



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

10/27

I approve subject to the attached comments.

*Richard A. Meserve*  
Richard A. Meserve

10/19/00

COMMISSIONER

October 13, 2000

COMEXM-00-0002

MEMORANDUM TO: Chairman Meserve  
Commissioner Dicus  
Commissioner Diaz  
Commissioner Merrifield

FROM: Edward McGaffigan, Jr. *E. McGaffigan, Jr.*

SUBJECT: EXPANSION OF NRC STATUTORY AUTHORITY OVER  
MEDICAL USE OF NATURALLY OCCURRING AND  
ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL  
(NARM)

In 1997, while voting on Direction Setting Issue 7, "Materials/Medical Oversight," the Commission indicated its willingness to seek expansion of its statutory authority beyond Atomic Energy Act material to include NARM in an effort to make the national medical use program more uniform and consistent. At that time, the Commission did not pursue such legislation so as not to divert resources from the 10 CFR Part 35, "Medical Use of Byproduct Material," rulemaking initiative. Now that this rulemaking is concluding, I continue to believe that such legislation is a worthy goal especially in light of the comments received on the proposed Part 35 indicating that several States currently have no regulatory authority for NARM.

I propose that the Commission direct staff to provide the Commission with the legislative language that could be used to expand the NRC's statutory authority beyond Atomic Energy Act material to include medical use of NARM. This language should be developed in consultation with the Conference of Radiation Control Program Directors, Inc. (CRCPD) and the National Materials Working Group as part of its efforts to consider the roles and legal responsibilities of NRC, the Agreement States, the Organization of Agreement States, and the CRCPD. I also believe that staff should provide an estimate of the resources needed to implement such legislation.

SECY please track.

cc: EDO  
OGC  
OCA  
SECY

October 19, 2000

**COMMENTS OF CHAIRMAN MESERVE ON COMEXM-00-0002**

I agree with Commissioner McGaffigan's proposal to develop legislative language that could be used to expand the NRC's statutory authority to include the medical use of NARM. There is no sound reason to regulate radioisotopes produced by a reactor under a different regulatory regime than those produced by a cyclotron.

It is my view, however, that the issue associated with authority over NARM is only one of several anomalies in the jurisdiction that the NRC is accorded under the AEA. As a prelude to seeking expanded statutory authority over certain categories of NARM, I believe the staff should be directed to array the various dimensions in which our jurisdiction might appropriately be adjusted so as to assure that radioactive materials and other sources of ionizing radiation presenting similar risks are treated similarly. Although we may well conclude that political considerations urge a narrow focus to our legislative efforts, it would be helpful to undertake such a study so as to enable the Commission to determine what legislative adjustments to pursue. Because any such matter is unlikely to be a high priority issue in Congress, an effort to undertake a thoughtful examination of the broader issue should not delay Congressional action.

Any adjustment of NRC jurisdiction would have an effect on State authority. Accordingly, the development of a legislative package should be undertaken in consultation with the States (perhaps through the CRCPD).

Richard A. Meserve



COMMISSIONER

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2000 OCT 16 AM 8:16

October 13, 2000

*Greta Joy Dicus*  
Greta Joy Dicus

10/26/00

COMEXM-00-0002

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Commissioner Dicus  
Commissioner Diaz  
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I propose that the Commission direct staff to provide the Commission with the legislative language that could be used to expand the NRC's statutory authority beyond Atomic Energy Act material to include medical use of NARM. This language should be developed in consultation with the Conference of Radiation Control Program Directors, Inc. (CRCPD) and the National Materials Working Group as part of its efforts to consider the roles and legal responsibilities of NRC, the Agreement States, the Organization of Agreement States, and the CRCPD. I also believe that staff should provide an estimate of the resources needed to implement such legislation.

SECY please track.

- cc: EDO
- OGC
- OCA
- SECY

**COMMENTS OF COMMISSIONER DICUS ON COMEXM-00-0002:**

I agree with Commissioner McGaffigan's proposal to develop legislative language that could be used to expand NRC's statutory authority beyond the Atomic Energy Act material. However, I would go beyond the proposal offered to us by Commissioner McGaffigan, and further ask that the staff look into the various options as to which our regulatory jurisdiction could be expanded to include all aspects of NARM, and not only for medical purposes. In this respect, I agree with the comments of Chairman Meserve that this proposal be expanded.

I would also note that in the most recent briefing to the Commission, the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors (CRCPD) have encouraged the NRC to further explore this legislative option. Accordingly, I would agree Commissioner McGaffigan that any legislative language be developed in coordination with OAS and CRCPD.

*gfd*  
*10-26-00*



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REQUEST REPLY BY 10/27

COMMISSIONER

October 13, 2000

COMEXM-00-0002

MEMORANDUM TO: Chairman Meserve  
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Commissioner Diaz  
Commissioner Merrifield

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I propose that the Commission direct staff to provide the Commission with the legislative language that could be used to expand the NRC's statutory authority beyond Atomic Energy Act material to include medical use of NARM. This language should be developed in consultation with the Conference of Radiation Control Program Directors, Inc. (CRCPD) and the National Materials Working Group as part of its efforts to consider the roles and legal responsibilities of NRC, the Agreement States, the Organization of Agreement States, and the CRCPD. I also believe that staff should provide an estimate of the resources needed to implement such legislation.

SECY please track.

Approve, with comment.

cc: EDO  
OGC  
OCA  
SECY

*Nils J. Diaz*  
Nils J. Diaz 10/26/00

-REC'D BY HJD-

16 OCT 00 12:00

ORIGINAL

COMMISSIONER DIAZ' COMMENTS ON COMEXM-00-0002, EXPANSION OF NRC  
STATUTORY AUTHORITY OVER MEDICAL USE OF NATURALLY OCCURRING AND  
ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM)

I agree with Commissioner McGaffigan's position that the Commission should direct staff to provide the Commission with the legislative language to expand the NRC's statutory authority beyond Atomic Energy Act material to include the medical use of discrete sources of naturally occurring and accelerator-produced radioactive material (NARM). As I noted in my vote on COMSECY-96-057, "Materials/Medical Oversight(DSI-7)," there is no difference in the risk from radiations produced by byproduct material and NARM, and, consequently, there should be no difference in the Federal regulatory oversight of these materials. Now that the Commission has affirmed the revisions of the NRC's Medical Policy Statement and Part 35, "Medical Use of Byproduct Material," addressing the regulation of the medical use of discrete sources of NARM is an important next step in making the national medical use program more uniform and consistent. Addressing this issue now is also timely because of the increased use of accelerator-produced radioactive material in nuclear medicine programs.

The issue of NRC regulation of the use of discrete sources of NARM has been addressed for a number of years. Therefore, I believe that Commissioner McGaffigan's COM is timely. In August 1987, the Conference of Radiation Control Program Directors (CRCPD) urged NRC to seek legislative authority to regulate NARM. A 1988 NRC report, NUREG-1310, "Naturally Occurring and Accelerator-Produced Radioactive Materials- 1987 Review," noted that while Agreement States generally regulate and control discrete sources of NARM in the same way that they do Atomic Energy Act material, there are significant variations in their licensing, registration, and inspection programs. Most recently, the issue of Federal regulation of NARM was raised in comments on the revision of Part 35. Because this issue has been addressed on numerous occasions at both the state and Federal levels, staff can benefit from using previously generated documents in order to address this issue in a timely manner. Studies and positions that should be considered include NUREG/CR-5962, "Health and Safety Impacts from Discrete Sources of Naturally-Occurring and Accelerator-Produced Radioactive Materials (NARM)" (February 1993), model programs and regulations developed by the CRCPD, and programs in individual Agreement States.

Although by agreeing with COMEXM-00-0002 I am only approving staff to proceed with developing legislative language for medical uses of NARM, I believe that the staff should study "... the various dimensions in which our jurisdiction might appropriately be adjusted so as to assure that radioactive materials and other sources of ionizing radiation presenting similar risks are treated similarly," as the Chairman so aptly expressed.



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SECY please track.

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Commissioner Merrifield's comments on COMEXM-00-0002:

I agree with Commissioner McGaffigan's proposal to develop legislative language that could be used to expand NRC's statutory authority beyond the Atomic Energy Act material. I understand Commissioner McGaffigan's thoughts are to begin the process by focusing on the more narrow area of NARM as used for medical purposes; and eventually, it may be appropriate to propose expanding NRC authority in other areas. However, I agree with Commissioner Dicus' vote in that, if we are focusing on NARM, the initial proposal should be for all aspects of NARM and not solely medical uses of NARM. If there is a majority for this approach, I suggest that once the staff submits a legislative proposal with justification to the Commission, we can determine if the actual proposal submitted to Congress should be modified and to what degree. To some extent, expanding the effort beyond medical uses of NARM is included in the Chairman's vote. However, I view the Chairman's vote as a more universal effort which may be extended beyond NARM to include almost any use of radioactive material. While I believe the Chairman proposes an appropriate activity for Commission consideration, I am simply not sure of the total scope and schedule for the action as proposed by the Chairman. Therefore, as a first step, I propose that the staff develop a proposed scope, schedule (including appropriate milestones), and a rough estimate of resources for the effort involving all aspects of NARM and any other area that may be included in the broader proposal by the Chairman. In developing this document, the staff should consult freely with the Commission technical assistants to more clearly define the scope of the effort. Once the staff's input is provided to the Commission, it may be more appropriate to direct the staff to develop legislative proposals in distinct segments or for the whole program as outlined in the paper.

I agree also that the effort should be coordinated with the States after the scope of the effort is approved by the Commission.

 10/30/00