EDO Principal Correspondence Control

FROM: DUE: 07/10/07 EDO CONTROL: G20070434
DOC DT: 06/11/07
FINAL REPLY:

Michael S. Ford
Texas Radiation Advisory Board

TO:

Chairman Klein

FOR SIGNATURE OF : ** GRN ** CRC NO: 07-0410

Miller, FSME

DESC:

Changes to Training and Experience Requirements in 10 CFR Part 35 (EDATS: SECY-2007-0207)

ROUTING:

Reyes
Virgilio
Kane
Ash
Ordaz
Cyr/Burns
Mallett, RIV

DATE: 06/18/07

ASSIGNED TO: CONTACT:

FSME Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Ref. G20070299.

EDATS

Electronic Document and Action Tracking System

EDATS Number: SECY-2007-0207 **Initiating Office:** SECY

General Information

Assigned To: FSME
OEDO Due Date: 7/10/2007 5:00 PM
Other Assignees:
SECY Due Date: 7/10/2007 5:00 PM
Subject: Changes to Training and Experience Requirements in 10 CFR Part 35
Description:

CC Routing: Region IV
ADAMS Accession Numbers - Incoming: NONE
Response/Package: NONE

Other Information

Cross Reference Number: G20070434, LTR-07-0410, G20070299, LTR-07-0307
Staff Initiated: NO
Related Task:
Recurring Item: NO
File Routing: EDATS
Agency Lesson Learned: NO

Process Information

Action Type: Letter
Priority: Medium
Sensitivity: None
Signature Level: FSME
Urgency: NO
OEDO Concurrence: NO
OCM Concurrence: NO
OCA Concurrence: NO
Special Instructions: Ref. G20070299

Document Information

Originator Name: Michael S. Ford
Date of Incoming: 6/11/2007
Originating Organization: Texas Radiation Advisory Board
Document Received by SECY Date: 6/15/2007
Addressee: Chairman Klein
Date Response Requested by Originator: NONE
Incoming Task Received: Letter

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Jun 15, 2007 14:10

PAPER NUMBER:	LTR-07-0410	**LOGGING DATE:**	
ACTION OFFICE:	EDO		
AUTHOR:	Michael Ford		
AFFILIATION:	TX		
ADDRESSEE:	Dale Klein		
SUBJECT:	Capability issues on rules--10 CFR Pt 35 --between the NRC and TX Dept of State Health Services		
ACTION:	Direct Reply		
DISTRIBUTION:	RF, SECY to Ack		
LETTER DATE:	06/11/2007		
ACKNOWLEDGED	No		
SPECIAL HANDLING:	Ref: LTR-07-0307 dated 4/26/2007 from M. Ford		
NOTES:			
FILE LOCATION:	ADAMS		
DATE DUE:	07/10/2007	**DATE SIGNED:**	

Texas Radiation Advisory Board

Michael Ford, C.H.P.
Chair

1100 W. 49th Street
Austin, Texas 78756-3189
512/834-6688

June 11, 2007

Dr. Dale E. Klein, Chairman
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland 20852-2378

Dear Chairman Klein:

This letter is a follow-up to an informal email exchange that you and I had in January of this year regarding the Texas Radiation Advisory Board's concern over the changes to the training and experience requirements in 10 CFR 35. At that time, you had indicated that your staff would investigate the matter. In fairness to you and your staff, a formal letter is a more appropriate vehicle to transmit our concerns, and I should have taken that approach from the start.

Specifically, the TRAB is concerned with two changes that we feel unnecessarily weaken the implementation and enforcement of this rule: (1) the relaxation of the rigor associated with the 80 hrs of classroom and laboratory training, and (2) the assigned compatibility category that accompanies this change.

Regarding the changes to the T&E requirements, I will echo the sentiments you expressed recently at the Goizueta Leadership Center on June 5th where you stressed the importance of "highly qualified technical leadership" for nuclear industry executives – they need to understand the consequences of the decisions they make. There should be no less of a standard in medicine, where "highly qualified technical execution" of medical administrations involving radioactive materials should be the ultimate T&E objective.

The Commission's May 24th response to Mr. Charles Rose on the subject of the enforcement of T&E requirements indicates a standard of compliance that could be broadly interpreted, and hence may create varying levels of competence within the medical community. The letter to Mr. Rose essentially states: training course content will not be evaluated by the NRC; preceptor letters will be taken at face value; and even home study courses with no exam or proof of completion will be accepted.

The TRAB maintains a much different position: where the practice of medicine utilizing radioactive materials for therapy may ultimately result in injury and/or death to the patient, the most stringent of training standards should be defined and enforced.

During our April 14th board meeting, the TRAB voted unanimously to *not* recommend proposal of the repeal and new issue of 25 TAC 289.256, "Medical and Veterinary Use of Radioactive Material," which would implement the changes promulgated in 10 CFR 35. The attached basis and justification was developed by Dr. Darlene Metter of the TRAB, approved by Dr. Kim Howard, TRAB Medical Committee Chair, and is provided to more fully explain our position.

The Board's decision to not recommend proposal created a problem within the state of Texas. With the state recently being removed from heightened oversight, the Department of State Health Services is very keen on maintaining *absolute* compatibility with the NRC. The TRAB's recommendation has placed DSHS in a very difficult position in that regard, specifically due to the compatibility category assigned to this change in the regulation (Category B), which requires essentially *verbatim* language.

Somewhat strikingly, assigning the relaxation of the T&E requirements to the Compatibility B category creates two issues: (A) the less rigorous standard may call into question the "adequacy" of the overall rule with regard to the protection of the health and safety of the patient, the public, and the health care team; and (B) the compatibility category assignment is questionable since there are no compelling transboundary implications resident in these requirements, and the assignment ignores the admonition in 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, 62FR46524)

Regarding the latter prerequisite, the NRC has failed to demonstrate that "significant transboundary implications" exist that would trump patient or public safety. Quite simply, they do not exist.

It is difficult to understand a regulatory framework that seeks to lower an existing standard that, to date, has provided an adequate measure of protection for patients, the public and the health care team against a known and demonstrable hazard. This begs the question of why the change was brought about in the first place. During the discussions regarding this regulation, it has been offered that the change is an "elegant solution to a nonexistent problem." It's hard to disagree with that sentiment.

The approach being taken – that is, to lower a qualification standard due to the absence of data representing patient injuries, until, perhaps, data on patient injuries might be manifest – appears completely incongruent with the historical pattern of NRC regulation and enforcement, and I might add Mr. Chairman, completely out of step with your stated vision for the Commission.

To be clear, the NRC's *own policy* on program adequacy and compatibility provides sufficient latitude for the agreement state, with proper justification, to maintain a program that possesses more stringent requirements than what the NRC requires. The TRAB's justification for opposing this change centers principally on the strongly-held belief that the safety of the patient, the public and the health care team **always** trumps "significant transboundary implications" (i.e, interstate commerce").

There is no compelling argument to force an agreement state to adopt a less stringent standard, and in closing, *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.*

I am hopeful that the June 12th teleconference on this issue will bring about meaningful resolution on this matter. If you have any questions regarding the TRAB's position on this matter, please contact me at 806-477-5727, or Dr. Kim Howard at 903-315-2072.

Sincerely,

Michael S. Ford, CHP
Chair

Attachment

CC: Honorable Rick Perry, Governor, State of Texas
Charles Miller, Director, Office of Federal & State Materials & Environmental Management Programs, NRC
Roger Mulder, Texas State Energy Conservation Office
David Lakey, M.D., Commissioner, Texas Department of State Health Services
Kathy Perkins, Assistant Commissioner, Regulatory Services, DSHS
Richard Ratliff, Radiation Program Officer, DSHS
TRAB Members