NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Spectrum Health United 615 South Bower Street Greenville, MI 48838 REPORT NUMBER(S) 2015-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-35613	21-32293-01	April 23, 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 violations(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.

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

10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. The inspector specifically discussed 49 CFR 173.421(a)(2) and 49 CFR 173.422(a).

☐ 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	Ryan Craffey	Ryan Craffey	4/27/15
BRANCH CHIEF	Aaron McCraw		5/6/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02120	3	John A. Merchun, MD - RSO	(616) 225-9330

☑ Main Office Inspection Next Inspection Date: 04/23/2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a community hospital authorized to conduct diagnostic and therapeutic administrations of radiopharmaceuticals at its facility in Greenville, Michigan. At the time of the inspection, one of two nuclear medicine technologists conducted 5-8 administrations per day, Monday through Friday, using unit doses and daily bulk doses for any add-ons. Although authorized for therapeutic procedures, the licensee had not performed any such administrations to date, and has no plans to do so in the future. The hospital was considering transferring all activities to the license of an affiliated medical center in Grand Rapids, Michigan (030-01989). A medical physicist from the aforementioned medical center performed quarterly audits of the radiation safety program.

PERFORMANCE OBSERVATIONS

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication and exposure control, and to conduct independent and confirmatory surveys of the facility. The inspector was unable to observe the preparation or administration of any radiopharmaceuticals. However, the inspector was able to observe package receipt and instrument quality control, as well as demonstrations of dose preparation, administration and other activities. Through these observations and other discussions, the inspector found the technologist to be knowledgeable of radiation protection principles and regulatory requirements. The inspector also reviewed a selection of licensee records, including quarterly audits, dosimetry, spill reports, training, surveys, and waste disposal documentation.

The inspector noted a licensee-identified violation of 10 CFR 71.5(a) for the failure to comply with 49 CFR 173.421(a)(2) and 173.422(a) when, on April 16, 2015, the licensee transported a tissue sample containing 0.130 mCi of Tc-99m to an authorized recipient. The licensee intended to transport the sample as a limited quantity; however, the staff inadvertently sent it in an unlabeled package, which upon receipt was found to have a radiation level on its external surface of 2.0 millirem per hour. The inspector determined the root cause to be personnel error. As corrective action, the licensee revised its procedure to require that a labeled package be prepared prior to tissue collection, and retrained staff on holding these packages overnight to ensure that they meet the requirements of a limited quantity shipment. The inspector determined that the violation was self-identified, non-repetitive, non-willful and adequate corrective action had been taken, and therefore met the criteria for the NRC to not cite this violation.