

**Drop-In Visit by Michael Ford, Chair Texas Radiation Advisory Board**

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**Drop In Visit Agenda**  
**July 11, 2008**

10:00 a.m. Mr. Michael Ford, Chair, Texas Radiation Advisory Board, with Chairman Dale Klein

**TOPIC OF DISCUSSION**

- Texas Radiation Advisory Board's (TRAB) concerns regarding 10 CFR Part 35 training and experience rule changes and associated compatibility category

## • **EXECUTIVE SUMMARY**

### Purpose of the meeting

- To discuss the Texas Radiation Advisory Board (TRAB) concerns related to the training and experience (T&E) requirements in 10 CFR Part 35 and the associated compatibility category B designation.

### Issues to be addressed

- TRAB is concerned that the revised T&E requirements associated with the 80 hours of classroom and laboratory training is less stringent than the former requirements and that implementing the revised T&E requirements will increase the risk to patients and staff personnel.
  - Questioning the impact on standard of patient care and public safety
- TRAB is concerned that the assigned compatibility associated with the T&E requirement change has no compelling basis regarding transboundary implications to justify the compatibility category B assignment.
- TRAB questions whether NRC would elevate their Agreement State current status from “monitoring to heightened oversight” if they did not implement the revised T&E requirements (would keep existing more stringent requirements).

### Person to meet

- Michael S. Ford, CHP,  
Texas Radiation Advisory Board Chair

## CURRENT ISSUES

### EXPECTED DISCUSSION TOPICS

#### Adequacy of the revised T&E requirement change

##### Texas Radiation Advisory Board (TRAB) Position:

TRAB is requesting that NRC allow Texas to maintain its current and more stringent T&E requirements in the interest of protecting patient and public safety. TRAB is concerned that the revised T&E requirements are not as rigorous as the previous requirements as specified in 10 CFR Parts 35.390, 35.392, and 35.394, may call into question the “adequacy” of the overall rule with regard to protecting the health and safety of the patient, the public, and the health care team. TRAB believes that lowering a qualification standard based on the absence of data representing patient injuries appears to be incongruent with the historical pattern of NRC regulation and enforcement.

##### NRC Position:

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. 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 10 CFR Part 35 and the Agreement States were given a total of 150 days to comment on the proposed and draft final rules.

During the 2002 and 2005 revisions to the T&E rule, NRC addressed a number of issues related to concerns including: justification of a possible redesignation of T&E requirements as a 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 consideration of recommendations made by the Advisory Committee on the Medical Uses of Isotopes and the Agreement States, NRC determined that the current T&E requirements will ensure the safe medical use of byproduct material.

#### Assigned compatibility that accompanies the T&E requirement change

##### TRAB Position:

TRAB believes that the compatibility category assignment is questionable since there are no compelling transboundary implications resident in these requirements, and the assignment ignores the Commission’s own policy to “...limit this category to a *small number of program elements* (e.g., transportation regulations and sealed source and device registration certificates) that have significant transboundary implications.” (emphasis added, 62 FR 46524)

NRC Position:

The revision to 10 CFR Part 35 published on April 24, 2002 (67 FR 20250), designated the T&E requirements as Compatibility Category B, which requires an Agreement State to adopt requirements essentially identical to those of NRC. The staff recommended and the Commission decided that the revised T&E requirements fall into the category “significant transboundary implications” because regulations that ensure the safe use of byproduct material have direct and significant effect in multiple jurisdictions.

On March 30, 2005, the NRC published final rule (70 FR 16336) amending Part 35 to modify T&E requirements, which became effective on April 29, 2005. 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 Compatibility Category B designation remained unchanged in the 2005 revision.

NRC questioned Mr. Ford if he would like his concerns to be considered as a petition for rulemaking and he declined.

#### Effect on Agreement State status with compliance of more stringent T&E requirements

TRAB Concern:

TRAB is concerned that the NRC will elevate their current “Monitoring” status to “Heightened Oversight” if the Texas Department of State Health Services (DSHS) continued imposing its current T&E requirements. These concerns were expressed in a May 28, 2008, e-mail from Mr. Ford to Mr. Robert Lewis, Director of the Division of Materials Safety and State Agreements.

NRC Position:

Mr. Lewis replied to Mr. Ford’s e-mail via e-mail on May 30, 2008. The response indicated that a State can be placed on Heightened Oversight, at the direction of the Management Review Board (MRB), as a result of an Integrated Materials Performance Evaluation Program (IMPEP) review, periodic meeting, or other information provided to the MRB. This is in accordance with FSME’s State Agreements (SA) Procedure 122, “Heightened Oversight and Monitoring.” A State, however, has never been placed on Heightened Oversight after a periodic meeting that revealed the State is imposing more stringent requirements on its licensees than required based on the Compatibility designation.

The Texas Agreement State Program was put on Heightened Oversight after a periodic meeting in 2005 due to weaknesses identified in status of inspections, response to incidents and allegations, and adoption of compatible regulations. A periodic meeting was held on June 9, 2008, and it is expected that the compatibility finding will not change. However, the program has vastly improved in a number of areas and the MRB has discontinued its period of Heightened Oversight and instituted a period of Monitoring.

Additionally, Kathryn C. Perkins of DSHS submitted a letter, dated June 5, 2008, to Mr. Lewis asking similar questions regarding the status of the program if the rule is not adopted within the applicable three year timeframe.

The NRC's response letter has not been issued yet, but will denote that the NRC staff present at the June 9, 2008 periodic meeting will present the results of the meeting to the MRB at which time the MRB will determine the appropriate level of oversight. NRC staff intends to recommend that NRC monitoring be discontinued.

According to our records, Texas has three regulatory amendments that have not been adopted in final within the 3-year time frame; however, all have been addressed as proposed rules. Although the T&E rule is considered a Compatibility B, the absence of this rule alone would not create an unnecessary gap, conflict, or disruptive duplication. Texas is not the only State that has not adopted the new T&E requirements. The NRC is assured that public health and safety continues to be adequately protected while the State completes its process of adopting a compatible rule.

## **BACKGROUND**

January 16, 2007

- E-mail from Mr. Ford to Dr. Klein indicating TRAB's concerns with the 10 CFR Part 35 T&E requirements. TRAB advised the State to maintain its more stringent requirements despite the Compatibility Category B assignment. E-mail noted that the NRC policy on Adequacy and Compatibility of Agreement State Programs (62 FR 46517) includes several points of relief that would allow the State to have more stringent requirements.

April 26, 2007

- Letter submitted from David L. Lakey, M.D., of DSHS to Dr. Klein (ADAMS Accession ML071770403). Letter indicates that the TRAB unanimously voted against adoption of the 10 CFR Part 35 regulations due to the T&E compatibility requirements. Compatible requirements would have to be made less stringent. Letter indicated that a response was requested from the NRC to Mr. Ford in order for DSHS to make the correct decision on the path forward regarding the rulemaking process.

June 11, 2007

- Letter from Mr. Ford to Dr. Klein (ADAMS Accession ML071700611). Letter formally indicates concerns with (1) relaxation of the rigor associated with the 80 hours of classroom and laboratory training and (2) the assigned compatibility that accompanies the T&E requirement change.

June 12, 2007

- At the Advisory Committee on the Medical Uses of Isotopes Meeting, the TRAB requested that the compatibility category B designation be changed to C. TRAB would like DSHS to continue to have stricter T&E requirements for all physicians authorized to use iodine or other byproduct material in therapeutic applications. TRAB indicated that a non-standard certification or generic training process would result in unknown quality of training and patient care. TRAB notes that there is also a financial impact of non-standardized programs due to the monitoring and review to ensure the quality of T&E. Lastly, TRAB notes that basic science and T&E needs to be through an accredited institution.

June 27, 2007

- NRC letter to DSHS in response to a proposed regulation package sent to NRC for review (ADAMS Accession ML071790041). There were a number of comments made regarding DSHS' equivalent 10 CFR Part 35 regulations. Comments indicated that changes are needed in order to meet the Compatibility B designation.

July 13, 2007

- Conference call between Mr. Ford and NRC staff regarding TRAB's concern over the changes to the 10 CFR Part 35 T&E requirements. Mr. Ford questioned if there might be 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 that would allow DSHS to have stricter T&E requirements.

August 28, 2007

- NRC Letter from Luis A. Reyes to Mr. Ford (ADAMS Accession ML071720032). concluding NRC's Policy Statements do not allow Agreement States the latitude to have more stringent requirements for program elements that are designated Category B.

May 28, 2008

- E-mail to Mr. Lewis from Mr. Ford questioning whether the results of the June 9, 2008, periodic meeting with the State implementing stricter requirements could result in the State being put on "Heightened Oversight."

May 30, 2008

- E-mail response from Mr. Lewis to Mr. Ford's May 28, 2008, e-mail. E-mail stated that the Compatibility Requirements indicator in the IMPEP review considers the State's entire regulations in whole in comparison to the NRC's. Also stated that States are put on Heightened Oversight when a number of issues or weaknesses are identified. The compatibility finding will not be changed as a result of DSHS not yet adopting the final rule.

June 5, 2008

- Letter from Ms. Perkins to Mr. Lewis regarding the status of DSHS if the rule is not adopted within the appropriate three year timeframe (ADAMS Accession ML081750254).



June 9, 2008

- Periodic review of DSHS (ADAMS Accession ML081840367). Dr. Charles Miller, Director of Federal and State Materials and Environmental Management Programs, attended the periodic meeting and discussed the issues relating to the Texas Agreement State status regarding elevating their status from “Monitoring” to “Heightened Oversight” if DSHS continued to implement more stringent T&E requirements.

TBD

- NRC letter to Ms. Perkins from stating that the MRB will determine the appropriate level of oversight for the State; however, the staff will be recommending to the MRB that NRC discontinue their current Monitoring status (ADAMS Accession ML081780136).