

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Oncology Hematology Associates of Southwest Indiana 3699 Epworth Road Newburgh, IN 47630 REPORT NUMBER(S) 2015-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-37836	4. LICENSE NUMBER(S) 13-32700-01	5. DATE(S) OF INSPECTION August 17, 2015	

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)

Contrary to 10 CFR 71.5(a) and 49 CFR 172.704(c)(2), three of Oncology Hematology Associates of Southwest Indiana's hazmat employees did not receive the training required by 49 CFR 172 Subpart H at least once every three years.

As corrective action, the licensee obtained the required training, and had all three employees complete the training, including a quiz, on August 18, 2015. The licensee also committed to adding the required training to its on-line training portal to help ensure that these employees complete it at the required frequency.

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	Terri Wade	<i>Terri Wade</i>	9-1-15
NRC INSPECTOR	Ryan Craffey	<i>Ryan Craffey</i>	8/21/15
BRANCH CHIEF	Aaron McCraw	<i>Aaron McCraw</i>	8/28/15

Docket File Information
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6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Zhongshan (John) Zhang - RSO	4. TELEPHONE NUMBER (812) 471-1200
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Main Office Inspection Next Inspection Date: 08/17/2017

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a standalone cancer treatment center authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals, and to conduct fractionated HDR treatments at its facility in Newburgh, Indiana. At the time of the inspection, the licensee performed up to eight PET scans daily, approximately 8-10 therapeutic administrations of I-131 annually, and had completed 10 HDR treatments (mammosite, vaginal cylinder and prostate) to date in 2015. The licensee was considering requesting authorization to administer Ra-223 Xofigo, but was likely at least a year away from being ready to make the request. The licensee's Radiation Safety Committee (RSC) met quarterly to review the content and implementation of the radiation safety program.

PERFORMANCE OBSERVATIONS: The inspector toured the Newburgh facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys of the facility, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of two PET scans using F-18, as well as demonstrations by licensee staff of package receipt, area surveys, waste handling, remote afterloader spot checks, and the treatment planning and verification process for brachytherapy. Through these observations, demonstrations, and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles, ALARA practices, and licensee procedures. The inspector also reviewed a selection of the licensee's records, including RSC minutes, routine nuclear medicine documentation, HDR source exchanges, dosimetry, and a representative sample of written directives for I-131 administrations and HDR treatments.

The inspector identified a violation for the failure to comply with the applicable requirements of the U.S. Department of Transportation (DOT) regulations in 49 CFR 172.704(c)(2) for recurrent hazmat training, as required by 10 CFR 71.5 (a). Specifically, the licensee had not provided adequate hazmat training to those who handled packages containing radioactive materials at least once in the last three years. These employees last took this training specific to radioactive materials in 2008. The inspector determined that the root cause of the violation was a lack of understanding of DOT requirements. As corrective action, the licensee obtained the required training, and had the three hazmat employees complete the training, including a quiz, on August 18, 2015. The licensee also committed to adding the required training to its on-line training portal to help ensure that hazmat employees complete it at the required frequency.