

N O T A T I O N   V O T E

RESPONSE SHEET

TO:                    John C. Hoyle, Secretary

FROM:                COMMISSIONER MCGAFFIGAN

SUBJECT:            SECY-97-054 - FINAL RECOMMENDATIONS ON  
POLICY STATEMENTS AND IMPLEMENTING  
PROCEDURES FOR: "STATEMENT OF PRINCIPLES  
AND POLICY FOR THE AGREEMENT STATE PROGRAM"  
AND "POLICY STATEMENT ON ADEQUACY AND  
COMPATIBILITY OF AGREEMENT STATE PROGRAMS"

Approved ☒                    Disapproved \_\_\_\_\_                    Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_                    Request Discussion \_\_\_\_\_

COMMENTS:

*See attached*

*Edward M. Gaffigan*

SIGNATURE

Release Vote ☒ / ☐ /

*6/26/97*

DATE

Withhold Vote ☐ / ☐ /

Entered on "AS"    Yes ☒                    No \_\_\_\_\_

Commissioner McGaffigan's comments on SECY-97-054:

I have reviewed the proposed final policy statements and procedures for the Agreement State program and approve them for implementation. Based on my review, and consideration of input provided by the staff during a briefing to Commission office staff on April 30, 1997, I have the following comments and positions on the proposals in SECY-97-054.

1. I commend the staff for working diligently and closely with the Agreement States to finalize the two policy statements and associated implementing procedures for the Agreement State program in a timely manner. These documents provide more clear, concise, and comprehensive guidance for the Agreement State program.
2. I believe that the working group's designation of certain NRC requirements as necessary for public health and safety provides much needed clarity and specific guidance on requirements needed for a finding of Adequacy.
3. I agree with the staff's interpretation of the Atomic Energy Act that NRC and Agreement State program compatibility must be maintained on a continuing basis to ensure compliance with the Agreement and thereby adequately protect public health and safety. In fact, I believe that section 274j(i) and d.(2) mandate periodic NRC reviews for adequacy and compatibility.
4. I agree with the staff that the phase-in approach for Agreements with States previously proposed should not be implemented. I believe that the current agreement process--wherein a prospective Agreement State consults with the NRC regarding entry into an agreement, formally submits an application, responds to NRC identified deficiencies or questions, participates in meetings with NRC to address specific issues, and coordinates the exchange of technical information--provides ample opportunity for both the NRC and the State to identify and resolve issues of concern prior to a final decision on the agreement application. The staff's diligent review of the State's application and thorough coordination with the State coupled with the improved guidance in the final policy statements and implementing procedures provide the necessary tools for NRC to reach informed decisions regarding new agreements while not imposing burdens on the State such as those identified by the commenters.
5. I agree with the flexibility provided to the Agreement States to adopt legally binding requirements (such as specific license conditions) in lieu of regulations applicable to specific licensees or groups of licensees. This approach will ensure that Agreement States have a method to impose necessary requirements in a timely manner.
6. I agree in part and disagree in part with the staff's proposal on the quality management program requirements (QM rule). I agree with the staff's approach to review existing AS QM requirements within the context of IMPEP, and to review Agreement State QM rules submitted to NRC in the future.

I do not agree with the staff's proposal that Agreement States adopt the current QM rule within 3 years after Commission approval of the final policy statement. In 1995, the Commission approved a letter to Agreement States to inform them that NRC would defer Agreement State findings of compatibility on the QM rule based on the uncertainty regarding modifications to the rule. These uncertainties continue to exist and will not be resolved until Part 35 is revised on or before June 30, 1999<sup>1</sup>, as directed by the Commission in the SRM on DSI 7. Therefore, I see no basis to change our regulatory approach at this time. Rather, the NRC should continue to defer findings on Agreement State QM rules until NRC issues revised QM requirements and an effective date for the Agreement States is identified, which could be earlier than the normal 3-year interval for Agreement State implementation of an NRC rule.

7. I agree with the staff's proposal to make Agreement State reporting of events to NRC's Nuclear Materials Event Database an item of compatibility as it will likely result in increased reporting of events and a more comprehensive database on which to base decisions that impact the national materials use program.
8. It is my understanding that the staff intends to forward separate papers on two related issues: 1) whether additional NRC regulations or guidance are needed to address Ethics/Conflict-of-Interests/Financial Disclosure requirements of Agreement State programs; and 2) whether existing agreements will be grand-fathered or revised when a standard agreement is approved by the Commission.

Regarding item 1, I encourage the staff to forward recommendations to the Commission in a timely manner; the Utah-Envirocare matter clearly raises the question as to the applicability of, and need for, conflict of interest requirements for Agreement State regulators. Regarding item 2, the benefit of modifying existing Agreements for the sole purpose of uniformity is not apparent, and resources may be diverted from more high priority issues for such an unnecessary task. Instead, the staff might consider focusing its efforts, as resources allow, to ensure that NRC has maintained adequate documentation of the original Agreement and subsequent amendments for each of the 30 Agreement States.

9. Since Agreement States will need to modify their regulations to accommodate revised or new compatibility assignments for some NRC requirements, it is important that NRC staff (with or without the assistance of the WG) continue to critically review the table entries to identify inconsistencies, errors or omissions, and verify the appropriateness of the compatibility assignments.

For example, the compatibility assignments for 10 CFR 30.10, 40.10, and 70.10 are inconsistent with one another, and the compatibility assignments for mobile nuclear medicine (35.29, 35.80) and the definition of brachytherapy source (35.2) warrant re-evaluation. Specifically, mobile nuclear medicine has transboundary implications.

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<sup>1</sup> I do not agree with the staff's proposal in SECY-97-115 to extend this rulemaking date by 10 months.

and the definition of brachytherapy source, if varied, could create conflicts, gaps, or duplications since these sources are manufactured and distributed nationwide.

10. Regarding comment number 5 of Commissioner Dicus' vote, I do not agree that the Commission should revisit its recent decision to assign a compatibility level II to the final rule on radiological criteria for license termination, and I fully support the Commission's prior decision on this matter. As a result of Commission direction, the staff is working diligently to issue the final cleanup rule; it would be counterproductive and untenable for the Commission to change its direction to the staff on this issue in the absence of new and compelling information. In my view, there is no new or compelling information that would warrant reconsideration of this issue. Moreover, in finalizing and affirming the cleanup rule, the Commission found that the standards that it established in the rule provide "a sufficient and ample margin of safety for protection of public health and safety" beyond the basic 100 mrem/y limit that is imposed in other regulations. See, e.g., Radiological Criteria for License Termination - Final Rule (Statements of Consideration), p.26. The Commission did not determine that the standards it has adopted in the cleanup rule constitute "basic radiation protection standards." Were we now to state, for purposes of changing the compatibility category for this rule, that the rule establishes basic radiation protection standards, I believe that we would substantially undermine the bases for, and findings on, the cleanup rule and consequently increase the likelihood that the rule will be successfully challenged in court.
11. Regarding comment no. 2.b. of Commissioner Rogers' vote, I agree that the definition of "basic radiation protection standards" that is in the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" should be modified to reflect recent Commission policy on certain dose limits that would appear to meet this definition (e.g., the "constraint" rule and the license termination rule) but have been determined not to be basic radiation protection standards.
12. The Commission recently directed the staff via the SRM on DSI 22 to develop an implementation plan to move the responsibility for preparation and coordination of rulemaking from the Office of Nuclear Regulatory Research to the Program Offices. While I recognize that the current draft of Management Directive 5.9 was prepared prior to this Commission decision, the staff should revise the directive to ensure that the final version accurately reflects this change in rulemaking responsibility (suggested edits attached).

# U. S. Nuclear Regulatory Commission

## Volume: 5 Governmental Relations and Public Affairs

### OSP

- Assists in the review, evaluation, and determination of those NRC regulations that an Agreement State should adopt as a legally binding requirement for the purpose of compatibility or health and safety. (c)
- Coordinates, with other NRC offices, the review of Agreement State regulations and program elements. (d)

#### Office of the General Counsel (033)

- Assists in the review, evaluation, and determination of those NRC program elements and regulations <sup>that</sup> an Agreement State should adopt for the purpose of compatibility or health and safety. (a)
- Advises staff on findings regarding the adequacy and compatibility of Agreement State regulations and program elements. (b)

#### Director, Office of Nuclear Regulatory Research (RES)

~~(034)~~ move to (035)

- Reviews, evaluates, and determines those NRC regulations an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (a)

- Assists in the review, evaluation, and determination of those NRC program elements an Agreement State should adopt for compatibility or health and safety. (b)

and regulations that

the purpose of

Approved: (Date)



# U. S. Nuclear Regulatory Commission

## Volume: 5 Governmental Relations and Public Affairs

### OSP

#### Director, Office of Nuclear Material Safety and Safeguards (NMSS)

(035) note (034)

Assists in the review, evaluation, and determination of those NRC program elements ~~and regulations~~ an Agreement State should adopt for the purpose of compatibility or health and safety. (b)

#### Director, Office for Analysis and Evaluation of Operational Data (AEOD)

(036)

Assists in the review, evaluation, and determination of those NRC program elements and regulations, <sup>that</sup> an Agreement State should adopt for the purpose of compatibility or health and safety.

#### Regional Administrators

(037)

Assists in the review, evaluation, and determination of those NRC program elements and regulations, <sup>that</sup> an Agreement State should adopt for the purpose of compatibility or health and safety.

### Applicability

(5.9-04)

The policy and guidance in this directive and handbook apply to all NRC employees who are responsible for and participate in the review and evaluation of Agreement State regulatory programs or are involved in development and promulgation of NRC regulations or program elements for byproduct, source, and special nuclear materials.

Reviews, evaluates and determines, in coordination with other NRC offices, those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (a)

Approved: (Date)



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

OFFICE OF THE  
SECRETARY

June 30, 1997

- Duplicate -

MEMORANDUM TO: L. Joseph Callan  
Executive Director for Operations

FROM: *John C. Hoyle*  
John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY 97-054 - FINAL  
RECOMMENDATIONS ON POLICY STATEMENT AND  
IMPLEMENTING PROCEDURES FOR: "STATEMENT OF  
PRINCIPLES AND POLICY FOR THE AGREEMENT STATE  
PROGRAM" AND "POLICY STATEMENT ON ADEQUACY  
AND COMPATIBILITY OF AGREEMENT STATE  
PROGRAMS"

The Commission has approved the final "Statement of Principles and Policies for the Agreement State Program," final "Policy Statement on Adequacy and Compatibility of the Agreement State Programs," and the accompanying implementation procedures, subject to the following comments:

1. the "NRC" compatibility category identifies regulations that are reserved to the NRC but allows states to adopt them for clarity, but the policy omits certain NRC regulations that Agreement States may not adopt because the areas in which they apply are reserved to the NRC. The Policy and procedure should be revised to identify specifically the regulations in the "NRC" category that the States may adopt for clarity and a separate category ("NRC-X or some similar designation) created for those regulations, such as 10 CFR Part 70.21 and much of 10 CFR Part 50 that are reserved for the NRC and that States may not adopt and still be found to have compatible regulatory programs. The flow chart in Appendix A to Handbook 5.9 should also be revised to reflect this distinction.

(EDO)

(SECY Suspense: 8/29/97)

2. The flow chart in Appendix A to Handbook 5.9 should be revised to clarify that regulations required for health

SECY NOTE: THIS SRM, SECY-97-054, AND THE COMMISSION VOTING  
RECORD CONTAINING THE VOTE SHEETS OF ALL  
COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5  
WORKING DAYS FROM THE DATE OF THIS SRM.

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and safety may also be included in compatibility categories A,B, and C as well as in the Health and Safety category. For the same reason, the staff should also add the following sentence to the last paragraph of page 27 in the Federal Register Notice: "Many program elements for compatibility also impact public health and safety; therefore, they may also be considered program elements for adequacy."

(EDO) (SECY Suspense: 8/29/97)

- 3.a. The staff should prepare a letter to the Agreement States identifying the regulations that have been upgraded from former category 3 to new categories A,B, or C, or from former category 2 to new categories A or B since these changes will require the States to take action for any regulations that would fall into a higher compatibility category. The letter should also indicate the potential impact of the changes upon a finding of compatibility, and the date that State action is to be completed.

(EDO) (SECY Suspense: 9/30/97)

- 3.b. At the same time, the staff needs to continue to review its regulation and other program element tables to identify inconsistencies, errors, or omissions, and to verify the appropriateness of the compatibility assignments. In that regard, the compatibility assignments for 10 CFR 30.10, 40.10, and 70.10 are inconsistent with each other, and the compatibility assignments for mobile nuclear medicine (35.29, 35.80) and the definition of brachytherapy source (35.2) warrant further evaluation.

(EDO) (SECY Suspense: 8/29/97)

4. With respect to the question of whether existing agreements with the States will need to be amended after the proposed policy is approved, the staff should write the standard agreement so as to ensure that existing agreements remain valid and that amendments will be limited to those required by a truly compelling legal or policy needs. If modification of the Policy Statements will be needed, the Commission should be promptly informed.

(EDO) (SECY Suspense: 9/30/97)

5. The staff should prepare guidance for the Management Review Board regarding adequacy and compatibility determinations. Such guidance would also enable the States to perform self assessments of their programs, should they choose to do so, with some confidence that the NRC's review would produce similar conclusions.

(EDO) (SECY Suspense: 1/30/98)



6. The staff should continue to defer findings on Agreement State QM rules until NRC issues a revised Part 35 rule as directed in the SRM on DSI-7 and an effective date for Agreement State implementation has been set. Such a date could be earlier than the normal 3-year interval for Agreement State implementation of an NRC rule.

(EDO) (SECY Suspense: 8/29/97)

7. The staff should modify the definition of "basic radiation protection standards" contained in the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" to reflect recent Commission decisions on the imposition of constraints, such as the "constraint" rule on air emissions and the license termination rule.

(EDO) (SECY Suspense: 8/29/97)

8. The draft of Management Directive 5.9 contained in SECY-97-054 should be modified to reflect the Commission's direction to the staff in the SRM on DSI 22 to develop an implementation plan that would reassign responsibility for preparation and coordination of rulemaking from Research to the Program Offices. Suggested editorial changes to accomplish this objective are attached.

(EDO) (SECY Suspense: 8/29/97)

9. Since the staff's proposal would make Agreement State reporting of events to NRC's Nuclear Materials Event Database an item of compatibility, references in the text to voluntary reporting should be eliminated, and the staff should make it clear that reporting of materials events is mandatory.

(EDO) (SECY Suspense: 8/29/97)

10. The staff should submit an information paper to the Commission describing their actions to maintain frequent contact with the individual Agreement States to assess their program status and the procedure that will be used for this purpose and the staff's plans for review of draft State regulations as well as closing out the review of revisions of State regulations for compatibility with Part 20. The paper should also include the resource requirements in headquarters and the field needed to meet these responsibilities. The staff should also inform the Commission how it monitors and reviews State actions, including the review of draft regulations, and inform the Commission of any unexpected or significant problems that develop.

(EDO) (SECY Suspense: 9/30/97)

11. The staff should provide its recommendations with respect to ethics, conflict-of-interest, and financial disclosure requirements for the Agreement State Program in a timely manner.

(EDO)

(Secy Suspense: 7/30/97)

Attachment:  
As stated

cc: Chairman Jackson  
Commissioner Rogers  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
OGC  
CIO  
CFO  
OCA  
OIG  
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)  
PDR  
DCS

Directive 5.9, Adequacy and Compatibility of Agreement State Programs should be changed as noted below.

1. On page 3, under Office of the General Counsel, line 2, insert 'that' after the word 'regulations.'
2. On page 3, under Director, Office of Nuclear Regulatory Research, change the parenthetical to (035) and move this section to that position.
3. On page 3, under Director, Office of Nuclear Regulatory Research, delete the entire first bullet.
4. On page 3, under Director, Office of Nuclear Regulatory Research, in the second bullet (now the first), line 2, insert 'and regulations that' after 'elements.' Also, insert 'the purpose of' after 'for.'
5. On page 4, under Director, Office of Nuclear Material Safety and Safeguards (NMSS), change the parenthetical to (034) and move this section to that position.
6. On page 4, under Director, Office of Nuclear Material Safety and Safeguards (NMSS), insert a new first paragraph which states: "Reviews, evaluates and determines, in coordination with other NRC offices, these regulations that an Agreement State should adopt as legally binding requirements for the purpose of compatibility or health and safety. (a)"
7. On page 4, under Director, Office of Nuclear Material Safety and Safeguards (NMSS), in what is now second paragraph, line 2, delete 'and regulations.'
8. On page 4, under Director, Office of Nuclear Material Safety and Safeguards (NMSS), in what is now second paragraph, after the end of line 3, add '(b).'
9. On page 4, under Director, Office for Analysis and Evaluation of Operational Data (AEOD), line 2, insert 'that' after 'regulations.'
10. On page 4, under Regional Administrators, line 2, insert 'that' after 'regulations.'