

26 July 2013

ALL AGREEMENT STATES

NOTIFICATION OF LICENSING GUIDANCE FOR VIEWRAY™ SYSTEM FOR RADIATION THERAPY (FSME-13-071)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC), in conjunction with the Agreement States through a joint working group, has issued licensing guidance for the ViewRay™ System for Radiation Therapy (ViewRay™ System).

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

Discussion: 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. As of the date of this letter, 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>.

FSME-13-071

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If you have any questions regarding this correspondence, please contact me at (301) 415-3340 or the individual named below:

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Enclosure:
ViewRay™ System Licensing Guidance

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| DATE | 07/15/13 | 7/24/13 | 7/24/13 | 7/24/13 | 7/26/13 | 7/26/13 |

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