

July 26, 2013

MEMORANDUM TO: James W. Clifford, Director
Division of Nuclear Materials Safety
Region I

Anne T. Boland, Director
Division of Nuclear Materials Safety
Region III

Anton Vegel, Director
Division of Nuclear Materials Safety
Region IV

FROM: Brian J. McDermott, Director **/RA Pamela Henderson for/**
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: LICENSING GUIDANCE FOR VIEWRAY™ SYSTEM FOR RADIATION THERAPY

On July 24, 2013, the U.S. Nuclear Regulatory Commission (NRC), in conjunction with the Agreement States through a joint working group, issued licensing guidance for the ViewRay™ System for Radiation Therapy (ViewRay™ System).

The ViewRay™ System is the first real-time image-guided radiation therapy device that will require licensing.

The Agreement States approached the NRC in 2012 to develop licensing guidance for two new radiation therapy devices, the ViewRay™ System and the MASEP® Infini™ stereotactic rotary gamma ray system (MASEP® Infini™ System). A joint working group was formed with members from the Agreement States and NRC staff. The Working Group focused their efforts on the ViewRay™ System initially because Ohio had issued the Sealed Source and Device Registration (SSD) for this device prior to the formation of the Working Group.

CONTACT: Sophie Holiday, MSSA/RMSB
(301) 415-7865

As of the date of this memorandum, the SSD for the MASEP[®] Infini[™] System has not been issued. The Working Group plans to reconvene once the SSD for the MASEP[®] Infini[™] System has been issued.

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." The Working Group concluded that the existing teletherapy regulations in 10 CFR 35.600 did not adequately align with some of the key features of the ViewRay[™] System. 10 CFR 35.1000 was designed to address the needs of emerging medical technologies without having to revert to rulemaking.

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 the licensing guidance.

The licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Enclosure:
ViewRay[™] System Licensing Guidance

As of the date of this memorandum, the SSD for the MASEP[®] Infini[™] System has not been issued. The Working Group plans to reconvene once the SSD for the MASEP[®] Infini[™] System has been issued.

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." The Working Group concluded that the existing teletherapy regulations in 10 CFR 35.600 did not adequately align with some of the key features of the ViewRay[™] System. 10 CFR 35.1000 was designed to address the needs of emerging medical technologies without having to revert to rulemaking.

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 the licensing guidance.

The licensing guidance may also be found on the NRC Medical Uses Licensee Toolkit at <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.

Enclosure:
ViewRay[™] System Licensing Guidance

DISTRIBUTION:
MSSA r/f FSME r/f RidsFsmeOd

ML13159A014

OFC	DMSSA/RMSB	DMSSA/RMSB	DMSSA/RMSB	DMSSA	DMSSA
NAME	SHoliday	MFuller	CEinberg	PHenderson	PHenderson for BJMcDermott
DATE	7/15/13	7/24/13	7/24/13	7/26/13	7/26/13

OFFICIAL RECORD COPY