

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

*Viewray Incorporated  
Temporary job site at Washington University  
in St. Louis*

2. NRC/REGIONAL OFFICE

*Region III  
2443 Warrenville Rd.  
Select a location (Use keyboard arrows to select)...  
Lisle, IL 60532*

REPORT NUMBER(S) *2016-001*

3. DOCKET NUMBER(S)

*030-38654*

4. LICENSE NUMBER(S)

*34-35077-01*

5. DATE(S) OF INSPECTION

*1/27/16*

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	<i>Robert G. Gattone, Jr.</i>	<i>Robert G. Gattone, Jr.</i>	<i>1/27/16</i>
BRANCH CHIEF	<i>Ann T. McCraw</i>	<i>[Signature]</i>	<i>2/3/16</i>

**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Viewray Incorporated Temporary Job Site at Washington University in St. Louis  REPORT NUMBER(S) 2016-001	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S)  030-38654	4. LICENSE NUMBER(S)  34-35077-01	5. DATE(S) OF INSPECTION  January 27, 2016
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6. INSPECTION PROCEDURES USED  87126, 87127	7. INSPECTION FOCUS AREAS  87126: 02.01, .02, .04, & .05; 87137: 03.01, 03.02
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  03226	2. PRIORITY  2	3. LICENSEE CONTACT  David Breuning, RSO	4. TELEPHONE NUMBER  (440) 703-3210
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Main Office Inspection                      Next Inspection Date:           No Change            
 Field Office Inspection \_\_\_\_\_  
 Temporary Job Site Inspection at Washington University in St. Louis

**PROGRAM SCOPE**

The licensee is authorized to: conduct installation, testing, removal, and repair of non-radioactive components of the ViewRay System (System); perform routine and non-routine maintenance of the System; provide customer training and instruction on the System; possess cobalt-60 incident to performance of leak tests on customers' sealed sources as a commercial service; and install and remove System depleted uranium heads. Licensed activities are to be done at temporary job sites in NRC jurisdiction.

**Performance Observations**

The inspector observed licensee employees demonstrate how they had done repairs on a System involving software upgrades, magnet cooling repairs, and source beam adjustments. Specifically, the inspector: (1) observed selected staff don dosimeter badges while conducting licensed activities; (2) observed that survey instruments used by the licensee were appropriate and calibrated as required; (3) conducted a confirmatory survey with an NRC-owned, calibrated instrument that resulted in a maximum of 0.06 milliroentgens per hour near the surface of a System head with the shutter closed and locked, and the licensee's measurement of the same area was similar to the inspector's measurement; (4) noted that licensee staff used time, distance and shielding to reduce their exposure to radiation; (5) noted that a licensee employee conducted area surveys to prevent unnecessary exposure; (6) noted that a licensee employee knew the action level for area surveys and how to respond if the action level is exceeded; and (7) observed a licensee employee demonstrate how he would respond to conflicting radiation exposure indicators.