Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Standing Subcommittee on Training and Experience Requirements

Subcommittee Status Report

September 16, 2016

SubCommittee Members:

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Charge

To periodically review training and experience (T&E) requirements currently in effect making recommendations for changes as warranted.

Background

Beginning in 2014, stakeholders expressed concerns that the 10 CFR 35.396 T&E requirements currently in effect, 700 hours in total, adversely affects patient care by limiting use of parenterally administered alpha and beta emitting radiopharmaceuticals to physicians who complete the requisite 10 CFR 35.390 T&E requirements, thus resulting in a shortage of authorized users (AUs). A subcommittee of the ACMUI, charged with looking into this situation, provided their report on March 10, 2016 and did not find evidence to support these concerns. The subcommittee recommended against changing the T&E requirements currently in effect. The subcommittee also noted that over the nearly fifteen years since these requirements went into effect new radiopharmaceuticals, both diagnostic and therapeutic, have been developed. Furthermore, the educational paradigm has evolved from “experience-based” to “competency-based”. Therefore, the subcommittee recommended, and the ACMUI approved, the creation of a standing subcommittee to periodically review and, when warranted, recommend changes to the T&E requirements.

Standing Subcommittee Focus

Part 35 of the Code of Federal Regulations (CFR) pertains to the medical use of byproduct material. The specific parts of part 35 that will be the initial focus of the subcommittee include:

Subpart D-Unsealed Byproduct Material Written Directive Not Required

35.190 Training for uptake, dilution, and excretion studies.

35.290 Training for imaging and localization studies.

Subpart E- Unsealed Byproduct Material Written Directive Required

35.390 Training for use of unsealed byproduct material for which a written directive is required.

35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).

35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).

35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

Standing Subcommittee Considerations

The standing subcommittee is charged with the responsibility to "periodically review" the T&E requirements. However, what constitutes a reasonable periodic review? Fifteen years is too long an interval, while at the other extreme one year probably is neither a practical nor a useful interval. The subcommittee believes that the T&E requirements should be reviewed at least once every five years, and more frequently if warranted. The subcommittee is not certain how T&E changes in one section of Part 35 will affect T&E requirements in other sections. The subcommittee is also uncertain, given the time needed to make changes to Part 35 and the status of the most recent change to Part 35, how quickly any proposed changes to Part 35 T&E requirements can be considered and instituted.

An important issue that the subcommittee will need to address is "competency". In other words, what constitutes satisfactory completion of T&E requirements? Can merely completing a predetermined number of hours of T&E be equated with competency? This is not an issue now because the vast majority of physicians seeking AU status satisfy the T&E requirements by obtaining certification through a Medical Specialty Board whose certification process is recognized by the NRC or an Agreement State. The situation is different, however, for physicians seeking AU status through an alternate pathway. For example, it has been suggested that 80 hours of T&E is sufficient for hematologists/oncologists to

administer one or perhaps two different parenterally administered therapeutic radiopharmaceuticals to patients with malignant diseases. The number of hours aside, how will the consistency and quality of the T&E be assured and how will competency be determined? Would a Medical Specialty Board, or Boards, assume the responsibility for establishing a "curriculum" and administering a "certification examination"? If so, what criteria would the NRC use to recognize the board? How many different categories of therapeutic radiopharmaceuticals can the NRC and Agreement States manage for medical licenses?

Standing Subcommittee Plan

First and foremost, the subcommittee recognizes that any recommendations for or against changes in T&E should be made to ensure that the requirements and provisions in part 35, which "provide for the radiation safety of workers, the general public, patients, and human research subjects" are satisfied, while simultaneously ensuring that patient access to these procedures is not unnecessarily compromised.

The subcommittee intends to begin:

A thorough review of T&E requirements in CFR sub parts D (35.190, 35.290), and E (35.390, 35.392, 35.394, 35.396);

To make recommendations for/against changes in these T&E requirements for presentation at the Spring 2017 ACMUI meeting.

The subcommittee

Welcomes stake holder and NRC input throughout the process;

Asks the full ACMUI for suggestions on how to improve the subcommittee's considerations and plan.

Requests that the Medical Team appoint an NRC contact to assist the subcommittee in its work.