to be filled by an individual specifically degreed in that area.

The second area of concern is in the area of staffing. The guideline lists the Commission's staffing recommendations in specific numbers (3 - 4 professional technical person-years). We recommend avoiding the use of specific numbers in a quidance that is intended for a diversity of programs. Each state must determine the number of positions required for a program.

Sincerely,

Don J. Wom

Environmental Management Branch

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May 16, 1990

PROPOSED RULE MISC. 90-2. (55 FR. 10851)

MAY 25 P2:52 '90

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

Mr. Samuel Chilk, Secretary Docketing & Service Branch U.S. Nuclear Regulatory Commission One White Flint North 11555 Rockville Pike Rockville, Md 20852

Commonwealth Edison

Downers Grove, Illinois 60515

1400 Opus Place

Proposed General Statement of Policy; Subject: Evaluation of Agreement State Radiation Control Programs (FR Vol. 55 No. 57 - 3/23/90)

Dear Mr. Chilk:

This presents Commonwealth Edison Company's (CECo) comments on the Nuclear Regulatory Commission's proposal to modify the criteria for evaluating Agreement State programs by adding criteria specifically related to the disposal of low-level radioactive wastes (LLW). CECO's interest in these proposed additional guidelines stems from its unique position in the State of Illinois and the Central Midwest Low-Level Radioactive Waste Compact. CECo, as the nation's largest nuclear utility and supplier of electricity for greater Chicago and Northern Illinois is also the largest single generator of LLW in Illinois and the Central Midwest Compact.

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These circumstances make it extremely important to the health and welfare of Illinois that safe, timely and economic LLW disposal capacity be available in the Central Midwest Compact. CECo has reviewed the additional proposed guidelines for their potential to adversely impact the current progress in developing a LLW disposal facility in Illinois. The results of that review indicate that the proposed additional guidelines should be consistent with maintaining progress, provided they are modified as discussed below. Otherwise, CECo believes that the additional guidelines should not be adopted because of their potential for delaying a LLW disposal facility which would result in net adverse impacts on the public health and safety.

CECo's detailed views on the proposed additional guidelines are presented in the attachment. CECo is especially concerned that the NRC would now require a statutory separation of the regulatory functions from the developmental and operational functions for low level waste management. The factual basis for reversing the previous acceptance of an administrative separation of those functions has not been provided. Because such a statutory change could significantly delay progress on an LLW disposal facility in Illinois, CECo is opposed to the addition of this guideline.

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CECo also believes that the guidelines which suggest that the state radiological agency be responsible for the non-radiological aspects of LLW disposal are inconsistent with the state's authority. Accordingly, CECo believes that such guidelines should not be adopted.

CECo appreciates the opportunity to comment on this proposed general statement of policy.

Sincerely. Kovach

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Nuclear Ligensing Manager

ATTACHMENT CECO'S DETAILED COMMENTS ON PROPOSED ADDITIONAL GUIDELINES FOR AGREEMENT STATE REGULATION OF LLW DISPOSAL

Legislation and Regulations

1(a) - Agreement Sates should have clear legal authority to issue regulations for low-level radioactive waste management and disposal and to regulate disposal pursuant to applicable laws and regulations.

The Illinois Department of Nuclear Safety (IDNS) already has the requisite level of authority under state law. Therefore, if the NRC agrees that IDNS's authority already meets this guideline, it would not unduly interfere with the state regulatory process. Otherwise, this guideline should be limited to the level of authority currently vested in IDNS.

1(b) - Statutes should provide for the separation of the regulatory function from the developmental and operational functions.

The retroactive application of this guideline to Agreement State programs which already have been reviewed and accepted by the NRC will result in significant, unnecessary delay in the development of a LLW disposal facility in Illinois. When the NRC entered into an Agreement with Illinois, the NRC knew that IDNS would be both the developer and regulator of the regional LLW disposal facility but found that IDNS could perform both functions without conflicts of interest. The NRC has not provided any reason for now finding that such conflicts cannot be avoided without a statutory change. In particular, the fact that the facility development process is nearing the end of its early stages does not imply that there is now a greater need to separate the functions by statute.

Any NRC imposed need to modify the statutory structure of the development process for a LLW disposal facility will slow that process down and add unnecessary costs by requiring the State to create another entity charged with the development process. Moreoever, a NRC mandated statutory change presents the opportunity for other radical changes in Illinois' Low Level Radioactive Waste Management Act and further raise the potential for delays. Under these circumstances, there is no basis for the NRC now to question the Agreement which it previously found adequate.

<u>Organization</u>

l(a) - The state agency should have the capability to acquire a broad range of technical and vendor services on a timely basis.

IDNS has clearly demonstrated its ability to obtain expert technical assistance; so, this guideline will not unduly delay the state regulatory process if that demonstrated capability is consistent with the NRC's expectations.

1(b) - To avoid conflicts of interest, the state agency should avoid contractors which are affiliated with the developmental or operational aspects of LLW management at permanent disposal facilities. While the concern about potential conflict of interest is valid, there is counterbalancing concern arising from the fact that there are only a limited number of technically competent expert contractors in the field of LLW disposal. Therefore, a strict application of this guideline could unduly limit the technical expertise available to IDNS. Only if this guideline was applied consistent with IDNS's past practice regarding contracting for expertise would it not interfere in the state regulatory process.

Management and Administration

1 - An emergency response plan should be developed for emergencies associated with LLW disposal. The plan should be developed by the state radiological agency but should cover both radiological and non-radiological emergencies.

A reasonable emergency response plan is consistent with the adequate protection of public health and safety. However, the NRC should not require IDNS to address both radiological and non-radiological emergencies. Rather, the NRC should defer to the allocation of responsibilities established by the State of Illinois.

2 - The state agency should have an adequate budget.

The current statutory provisions for facility development and LLW disposal fees provide adequate assurance that IDNS will have the resources necessary to regulate the LLW disposal facility.

3 - The state regulatory agency should have access to radiological and non-radiological laboratory support.

Access to radiological laboratory support is consistent with a sound regulatory program for IDNS. However, access to non-radiological laboratories could exceed IDNS's needs under the scope of its jurisdiction, and should not be required.

4 - The state agency should appoint an overall project manager (PM) for the review of a license application for a LLW disposal facility. That PM should have training or experience in one or more of the major disciplines related to the technical reviews of the license application.

This guideline is an unnecessary intrusion into the management of the agency of a sovereign state. The NRC has made no showing that this guideline is necessary for the adequate protection of the public health and safety. Accordingly, this guideline should be dropped.

5 - A license document management system may be useful for dealing with the diversity and volume of documents associated with a LLW disposal licensing actions.

This guideline is unnecessary because there is no evidence that it will enhance the adequate protection of the public health and safety. The organization of the records for a licensing decision should be left to the state licensing agency so that it may proceed in accordance with the needs of state law.

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6 - Opportunities should be provided for public involvement in every major phase of the process for developing a LLW disposal facility.

CECo agrees that public participation is essential to public acceptance of an LLW disposal facility. However, the current level of public interest in the development of a LLW disposal facility indicates that a guideline providing for such participation is not necessary. Because public involvement is primarily a local issue, the NRC should not adopt this guideline.

Personnel

1 - A staff trained and experienced in key technical disiplines related to LLW disposal is the cornerstone of an effective regulatory program for the disposal of LLW.

As long as this guidance is interpreted reasonably, it should not unduly interfere with the state regulatory process.

2 - The LLW technical staff should include engineers, earth scientists and environmental scientists.

This guideline should not unduly interfere with the state regulatory process so long as technically competent individuals may be found to satisfy this guidance even if they do not have the appropriate paper credentials. Therefore, this guidance should provide the flexibility necessary by only suggesting areas of technical expertise without requiring individuals to hold paper qualifications in those areas.

3 - The state agency should devote 3-4 professional technical person-years to regulating the operation of a LLW disposal facility.

This guideline is consistent with experience.

4 - The state agency should ensure that the regulators of LLW disposal receive specialized training.

There can be no doubt that technical experts need specialized training. Therefore, as long as specialized training is appropriately limited, this guideline should not interfere unduly in the state regulatory process.

Licensing

1 - The state agency should adopt specific guidelines related to specific technical actions associated with the disposal of LLW.

State agencies should not be limited in their alternatives for structuring a sound regulatory process. Accordingly, IDNS should not be required to adopt a set of guidance documents like those prepared by the NRC. As long as IDNS can demonstrate the technical quality of its decisions, such documents should not be required.

2(a) - The state agency should provide systematic documentation of the approval process for waste packages, solidification and stabilization processes or other vendor products.

- 3 -

Systematic documentation should be part of any reasoned decision-making process. However, if this guideline is intended to require IDNS to adopt the kinds of documentation used by the NRC, such guidance would unnecessarily interfere in the state regulatory process. Therefore, this guideline should be adopted only if it will be applied flexibly to find any reasonable type of state documentation acceptable.

2(b) - The state agency should consider the activities related to waste form as important as those related to the development and regulation of a LLW disposal facility.

This guideline intrudes too far into the inherent authority of IDNS to allocate the weights it will place on waste form and the integrity of the LLW disposal facility. As long as the waste form and LLW disposal facility meet minimum acceptable criteria, there is no safety reason for the waste form to be given more or less weight than is given to the facility. Accordingly, this guideline should not be adopted.

(3) - The state agency should develop licensing guides, standards and procedures which apply specifically to licensing a LLW disposal facility.

This guideline will not unduly interfere with the state regulatory process if the guides and standards already developed by IDNS satisfy the NRC's expectations.

<u>Compliance</u>

1 - State inspection procedures should provide for the inspection of licensees' waste generation activities under state jurisdiction. This would include waste classification, treatment packaging and labeling.

IDNS clearly has the authority to inspect those activities over which it has jurisdiction. However, the division of jurisdiction between IDNS and the NRC is not clear with respect to waste processing. The NRC has jurisdiction over each licensee's Process Control Program (PCP). Therefore, state authority over the PCP should be pre-empted. Instead of promoting dual inspection of the PCP, the NRC should provide that states are to accept the results of NRC inspections as providing an adequate level of assurance for the state regulatory process.

2 - States should adopt inspections for all phases of the LLW disposal process including non-radiological activities.

This guidance unduly interferes with state law allocation of responsibility for regulating the radiological and non-radiological aspects of LLW. The NRC should limit its guidance to radiological matters only.

3 - State should use multi-disciplinary team inspections.

This guidance is not necessary to ensure the adequate protection of the public health and safety but does intrude into the authority of the state to structure its regulatory program consistent with its determination of how best to ensure public health and safety. Accordingly, this guideline should not be adopted.

- 4 -

4 - The state agency should have the capability of confirming non-radiological as well as radiological aspects of licensed operations.

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As discussed above, this guideline in an undue intrusion into the state's allocation of regulatory authority and, thus, should not be adopted.

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Nuclear Information and Resource Service 1424 16th Street, N.W., Suite 601, Washington, D.C. 20036 (202) 328-0002E OF SECRETARY DOCKETING & SERVICE BRANCH

DOCKET NUMBER

PROPOSED RULE

R MISC. 90-2

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(55 FR. 10851

Nuclear Information and Resource Service Comments on NRC Proposed Revision to general statement of policy, March 23, 1990 Federal Register pp. 10851-10861. Evaluation of Agreement State Radiation Control Programs: Proposed General Statement of Policy May 22, 1990

The Nuclear Information and Resource Service (NIRS) appreciates the opportunity to comment on the proposed revisions to NRC's Agreement State Policy.

With regard to basic radiation protection standards, NRC states that it is important to "strive for a high degree of uniformity in technical definitions." This should not preclude states from setting stricter standards than the NRC. If states are expected to bear full responsibility for "low-level" radioactive waste and waste sites, it makes sense for them to have the commensurate authority to design and enforce exposures limits that are acceptable to those physically (and financially) experiencing the risk, the residents of the state and, possibly, neighboring states.

In light of the recent BEIR V report (National Academy of Sciences, National Research Council, Dec. 19, 1989) conclusion that low dose radiation causes three to fourteen times more cancer and leukemia deaths than believed in 1980 (BEIR III), and due to the fact that the NRC (10 CFR 20) regulations expected to be implemented in 1991 allow INCREASED concentrations of (2/3) the radioactive elements in air and water, it is essential that agreement states have the authority to set standards equal to or stricter than the federal standards. Certainly the federal standards should be the minimum protection that states provide, but states must not be prohibited from providing greater protection.

Further, since the Environmental Protection Agency is being prevented from finalizing and its Atomic Energy Act-authorized standards for "low-level" radioactive waste dumps, such facilities are being developed void of the stricter federal standards that might more adequately protect the public and the environment. Absent those standards, states should not be

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Postmark Date 5/2/90 Copies Received 1 Add'l Copies Reproduced 3 Special Distribution RIDS, PDR, Hiller inhibited from providing greater protection in design or practice.

The NRC is clearly more concerned with protecting the industry when it uses arguments about needing uniform exposure limits to make for uniform packaging or other requirements for "low-level" radioactive waste disposal. If a state chooses to be more protective of the environment and its citizens than the NRC, of what concern is that to the federal regulator? It is the state and its residents that bear the financial, legal, health and safety liability from commercially generated radioactive waste. If the generators in a state or compact want to "dispose" in a state, they ought to meet the minimum federal and the state standards.

The above comment applies to Status and Compatibility of Regulations (Program Element: Legislation and Regulations) for state "low-level" radioactive waste sites and UMTRCA in 10 CFR parts 20, 61 and 40. States should have a uniform bottom line standard (federal standard) with the authority to go beyond, setting stricter standards that are reasonable for that state. Rather than a blanket prohibition on stricter-than-federal state standards, perhaps NRC should provide guidance to states desiring stricter standards to facilitate compliance by out of state polluters whose discharges or waste packaging have an impact on that state.

Having the same language and terminology is important, but states must have the authority to set their own, verifiable performance objectives and enforce that they are met, as long as they are at least as strict as NRC's.

"Budget"

NIRS suggests a budgeting authority which charges the generators, based on length of hazardous life of the waste, for all functioning of a waste facility, with reasonable cost projections for the entire hazardous life of the waste. Generators whose waste is short-lived need not be charged for facility maintenance beyond the years needed to isolate their waste. Producers of long-lived, highly concentrated waste should pay whatever the cost to isolate the waste for its entire hazardous life. Cost projections should include remedial action and long-term storage and maintenance. We question the ability of a state to guarantee "stable and protected funding" for waste dumps which will be hazardous for hundreds to millions of years. State budgeting simply cannot be relied upon for such time periods. Further, by following NRC's 10 CFR 61 regulations or its guidance for alternatives to shallow land burial, states will inevitably face high costs of remedial action or exhumation in the future. These costs and activities are not projected in any computer model scenarios or insurance coverage proposals to our knowledge. Ignoring this potential up-front is irresponsible by both federal and state agencies.

"Qualifications for Technical Staff"

NIRS suggests that agreement state agencies (and the NRC for that matter) should employ a geneticist familiar with radiation and its teratogenic, mutagenic and genetic effects on humans.

"Public Information" and "Adequacy of Product Evaluations"

NIRS suggests that the information and evaluations of waste form, packaging and stabilization processes be made public. Some of this information is currently considered a "trade secret." If the public is to even consider accepting a storage or disposal site, the form, packaging and stabilization processes upon which the state will rely for long-term isolation from the environment, must be understood and agreed to by local residents and state residents, who are expected to provide "funding (that is)...stable and protected from competition from or invasion by other State programs." Since state taxpayers are subsidizing nuclear power plants by taking on the waste, the form and condition should be public information to residents of that state.

The NRC states in this proposed policy that "there be provisions for protecting proprietary information..." NIRS suggests that "proprietary" be very narrowly construed and not apply to health and safety issues or to information on radiation measurements and doses or to the integrity of the site and waste within the site. Such information must be open to public scrutiny.

Diane Daryo 5-22-90

VANKEE ATOMIC ELECTRIC COMPANY

Telephone (508) 779-6711 TWX 710-380-7619

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580 Main Street, Bolton, Massachusetts 01740-1398

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May 21, 1990

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Acknowledged by card

United States Nuclear Regulatory Commission Washington, DC 20555

Attention: Secretary, Docketing and Service Branch Mr. Chilk

Subject: Evaluation of Agreement State Radiation Control Programs; Proposed General Statement of Policy (55FR10851)

Dear Mr. Chilk:

Yankee Atomic Electric Company (YAEC) appreciates the opportunity to comment on the subject proposed revision to the NRC's general statement of policy regarding the Evaluation of Agreement State Radiation Control Programs. YAEC owns and operates a nuclear power plant in Rowe, Massachusetts. Our Nuclear Services Division (NSD) also provides engineering and licensing services for other nuclear power plants in the northeast, including Vermont Yankee, Maine Yankee, and Seabrook.

We have reviewed the Commission's proposed revisions to its guidelines for reviewing Agreement State Radiation Control Programs and generally agree with the results. The NRC shows a willingness to work cooperatively with the state agencies to effectively manage low level radioactive wastes. We trust, however, that the NRC will demand the same degree of professionalism, technical expertise, and attention to safety from the states as it does from its other licensees. The states have been tasked to establish and maintain the Radiation Control Programs in a safe and responsible manner. The programs must not be used as a vehicle to impede the sanctioned use of nuclear power.

We have one suggestion related to Staffing Level (Category II). In these days of increased emphasis on fiscal responsibility, we believe it might be easier for NRC to deal with the state agencies on a collaborative basis. This collaboration would enable establishment of optimal staffing levels consistent with the actual working requirements of each facility in lieu of prescribing a single, general staffing level requirement for all state programs.

Very truly yours,

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D. W. Edwards Director, Industry Affairs

RTY/dhm

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DEPARTMENT OF HEALTH

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May 10, 1990

Carlton C. Kammerer, Director State Programs Office of Governmental & Public Affairs U.S. Nuclear Regulatory Commission Washington, D.C. 20055

Dear Mr. Kammerer:

This is in reference to the Federal Register Notice on the proposed revisions to the "Guidelines for NRC Review of Agreement State Radiation Control Programs." We feel that the criteria and information contained within the guidelines are generally acceptable and will provide the means to ensure uniformity between Agreement States and the NRC. However, we think the requirement in Item 3 under "Management and Administration," which recommends that each state's radiation control program should have access to laboratory facilities which can test the performance of the packages and materials, should be revised. This requirement should be consistent with the current NRC policy relating to the evaluation of topical reports. Currently, the NRC performs independent reviews and evaluations of topical reports (i.e., qualifications of waste solidification agents, highintegrity containers, and other means of classifying waste), and states (with operating low-level disposal sites) are provided copies of reports, staff comments, and applicants' responses, for comment and consideration in the NRC reviews.

Assessments of the laboratory performance of waste packages and engineering materials are directly related to the specialized reviews currently conducted by the NRC for topical reports; i.e., structural analysis of disposal containers, corrosion behavior of containers, leaching phenomena, impact of soil conditions, trench and burial environment, alkali-aggregate reactions, biodegradation, thermal loads, and radiation and ultraviolet stability. Since the NRC is already performing the topical report reviews, it makes sense for the NRC, as the central organization with specialized technical personnel, to also perform the laboratory assessments, rather than require each state to duplicate manpower, expertise, etc. for its own infrequent reviews.

This approach will achieve the following objectives:

- Maintain consistency and uniformity among the Agreement States and the NRC in interpreting and implementing the rules and regulations of 10 CFR Part 61 regarding waste packages and engineering materials during the review process.
- Maintain efficient use of state resources by not requiring each state to duplicate manpower, expertise, etc. for infrequent reviews.

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Carlton C. Kammerer, Director Page Two

-- Maintain and increase quality and timeliness of reviews by having one central organization perform the reviews. From a practical standpoint, the same work performed infrequently by many groups may not result in the same quality and timeliness of reviews.

If you have any questions, please feel free to contact me at (206) 753-3459.

Sincerely,

Gary Robertson, Head Waste Management Section

GR:krf

DOCKET NUMBER MISC. 90-2 BOPOSED RULE (55 FR 10851) DOCKETED USNRC

STATE OF NEVADA

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MYLA C. FLORENCE Administrator

BOB MILLER Governor

JERRY GRIEPENTROG Director

May 9, 1990

The Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

ATTENTION: Docketing and Service Branch

Dear Mr. Secretary:

Please accept for the record, my comments on the proposed revisions to the "Guidelines for NRC Review of Agreement State Radiation Control Programs" which was published in the Federal Register on March 23, 1990 (55 FR 10851).

1. In the section on "Supplementary Information" the statement is made: "The guidance is considered to be flexible enough to be responsive to low-level radioactive waste disposal control programs which predated 10 CFR Part 61". In fact, however, there are additional requirements that states with operating LLW disposal sites would have to meet even though the existing programs for regulating the disposal sites have been found to be adequate by NRC agreement state program reviewers for a number of years. The following are examples:

(a) In "Management and Administration" under "Laboratory Support", the statement is made: "...the RCP should have access to laboratory facilities which can test the performance of the packages and materials". While the state may require the vendor to conduct certain tests on packages or to construct packages to certain standards, or require the site operator to conduct certain tests on soils or provide soils to meet certain standards, the state should not have to conduct or pay for any such tests. NRC accepts test data from vendors on high integrity containers, casks and devices that it approves for licensing or certifies for use, why shouldn't states operate in a compatible manner?

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May 9, 1990 The Secretary of the Commission Page 2

(b) In "Personnel" the statement is made: "The Commission does consider a cadre of full-time staff with training and experience in the general backgrounds specified above necessary to direct the various specialists...". The general backgrounds that were listed for the various specialists were: health physics or radiation protection, engineering, earth science and environmental science.

Unless a statement is made that the general backgrounds could be contained in one person, it appears the program would have to have one health physicist or radiation protectionist and one engineer, one geologist and one environmental scientist. In the states with operating LLW disposal sites the staffs do not have four people with those specified backgrounds. While some of this expertise would be needed on new site selection and characterization, it could be procured under contract as required.

(c) Under the indicator "Staffing Level", the Commission recommends an RCP staff effort of 3-4 professional technical person-years for the regulation of the operation of low-level radioactive waste disposal facilities. This level of staffing is evidently considered de minimus, as the statement is made in the paragraph on staffing level: "The staff reiterates that, during certain key periods, the RCP will need to be augmented with additional staff or consultants".

The minimum amount of staff effort needed to regulate a LLW disposal site must be based in some way on the site operations. The type of site involved, arrid or wet; the amount and type of waste received; the mode of operations: shallow land burial, above land storage, etc.; number of employees and other factors, determine regulatory requirements because of their effects on health and safety.

The volume of waste now being buried at existing LLW sites has decreased significantly during the past year, apparently due to surcharges, compaction of waste and long term storage at generator sites. This situation has reduced the amount of inspection time spent on incoming shipments and the person-years spent by the site operator on burial of radioactive waste. At least at the Beatty site, we don't need 3-4 state persons for regulation of that operation.

As I understand it, most of the future LLW disposal procedures will not involve shallow land burial but instead, consist of placement of waste in structures, either on top of the ground or partly May 9, 1990 Secretary of the Commission Page 3

buried in the ground. While geologists, hydrologists, and environmental specialists would be needed during the site selection process, they shouldn't be needed in the operational or closure phases of the site.

As indicated above, the amount of waste going to the three commercial LLW disposal sites is decreasing. If in the future the number of disposal sites increases, then each site will have even a smaller share of the waste for disposal than do the present sites. Again, it would not seem logical to require 3-4 state persons to regulate each site.

In summary, I recommend the following changes in the proposed Commission guidelines for regulation of LLW disposal in agreement states:

1. That the Commission spcify the proposed guidelines apply only to LLW disposal facilities put into operation subsequent to the effective date of 10 CFR Part 61.

2. Delete the requirement that states must test packages and materials and allow the states to evaluate vendor tests as NRC does.

3. Clarify that the RCP training and experience in engineering, earth science and environmental science does not mean that the staff must include three individuals: one engineer, one geologist and one environmental scientist.

4. Delete the specific number of RCP staff for regulation of LLW sites. The number of staff to be involved in that program should be proposed by the state when the size of the regulatory effort can be evaluated, and reviewed by the NRC for adequacy, just like the rest of the agreement state program.

Sincerely,

Weden

John Vaden, Manager Low Level Waste Project

JV/kf wp:secretary



JAMES J. BLANCHARD, Governor

90 MAY -4 P4:20

DEPARTMENT OF PUBLIC HEALTH

3423 N. LOGAN P.O. BOX 30195, LANSING, MICHIGAN 48909 OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

Raj M Wiener, Director

May 1, 1990

Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Attention: Docketing and Service Branch

Gentlemen:

The purpose of this letter is to transmit staff comments on the proposed revisions to the U.S. Nuclear Regulatory Commission's general statement of policy on "Guidelines for NRC Review of Agreement State Radiation Control Programs" provided to this office under a March 20, 1990 cover from Carlton Kammerer, Director for State Programs, Office of Governmental and Public Affairs.

Following are our comments:

- 1. We agree in principle with the statements in "Organization," pages 5 and 6, Item 1, and in "Contractual Assistance," page 32, that regulatory programs avoid contractors affiliated with the developmental or operational aspects of low-level waste (LLW) management. However, such avoidance can result in a problem when many contractors may pass up an opportunity to bid on a regulatory proposal in order to compete for the more lucrative developmental or operational contracts. The shortage of qualified firms working on LLW projects across the country could exacerbate this problem.
- 2. Under "Management and Administration" on page 8, item 4, we agree that a project manager for complex licensing actions involving an LLW disposal facility should have training or experience in one or more of the main disciplines related to technical reviews which he will be coordinating, such as health physics, engineering, earth science, or environmental science.





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Secretary of the Commission May 1, 1990 page two

> We believe the list of disciplines found on page 37 under "Program Element: Management and Administration" should mirror the list found on page 8 and include "health physics." We believe "health physics" should be consistently referenced as the one of the main technical disciplines within the context of an effective LLW disposal regulatory program.

- 3. The discussion in "Licensing," page 12, item 1, appears to be significantly simplified from that which appeared in the previous draft. We believe that some of the wording from the draft version should be reinserted to more thoroughly specify the significant elements to be incorporated within an acceptable LLRW licensing program. Elements relating to "waste characteristics" and "facility design and construction" should be explicitly relisted. We believe these additional elements are especially important to designated host states seeking control of LLW disposal involving alternative technologies.
- The discussion beginning in "Compliance," page 13, recognizes 4. the need for inspection and enforcement of 10 CFR 61 or associated state regulations related to classification, treatment, packaging, and labelling of LLW by generators. It has been our understanding that inspection and enforcement activities by an Agreement State at the site of a nuclear power plant would not be allowed by the NRC. Other LLW generators may also exist for which the NRC would not relinquish on-site inspection and enforcement regulatory authority (e.g., federal government licensees). Although a designated host state may be expected to accept LLW from these facilities at an LLW disposal facility, it is unclear how extensive an Agreement State's authority may be at the site of LLW generation. We request that the NRC provide clarification concerning limitations of a state regulatory control program, pursuant to an Agreement, to regulate certain types of licensees who generate LLW.
- 5. Under "Status and Compatibility of Regulations" in "Program Element: Legislation and Regulations," page 28, an Agreement State must have regulations that are "essentially identical" with the 10 CFR 61 performance objectives. The exact meaning and significance of this requirement is a matter of concern to Michigan as we proceed to develop state regulations, which may not be identical to NRC regulations, as part of our NRC Agreement negotiation effort. Early clarification and consistent interpretation of the requirement of "essentially identical" will be integral to productive negotiations and

Secretary of the Commission May 1, 1990 page three

> associated rulemaking. Perhaps partially due to the new responsibilities placed upon states by federal law (the Low-Level Radioactive Waste Policy Amendments Act of 1985, including Title II of this Act), we believe that a perception exists that an effective state regulatory program for LLW disposal must be equipped with the authority to set standards more stringent than those of the NRC. We believe that designated host states which have mandated an alternative technology for LLW disposal would benefit from a more flexible approach in establishing a regulatory program through an NRC The requirement that regulations be regulatory Agreement. "essentially identical" may serve as a disincentive for states potentially interested in becoming Agreement States because of the perceived minimal gain in regulatory control and stringency.

6. With regard to "Program Element: Personnel," the third paragraph on page 41 of the proposed revision indicates that "processing a license application would require a minimum of eight staff-years, plus contractual assistance, to complete a review within 15 months from the date of receipt of the application."

We believe that the total number of professional-technical person-years, incorporating both regulatory staff and contractual assistance, should be specified. Many states may discover that outside contractual assistance may not be available, due to circumstances outlined in Comment 1 above.

We also believe that the total professional-technical staffyears will be significantly more than 8 staff-years for issuance of a construction and operating license for a disposal facility in Michigan. A Michigan facility, as well as other facilities scheduled to be sited in some of the other host states, is required to incorporate engineered barriers and other design features not specifically addressed by 10 CFR 61. The Safety Evaluation Status Report for the Prototype License Application Safety Analysis Report, Earth-Mounded Concrete Bunker, NUREG-1375, may be a better indicator of the potential for increased staff efforts beyond current estimates. Page x of NUREG-1375 states that 2 person-years of LLW staff time and 1/2 person-year of consultant time were required for this admittedly partial review effort. The Executive Summary indicates that several areas (e.g., site characterization, independent calculations, data collection and validation, etc.) were not reviewed and that the PLASAR review did not provide specific details on most other areas to allow a full evaluation Secretary of the Commission May 1, 1990 page four

> of this application, including the performance assessment aspect. As a regulatory agency, we believe that a considerable staff effort will be required to evaluate these details in order to ensure that the health and safety of the people of Michigan will be protected.

Thank you for the opportunity for comment on these proposed revisions. If you have questions concerning these comments, please contact me or George Bruchmann of my staff.

Very truly yours,

Lee E. Jager, P.E., Chief

Lee E. Jager, P.E., Chief Bureau of Environmental and Occupational Health

LEJ:RSM





4814 South 40 Street

Phoenix, Arizona 850400 APR 13 P 3:37 (602) 255-4845

April 9, 1990

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

The Secretary of the Commission ATTN: Docketing and Service Branch U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dear Sir:

The Agency has reviewed the proposed revisions to "Guidelines for NRC Review of Agreement State Radiation Control Programs," provided in the All Agreement State letter dated March 20, 1990. The Agency interposes no objection to the revision as proposed.

The Agency, however; provides the following comment in regard to the indicator "Training": The proposed guidelines, "emphasize the diversity of regulatory activities associated with waste disposal...and...the difference in these activities from those normally associated with the radiation control program." Therefore, the presentation of additional, specialized training in low-level waste management, transportation and disposal by the NRC for Agreement State personnel is considered a necessity to meet the guidelines. For many States, budget constraints limit the courses available for training personnel to those offered by the NRC.

Sincerely,

F. Tedford

Charles F. Tedford Director

CFT:np

Acknowledged by card 5/10/90

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NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY DOCKETING & SERVICE

Evaluation of Agreement State Radiation Control Programs:

Proposed General Statement of Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed revision to general statement of policy.

SUMMARY: The Nuclear Regulatory Commission proposes to revise its general statement of policy, "Guidelines for NRC Review of Agreement State Radiation Control Programs." The proposed revision to the guidelines was prepared by the NRC to incorporate changes specifically related to the regulation of low-level radioactive waste disposal in permanent disposal facilities. This statement of policy is being proposed 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, including, where appropriate, the low-level radioactive waste disposal program. The Commission considers that these revisions are necessary given the present and potential low-level waste regulatory responsibility in Agreement States and is requesting comments on them.

DATES: Comments are due on or before May 22. 1990.

ADDRESSES: Written comments may be mailed to The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may also be delivered to the Commission at 11555 Rockville Pike, Rockville, Maryland from 7:45 am to 4:15 pm Monday through Friday. Copies of comments received by NRC may be examined at the NRC Public Document Room, 2120 L Street, NW (Lower Level) Washington, DC. 3/23/90 FOR FURTHER INFORMATION CONTACT: Vandy L. Miller, State Programs, Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-0326.

SUPPLEMENTARY INFORMATION: On June 4, 1987, the NRC published in the Federal Register final revisions to its General Statement of Policy, "Guide for Evaluation of Agreement State Radiation Control Programs" (52 FR 21132). The guidance as supplemented in that general statement of policy was intended to apply to the review of all aspects of Agreement State Radiation Control Programs, including uranium and thorium recovery programs and low-level radioactive waste management programs.

In the review of low-level waste disposal control programs within the framework of the current guidelines, it has become apparent that some aspects of the low-level waste disposal control program for States regulating the disposal of low-level radioactive waste in permanent disposal facilities would benefit from guidelines which are more specific to those activities. This circumstance, coupled with the fact that by 1993 as many as 14 additional Agreement States may be licensing the disposal of low-level waste in permanent disposal facilities in compliance with the requirements of the Low-Level Radioactive Waste Policy Amendments Act of 1985, has prompted this proposed revision. All Agreement State Radiation Control Programs have regulatory responsibilities related to radioactive waste. However, in non-sited states, these responsibilities related primarily to waste generation and transportation activities.

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The NRC is proposing herein additional revisions to its General Statement of Policy, "Guide for Evaluation of Agreement State Programs," in order to specifically address the process for review of State programs which regulate the disposal of low-level radioactive waste in permanent disposal facilities. The revision will also be of use in reviewing State programs which regulate the packaging, treatment, storage, processing, and transportation of low-level radioactive waste. The supplemental guidance takes into account the regulatory requirements of 10 CFR Part 61 and the experience of States with low-level radioactive waste regulatory programs. The guidance is considered to be flexible enough to be responsive to low-level radioactive waste disposal control programs which predated 10 CFR Part 61.

Suggested major revisions in the guidelines are in the form of additional considerations for States regulating the disposal of low-level radioactive waste in permanent disposal facilities. These proposed revisions are not intended to change the policy or procedures by which other aspects of an Agreement State's radiation control program (RCP) is reviewed. The revisions are highlighted by arrows to facilitate idenitifcation of the changes to the guidelines.

The NRC in the development of these revisions received input from State radiation control programs. A preliminary draft of the proposed revisions were sent to all 50 States. Comments were received from 21 States and these comments were incorporated where appropriate.

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Major revisions suggested for States regulating the disposal of low-level radioactive waste in permanent disposal facilities and the reasons for the suggested revisions are as follows:

Legislation and Regulations

1. Agreement States should have clear legal authority to issue regulations for low-level radioactive waste management and disposal and to regulate disposal pursuant to applicable laws and regulations. Further, statutes should provide for the separation of the regulatory function from the developmental and operational functions. In many States which will be regulating the disposal of low-level waste in permanent disposal facilities, existing legislation which establishes the authority of the State RCP may be adequately broad. However, because of the complexity and diversity of low-level radioactive waste (LLW) regulation, it is essential that States which will have the responsibility of regulating the disposal of LLW in permanent disposal facilities revisit their enabling legislation and effect changes if necessary.

States which will be hosting facilities for waste disposal have chosen diverse paths to implement the developmental and operational responsibilities for disposal under the Low-Level Radioactive Waste

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Policy Act. In the early stages of program development, it is sometimes difficult for States to separate the developmental and operational functions from the regulatory functions. The Commission considers separation of the regulatory function from the developmental and operational waste management functions essential to assure the avoidance of conflict of interest and, ultimately, to protect public health and safety. Therefore, State statutes addressing radioactive waste management should clearly distinguish between and provide a mechanism for separation of waste management regulatory functions and waste management developmental and operational functions for the disposal of low-level radioactive waste in permanent disposal facilities.

Organization

 The Commission suggests a new Category II indicator, "Contractual Assistance," for States regulating the disposal of low-level radioactive waste in permanent disposal facilities. The indicator stresses the importance of having the capability to acquire a broad range of technical and vendor services on a timely basis. Regarding the regulation of LLW in permanent disposal facilities, these

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services are likely to be both radiological and non-radiological in nature. Because of the potential for conflict of interest, the Commission also suggests that the RCP avoid contractors which are affiliated in some way with the developmental or operational aspects of LLW management at permanent disposal facilities.

Management and Administration

- 1. Within the indicator "Quality of Emergency Planning" the Commission recommends an emergency response plan specifically addressing emergencies associated with low-level waste for States regulating the disposal of low-level radioactive waste in permanent disposal facilities. The diversity of activities associated with the transportation, handling, storage, and disposal of LLW suggests the potential for both radiological and non-radiological emergencies or unusual occurrences which should be covered in the State RCP radiological emergency response plan. The plan should at a minimum be reassessed in light of LLW regulatory responsibilities and its content evaluated against plausible LLW emergencies (spills, fires, sudden releases to the biosphere, etc.).
- 2. Within the indicator "Budget," the Commission recommends adequate budgetary resources in the RCP. It should be recognized that the level of effort required of the RCP in States regulating the

disposal of low-level radioactive waste in permanent disposal facilities will be a function of the life cycle of a low-level waste disposal facility. During licensing and operations, the regulatory program will be more resource intensive than during site development or post-closure. A State should have adequate budgetary resources to respond to the changing needs of the RCP in a way that is not disruptive to the program's mission. During resource intensive periods where growth is mandated, the budget should allow for the orderly mobilization of personnel and contractual resources as well as goods and services. During periods when less resources are required, the budget should allow for orderly demobilization that has minimal impact on employee morale.

3. Within the indicator "Laboratory Support," the Commission recommends a diversity of laboratory services beyond those normally associated with a State RCP for States regulating the disposal of low-level radioactive waste in permanent disposal facilities. Since the non-radiological performance of waste packages and engineering materials can affect the potential for radioactive releases from a waste site, the RCP should have access to laboratory facilities which can test the performance of the packages and materials. In addition, environmental monitoring associated with regulation of waste facilities involves a diversity of sampling media, sampling

procedures, and testing procedures for both radioactive and non-radioactive constituents. Laboratory facilities should be available which can respond to this diversity of environmental monitoring needs.

4. Within the indicator "Management," the Commission recommends the use of an overall project manager for complex licensing actions. This recommendation is particularly applicable to the review of an initial license application or major amendment for a low-level radioactive waste permanent disposal facility. The project manager should have training or experience in one or more of the main disciplines related to the technical reviews which he will be coordinating such as health physics, engineering, earth science or environmental science. The complexity and diversity of reviews associated with such an action suggest the need for one individual to plan the work effort, mobilize and direct the resources, specify level of effort and desired end products, assemble and integrate the results of technical reviews, and promulgate the results. Depending on the State's organizational structure, the results may be in the form of a licensing decision made by the project manager in concert with his or her immediate management or in the form of recommendations passed on to an independent licensing authority.

5. Within the indicator "Office Equipment and Supplies," the Commission

suggests that a license document management system may be useful for dealing with the diversity and volume of documents associated with a LLW disposal licensing action. This may be as simple as an upgraded filing system which is responsive to all the various categories of LLW documents. In its extreme it could be a highly sophisticated electronic data management system with a continuing need for database management. Regardless, the Commission believes that such a document management system greatly facilitates the licensing process.

6. Within the indicator "Public Information," the Commission recommends public involvement in major licensing actions associated with a LLW facility. Public involvement has become a vital entity in the decision making process within developmental aspects of low-level waste management. It is the opinion of the Commission that this involvement can and should carry over into the licensing process. The public should be informed of major licensing issues, given an opportunity to comment on or supplement those issues, and given an opportunity to participate in the resolution of those issues.

Personnel

 The Commission considers the cornerstone of an effective low-level waste disposal regulatory program for States is

a staff with training and experience in key technical disciplines related to waste management. At a minimum these include health physics or radiation protection. engineering, earth science, and environmental science. The Commission considers that there are a number of specialty areas within these umbrella disciplines and other separate technical areas which must be addressed in the process of licensing and regulation of low-level waste disposal. However, the Commission understands that it is unrealistic to expect that State RCP will be represented by all of these disciplines on a full-time basis. It is more realistic to expect that the various specialty disciplines will be accessed on a case specific basis through a contract or an interagency agreement. The Commission does consider a cadre of full-time staff with training and experience in the general backgrounds specified above necessary to direct the various specialists, to understand and evaluate their products, to integrate those products into a regulatory support document, and to take regulatory action based on the results of these activities.

2. Within the indicator "Qualifications of Technical Staff," the Commission recommends the use of engineers, earth scientists, and environmental scientists for States regulating the disposal of

low-level radioactive waste in addition to staff with the type of training and experience usually associated with a State RCP, as discussed above.

- 3. Within the indicator "Staffing Level," the Commission recommends an RCP staff effort of 3-4 professional technical person-years for the regulation of the operation of low-level radioactive waste disposal facilities. Staff resources should be adequate to conduct inspections on a routine basis during operation of the LLW facility, including inspection of incoming shipments and licensee site activities. The staff reiterates that, during certain key periods, the RCP will need to be augmented with additional staff or consultants.
- 4. Within the indicator "Training," the Commission recommends that the State take advantage of opportunities for specialized training for staff responsible for regulation of uranium mill programs and low-level waste programs. This represents no change in the guidelines related to mill programs. It does seek to emphasize the diversity of regulatory activities associated with waste disposal in permanent facilities and, in many cases, the difference in these activities from those normally associated with the radiation control program. Specialized training in response to these differences is suggested.

Licensing

 Within the indicator "Technical Quality of Licensing Actions," the Commission recommends the addition of specific guidelines related to the technical quality of licensing actions associated with the disposal of low-level radioactive waste. The additional guidelines are intended to address the elements of LLW licensing that may not be otherwise addressed in radioactive materials or facilities licensing. These include such elements as:

 waste product and volume;
 personnel qualifications;
 facilities and equipment;
 operating and emergency procedures;
 applicant's financial qualifications and assurances;
 closure and decommissioning procedures; and (7) institutional arrangements with other institutions.

2. Within the indicator "Adequacy of Product Evaluations," the Commission recommends the systematic documentation of the approval process for waste packages, solidification and stabilization processes, or other vendor products employed to treat radioactive waste for disposal. Within the 10 CFR Part 61 systems approach to radioactive waste disposal, the Commission considers the waste form to be a vital component of waste containment. For this reason, approval of the systems, components, and products which comprise the waste form is as important to the overall performance of the permanent waste disposal facility as the approval of the facility itself.

3. Within the indicator "Licensing Procedures," the Commission recommends the development and use of licensing guides, standards, and procedures which apply specifically to LLW licensing. The reason for this recommendation relates to the uniqueness and complexity of the LLW licensing process. Specific procedures and approval standards will facilitate the licensing process for both the licensee and the regulator by allowing a common understanding of the process by which an application will be reviewed and the standards against which an application will be evaluated.

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Compliance

1. Within the indicator "Status of Inspection Program," the Commission specifies that inspection procedures in all Agreement States should provide for the inspection of licensees' waste generation activities under the State's jurisdiction. The Commission recognizes that States regulating the disposal of low-level radioactive wastes within their borders have little, if any, means to assure that wastes entering from another State has been properly classified, packaged, and labelled. Implementation of 10 CFR Part 61

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requirements for classification, treatment, packaging, and labelling of low-level radioactive waste by waste generators is considered a cornerstone of the systems approach to radioactive waste management. Therefore, the Commission considers that all agencies which regulate waste generator activities have the primary obligation to ensure, through their regulatory activities, that generators are in compliance with these requirements.

2. Within the indicator "Status of Inspection Program," the Commission recommends that the RCP should include provisions for the various types of inspections that will be required during the various phases of the LLW facility life cycle. Many of the inspections associated with a LLW facility will be non-radiological in nature, concerned instead with construction practices, performance of engineering materials and engineered systems, and verification of system performance. This suggests the need for the multidisciplinary approach to compliance assessment that is suggested in other parts of the regulatory program.

In addition, inspections should be conducted on a routine basis during the operation of the LLW facility, including inspection of incoming shipments and licensee site activities.

- 3. Within the indicator "Inspectors Performance and Capability," the Commission recommends multidisciplinary team inspections. The reason for this recommendation is discussed in 2 above.
- 4. Within the indicator "Confirmatory Measurements", the Commission recommends that the RCP for States regulating the disposal of low-level radioactive waste facilities have the capability of confirming non-radiological as well as radiological aspects of licensed operations. Because of the importance of soils and engineering materials in overall facility performance, the RCP should have the capability of confirming performance of the materials. Furthermore, because of the diversity of material which will be disposed of at the facility, it is important that the RCP be able to confirm the presence or absence of both radiological and non-radiological constituents in environmental analyses.

GUIDELINES FOR NRC REVIEW of AGREEMENT STATE RADIATION CONTROL PROGRAMS, 1990

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 U.S. 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.

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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 editorial changes reflecting the experience gained with the 1981 policy statement. ►Those changes were promulgated in June 1987.◄

►In 1988, the Commission staff initiated revisions to the Review Guidelines to improve reviews of State regulatory programs for the disposal of low-level radioactive waste. The revised document will be used by NRC in its review of those State programs which regulate the disposal of low-level radioactive waste in permanent disposal facilities. It will also be used to strengthen the review of State programs which regulate other aspects of radioactive waste management, such as packaging, treatment, storage and transportation. <

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 element, (b) indicators which address specific functions within the program element, and (c) guidelines which delineate specific objectives or operational goals under each indicator.

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 (and the Program Elements of which they are a part) are:

- ° Legal Authority (Legislation and Regulations)
- Status and Compatibility of Regulations (Legislation and Regulations)
- ° Quality of Emergency Planning (Management and Administration)

° Technical Quality of Licensing Actions (Licensing)

° Adequacy of Product Evaluations (Licensing)

° Status of Inspection Program (Compliance)

° Inspection Frequency (Compliance)

^o Inspectors' Performance and Capability (Compliance)

^o Response to Actual and Alleged Incidents (Compliance)

° Enforcement Procedures (Compliance)

These indicators address primary 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 (and the Program Elements of which they are a part) are:

 Location of Radiation Control Program Within State Organization (Organization)

° Internal Organization of Radiation Control Program (Organization)

° Legal Assistance (Organization)

- ° Technical Advisory Committees (Organization)
- ° Contractual Assistance (Organization)
- ° Budget (Management and Administration)
- ° Laboratory Support (Management and Administration)
- ° Administrative Procedures (Management and Administration)

° Management (Management and Administration)

- Office Equipment and Support Services (Management and Administration)
- ° Public Information (Management and Administration)
- ° Qualifications of Technical Staff (Personnel)
- ° Staffing Level (Personnel)
- ° Staff Supervision (Personnel)

° Training (Personnel)

° Staff Continuity (Personnel)

° Licensing Procedures (Licensing)

^o Inspection Procedures (Compliance)

° Inspection Reports (Compliance)

° Confirmatory Measurements (Compliance)

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 primary program functions, 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. 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 274 j of the Act. 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.

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 Programs" will be used by the NRC staff during its onsite reviews of Agreement State programs. At least once each year, there will be

onsite communication between the NRC staff and each State either as a result of a routine review or a review site visit. A routine review is a total assessment of each Agreement State program and is conducted at least biannually. A review visit is a trip to the Agreement State to assess the status of the State program and to address any special concerns within the State program. Additional contacts may also be made through special or follow-up reviews.

In making a finding of adequacy, the NRC considers areas of the State program which are critical to 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 and safety. Basic radiation protection standards, such as exposure limits, also directly affect the State's 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.

►It should be noted that the categories of indicators, and the significance thereof, apply equally to the regulation of uranium and thorium recovery and associated wastes; low-level radioactive waste management; as well as the overall radiation control program. Any differences in the guidelines for review of uranium mill tailings programs or low-level waste programs are specified within the individual program elements. ◄

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 by which the licensee 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.
- States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level waste management and disposal. The

statutes should also provide regulatory program authority and provide for the separation of regulatory functions from developmental and operational functions.¹

Status and Compatibility of Regulations (Category I)

- ^o 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.
- ^c For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than three years.
- The level of separation (e.g., separate agencies) should be determined for each State individually. In selecting this level, each State should have a system of checks to demonstrate that conflicts of interest between the regulatory function and developmental and operational functions will not occur.

- ^o The RCP has established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within three years of adoption by NRC.
- ° Opportunity should be provided for the public to comment on proposed 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

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

- ^o 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.
- ^o 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)

- ^o 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.
- ^o 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)

^o 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.
- ^o 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.
- ^o 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.

Contractual Assistance (Category II)

- Because of the diversity and complexity of low-level radioactive waste disposal licensing and regulation, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for timely acquisition of technical and vendor services necessary to support these functions that are not otherwise available within the RCP.
 - ^o The RCP should avoid the selection of contractors who have been selected to provide developmental or operational services associated with the LLW facility.

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, contract services, 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 in response to incidents at licensee facilities which takes into account such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc. ►Plans for States regulating the disposal of low-level radioactive waste in permanent disposal facilities should include response to emergencies associated with the disposal of low-level radioactive waste.
- ^o 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.

- ^o 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.
- ^o 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)

^o 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. >States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have adequate budgetary resources to allow for changes in funding needs during the LLW facility life cycle. The sources of program funding should be stable and protected from competition from or invasion by other State programs.◄ 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)

- ^o The RCP should have laboratory support capability in house, 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.
- ➤° In addition, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level waste disposal, including testing of soils, testing of environmental media, testing of engineering properties of waste packages and waste forms, and testing of other engineering materials used in the disposal of low-level radioactive waste.

Administrative Procedures (Category II)

^o 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-ofinformation 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, inquiries, 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 funding.

- [◦] Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers,>low-level radioactive waste disposal facilities, Type A broad scope licenses, and any licenses which have the potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports and enforcement actions should also be performed.
- ➤ For the implementation of very complex licensing actions, such as initial license reviews, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the technical reviews which the Project Manager will be coordinating, such as engineering, earth science or environmental science. ◄
 - ^o 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)

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- ^o The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to large (greater than 300-400 licenses) programs. Similar services should be available to regional offices, if utilized.
- ➤° States regulating the disposal of low-level radioactive waste in permanent disposal facilities should develop and implement a license document management system commensurate with the volume and diversity of materials associated with a low-level waste disposal facility license.
 - ° Professional licensing, inspection, and enforcement staff should not be used for fee collection and other clerical duties.

Public Information (Category II)

- ^o 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 proprietary information and clearly personal information from public disclosure.
- ° Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws

during the process of major licensing actions associated with UMTRCA and low-level radioactive waste in permanent disposal facilities.

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. ►In addition, in States regulating low-level radioactive waste facilities, the RCP should be staffed with individuals with training and experience in engineering, earth science, and environmental science. 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. ➤ For States regulating uranium mills and mill tailings, staff training and experience should also include hydrology, geology, and structural engineering.² For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or mechanical engineering, geology, hydrology, and other earth science, and environmental science. ◄
- Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

² 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; January 23, 1981, 46 FR 36969; July 16, 1981, and 48 FR 33376; July 25, 1983).
Staffing Level (Category II)

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- Professional staffing level should be approximately 1-1.5 person-years per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity.
- For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years of effort, (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978.
- States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow an annual baseline RCP staff effort of 3-4 professional technical person-years. Staff resources should be adequate to conduct inspections on a routine basis during operation of the LLW facility, including inspection of incoming shipments and licensee site activities. During periods of peak activity, additional staff or speciality consultants should be available on a timely basis. For example, processing a license application would require a minimum of eight staff-years, plus contractual assistance, to complete a review

within 15 months from the date of receipt of the application, as required under Section 9(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985. \blacktriangleleft

Staff Supervision (Category II)

- Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel.
- Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy.
- ^o Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Training (Category II)

 Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices.

- ^o The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology.
- In States with regulatory responsibility for uranium mills or the disposal of low-level radioactive waste in permanent disposal facilities, staff should be afforded opportunities for training which is consistent with the needs of those programs.

Staff Continuity (Category II)

- Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries.
- Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area.
- * The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Program Element: Licensing

It is necessary in licensing by-product, 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); consultation and prelicensing inspection of complex facilities (e.g., waste disposal sites, mills, irradiators, etc.); 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

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actions. >Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet current regulatory guidance for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process. <

- ° Prelicensing visits should be made for complex and major licensing actions.
- ^o Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions.
- ^o 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.

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Adequacy of Product Evaluations (Category I)

- RCP evaluations of manufacturer'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.
- ^o The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.
- ^o 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.
- ➤ Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Licensing Procedures (Category II)

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- ^o The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.
- In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans and procedures for license review, minimum approval standards, and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process.
 - ° License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions.
 - ^o The present compliance status of licensees should be considered in licensing actions.
 - ^o 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.

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 Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

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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 include, 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 inspection program in all States should provide

for the inspection of licensee's waste generation activities under the State's jurisdiction.

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- ➤ ° In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for pre-operational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the LLW facility, including inspection of incoming shipments and licensee site activities.
 - ^o 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.
 - ^o At least semiannual inspection planning should be done for number of inspections to be performed, assignments to senior versus 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.

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Inspection Frequency (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.
- ➤° For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment.

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^o 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)

- or Induiries 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 than 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 significant public interest and concern, e.g., transportation accidents.

- Investigations should include in-depth 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 should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating 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.
- ^o 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)

 ^o 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.

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- ^o Enforcement letters should be issued within 30 days following inspections 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.
- ^o Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent reoccurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses.
- ^o 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.
- ^o 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.

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- 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.
- ^o 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 non-routine inspections.
- For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

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Inspection Reports (Category II)

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- ^o 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 licensees' programs, and indicating the substance of discussions with licensee's 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)

^o Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. ➤In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, measurements should also be adequate to confirm non-radiological aspects of facility operations such as soils and materials testing and environmental sampling and analysis to demonstrate compliance with 10 CFR Part 61 and assure facility performance.◄

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- RCP instrumentation should be acequate 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 Samplers, Hi and Lo Volume; Lab Counters, Detect 0.001
 uC/wipe; Velometers; Smoke Tubes; and 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 contract. Exceptions for other State Agencies, e.g., a State University, may be made.

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^o 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 Rockville, MD this 19th day of Waren 1990

For the Nuclear Regulatory Commission.

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Samuel J. Chilk, Secretary of the Commission