

April 28, 2016

The Honorable Joseph J. Heck
United States House of Representatives
Washington, DC 20515

Dear Congressman Heck:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of April 1, 2016, to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), Subcommittee on Training and Experience (T&E) Requirements for Alpha and Beta Emitters. Your letter outlined several concerns with these training requirements.

ACMUI members are not full-time NRC employees; rather they are special government employees who work periodically and as needed, reporting their recommendations directly to NRC staff. In order to be responsive, I am replying to your letter, providing information based solely upon the outcomes of ACMUI discussions during the March 10, 2016, ACMUI public meeting on T&E requirements for alpha and beta emitters. NRC staff will share your letter and our response with the ACMUI.

I have been assured that the ACMUI subcommittee reviewed your January 5, 2016, letter prior to drafting its report that recommended maintaining the current 700 hour T&E requirements. The full ACMUI also reviewed your letter prior to the March 10 meeting, where it discussed the subcommittee report. The full committee also reviewed correspondence from other interested parties and took into consideration comments from members of the public and other health care professionals during the meeting.

In its report, the subcommittee found that it could not conclude that the T&E requirement was the sole or principal cause of the decreased use of these radiopharmaceuticals containing alpha and beta emitters. In addition, the safety ramifications of a change in this requirement are potentially significant, and thus the subcommittee recommended no changes to the T&E requirement. The subcommittee also recognized the need for a thorough review of the current T&E requirements, on the basis that it has been nearly 15 years since the current requirements were established. Since that time, new radiopharmaceuticals have been introduced and will continue to be introduced, and the educational paradigm has shifted away from prescriptive curricula (i.e., a specific number of classroom hours) to competency-based education (i.e., learning concrete skills). The subcommittee's other recommendation in the report was for the ACMUI to establish a standing subcommittee with the specific charge of periodically reviewing the radiopharmaceutical T&E requirements and making recommendations for changes, as warranted.

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One member of the ACMUI, a patients' rights advocate, submitted a differing opinion in which she disagreed that the current requirements do not create some barriers to patient access to care. Ultimately, the full committee, including the patients' rights advocate, voted unanimously to accept the subcommittee's report.

If you need any additional information, please contact me or Eugene Dacus, Director of the Office of Congressional Affairs, at (301) 415-1776.

Sincerely,

/RA/

Victor M. McCree

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/RA/

Victor M. McCree

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