



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001**

December 4, 2019

MEMORANDUM TO: Christian Einberg, Chief
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

FROM: Sarah L. Lopas, Project Manager */RA/*
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT: SUMMARY OF NOVEMBER 4, 2019, CLOSED MEETING BETWEEN
THE U.S. NUCLEAR REGULATORY COMMISSION AND BAYER
HEALTHCARE REGARDING RADIONUCLIDE THERAPIES

On November 4, 2019, U.S. Nuclear Regulatory Commission (NRC) staff met with Bayer Healthcare (Bayer) staff during a closed meeting at NRC headquarters in Rockville, Maryland. The purpose of the closed meeting was for Bayer to present proprietary information related to their targeted radionuclide therapies, including market research, radiation safety training, and emerging technologies. Bayer discussed their recent market research data on patient access barriers to one of its radiopharmaceuticals, Xofigo® (radium-223). This data was updated from a similar set of data Bayer provided to the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in July 2018 (this data can be found on page 58 of the ACMUI's September 2018 public teleconference transcript, which is available at Agencywide Documents Access and Management System [ADAMS] Accession No. ML18221A170). Bayer's discussion highlighted the availability of nuclear medicine physicians and patients' unwillingness to travel for treatments. Bayer provided an overview of its proprietary radiation safety training program for physicians using Xofigo®, as well as an update on research and development efforts in its targeted radionuclide therapy portfolio.

The enclosure lists the closed meeting attendees, including one representative from the U.S. Food and Drug Administration. No written materials were prepared or distributed by the NRC staff for this meeting.

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DATE: December 4, 2019

ENCLOSURE:
As stated

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***via email**

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DATE	12/4/19	12/4/19	

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THE U.S. NUCLEAR REGULATORY COMMISSION (NRC) AND BAYER
HEALTHCARE REGARDING RADIONUCLIDE THERAPIES**

November 4, 2019

Meeting Participants

Name	Affiliation
Chris Einberg	U.S. NRC, Office of Nuclear Material Safety and Safeguards, Division of Materials Safety, Security, State, and Tribal Programs, Medical Safety and Events Assessment Branch (NRC/NMSS/MSST/MSEB)
Lisa Dimmick	NRC/NMSS/MSST/MSEB
Maryann Ayoade	NRC/NMSS/MSST/MSEB
Donna-Beth Howe	NRC/NMSS/MSST/MSEB
Sarah Lopas	NRC/NMSS/MSST/MSEB
Kellee Jamerson	NRC/NMSS/MSST/MSEB
Libero Marzella	U.S. Food and Drug Administration, Office of Drug Evaluation IV
William Goeckeler	Bayer Healthcare
Shaemus Gleason	Bayer Healthcare
Ashley Cockerham	Mercurie Consulting

Enclosure