Texas Radiation Advisory Board

Michael Ford, C.H.P.
Chair

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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.

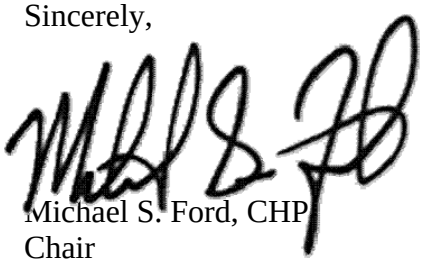
The approach being taken – that is, to lower a qualification standard due to the absence of data representing patient injuries, until, perhaps, data on patient injuries might be manifest – appears completely incongruent with the historical pattern of NRC regulation and enforcement, and I might add Mr.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

TEXAS RADIATION ADVISORY BOARD
Medical Committee

Basis for denial of proposed rule change to
25 TAC 289.256, Medical and Veterinary Use of Radioactive Material (Repeal and Reissue)

Discussion

The training requirements (10 CFR 35.392) for individuals who desire the use I-131 for therapeutic purposes requiring a written directive and who are not engaged in other nuclear medicine procedures are 80 hours of training and experience in addition to oral administration to 3 patients or research subjects of <= 33 mCi (1.22 GBq) of I-131.

The training requirements (10 CFR 35.394) for individuals who desire the use I-131 for therapeutic purposes requiring a written directive and who are not engaged in other nuclear medicine procedures are 80 hours of training and experience in addition to oral administration to 3 patients or research subjects of > 33 mCi (1.22 GBq) of I-131.

This training content includes: radiation physics instrumentation, mathematics pertaining to the use and measurement of radioactivity, radiation biology and protection (biological effects of ionizing radiation, means of reducing radiation exposure, calculation of the radiation dose, evaluation of radiation overexposure, medical management of persons overexposed to ionizing radiation, management and disposal of radioactive substances, and establishment of radiation safety programs in accordance with federal and state regulations), and radiopharmaceutical chemistry of byproduct material for medical use.

The required supervised work experience is to be under an authorized user (who satisfies the NRC training and experience requirements of 10 CFR 35.390, 35.392 or 35.394) in ordering, receiving and unpacking radioactive material safely, perform related radiation surveys pertaining to the shipping of radioactive materials, performing quality control procedures on instruments used to determined the activity of dosages, performing checks for the proper operation of survey meters, calculating, measuring and safely preparing patient subject dosages, using administrative controls to prevent a medical event involving the use of unsealed byproduct material, using procedures to contain spilled byproduct material safely and using proper decontamination procedures, calculating, measuring and safely administering radio therapeutic agents, examining patients and reviewing their case histories to determine their suitability for radionuclide therapy, limitations, or contraindications, collaboration with the authorized user in the interpretation of radioisotope results, patient follow-up, and written attestation from a preceptor authorized user (who satisfies the NRC training and experience requirements of 10 CFR 35.390, 35.390, 35.392 or 35.394) regarding the individual's ability to practice competently and independently for the targeted radiotherapy.

At the present time this training and experience needs to be obtained in an ACGME- or COPT-AOA- accredited medical teaching institution. Proof of alternative training that includes the topic and hours listed may be accepted on a case-by-case basis if the agency, after providing the Medical Committee of the Texas Radiation Advisory Board with the opportunity to review and comment, determines that the alternative training would give an equal or greater level of training to the current standards.

The current standards of ACGME or COPT-AOA- accreditation assures a certain quality standard of training, which is routinely reassessed by the accrediting organizations and annually validated through the board certification process. Yearly national in-service training examinations also assist in this validation process.

Of critical significance is that the training and experience being requested is focused on treatment or the therapeutic (and not diagnostic) use of radioiodine. Iodine-131 is the most dangerous radiopharmaceutical routinely used in nuclear medicine. Proper training and experience with this agent is crucial for the safety of the patient, public and health care team. Hence, a high priority on appropriate training and experience is mandatory and needs to be proven equal to or of a higher level of training than the current standard. As noted above, this latter situation can be reviewed by the Medical Committee of the Texas Radiation Advisory Board on a case-by-case basis.

Specific Concerns

1. Major impact on standard of patient care and public safety

Current practice: ACGME sets and monitors training requirements maintaining a tight relationship with board certification requirements, the authorized user/preceptor has followed their students over time (1-4 years) and can testify to the successful incorporation of the T&E so that the student is able to understand and perform I-131 therapies in a safe, competent and independent manner

Result: Ensuring a quality standard for patient care at the accreditation and training levels

Proposed practice: Allow certification via a non-standardized generic training process (< 10-day, one-time course)

Result: Unknown quality of training received; the proposed course is a brief passive presentation to an unknown audience, the course administrators are not able or are very limited in their ability to verify incorporation of the presented T&E to ensure that the student is able to perform I-131 therapies in a safe, competent and independent manner, resulting in a questionable quality of future patient care and the likelihood of lowering the T&E standards; inability to confirm fulfillment of training (.i.e., any self appointed organization can provide the T&E in whatever mode they chose without regulation or supervision and provide a completion certificate)

2. Major inherent difference between therapeutic and diagnostic procedures which amplifies the futility and limited understanding behind this proposal.

Rationale for concern:

a) Basic science training and experience (T&E) are the most important aspects of therapy with I-131. This concept is reinforced by the NRC's strictest T&E for therapeutic I-131 procedures which in turn can only be performed by a qualified authorized user.

b) Diagnostic studies: These are procedures for "imaging and localization" and can be interpreted by non-authorized users as long as there is a qualified authorized user who is responsible and supervises the procedure. The primary (~ 90%) diagnostic radiopharmaceutical is Technetium-99m (short half-life, low energy).

c) Therapeutic studies: These I-131 procedures are for treatment of benign and malignant thyroid disease. I-131 is the most hazardous radiopharmaceutical (long half-life, high energy gamma and beta emission) routinely utilized in nuclear medicine.

If an individual does not place a high priority in their T&E for I-131 therapy, their comprehension of this hazard is in question, and hence a concern should exist regarding their ability to practice this procedure safely, competently, and independently ***and*** in the best interest of the patient, public and health care team.

3. T&E: active and passive learning

Current practice: Emphasis on active and passive learning through standardized accreditation; a structure and process are in place with an outcome measure through standardized training requirements, a cycle of program compliance reviews via individual site visits, and board certification exams.

Proposed practice: A non-standardized passive structure is presented without a process and outcome measure to ensure that the individual can apply the acquired knowledge for I-131 therapy competently and independently.

Concern: Questionable retention of knowledge during 8 consecutive 10 hour lecture days. Studies have demonstrated an optimum of 20% information retention for a 1 hour lecture which markedly decreases over time. A passive lecture does not qualify for training experience which is traditionally an active participatory process. With the Institute of Medicine's reports in 2000 "To Err is Human" and in 2001 "Crossing the Quality Chasm", our patients (the people of Texas) deserve and demand the highest standard of care. In our opinion, the proposed practice does not provide such a standard.

4. Financial impact on the State of Texas

Current Practice: ACGME currently monitors training programs with regular site visits and reviews (~2-5 years). This robust oversight function is difficult to replace from a cost standpoint.

Proposed Practice: A self-appointed organization utilizing a non-standardized process for T&E followed by a completion certificate.

Concern: Monitoring and review processes have NOT been proposed for these non-standardized programs. Who will be responsible for performing this oversight to assure that a program is maintaining a certain performance standard? Who will fund these processes? How often will these review cycles occur? Is there a remediation process and follow up if a program is cited to be below a set performance standard? These processes will add a huge financial burden on the State and people of Texas.

5. **Access to basic science T&E through an accredited institution**

Proposed Practice: Limited access to accredited institutional resources, limited time available for T&E, accredited institutional will not allow non-residents access to their resources.

Concern: A new therapeutic procedure is to be learned. The hazards of I-131 are not innocuous. I also do not know of a training program that will refuse to allow an individual reasonable access to their learning resources. The Graduate Medical Education programs welcome individual physicians who desire additional training. This is offered and occurs in our radiology and nuclear medicine programs through our education division (i.e. clinical preceptorships ranging from a few days to several months).