



DOD SP73
Working Group
RLR/3
PHL
SCD
CHM
Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive
Moraga, CA 94556-1551
510/283-1850
Fax: 510/283-1850

Henry H. Kramer, Ph.D., FACNP
Executive Director

October 30, 1996

Mr. Richard L. Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

96 OCT 31 PM 5:24

NSF

RE: Report of the Joint NRC-Agreement State Working Group for the Development of Implementing Procedures for the Final Policy Statement on the Adequacy and Compatibility of Agreement State Programs

Dear Mr. Bangart:

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is comprised of manufacturers of radiopharmaceuticals, life science research radiochemicals, and radioactive sealed sources used in medicine and quality and safety assurance. Members of CORAR attended the November 1994 workshop and have otherwise demonstrated previous interest in NRC's policy on the Adequacy and Compatibility of Agreement State programs, and have been provided notice of the above referenced report. These members appreciate the opportunity to review and comment on this report and attachments and the following comments are submitted on behalf of CORAR for your consideration.

General Comments

As manufacturers and distributors of radioactive materials used in every state in the U.S., CORAR member companies are acutely aware of the increasing difficulties encountered in the effort to conduct interstate commerce in numerous regulatory jurisdictions with varying requirements for licensing, registration and distribution of products. CORAR recognizes the important need for federal and state regulations to be uniform and compatible. Our industry has repeatedly expressed the need for consistency between the regulations of the NRC and the Agreement States as well as between the Agreement States themselves. We applaud the efforts of the Working Group and their recognition of the need to ensure Agreement State compatibility while providing an overall level of protection of public health and safety that is equivalent to that provided by the NRC without creating conflict, duplication or gaps or otherwise jeopardizing an orderly pattern in the regulation of "agreement material" on a national basis.

Specific Comments

1. Working Group Revised Policy Statement

1.1 Adequacy

We agree that an Agreement State's radiation control program should be adequate to assure the protection of public health and safety. We also agree with the revision of the policy statement which states that an Agreement State's program, when compatible with that of the Commission does, not effect the State's obligation to maintain an adequate program. While the policy statement states that the overall level of protection provided by the elements of a State program should be equivalent to, or more stringent than, the level of protection provided by the NRC program, we agree with the distinction made between adequacy and compatibility and the designation of both adequacy and compatibility as "core concepts" of the Agreement State program.

1.2 Compatibility

We agree with the definition of a compatible Agreement State program as one which does not create conflict, duplication, gaps or other conditions which jeopardize an orderly pattern in the regulation of agreement material on a national basis. We are particularly appreciative of the attention paid to concerns over areas of regulation related to activities involving significant transboundary implications. Although the policy statement seems to balance the need for adequacy and compatibility, we recommend that the policy statement address with more emphasis the need to ensure adequacy for the purpose of protection without State adoption of more stringent regulations that have presented particular hardship in the effort to conduct interstate commerce.

We recommend that the policy statement address the need we feel exists for communication by the Agreement States to the Commission when States adopt regulations that are more stringent than, or otherwise conflict with, those of the Commission. Although the policy statement says compatibility ensures adequacy, the door is left open for States to adopt more restrictive requirements in the areas of licensing, distribution and transportation that may jeopardize an orderly pattern in the regulation of agreement material on a national basis. The policy statement should make a provision for the notification of the Commission by States in this situation, and a mechanism for the subsequent communication of such a conflict to the regulated community. This is particularly important to companies conducting interstate commerce.

1.3 Three Component Approach to Compatibility

Although the approach taken to establish varying degrees of adoption of NRC requirements by Agreement States is basically sound, the key to classification is

unnecessarily complex. Perhaps the use of multiple categories in the third component could be simplified or seven overall categories could be used rather than three.

We agree that the first component encourages States to adopt standards essential to basic radiation protection that are "essentially identical" to those of the NRC. We recommend that the standards adopted by NRC and the States for protection of the public be not only essentially identical to each other but also essentially identical to standards recommended by scientific organizations such as the NCRP and ICRP.

The policy statement has identified in the second component the need for the States to adopt regulations essentially identical to the Commission in areas of regulation related to activities involving significant transboundary implications. This is an important step in the effort to achieve compatibility for the purpose of lifting barriers to interstate commerce. We recommend that this second component be expanded by including the area of regulation covered in component 3 a. Component 2 should also include the adoption by States regulations and program elements to avoid conflicts, duplications, gaps, or other conditions which jeopardize an orderly pattern in the regulations of agreement material on a national basis that are also essentially identical to those of the Commission.

2. Working Group Report

2.1 Executive Summary

We agree with the recommendation made by the Working Group that the revisions to the policy statement should be sent to all the Agreement States and other interested parties for comment prior to final Commission approval. CORAR is appreciative of the opportunity to comment.

2.2 Section 3.2.1 - Background

As previously stated, we agree with the definition of a compatible Agreement State program. This definition provides clarity and should, along with the component criteria, enhance the implementation of this policy.

2.3 Section 3.2.2.2 - Compatibility Component 2

The examples of activities covered under compatibility component 2 should be expanded to include the following:

- licensing of agreement material (e.g. exempt quantities, general license provisions)
- reciprocity requirements

- add radiopharmaceuticals and other medical products to the examples of products distributed nationally which require approval

2.4 Section 3.2.2.3 - Compatibility Component 3

Also as previously stated, compatibility component 3.a. should be integrated into component 2 with adoption by Agreement States of Commission regulations which are essentially identical.

2.5 Section 3.4 - Classification Process

As explained in comment 1.3 above, step 3 in the process on page 10 of the report should be modified to read as follows:

Do the essential objectives of the regulation or program element address or define an issue that has a significant, direct transboundary implication or create a conflict or gap? If the answer is "yes", the compatibility component is "2".

2.6 Section 4.1 - Clarifying the Distinction Between the Terms "Adequacy" and "Compatibility"

We agree that the term "adequacy" needs to be clarified. The treatment in Attachment 2, pages 2 and 3 is now much clearer than before.

Also, we are in total agreement with the point in the third paragraph on page 12 that Agreement States generally would not focus the emphasis of their efforts on issues including the goal of avoiding unreasonable burdens on firms operating in multiple states, and the same incentives and pressures that drive the regulation of public health and safety within the state do not exist in relation to the effects of the Agreement State's program on a national basis. We applaud the position expressed in this section of the report that the type of NRC oversight in the area of compatibility as reflected in the new Policy is justified in order to ensure that Agreement State programs reflect these national concerns.

2.7 Section 4.4 - Use of the Term "Public Dose Limits"

We agree that the NRC should use the terms "public" and "occupational" to consistently clarify the intended application.

3. Revision 1 to Procedure B.7

The pages of this procedure should be numbered to facilitate comments. Also, as previously stated, the key to the classifications are unnecessarily complex. Also as previously stated, component 3.a should be integrated into component 2 as the Agreement

States should adopt NRC regulations with essentially identical language as conflict, duplication and gaps result in significant transboundary implications.

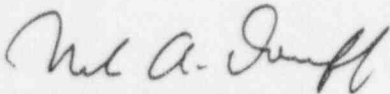
We agree that Appendix C of 10 CFR 20 should be strictly compatible with the quantities listed in Agreement State regulations. The same applies to 10 CFR 30.71 Schedule B. In both Appendix C and Schedule B, the specified radionuclides need to be identical with those specified in the Agreement State regulations to avoid incompatibility when the NRC chooses to specify a radionuclide and the States decide to use default quantities or vice versa for the same radionuclide.

Procedure B.7 should also include sections on 10 CFR 30 and 10 CFR 110 compatibility classifications.

In closing, we again express our appreciation in the effort the Working Group has invested in developing a policy and system that is designed to address the significant problem of regulatory inconsistency between the NRC and the Agreement States. Although we have expressed the preceding comments to improve the outcome of the Working Group to date, we feel that the report, policy statement and implementing procedure generally address the key concerns associated with adequacy and compatibility.

We are also appreciative of the opportunity to express our view of the report and attachments and CORAR is willing to provide additional input or provide other assistance to the Working Group. Should you have any questions concerning the comments expressed in this letter, please feel free to contact us.

Sincerely,



Mark A. Doruff, CHP
Council on Radionuclides and Radiopharmaceuticals



Page 1 of 6

FAX TO: Cardelia Maupin - US NRC

FAX NO.: 301-415-3502

FROM: Mark Doruff - Amersham Corporation
Phone 847-593-6300 X 309
Fax 847-437-1699

DATE: October 31, 1996

SUBJECT: Policy Statement on Adequacy and Compatibility of Agreement State Programs

Cardelia:

I have attached comments on the Working Group report and attachments that were submitted yesterday via overnight mail by the Council on Radionuclides and Radiopharmaceuticals. These comments were sent to Mr. Bangart's office, but I send you this fax in case the mail route did not get our comments to Mr. Bangart by the requested date (today). You were designated as the contact in a letter from Mr. Bangart to Amersham dated September 30, 1996.

Please call me if you have any questions.

Regards,

NRG FILE CENTER COPY

060017

SP-C-6