May 2, 2002

Mr. Kirksey E. Whatley, Director
Office of Radiation Control
Alabama Department of Public Health
201 Monroe Street, P.O. Box 303017
Montgomery, AL 36130-3017

Dear Mr. Whatley:

This letter is in response to your April 10, 2000 e-mail message commenting on the revision of 10 CFR Part 35. Your comments and concerns, regarding the compatibility Category B designation for training and experience (T&E) requirements, were forwarded to the Commission at that time. We regret the delay in formally responding to your e-mail. This response coincides with the Commission's recent approval of the revised Part 35 final rule and its transmittal to the Federal Register (FR) for publication. We note that your comments are consistent with other comments regarding compatibility designations received throughout the rulemaking process. These comments were also shared with the Commission and discussed publicly. Any issues of a health and safety nature with respect to the T&E requirements and their compatibility category as identified in these comments are adequately addressed in the FR Notice for the revised rule.

Based on our interpretation of the specific comments you raised in your e-mail message, we offer the following responses for your consideration:

1. Rationale for change in compatibility Category from C to B for the T&E requirements in Part 35.

The assignment of compatibility categories to program elements and regulations is complex, and is made with a great deal of thought in accordance with our procedures. The assignment of compatibility categories to each requirement in the revised rule was made in accordance with the Nuclear Regulatory Commission's (NRC) 1997 Policy Statement on Adequacy and Compatibility of Agreement State Programs (the Policy) and our implementing procedures in Management Directive 5.9. Compatibility categories are needed to ensure that byproduct material is used with at least a minimum level of safety nationwide; to address areas having transboundary implications; and to avoid conflict, duplication, gaps or other condition that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. Those program elements (including regulations) which are not required for compatibility, as noted in the Policy, may be required because of their health and safety (H&S) significance. The staff reviewed and revised, where appropriate, the compatibility categories for each requirement in the final rule. Each requirement has an accompanying rationale explaining its H&S significance or its need based on compatibility between NRC and Agreement State programs.

We do not agree that the Abnormal Occurrence Reports (AOR) support the need for more training for authorized users of Sodium Iodide-131. It should be recognized, that based on a review of AOR data, the majority of Sodium Iodide-131 medical misadministrations occur in hospitals where physicians typically exceed minimum T&E requirements versus freestanding facilities or private offices where physicians meet minimum T&E requirements. The historic AOR data does not support, based on health and safety considerations including the low probability of such events, an increase in T&E requirements for these or any other category of authorized user. After careful consideration of this complex issue, the Commission arrived at a consensus that, in its judgment, there is a greater benefit to uniformity and consistency, nationwide, in applying compatibility Category B rather than Category C to Agreement State T&E requirements.

On balance, the Commission determined that T&E requirements represent significant trans-boundary issues that have direct and significant effects in multiple jurisdictions. Therefore, the Commission followed the 1997 Policy in determining that compatibility Category B is more appropriate than Category C for the T&E requirements in Part 35 to ensure consistency between NRC and the Agreement States. State action to adopt more restrictive T&E requirements could create nonuniformity and inconsistency in the provision of medical services across State boundaries and result in increased costs to the national health care delivery system. This is true, not just for nuclear medicine licensees, but for all authorized users of byproduct material in Part 35.

2. Risks associated with Sodium Iodide-131.

In writing a risk-informed, performance-based regulation, the staff considered misadministration and abnormal occurrence report data along with the potential health impacts associated with Sodium Iodide-131 administration errors and could not justify increasing the T&E requirements on a health and safety basis, nor based on past performance. The NRC's Advisory Committee on Medical Use of Isotopes (ACMUI) agreed with this finding. Abnormal Occurrence Reports for Fiscal Years 1992 - 1999 were reviewed, and 29 reports involving therapeutic amounts of Sodium Iodide-131 were identified. These events occurred at 26 hospitals and 3 imaging centers. The fact that Sodium Iodide-131 misadministrations are the most frequent type of reported misadministration primarily reflects the greater frequency of Sodium Iodide-131 diagnostic and therapeutic administrations compared to other events that could lead to misadministrations. Currently, most administration errors in diagnostic nuclear medicine including Sodium Iodide-131, do not meet the reporting threshold.

3. Can Alabama be more restrictive than NRC?

NRC program elements or regulations identified as compatibility Category "B" do not provide flexibility for Agreement States to be more restrictive. Therefore, your regulations must be essentially identical to Part 35 so that there are consistent T&E requirements for the medical use of byproduct materials.

We appreciate your interest in these matters.

Sincerely,

/RA Josephine M. Piccone Acting for/
Paul H. Lohaus, Director
Office of State and Tribal Programs

cc: T. E. Hill, Georgia
D. K. Walter, Alabama

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