



CHAIRMAN

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

September 8, 1994

R. Bangert

The Honorable Mike Synar, Chairman
Subcommittee on Environment, Energy
and Natural Resources
Committee on Government Operations
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

As a result of the hearing your Subcommittee held on August 2, 1993, the Commission moved to improve a number of areas in the Agreement States program. While these improvements are underway, the normal program reviews of Agreement States have continued. The current status of each Agreement State's regulatory program is shown in Enclosure 1.

The most important change is the increased time that NRC managers have devoted to overseeing the Agreement States program during the past year, including the Commission's review and approval of all policy initiatives for the Agreement States program. Shortly after the hearing, the Commission initiated a number of improvements to the program (Enclosure 2). In one initiative, the Commission approved publication of a draft Agreement States program "umbrella" policy statement for comment (Enclosure 3). The draft policy statement, among its other recommendations, proposes a phased approach for any new agreements. Using this approach, a new Agreement State would first regulate licensees with less complex programs and only after successfully demonstrating its effectiveness during this first phase would the new Agreement State regulate licensees with more complex programs. The draft policy statement also would establish a probationary status category for Agreement State programs which develop significant problems.

In another initiative, NRC has developed proposed procedures for suspending or terminating an Agreement State program. The staff further developed draft guidance to involve top agency managers and the Commission in Agreement States program issues which will be considered along with the pilot program described in Enclosure 6, and guidance to provide technical assistance to Agreement States (Enclosure 4). Additionally, the Commission published for comment a draft policy statement on Agreement State adequacy and compatibility (Enclosure 5). The comment periods for both draft policy statements have not yet closed. In response to other GAO recommendations, the Commission approved a pilot program that uses common performance indicators to assess materials programs in both NRC's Regional Offices and Agreement States (Enclosure 6). Moreover, during the past year, the Commission received four briefings on Agreement State issues or related matters and now routinely reviews all reports that propose to withhold from an Agreement State a finding of either adequacy or compatibility.

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The Commission has strengthened management of the Agreement States program, as well, by reassigning resources within the Office of State Programs (OSP). Staff from the State liaison program have been reassigned to the Agreement State program to complete Agreement State improvements. The Commission obtained additional resources for the Agreement States program through a technical assistance contract with Oak Ridge National Laboratory. The budget for Fiscal Years 1995 through 1999 includes provisions for an increase in OSP staffing by two full-time employees beginning in Fiscal Year 1996. OSP managerial overhead was reduced by eliminating one Senior Executive Service position, and thus one level of supervision. Finally, OSP is managed by a new Director and Deputy Director.

A central policy theme guiding the evolution of the Agreement States program is the need to regulate materials licensees more consistently across the nation in Agreement States and in non-Agreement States. Although the Commission has yet to evaluate the pilot program, the use of common performance indicators to assess materials programs both in NRC Regional Offices and in Agreement States, if adopted by the Commission, should improve consistency. Training of both NRC and Agreement State inspectors and license reviewers will now be a centralized responsibility of the NRC's Technical Training Center. An agency electronic data base will be operational this fall that describes all materials events (misadministrations, overexposures, lost sources, contamination events, and contaminated sites, for example) that occur in the United States. Agreement States will have shared access to the electronic data base. In addition, the Commission has increased resources applied to an independent evaluation of materials-related operating experience in order to improve the likelihood that safety-significant lessons will be communicated promptly to regulatory and industry organizations. During the past year, a growing number of technical specialists from NRC's Office of Nuclear Material Safety and Safeguards participated in program reviews of the Agreement States. For example, the evaluation of Agreement State reviews of the design of radioactive sealed sources and devices containing radioactive material by these technical specialists revealed a number of findings that will lead to greater consistency in the way that the NRC and the Agreement States conduct these reviews. These in-depth reviews have increased the level of assurance for the protection of public health and safety in the use of these devices.

The Commission's ongoing evaluation of existing Agreement State policies and procedures has already resulted in some changes to existing practices. For example, we no longer find an Agreement State "compatible" based solely on its commitment to promulgate a regulation; the compatibility finding is made only after the Agreement State actually promulgates the rule. As the result of another change, each Agreement State program review report now contains the basis for the assessment for each of the 30 program indicators. Finally, we have reaffirmed our position that an Agreement State can be suspended or terminated not only for reasons of inadequacy but also for reasons of incompatibility.

Changes to the Agreement States program of this scope and magnitude necessarily involve active participation and buy-in on the part of the Agreement States. NRC has substantially increased its outreach activities to the Agreement States and is requesting their comments on proposed substantive changes to the Agreement States program and on the development of new or revised NRC regulations in the materials program area. NRC has developed an electronic bulletin board to receive comments about the need for a rulemaking and alternative rulemaking options before the agency drafts a proposed rule. Since your Committee's hearing, the need for strengthening the Agreement States program and the proposed changes themselves were discussed at two Agreement State Managers' workshops, at the annual Agreement States meeting, at two Electronic Event Data Base workshops, at a general meeting with officials of the Organization of Agreement States (OAS), and at a meeting that I held with OAS officials.

In addition to the changes in the overall Agreement State program, NRC staff have been working actively with the State of Maryland to follow-up on 33 misadministrations that occurred at Sacred Heart Hospital (SHH) in Cumberland, Maryland, in 1987-1988. In the fall of 1993, NRC's General Counsel and the Executive Director for Operations met with the State's Deputy Attorney General and the Secretary of the Department of the Environment to discuss the misadministrations and the need for additional review activities. NRC then established a Task Force, consisting of members of the NRC staff and an NRC medical consultant, to review all available information in NRC and State of Maryland files. The State of Maryland is cooperating in a joint effort with the NRC to obtain additional information from SHH. The purpose of the NRC's review is to determine whether required actions, notifications, and follow-up were completed and to ascertain the generic lessons that should be learned from review of this incident. In addition, the broader scope of the NRC review also includes a review of the State's and NRC's handling of the misadministrations and subsequent reporting of them to management, the public, and Congress. The lessons learned from this review may result in additional changes to NRC's Agreement State program.

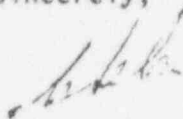
I would like to close by outlining the Commission's general expectations for the Agreement States program for the next five years and perhaps beyond. Although we firmly believe that the current program adequately protects public health and safety, we believe as firmly that the NRC must continue to improve our management of the Agreement States program. After making the necessary changes described in this letter, the program must be allowed to mature and stabilize around the new policies, procedures, and guidelines if it is to function effectively. We will continue efforts to improve the Agreement States program and to establish higher standards of performance, both for the NRC and the Agreement States. However, program changes over the longer term should be more incremental in nature. For the very long term, we are considering developing strategies to address long-range options for the Agreement States program that will provide guidance for continued management of the materials programs in Agreement States, and to some extent, in the non-Agreement States.

The Honorable Mike Synar

4

Much has been accomplished to date; more work remains. I trust that you will find the Commission's actions responsive to the Committee's concerns. I will be pleased to respond to any questions that you may have.

Sincerely,



Ivan Selin

Enclosures:

1. Agreement States Status
2. COMIS-93-013, August 25, 1993; SECY-93-272, October 1, 1993
3. Draft Statement of Principles and Policy for the Agreement State Program and Four Additional Attachments
4. Programmatic Assessment Group (PAG) Recommendations Addressing COMIS-93-013 Area 2, June 29, 1994
5. Adequacy and Compatibility for NRC and Agreement State Radiation Control Programs Necessary to Protect Public Health and Safety, Draft Statement of Policy, July 15, 1994; SECY-93-349, April 20, 1994
6. SECY-94-011, January 19, 1994 and Staff Requirements Memorandum, March 16, 1994

cc: Rep. J. Dennis Hastert

CURRENT STATUS - AGREEMENT STATES DATA
August 29, 1994

STATE	YEAR OF REVIEW	ADEQUATE	COMPATIBLE
Alabama	1993	x	FW ¹
Arizona	1992	x	FW
Arkansas	1993	x	x
California	1993	FW ²	FW
Colorado	1993	x	x
Florida	1993	x	x
Georgia	1993	x	FW
Illinois	1992	x ²	x
Iowa	1993	x	x
Kansas	1993	x	FW
Kentucky	1992	x ²	x
Louisiana	1993	FW	FW
Maine	1993	FW ²	FW
Maryland	1991	x ²	FW
Mississippi	1993	x	x
Nebraska	1992	FW ²	FW
Nevada	1993	x ²	FW
New Hampshire	1993	x ²	FW
New Mexico	1992	x ²	FW
New York	1992	x	FW
North Carolina	1993	x ²	FW
North Dakota	1993	x	FW
Oregon	1993	x	x
Rhode Island	1994	x	x

¹Please note that "FW" indicates that the finding was withheld.

²The findings identified are based on the specified year of the review. The 1994 routine review or follow-up review has been completed. However, the final report documenting the findings from the review has not been finalized.

STATE	YEAR OF REVIEW	ADEQUATE	COMPATIBLE
South Carolina	1993	x	x
Tennessee	1994	x	x
Texas	1993	x ²	x
Utah	1992	x ²	x
Washington	1992	x	x

ENCLOSURE 4

(The Commission limited the role of the Management Review Board (MRB) to a review of reports related to the pilot program. As a result, reference to MRB activities were not incorporated into Management Directive 5.6 as noted in this Enclosure. Following the completion of the pilot program the Commission intends to reevaluate the role of the MRB).



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20585-0001

June 29, 1994

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: PROGRAMMATIC ASSESSMENT GROUP (PAG) RECOMMENDATIONS
ADDRESSING COMIS-93-013 AREA 2

COMIS-93-013, Improvements in the NRC's Agreement States Program, requested that the staff review and prepare for Commission consideration recommendations to improve the NRC's Agreement States program to assure adequate protection of the public health and safety. In my memorandum of May 2, 1994, I provided you with the Programmatic Assessment Group's (PAG) recommendations regarding the first area for consideration in COMIS-93-013.

This memorandum transmits the PAG's recommendation regarding the second area the Commission suggested for the PAG consideration, "Action levels for top management and Commission involvement." In this area, the Commission requested that the staff: (1) prepare directives on Section 274 matters to be brought to the Commission's attention, and those which must be approved by the Commission; (2) prepare guidance on when the NRC should consider getting involved in an Agreement State program in a technical assistance capacity; and (3) prepare guidance on briefings for the Commission by the staff and appropriate Agreement State officials on Agreement States experiencing difficulties. In keeping with the PAG's goal of bringing a fresh perspective to the issues under its consideration and of serving as an integrative mechanism, the PAG has considered current initiatives, such as the Integrated Materials Performance Evaluation Program, the draft Statement of Principles and Policy for the Agreement State Program, and the draft Policy Statement for Agreement States Adequacy and Compatibility, in making its recommendations.

To ensure the involvement of the Commission and senior management, the staff recommends that the material in Enclosure 1 be incorporated into Management Directive 5.6, "Integrated Materials Performance Evaluation Program," to address those items that are identified during the review of an Agreement State program or an NRC regional program. Management Directive 5.6 was provided to the Commission as an enclosure to SECY-94-011 dated January 19, 1994. If the Commission approves the use of the Management Review Board at the conclusion of the pilot program to evaluate common performance

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indicators, it is the staff's view that the modified Management Directive 5.6, along with the actions and concomitant procedures¹ recommended in the draft Statement of Principles and Policy for the Agreement States Program, will ensure involvement of the Commission and senior management, following a program review. The staff has committed to provide the Commission annual briefings on the status of the Agreement State Program including areas where Agreement States are experiencing difficulties. These staff briefings are normally scheduled for mid-summer.

For significant program and policy issues initiated or identified by the staff, dealing with Section 274 matters, the Commission will be informed by memorandum or Commission paper and briefed when appropriate. In addition, the Organization of Agreement States, has historically accepted the Commission's invitation to provide an annual briefing, and is prepared to brief the Commission at other times as appropriate, to discuss specific Agreement States' issues.

To address the Commission's request regarding NRC guidance on providing technical assistance to Agreement States, a proposed Management Directive 5.11, "Technical Assistance to Agreement States" is enclosed (Enclosure 2). The proposed Management Directive is an update of, and supersedes, previous Office of State Programs internal procedures. The Management Directive briefly defines the three types of technical assistance which NRC can furnish, and provides broad guidance on the basis, extent, and conduct of such assistance.

Once the Commission considers the recommendations herein and gives its approval, Draft Management Directive 5.6 will be modified as appropriate. Draft Management Directive 5.11 will be discussed with Agreement States at a public meeting in July, then processed as final. The PAG intends to continue its review and discussion of the other areas in COMIS-93-013.

SECY, please track.


James M. Taylor
Executive Director
for Operations

Enclosures:
As stated

cc: SECY
OGC
OPA
OCA

¹ "Levels of Agreement State Program Review Findings" and "NRC Actions as a Result of These Findings" sections VII and VIII respectively.

U.S. NUCLEAR REGULATORY COMMISSION

Volume 5: Governmental Relations and Public Affairs

(NMSS/OSP)

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP)

DIRECTIVE 5.6

Policy.
(5.6-01)

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to evaluate the Regional materials programs and Agreement State Radiation Control Programs in an integrated manner using common performance indicators. The integrated materials performance evaluation program (IMPEP) described in this directive will help assure that the public health and safety is being adequately protected throughout the United States. This directive and its associated handbook define the objectives, responsibilities, terms, and procedures for conduct of this program.

Objectives.
(5.6-02)

To establish the process by which the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs (OSP) conduct their biennial assessments of the NRC regions and Agreement States, in order to determine the adequacy of their programs. (021)

To provide NRC and Agreement State management with a more systematic and integrated approach to evaluate the strengths and weaknesses of their nuclear material licensing and inspection programs, as conducted by the NRC regional offices and the Radiation Control Programs in each of the Agreement States. (022)

To provide significant input in the regulatory decision-making process, and indicate areas in which the NRC and States should dedicate more resources or management attention. In this way, the assessments should be instrumental in improving State or regional performance, thus ultimately leading to improved licensee performance. (023)

Organizational Responsibilities and Delegations of Authority
(5.6-03)

ENCLOSURE 1 (see next 2 pages for recommended modifications.)

The Executive Director for Operations (or designee) (EDO)
(031)

- o Provides oversight for the activities described herein. (a)
- o Chairs Management Review Boards. (b)
- o Signs final reports issued to each region and State. (c)
- o Issues orders for an Agreement State emergency suspension actions and informs the Commission of each action. (d)

The Management Review Board (MRB)
(032)

- o Reviews the factual findings of biennial team assessment reports for each region and State. (a)
- o Determines level of review finding, as applicable: adequate, marginally adequate, or inadequate, as well as compatible or not compatible. (b)
- o Recommends for Commission approval NRC action as a result of the review finding, as applicable: probation, suspension, or termination. (c)
- o May recommend emergency suspension action to the EDO in those cases requiring immediate action to protect public health and safety because the State has failed to take necessary action within a reasonable time. (d)

The Director, Office of Nuclear Material Safety and Safeguards (NMSS) and the Director, Office of State Programs (OSP)
(032) (033)

- o Implement the requirements of this directive within NMSS and OSP. Provide staffing support and training for review teams, as needed. (a)
- o Establish a schedule and develop a detailed review regimen for conducting the reviews in each region and State. (b)
- o Monitor the IMPEP process; evaluate and develop IMPEP policy, criteria, and methodology, and assess the uniformity and adequacy of the implementation of the program. (c)
- o Issue draft reports and prepare final reports for each region and State for consideration by Management Review Board and signature by the EDO. (d)
- o Participate as needed on Management Review Boards. (e)
- o Prepare an annual report on the status of the national materials program. The report is to be coordinated with the Organization of Agreement States, discussed at the NRC Senior Management Meeting, and presented to the Commission in an annual public meeting. (f)

The General Counsel
~~(033)~~ (034)

- o Participates as needed on Management Review Boards (a)

The Director, Office for Analysis and Evaluation of Operational Data (AEOD)
~~(034)~~ (035)

- o Provides the operational performance data for each State and region (e.g. misadministrations, overexposures, number of lost or abandoned devices, or contamination events) in a format suitable for analysis by the review teams. (a)
- o Participates as needed on Management Review Boards. (b)

Regional Administrators
~~(035)~~ (036)

- o Implement the requirements of this directive and handbook within their respective regions. (a)
- o Provide staffing support for review teams, as needed. (b)

Applicability.
(5.6-04)

This directive and handbook apply to and must be followed by all NRC headquarters and regional employees who are responsible for and participate in the IMPEP. (a)

This directive and handbook apply to regulation of byproduct, source, and special nuclear materials safety activities within a set of common performance indicators. Certain non-reactor functions that continue to be conducted from NRC Headquarters, such as fuel cycle licensing, uranium and thorium milling, sealed source and device reviews, and safeguards activities are excluded from this set of indicators since they are not common to regional and State activities. This exclusion does not prohibit NMSS and DSP from using other indicators and/or performance standards to supplement those described in this directive. (b)

Handbook.
(5.6-05)

Handbook 5.6 presents the performance indicators that will be used, the performance standards against which these indicators will be evaluated.

MANAGEMENT DIRECTIVE

To: All NRC Employees

Subject: Transmittal of Management Directive 5.11, "Technical Assistance to Agreement States."

Purpose: Directive 5.11 replaces and revises Office of State Programs Internal Procedure D.12 "Special Technical Assistance to Agreement States," and addresses the agency response to requests for technical assistance from Agreement States.

Office and Division of Origin: Office of State Programs

Contact: Director, Office of State Programs

Date Approved: xxxxxx xx, 199x

Volume: 5 Governmental Relations and Public Affairs

Directive: 5.11 "Technical Assistance to Agreement States"

Availability: Distribution Unit

ENCLOSURE 2

Technical Assistance to Agreement States Directive 5.11

Policy (5.11-01)

It is the policy of the U.S. Nuclear Regulatory Commission (NRC) to provide assistance to Agreement States on technical issues as appropriate. There are three types of technical assistance: routine technical assistance, special technical assistance; and programmatic technical assistance (see 5.11-04 Definitions). Under normal circumstances, routine technical assistance is provided to Agreement States as a normal part of NRC's day-to-day interaction with States. There are circumstances, however, that require a response above the normal level of interaction. Such cases may be where a State does not have the special technical expertise available to the NRC to address a particular need or when a State is experiencing a temporary constraint on resources. Technical assistance to an Agreement State in the latter circumstance will be on a case-by-case basis where the NRC believes that such assistance is necessary to ensure adequate protection of the public health and safety. In providing technical assistance to Agreement States, NRC will concentrate its resources on those areas which an Agreement State may not be able to address through its own expertise or contractual support for its program. All regulatory decisions remain the responsibility of the Agreement State. This Management Directive is an update of, and supersedes, an Office of State Programs Internal Procedure "Special Technical Assistance" (dated 6/24/83), to recognize the maturity demonstrated by the Agreement States in the management of their radiation control programs, as well as to implement the experience gained in the intervening years. This directive describes how technical assistance to Agreement States will be provided by the NRC.

Objectives (5.11-02)

- To establish a process for determining when special technical assistance or programmatic assistance should be provided by NRC to Agreement States.
- To establish a process for determining the extent and conduct of such assistance.

Organizational Responsibilities and Delegations of Authority (5.11-03)

The Commission (031)

Approves policy matters related to providing technical assistance to Agreement States.

The Executive Director for
Operations (EDO)
(032)

- Provides oversight for the activities described herein.

The Director, Office of State
Programs (OSP)
(033)

- Coordinates the review of technical assistance requests from Agreement States with regional administrators and directors of affected program offices.
- Reviews technical assistance requests to ensure that they are consistent with Commission policy and that they contain:
 - sufficient information to enable the NRC to provide an adequate technical response to the issues addressed in the State's request.
 - evidence that the State had pursued alternative means of addressing the issue on their own including attempting to obtain assistance from other agencies within the State, consultants or contractors, other Agreement States, and independent organizations such as the Conference of Radiation Control Program Directors (CRCPD).
- Coordinates any recommendations on the request and provides the agency response to the State as appropriate.
- Ensures that appropriate headquarters and regional offices have input into the development of the response to the request.
- Assists office directors and regional administrators in determining the appropriate means for providing the assistance, including the level of staff involvement and the timing of the agency response.
- Plans, schedules, and arranges meetings with the State to coordinate the assistance.

**Office Directors and
Regional Administrators
(034)**

- Advise the Director, OSP and other affected offices of initial inquiries from States for technical assistance.
- Evaluate ability to respond to technical assistance requests from the Agreement States and provides this information to OSP.
- Participate in meetings with State officials as required to clarify the assistance request and to assure the timely and appropriate response to the request.
- Approve and provide the requested assistance in the timeframe agreed upon.

**The Director of a Lead Office, Regional
Administrators, or the Director, Office of
State Programs
(035)**

- Take the lead in developing a response to a technical assistance request. Consider NRC resource availability, both in terms of the expertise required and staff, as a factor in determining the extent and duration of the special technical assistance.
- Ensure coordination with other affected program offices or regions.
- Acknowledge all written requests for special technical assistance that come through their respective offices.
- Where additional clarification of the request is necessary, the lead office will prepare correspondence confirming the agreed upon technical assistance.
- Ensure that neither NRC nor its contractors and/or consultants will act in a decision-making capacity.

**Definitions
(5.11-04)**

Routine Technical Assistance. Technical assistance provided to Agreement States as a normal part of NRC's day-to-day interaction with Agreement States. Such assistance may include, but not be limited to, the discussion of minor technical issues in licensing and compliance.

Special Technical Assistance. Technical assistance requiring specific assignment of NRC staff or consultants for a specified period and for a specific job. Special technical assistance projects will be designated as such by the appropriate Regional Office or the Director, OSP.

Programmatic Technical Assistance. General technical assistance provided to an Agreement State which is experiencing problems of a programmatic nature. Such assistance will usually involve support in the licensing and/or inspection aspects of the State's regulatory program.

Applicability
(5.11-05)

Employees
(051)

This directive applies to and must be followed by all NRC headquarters and regional employees who are responsible for accepting and responding to technical assistance requests from an Agreement State as authorized under Section 274 of the Atomic Energy Act of 1954, as amended.

References
(5.11-06)

1. The Atomic Energy Act of 1954, as amended (42 U.S.C. 2011, et seq.).
2. NRC Policy Statement for the Agreement State Program.