Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee on Training and Experience Requirements for All Modalities

Subcommittee Draft Interim Report

February 19, 2018

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Charge

The specific charge of this subcommittee is to periodically review the training and experience requirements (T&E) currently in effect for all modalities, which includes both unsealed byproduct materials (10 CFR 35.100, 35.200, 35.300, & 35.1000) and sealed byproduct materials (10 CFR 35.400, 35.500, 35.600, & 35.1000) and to make recommendations for changes as needed.

Guiding principle

The subcommittee recognizes that any recommendations for or against changes in T&E should 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.

Background

In June 2015, as a result of concerns expressed by various stakeholders, a subcommittee was formed to determine if the 700 hour training requirement placed a hardship on patient access to alpha and beta emitting therapeutic radiopharmaceuticals and if necessary, to make recommendations for potential changes and establish recommendations for the total number of hours of Training & Experience for Use of Unsealed Byproduct Material for Which a Written Directive is Required (10 CFR 35.390). Based on its investigation, the subcommittee concluded

that the current requirement of 700 hours for authorized users (AUs) does not adversely affect patient access to these radiopharmaceuticals and that no change in the T&E requirements was warranted. The subcommittee did note, however, that nearly 15 years had passed since the requirements had been updated and recommended that the ACMUI form a subcommittee to periodically review the T&E requirements for all modalities currently in effect and to make recommendations for changes as needed. The ACMUI accepted this recommendation and the Subcommittee on Training and Experience Requirements for All Modalities was formed. The subcommittee developed a procedure for review of the T&E requirements and in order to optimize the review process the plan was to begin with 10 CFR 35.100, followed by 35.200, 35.300, etc. Due to ongoing concerns about patient access, however, the subcommittee was directed to prioritize the review of the Training & Experience Requirements for Use of Unsealed Byproduct Material for which a written directive is required. (10 CFR 35.390)

Current Status

There have been two developments since the ACMUI recommended against changing T&E requirements under 10 CFR 35.390. On January 26, 2018 the USFDA approved lutetium-177 dotatate for treatment of certain neuroendocrine tumors given the encouraging results obtained with this agent in clinical trials. In contrast to other therapeutic radiopharmaceuticals which have been approved for very specific situations/indications, such as when other treatments have failed, the indications for lutetium-177 dotatate are much broader: treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults (NDA 208700 Approval Letter). Given the excellent results obtained with lutetium-177 dotatate in clinical trials, the broad indications for its use, and the fact that neuroendocrine tumors are the second most common gastrointestinal tumor, it is likely that there will be considerable demand for this agent.

In another interim development, the subcommittee notes, with some concern, the precipitous decrease in the number of first time candidates sitting for the Certification Examination of the American Board of Nuclear Medicine; in 2016 fewer than 50 individuals sat for this examination, in contrast to 80-100 individuals in the past. Furthermore, a review of the Accreditation Council for Graduate Medical Education data base shows a steady decline over the past decade in both the number of Nuclear Medicine Residency Programs and the number of residents enrolled in those programs: from 57 programs with 161 residents in academic year 2007-2008 to 41 programs with 75 residents in academic year 2017-2018. While it is difficult to judge the impact of this decline on patient access, the numerous letters that have been written, and the discussions and presentations on this topic that have taken place over the past few years have focused on whether or not there is a sufficient number of AUs; no data have been

offered to suggest there is a surplus, nor have future needs been addressed. Thus the subcommittee views the decrease in the number of nuclear medicine physicians as a potentially serious problem, perhaps not immediately, but certainly in the future.

In view of the potential problems in patient access that could be created by an increase in the number of procedures combined with a decrease in the number of AUs, the subcommittee believes that it is time to reconsider the creation of an alternative pathway for AUs for 10 CFR 35.390, "Training for Use of Unsealed Byproduct Material for Which a Written Directive is Required." While the requirements of an alternative pathway are beyond the scope of this interim report, the subcommittee offers the following items for consideration: the length and scope of the training, the minimum number of administrations that an individual must perform and whether a total number is sufficient or a specific number per class (alpha and beta), written certification versus formal examination, and maintenance of competence.

The subcommittee welcomes comments and suggestions.