DCD(SP05) RAB2 PHL SCD CHM

STATE OF NEW YORK DEPARTMENT OF HEALTH

Office of Public Health II University Place Albany, New York 12203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

December 9, 1996

Richard Bangart
Director, Office of State Programs
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bangart:

This letter is in reference to the Report of the Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs.

The implementing procedures for compatibility go beyond what is described in the policy statement and continue to impose detailed NRC regulations on Agreement State licensees. Further, we are concerned over the policy itself which mandates the adoption of rules based on subjective classifications vaguely described as "gaps" or "conflicts" (Component 3a) and similarly subjective concepts of health and safety (component 3b*). Although the rules which fall into these categories are often important, it is disturbing that the NRC continues to feel compelled to micro-manage state programs despite the experience and broader authority of Agreement States Programs. The implementation plan as well as the policy statement appear to continue the policies of the past in the wrong direction, and should be revised.

Additional comments can be summarized as follows:

1) The language on flexibility is misleading, indicating in some areas room for a state to maneuver within the limitations of its legislative and rule-making process, but in other sections saying the opposite. For instance, the use of legally binding requirements (LBR's) as a means of fulfilling the compatibility requirements implies some flexibility for adopting rules. However section (D) of Part IV instructs states to use regulations rather than an alternative LBR following the guidance in that section. The guidance criteria in section (D) would indicate that nearly all compatibility rules would require regulations; in effect the idea of alternatives to regulations is not really an option.

2) Components 3.a. and 3.b.* make sense as a concept; clearly there are certain common issues all states need to be aware of. However *requiring* states to adopt certain methods of regulation ventures into micro-management of state programs

1/0

2 University Place, Albany, NY 12203 518/458-6485 FAX 518/458-6434

often based on poorly reasoned concepts and one agency's opinions of what actions are effective and necessary as regulations.

-Component 3.b.* should be separated as items for the Agreement States' information only; no adoption as written is necessary. It would be the Agreement States' decision as to how to implement, or whether to implement those rules.

-Component 3.a. should be reconsidered and only those items that clearly result in duplication retained. The broadly described "undesirable consequences", "conflicts" and "gaps" described in Part II, Section (B) for Component 3.a. has allowed this to become the designated component for all the detailed rules that are not truly necessary *for compatibility purposes*, and could not rightfully be designated in Components 1 or 2. If a rule cannot be classified under Component 1 or Component 2 then it is not appropriate to create additional categories to make room.

3) Some of the items included are much too detailed for inclusion in a national policy. This includes details of package receipt, the definition of "person" (Part 20), definitions of prescribed dosage and written directive, the quality management plan, release of patients (Part 35), and broad radiation safety officer details (§ 30.21 as 3.b.*). The assignment of compatibility or adequacy seems to have neglected to remember that not all rules are mutually exclusive, and shortcomings are often addressed by other broader requirements and specifically through licensing actions.

In addition to the above comments, we urge you to consider the changes to the Adequacy and Compatibility Policy Statement adopted by Organization of Agreement States at the All Agreement State meeting earlier this year. If you have any questions, or need additional information, please contact me.

Sincerely,

Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

2 University Place, Albany, NY 12203 518/458-6485 FAX 518/458-6434

DCD(SP05) RHB2 PHL SCD CHM

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Office of Public Health II University Place Albany, New York 12203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

December 9, 1996

Richard Bangart
Director, Office of State Programs
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bangart:

This letter is in reference to the Report of the Joint NRC-Agreement State Working Group for Development of Implementing Procedures for the Final Policy Statement on Adequacy and Compatibility of Agreement State Programs.

The implementing procedures for compatibility go beyond what is described in the policy statement and continue to impose detailed NRC regulations on Agreement State licensees. Further, we are concerned over the policy itself which mandates the adoption of rules based on subjective classifications vaguely described as "gaps" or "conflicts" (Component 3a) and similarly subjective concepts of health and safety (component 3b*). Although the rules which fall into these categories are often important, it is disturbing that the NRC continues to feel compelled to micro-manage state programs despite the experience and broader authority of Agreement States Programs. The implementation plan as well as the policy statement appear to continue the policies of the past in the wrong direction, and should be revised.

Additional comments can be summarized as follows:

1) The language on flexibility is misleading, indicating in some areas room for a state to maneuver within the limitations of its legislative and rule-making process, but in other sections saying the opposite. For instance, the use of legally binding requirements (LBR's) as a means of fulfilling the compatibility requirements implies some flexibility for adopting rules. However section (D) of Part IV instructs states to use regulations rather than an alternative LBR following the guidance in that section. The guidance criteria in section (D) would indicate that nearly all compatibility rules would require regulations; in effect the idea of alternatives to regulations is not really an option.

2) Components 3.a. and 3.b.* make sense as a concept; clearly there are certain common issues all states need to be aware of. However *requiring* states to adopt certain methods of regulation ventures into micro-management of state programs

2 University Place, Albany, NY 12203 518/458-6485 FAX 518/458-6434

50

SP-C-6
Cross-Ref. Copy SP-AB-20-2

often based on poorly reasoned concepts and one agency's opinions of what actions are effective and necessary as regulations.

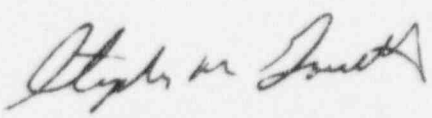
-Component 3.b.* should be separated as items for the Agreement States' information only; no adoption as written is necessary. It would be the Agreement States' decision as to how to implement, or whether to implement those rules.

-Component 3.a. should be reconsidered and only those items that clearly result in duplication retained. The broadly described "undesirable consequences", "conflicts" and "gaps" described in Part II, Section (B) for Component 3.a. has allowed this to become the designated component for all the detailed rules that are not truly necessary *for compatibility purposes*, and could not rightfully be designated in Components 1 or 2. If a rule cannot be classified under Component 1 or Component 2 then it is not appropriate to create additional categories to make room.

3) Some of the items included are much too detailed for inclusion in a national policy. This includes details of package receipt, the definition of "person" (Part 20), definitions of prescribed dosage and written directive, the quality management plan, release of patients (Part 35), and broad radiation safety officer details (§ 30.21 as 3.b.*). The assignment of compatibility or adequacy seems to have neglected to remember that not all rules are mutually exclusive, and shortcomings are often addressed by other broader requirements and specifically through licensing actions.

In addition to the above comments, we urge you to consider the changes to the Adequacy and Compatibility Policy Statement adopted by Organization of Agreement States at the All Agreement State meeting earlier this year. If you have any questions, or need additional information, please contact me.

Sincerely,



Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

2 University Place, Albany, NY 12203 518/458-6485 FAX 518/458-6434