ViewRay™ System for Radiation Therapy

Licensing Guidance

July 24, 2013, Revision 0

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10 CFR 35.1000 use

The ViewRay™ System for Radiation Therapy (here after the ViewRay™ System) is a radiation therapy device containing three cobalt-60 sources on a rotating gantry assembly, integrated with a Magnetic Resonance Imaging (MRI) system capable of imaging during treatment. It has been engineered such that its components and operation differ significantly from devices regulated in 10 CFR Part 35, Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units." Examples of new features that differentiate the ViewRay™ System from devices regulated in 10 CFR Part 35, Subpart H, include real time image guidance, multi-leaf collimation, and gating. As a result, the ViewRay™ System is regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Licensing Guidance

This guidance represents an acceptable means of complying with regulations that apply to the ViewRay™ System and is not intended to be the only means of satisfying requirements for a license. Therefore, to meet the requirements of 10 CFR 30.33 and 10 CFR 35.12, the applicant must provide the information requested below or may, unless the information is specifically required by regulation, submit alternative commitments for review by the NRC staff to determine whether the regulatory requirements are met. In addition, the commitments incorporated into the applicant's license by license condition will be reviewed during inspections.

Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, L, M and N. In some cases, the requirements for teletherapy and gamma stereotactic radiosurgery units also apply to the ViewRay™ System. However, in other cases departures from the requirements are needed to address the ViewRay™ System's unique features and operations.

General

Sensitive Security Related Information:

Certain sensitive security-related information such as information about quantities and locations of radioactive materials at licensed facilities is no longer released to the public. Submission of this type of information in an application must be marked as specified in Regulatory Issues Summary (RIS) 2005-31, available at:
http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf

Additional information on procedures for handling and marking security-related information and any updates are available at:
http://www.nrc.gov/reading-rm/sensitive-info.html.

Part 37

Applicants requesting authorization for the ViewRay™ System must request issuance of and comply with Increased Control and Fingerprinting Orders (prior to March 19, 2014) and with 10 CFR Part 37 (beginning on March 19, 2014). Applicants must comply with these requirements, including background investigations, access control, and physical protection, before taking possession of sources for this device.

Radionuclides, Form, Possession Limits, and Purpose of Use:

Identify the radionuclides, chemical/physical form, maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request.

Radionuclides, Form, Possession Limits

Authorization 6:	A.	Cobalt -60
	B.	Depleted Uranium
Authorization 7:	A.	Sealed sources (Best Theratronics Ltd. Model C-146)
	B.	Metal
Authorization 8:	A.	15,000 curies per source not to exceed 45,000* curies total (or 68,000 curies during source exchange)
	B.	4500 kilograms

Purpose of Use

Authorization 9:	A.	For 35.1000 medical use in a ViewRay™ System.
	B.	For shielding in a ViewRay™ System.

* The quantities requested require that licensees provide evidence of financial assurance for decommissioning in accordance with 10 CFR 30.35. Refer to NUREG-1757, Volume 3, Revision 1, Appendix A, for guidance on preparing and submitting financial assurance information.

Facility Address and Description [10 CFR 30.33(a)(2) and 10 CFR 35.12(b)(1)]**:**

Provide an address of use and submit a facility diagram and description of the location where the ViewRay™ System will be used or stored. The description should include additional equipment installed to meet the requirements in 10 CFR 35.615 (e.g.,

interlocks) and the shielding calculations including information about the type, thickness, and density of the installed shielding and a description of any beam stops. In addition, confirm that the floor beneath the ViewRay™ System is adequate to support the weight of the device. Refer to NUREG-1556, Volume 9, Revision 2, Section 8.20, for additional information that should be included.

Posting Requirements:

ViewRay™ System is subject to the posting requirements in 10 CFR 20.1902. Because the ViewRay™ System has been engineered such that its components and operation differ significantly from those of a teletherapy unit, the 10 CFR 20.1903(d) posting exemption does not apply.

Authorized Individuals [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(1)]**:**

NRC has determined that individuals meeting the guidance provided below will be considered qualified and authorized for the ViewRay™ System. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that an individual is qualified to be an authorized individual.

Because there were no units of the ViewRay™ System approved for medical use in the United States at the time this licensing guidance was published, there are no preceptors available to sign attestations. Therefore, the NRC is postponing requiring a written attestation until July 24, 2018 (five years after issuance of this guidance). At that time, attestations will be required for individuals who do not hold certification by a recognized specialty board. NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have become available.

Note: The manufacturer of the ViewRay™ System has indicated that training will be provided on-site with the installation of each system.

Identify each **authorized user** (AU) of the ViewRay™ System for Radiation Therapy and provide documentation of his/her training and experience. NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]," or other formats may be used to document this training and experience. The physician will be considered qualified for use of the ViewRay™ System if the licensee demonstrates that the individual meets the following:

1. Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AU for 10 CFR 35.600 medical use of a remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit; or is certified by a recognized medical specialty board listed on NRC's web site under 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic

radiosurgery units," or meets the criteria in 10 CFR 35.690(b)(1) and (2);

AND

2. Has received hands-on training in device operation, safety procedures, and clinical use for the ViewRay™ System. This training requirement may be satisfied by satisfactory completion of a training program provided by the ViewRay™ System vendor for new users or by receiving training supervised by an AU or **authorized medical physicist** (AMP), as appropriate, who is authorized for ViewRay™ System use.

Identify each **AMP** for the ViewRay™ System and provide documentation of his/her training and experience. NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience And Preceptor Attestation [10 CFR 35.51]," or other formats may be used to document this training and experience. The medical physicist shall be considered qualified for use of the ViewRay™ System, if the licensee demonstrates that the individual meets the following:

1. Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License) as an AMP for remote afterloader, teletherapy, or gamma stereotactic radiosurgery use; or is certified by a recognized specialty board listed on NRC's web site under 10 CFR 35.51, "Training for an authorized medical physicist;" or meets the criteria 10 CFR 35.51(b)(1) and (2);

AND

2. Has received hands-on training in device operation, safety procedures, clinical use, and the operation of a treatment planning system for the ViewRay™ System. This training requirement may be satisfied by satisfactorily completing either a training program provided by the ViewRay™ System vendor or by training supervised by an AMP authorized for ViewRay™ System use.

Identify the **Radiation Safety Officer** (RSO) for the ViewRay™ System and provide documentation of his/her training and experience. NRC Form 313A (RSO), "Radiation Safety Officer Training" or other formats may be used to document this training and experience. NRC recognizes that some applicants with new installations may have an individual who will have RSO responsibilities for the ViewRay™ System but may not have access to an operational ViewRay™ System at the time that the individual receives training on the radiation safety, regulatory issues, and emergency procedures. In this case, the individual who will have RSO responsibilities should complete supplemental hands-on radiation safety and emergency procedures training before the first patient treatment. The individual shall be considered qualified to be the RSO for the ViewRay™ System if the individual meets the following:

1. Is listed on a license or permit (NRC, Agreement State, Broad Scope License or NRC Master Materials License), as an RSO for medical use; or is certified by a recognized specialty board listed on NRC's web site under 10 CFR 35.50, "Training for Radiation Safety Officer," or meets the criteria in 10 CFR 35.50(b)(1), 35.50(c)(1), or 35.50(c)(2).

AND

2. Has received training in the radiation safety, regulatory issues, and emergency procedures for the ViewRay™ System. This training requirement may be satisfied by completing training that is provided by the ViewRay™ System vendor or supervised by an individual (RSO or AMP or AU) that is authorized for the ViewRay™ System.

Written Directive:

The ViewRay™ System delivers a therapeutic dose of radiation from byproduct material and under 10 CFR 35.40 requires a written directive. To assure that the dose is delivered in accordance with the AU's direction, the applicant should provide the following commitment:

> "For the ViewRay™ System use, the written directive will contain the patient or human research subject's name; the total dose, dose per fraction, number of fractions; isocenter and gantry angle positions, and treatment site."

When a written directive is needed, licensees are required under 10 CFR 35.41 to have procedures that provide high confidence that each administration is in accordance with the written directive. The applicant should provide the following commitment:

> "For the ViewRay™ System, we will develop, implement and maintain written procedures in accordance with 10 CFR 35.41. These procedures will include, but not be limited to, validation of geometric and dosimetric accuracy of each patient's treatments."

Specific Information on Radiation Safety Precautions and Instructions
[10 CFR 35.12(d)(1)(i)]

The applicant must submit the information required by 10 CFR 35.12(d). The applicant may simplify its submission by confirming the following:

> "For use of the ViewRay unit, we will meet the following requirements in 10 CFR Part 35, Subpart H:
>
> Section 35.600;

Section 35.605 (and retain records of the information described in Section 35.2605 for the retention period stated in Section 35.2605),

Section 35.610 (and retain procedures described in Sections 35.610(a)(4) and (d)(2) for the retention period stated in Section 35.2610),

Section 35.615 (with modifications to 35.615(f)(3) listed below),

Section 35.630 (and retain a copy of the information described in Section 35.2630 for the period stated in Section 35.2630),

Section 35.632 (with modifications listed below and retain a copy of the information described in Section 35.2632 with modifications discussed below for the period stated in Section 35.2632),

Section 35.635 (with modifications listed below and retain a copy of the information described in 35.2632 with the modifications discussed below for the period stated in Section 35.2632);

Section 35.642 (with modifications listed below and retain a copy of the information described in Section 35.2642 with modifications discussed below for the period stated in Section 35.2642),

Section 35.645 (with modifications listed below and retain a copy of the information described in Section 35.2645 with modifications discussed below for the period stated in Section 35.2645);

Section 35.652, and

Section 35.657 (with modifications listed below)."

Because of the ViewRay™ System's unique components and features the applicant should confirm the following:

In lieu of 35.615(f)(3):

"We will have either an Authorized User or Authorized Medical Physicist physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency."

To reflect the unique components and operation of the ViewRay™ System and to incorporate manufacturer's recommendations, the applicant should confirm the following:

"The periodic spot check requirements in 35.642(a) and 35.645(c) and (d) and the full calibration requirements in 35.632(b) and 35.635(b) are modified as follows:

1. We will perform spot checks to assure operation of the following upon each day of use, prior to patient use:

- Electrical interlocks at each room entrance;
- Source exposure indicator lights on the control console and in the facility;
- Radiation monitors used to indicate room exposures;
- Viewing and intercom systems;
- Imaging and treatment coordinate coincidence;
- Emergency off buttons;
- Laser alignment;
- Timer termination; and
- Couch positioning and repositioning.

2. We will perform spot checks to assure proper operation of the following weekly, in accordance with the operator's manual:

- The multi-leaf collimator (MLC) shape in comparison with the expected output; and
- Source positioning and timing.

3. We will perform spot checks to assure proper operation of the following monthly:

- The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b);
- The difference between the measurement made above and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- Emergency timing circuits;
- Timer accuracy and linearity over the range of use;
- On-off error;
- The accuracy of all distance measuring and localization devices in medical use;
- MLC settings versus radiation field for two patterns;
- MLC travel speed;
- Leaf position accuracy;
- Radiation Field MRI coincidence;
- Gantry angle indicator;
- Gating latency;
- Treatment room doors from inside and outside the treatment room;
- Electrically assisted treatment room doors with the unit's electrical power turned off (if applicable);
- Imaging and treatment coordinate coincidence (from multiple points that do not lie on the central axis) and

- Table retraction with the power off.

4. We will perform the following full calibration tests annually:

- Field size dependence of output consistency;
- Central axis depth dose consistency;
- Transmission of table, patient coils, and accessories;
- Output constancy with gantry angle;
- Gantry rotation isocenter;
- Gantry and couch coincidence;
- Couch top sag;
- Vertical table travel;
- MLC transmission;
- The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- The output for the range of field sizes and for the distance used for medical use;
- Leaf position repeatability;
- Dosimetry output calibration constancy;
- Segmental IMRT step-and-shoot test; and
- Coincidence of MRI and Radiation Field.

5. We will also perform the above monthly spot checks and annual full calibration tests before first medical use of the unit and before medical use under the following conditions: (1) Whenever spot check measurements indicate that the output differs by more than 5 percent from the output obtained at the previous monthly test corrected mathematically for radioactive decay; (2) Following replacement of any source or following reinstallation at a new location; (3) Following any repair that includes removal of any source or major repair associated with the source exposure assembly, or (4) Following any repairs or servicing of the MRI that could affect treatment delivery. We will use the results or tolerances specified in the operator's manual for all tests, as applicable."

Published Protocols Accepted by Nationally Recognized Bodies:

Procedures for full calibration measurements required by 10 CFR 35.632(d) and 35.635 (d) and for acceptance testing on treatment planning systems required by 10 CFR 35.657 must be in accordance with published protocols accepted by nationally recognized bodies. However, the ViewRay™ System contains certain components and features that are not addressed in the full calibration procedures or acceptance testing procedures accepted and published by nationally recognized bodies. In this case, the applicant may use procedures developed by the manufacturer.

The applicant should confirm the following:

"We will perform full calibration measurement procedures in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published required full calibration procedures for components and features of the ViewRay™ System. In the absence of published protocols accepted by nationally recognized bodies, we will use procedures developed by the manufacturer or equivalent procedures.

We will perform acceptance testing on treatment planning systems in accordance with published protocols accepted by nationally recognized bodies, except when nationally recognized bodies have not published procedures for acceptance testing on the treatment planning system for the ViewRay™ System. In the absence of published protocols accepted by nationally recognized bodies, we will use procedures developed by the manufacturer, if available, or equivalent procedures."

Full Inspection and Service of the ViewRay™ unit:

Under 10 CFR 35.655, NRC requires an inspection of teletherapy and gamma stereotactic radiosurgery units every five years or at source replacement, whichever comes first. While a number of systems external to the radiation vaults can be inspected and serviced prior to source replacement, areas inside the vaults can only be inspected and serviced in the absence of the sources. Therefore, the full inspection and service of the ViewRay™ System can only be performed at source exchange.

The ViewRay™ System Sealed Source and Device (SS&D) registration sheet requires pressure sensors to be replaced during the full inspection and servicing described in 10 CFR 35.655.

The applicant should confirm the following:

"We will commit to have each ViewRay™ System fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism and other safety components. In addition, we will commit to have the pressure sensors replaced during this inspection and servicing.

This inspection and servicing will only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

We will retain records of information described in Section 35.2655 for the retention period stated in Section 35.2655."

Procedures required by 10 CFR 35.610, 35.642 and 35.645
[10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(2)]

The applicant is required by 10 CFR 35.12(b)(2) to provide the safety procedures and instructions and procedures for spot checks in 10 CFR 35.610, 35.642, and 35.645,

as applicable. For the ViewRay™ System radiation safety program the procedures in 10 CFR 35.610, 35.642 and 35.645 are applicable, including the additional test procedures specified in the section above titled, "Specific Information on Radiation Safety Precautions and Instructions…"

The applicant must provide a copy of its:

Safety procedures and instructions for the ViewRay™ System, and
Periodic spot-check procedures for the ViewRay™ System

Notes to Licensees

Notification for AUs and AMPs

The NRC recognizes that if an AU or AMP satisfies the training and experience listed in the NRC's licensing guidance for the ViewRay™ System and is currently listed on a Commission or Agreement State medical use license or permit for the ViewRay™ System, the AU or AMP should be allowed to work under a different license for the medical use of the ViewRay™ System. A limited specific medical use applicant initially applying for authorization for the medical use of the ViewRay™ System or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU or AMP to work at its facility without the need to request an additional license amendment, provided the following conditions are met:

1) the AU or AMP meets the training and experience criteria listed in NRC's licensing guidance for the ViewRay™ System; and

2) the AU or AMP is currently listed for ViewRay™ System use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and

3) the licensee provides NRC a copy of the license or permit on which the AU or AMP was originally listed for the ViewRay™ System; and

4) the licensee provides documentation to NRC for each AU or AMP of the above listed conditions no later than 30 days after the date that the licensee allows the AU or AMP to work as an AU or AMP for the ViewRay™ System.

Change in Physical Conditions of Use

If the physical conditions of use exceed those reported in the Sealed Source and Device (SS&D) certificate, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Alterations to ViewRay™ Systems

This licensing guidance is based on the SS&D safety evaluation in Registration Sheet OH-1346-D-101-S. Modification of the sources, the device, or the source-device combination will require a new or amended SS&D certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use and safety of the modified ViewRay™ System.

Revisions to Existing ViewRay™ Radiation Safety Programs to Conform to Future Changes in Licensing Guidance

(Note: Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes," to the ViewRay™ System safety program that might otherwise require a license amendment).

The above licensing guidance may be revised as additional experience is gained regarding medical use of the ViewRay™ System. A licensee already authorized to use the ViewRay™ System and committed by license condition to follow the provisions in the guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform to the revised provisions.

An applicant initially applying for authorization for medical use of the ViewRay™ System (or a licensee applying later for an amendment to conform to revisions in this guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

The revision is in compliance with the regulations of the NRC or Agreement State;

The revision is based on the current guidance for the ViewRay™ System 35.1000 use posted on the NRC website;

The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

The affected individuals are instructed on the revised program before the change is implemented;

The licensee will retain a record of each change for 5 years; and

The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee's management representative who reviewed and approved the change.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

Inspection Frequency:

Licenses authorizing ViewRay™ Systems should be inspected every two years. Per Enclosure 1 to Inspection Manual Chapter 2800, licenses authorizing emerging technology in 10 CFR 35.1000 are assigned a Priority 2 inspection code.

Program Code:

NRC regions should use program code 02300.