

February 6, 2012

Christian Einberg
Chief, Radioactive Materials Safety Branch
Office of Federal and State Materials and
Environmental Management Programs
United States Nuclear Regulatory Commission
Mail Stop: T-8E24
Washington, DC 20555-0001

RE: Training Requirements for Radium-223

Dear Mr. Einberg:

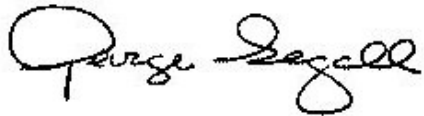
The SNM is an international scientific and professional organization founded in 1954 to promote the science, technology and practical application of nuclear medicine. Its 17,000 members are physicians, technologists and scientists specializing in the research and practice of nuclear medicine. In addition to publishing journals, newsletters and books, the Society also sponsors international meetings and workshops designed to increase the competencies of nuclear medicine practitioners and to promote new advances in the science of nuclear medicine.

We recently had a meeting with the representatives of Bayer Corporation who informed us about their scheduled meeting with NRC staff in mid February to discuss the training requirements for Radium-223 Chloride therapy for advanced prostate carcinoma involving skeleton. We were informed by Bayer that this radiopharmaceutical is currently under fast-track FDA approval process.

I would like to express the position of Society of Nuclear Medicine. We believe that the diplomates of American Board of Nuclear Medicine have the core knowledge necessary to safely administer therapeutic doses of all unsealed radioactive sources regardless of their mode of decay. The safe handling of this agent would not be substantially different than that for other radioactive parenteral therapeutic agents currently being administered. Additional training requirements for ABNM diplomates for therapeutic radiopharmaceuticals based on their mode of decay would adversely affect patient care since it would limit patient access to new therapies.

SNM appreciates the opportunity to provide input to the NRC concerning the training requirements for proper medical use of isotopes. Should you have any questions, please do not hesitate to contact Sue Bunning, Director of Health Policy and Regulatory Affairs, sbunning@snm.org or (703) 326-1182.

Sincerely,

A handwritten signature in black ink that reads "George Segall". The signature is written in a cursive style with a large initial "G" and a long, sweeping underline.

George Segall, MD

President

CC: Michael Fuller
Ashley Cockerham
Fred Fahey, DSc
Gary Dillehay, MD
Munir Ghesani, MD
Virginia Pappas
Sue Bunning