

August 13, 2013

ViewRay Incorporated  
ATTN: Chris A. Raanes  
President and CEO  
2 Thermo Fisher Way  
Oakwood Village, OH 44146

SUBJECT: RECEIPT OF LETTERS DATED APRIL 29, 2013 AND MAY 16, 2013

Dear Mr. Raanes:

I am writing in response to your letters dated April 29, 2013 and May 16, 2013 requesting consideration of the provided information during the development of licensing guidance for the ViewRay™ System for Radiation Therapy (ViewRay™ System).

A joint working group was formed with members from the Agreement States and NRC staff. The Working Group reviewed the information provided in the letters, the Sealed Source and Device Registration information, and various chapters from the ViewRay™ System Operator's Manual. In addition, members from the Working Group requested clarification and additional information from Mr. David Breuning, ViewRay's Radiation Safety Officer throughout the development of the licensing guidance. Based on this information, the Working Group concluded that the existing teletherapy regulations in 10 CFR 35.600 do not align with some of the key features of the ViewRay™ System.

The Working Group confirmed that the ViewRay™ System should be licensed using a customized licensing approach in accordance with 10 CFR 35.1000, "Other Medical Uses of Byproduct Materials or Radiation from Byproduct Materials." 10 CFR 35.1000 was designed to address the needs of emerging medical technologies without having to resort to creating new regulations. The process for creating new regulations is a multi-year process. NRC licenses emerging medical technology in accordance with 10 CFR 35.1000 when either of two conditions is met; the medical device or application cannot conform to all of the regulations in an existing section of 10 CFR Part 35 or when there are additional safety considerations that need to be addressed.

This licensing decision and guidance was shared with Mr. Garth Nobis, Vice President for Regulatory Affairs and Quality Assurance on July 24, 2013. The NRC licensing guidance for the ViewRay™ System (enclosure 1) may also be found online on the NRC Medical Uses Licensee Toolkit, at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

If the NRC becomes aware of future developments or as additional experience is gained related to the medical use of the ViewRay™ System, the NRC staff will consider revising this licensing guidance.

C. Raanes

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A presentation will be given at the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Meeting on September 10, 2013 from 11:00 a.m. to 11:30 a.m. The meeting will be held at NRC Headquarters, at 11545 Rockville Pike, Rockville, MD 20852.

For further information or for questions, please contact Sophie Holiday of my staff at (301) 415-7865 or via e-mail: [sophie.holiday@nrc.gov](mailto:sophie.holiday@nrc.gov).

I want to thank you for the cooperation that your staff has provided my staff and the members of the Working Group throughout this process.

Sincerely,

**/RA PHenderson for/**

Brian J. McDermott, Director  
Division of Material Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
ViewRay™ System Licensing Guidance

C. Raanes

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Sincerely,

Brian J. McDermott, Director  
Division of Material Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosure:  
ViewRay™ System Licensing Guidance

**ML13159A014**

<b>OFC</b>	DMSSA/RMSB	DMSSA/RMSB	DMSSA/RMSB	DMSSA	DMSSA
<b>NAME</b>	SHoliday	MFuller	CEinberg	PHenderson	BJMcDermott
<b>DATE</b>	8/08/2013	8/09/2013	8/09/2013	8/13/2013	8/13/2013

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