Via Electronic Submission

March 8, 2016

Advisory Committee on the Medical Use of Isotopes (ACMUI)
Subcommittee on Training and Experience for Alpha and Beta Emitters
c/o Sophie Holiday
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: ACMUI Report on Training & Experience For Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390

Dear ACMUI Committee Members:

Bayer Corporation LLC ("Bayer") appreciates the opportunity provided by the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) to submit comments on your Draft Report on Training & Experience for Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390. Bayer has more than 12,000 employees across the United States and is a world-class innovation company with more than 150 years of experience researching and developing new pharmaceuticals and medical devices. We focus our efforts where we can have the most beneficial impact on the lives of those who depend on our innovative products. Our mission is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

Christopher Leahy
Vice President
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On the basis of this long experience, Bayer wishes to share its perspective on your report.

In brief, we remain concerned that the requirement of 700 hours of Training and Experience for medical oncologists and urologists to become an authorized user of alpha and beta emitters is excessive and may have a detrimental impact on patient access to treatment in the community setting. In the case of our alpha-emitting product, Xofigo® (radium Ra 223 dichloride injection), is prepared by a centralized radiopharmacy, CardinalHealth Nuclear Pharmacy Service, and shipped to hospitals , physician offices and other treatment facilities as a patient-ready dose, personalized to individual patients and the expected treatment date and time of administration. Xofigo is administered by slow intravenous injection over one minute.

Given the relative safety of alpha and beta- emitting radiopharmaceuticals from a handling perspective on the part of the physician, we support a more focused approach to training. As such, we are supportive of recommendations submitted by the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR).[1]

As noted in the dissenting opinion of your report, we are also concerned about the logistical barriers that may exist for rural and community-based physicians that may see benefit in using an alpha- product for the treatment of their patients.[2] While patients may technically have access to treatment at major medical centers, the distance that patients must travel to reach an authorized treatment facility may impose an undue hardship on patients with severe and painful medical conditions making the journey difficult if not impossible. Thus, efforts to help improve access to these types of therapies are essential for ensuring adequate access for appropriate patient care, particularly when a more efficient training and experience approach for providers will achieve the desired outcomes for the necessary handling of alpha- and beta- emitting radiopharmaceuticals.

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Bayer appreciates NRC's ACMUI's consideration of our input and looks forward to working with ACMUI in the future to improve access to quality, affordable healthcare coverage.

Sincerely,

Christopher Leahy
Vice President
Head of Government Relations
and Policy
Bayer Corporation

[1] Guastella MJ. Letter to the ACMUI "Re: NRC Training and Experience Requirements for Alph- and Beta- Emitters." February 23, 2016.
[2] ACMUI Sub-Committee Draft Report on Training & Experience for Authorized Users of Alpha and Beta Emitters under 1- CFR 35.390. Submitted on March 10, 2016.