

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: ViewRay Incorporated 2 Thermo Fisher Way Oakwood Village, Ohio 44146-6536 REPORT NUMBER(S) 2016001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
3. DOCKET NUMBER(S) 030-38654	4. LICENSE NUMBER(S) 34-35077-01	5. DATE(S) OF INSPECTION August 5, 2016

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	Geoffrey M. Warren		8/5/16
BRANCH CHIEF	Aaron T. McCraw	Robert D. Sutton, p. for ATM	8/16/16

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.02, 03.04 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03226	2. PRIORITY 2	3. LICENSEE CONTACT David Bruening, RSO	4. TELEPHONE NUMBER (440) 703-3210
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Main Office Inspection Next Inspection Date: August 5, 2018

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced, inspection at the licensee's corporate office. The licensee was a service provider, authorized to perform installation, testing, removal, repair, maintenance, and customer training on the ViewRay system at temporary job sites in NRC jurisdiction. In addition, the licensee performed leak testing of cobalt-60 sources in the device. The company employed around 80 personnel worldwide, including five field service engineers, two installers, and several training staff who routinely work with licensed materials. Under a State of Ohio specific license, the licensee was a manufacturer/distributor for the system including depleted uranium shielding, though they did not distribute the cobalt-60 sources directly.

Performance Observations: Licensee personnel described or demonstrated the handling of material at temporary job sites, initial and annual training for authorized users, collection of leak tests, tracking of survey meters and electronic dosimetry, and emergency procedures. The inspector reviewed documentation of training, program audits, and other activities. The inspector noted no concerns with these activities. Interviews with licensee staff indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern. In January 2016, the licensee was inspected performing licensed activities at a temporary job site in St. Louis, Missouri, with no violations cited.

No violations were identified as a result of this inspection.

BB. for ATM