

August 28, 2007

Michael Ford, CHP, Chair
Texas Radiation Advisory Board
1100 West 49th Street
Austin, Texas 78756

Dear Mr. Ford:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter to Chairman Klein dated June 11, 2007, the Texas Department of State Health Services' (DSHS) letter to Chairman Klein dated April 26, 2007, and the conference call between you and NRC staff on July 13, 2007, regarding the Texas Radiation Advisory Board's (TRAB) concern over the changes to the training and experience (T&E) requirements in 10 CFR Part 35. Specifically, in your letter of June 11, 2007, you state that the TRAB is concerned with: (1) the relaxation of the rigor associated with the 80 hours of classroom and laboratory training; and (2) the assigned compatibility that accompanies this change. You also state that, "the TRAB is officially requesting that the NRC allow the State of Texas to maintain its existing and more stringent standard in the interest of patient and public safety." During the July 13, 2007, conference call, you stated that the TRAB believes that there is some latitude in the NRC's 1997 Principles and Policy Statement for the Agreement State Program and Policy Statement on Adequacy and Compatibility of Agreement State Programs (the "Policy Statements") that would allow the Texas DSHS to have stricter T&E requirements than what the NRC requires. You also stated that your letter of June 11, 2007, was not intended to be handled as a petition for rulemaking.

The above referenced letters and your comments from the July 13, 2007, conference call were given careful consideration. Based on a thorough review of the Statements of Consideration that support the 2002 and 2005 Part 35 rulemakings and the Policy Statements, we have concluded that the Policy Statements do not allow Agreement States the latitude to have more stringent requirements for program elements that are designated Compatibility Category B.

In the revision to 10 CFR Part 35 published on April 24, 2002 (67 FR 20250), the T&E requirements were designated as Compatibility Category B, which requires that an Agreement State adopt program elements essentially identical to those of NRC. While the Policy Statements state that the Commission will limit Category B to a small number of program elements that have significant transboundary implications, the staff recommended and the Commission decided, during the promulgation of the 2002 revision to 10 CFR Part 35, that the T&E requirements fall into this category of having "significant transboundary implications" because these regulations that ensure the safe use of byproduct material have direct and significant effect in multiple jurisdictions. The designation of Compatibility Category B is intended to establish uniformity regarding radiation safety requirements and ensure consistency of requirements for T&E among Agreement States and between the NRC and Agreement States.

On March 30, 2005, the NRC published the final rule in the *Federal Register* (70 FR 16336) amending Part 35 to modify T&E requirements, which became effective on April 29, 2005. The principal changes in the final rule revised the criteria that medical specialty certification boards must meet for their certification process to be recognized by NRC or Agreement States. The rule also included additional revisions to other training and attestation requirements. The NRC's designation of Compatibility Category B of the T&E requirements remained unchanged in the 2005 revision to the T&E regulations.

The promulgation of regulations at the NRC is a participatory process directly involving the Agreement States. NRC provides Agreement States with early and substantive involvement in the development of new regulations and policy. The compatibility categories were considered at the time that the rulemaking plan was formulated and were coordinated with the Agreement States. Furthermore, in addition to the normal 75-day public comment period, the Agreement States are always given an early opportunity to review and comment on proposed and final NRC rules prior to publication in the *Federal Register*. In the case of the T&E rule, Agreement State representatives served on both the NRC Working Group and Steering Group that developed the revision to Part 35 and the Agreement States were given a total of 150 days to comment on the proposed and draft final rules.

During both the 2002 and 2005 revisions to the T&E rule, NRC addressed a number of issues relating to your concerns, including: issues raised by the commenters to justify a redesignation of T&E requirements as Compatibility Category C; issues of adequacy of the T&E requirements; and the appropriate amount of T&E required for approval of authorized individuals. After careful consideration of recommendations made by the Advisory Committee on the Medical Uses of Isotopes and the Agreement States, NRC determined that the number of hours in the current T&E requirements ensures the safe use of byproduct material. Further, the NRC decided that the assignment of the specific Compatibility Categories to the requirements in the 2002 revision to the regulations was necessary to assure that byproduct material is used with a uniform level of radiation safety nationwide. Therefore, there was no basis in the 2005 revision to the T&E regulations for redesignating the T&E requirements from Compatibility Category B to Compatibility Category C.

With regard to your belief that there is some latitude in the Policy Statements that would allow the Texas DSHS to have stricter T&E requirements than what the NRC requires, you have highlighted the language in the policy that states that an Agreement State would have the flexibility to design its own program, including incorporating more stringent, or similar, requirements provided that the requirements for adequacy are still met and compatibility is maintained. As explained in the Policy Statements, Section 274 of the Atomic Energy Act requires that Agreement State programs be both "adequate to protect the public health and safety" and "compatible with the Commission's program." These are separate findings, based upon consideration of different objectives. The adequacy component addresses an acceptable level of protection of public health and safety within an Agreement State. Program elements for compatibility focus on the impacts of an Agreement State's regulations to ensure that conflicts, gaps, or disruptive duplication are not created in the collective national effort to regulate materials under the Atomic Energy Act.

The language that you have referenced is referring to a finding of adequacy. However, the compatibility levels assigned to the T&E requirements refer to the Agreement State's compatibility with NRC requirements, and therefore this language is not relevant to that finding.

The Policy Statements note that with the exception of those compatibility areas where all programs should be essentially identical to the extent possible, flexibility in program implementation accommodates individual State preference, State legislative direction and local needs and conditions. However, this flexibility can be provided only if the requirements for adequacy are met and compatibility is maintained.

We appreciate the efforts of TRAB and the Texas DSHS to support our common goal of protecting patients, the public and the health care team. Thank you for your continued interest in this matter.

Sincerely,

/RA/

Luis A. Reyes
Executive Director
for Operations

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