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
Schneider Regional Medical Center 9048 Sugar Estate St. Thomas, USVI 00802 REPORT NUMBER(S) 2018001	**U.S. Nuclear Regulatory Commission** **Region I, 2100 Renaissance Blvd, Suite 100** **King of Prussia, Pennsylvania 19406-2713**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03013764	55-17986-01	9/20/18, 12/20/18, & 3/4/2019

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) and corrective action(s):

[X] 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 the 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)

See continuation sheet.

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	Bernard Wheatley		3-19-19
NRC INSPECTOR	Leonardo Wardrobe		3/11/2019
BRANCH CHIEF	Donna Janda		4/4/19

*NRC FORM 591M PART 1 (07-2012) (RI Rev. 09/12/2013) G:\WBL Documents\WBL Inspection Records\R55-17986-01.2018001.591M-Part1.doc

SUNSI Review Completed By: /RA/ LWardrobe [x] Public [x] Non-Sensitive

This document becomes an NRC Official Agency Record once it is signed by the Branch Chief

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(Continued)

1. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) [30 microcuries (μCi)].

   Contrary to the above, on August 1, 2017, the licensee failed to have a written directive signed and dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) [30 microcuries (μCi)]. Specifically on August 1, 2017 the licensee administered 34.8 millicuries (mCi) of I-131 to a patient and the written directive was signed by a physician who was not an authorized user on the license for I-131 sodium iodide. However, the physician signing the written directive is certified by the American Board of Radiology as a Radiation Oncologist (Certification is valid until December 31, 2020) and was authorized to use unsealed radioactive material in accordance with 10 CFR 35.300 in an agreement state.

   This is a Severity Level IV Violation (Enforcement Policy 6.3.d)

   The licensee has committed to revise their procedure for I-131 administrations so that only an authorized user on the license can sign the written directives and has retrained all physicians in that procedure. In addition, the licensee's authorized user reviewed the treatment and concurred with the written directive.

2. 10 CFR 35.14(a) states in part that a licensee shall provide the Commission, a copy of the board certification and the written attestation(s) signed by a preceptor, the Commission or Agreement State License, no later than 30 days after the date the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user.

   Contrary to the above, the licensee failed to provide the Commission, a copy of the board certification and the written attestation(s) signed by a preceptor, the Commission or Agreement State License no later than 30 days after the date the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user. Specifically the Commission did not receive a copy of the board certification and the written attestation(s) signed by a preceptor, the Commission or Agreement State License by August 31, 2017.

   This is a Severity Level IV Violation (Enforcement Policy 6.3.d)

   The licensee has committed to revise their procedure for I-131 administrations so that only an authorized user on the license can sign the written directives and has retrained all physicians in that procedure.