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
Holland Community Hospital 602 Michigan Avenue Holland, Michigan 49423 REPORT NUMBER(S) 2016001	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
030-13801	21-18502-01	11/30/16

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 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.

_____ 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		11/30/16
BRANCH CHIEF	Aaron T. McCraw		12/21/16

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-13801	21-18502-01	November 30, 2016

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.09; 03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Edward J. Maas, M.D., RSO	(616) 392-5141

☑ Main Office Inspection Next Inspection Date: Nov. 2018

☑ Field Office Inspection 844 S. Washington Ave., Holland, MI

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection. The licensee was a 127-bed medical facility located in Holland, Michigan, with authorization to use byproduct materials in Sections 35.100, 35.200, and 35.300, as well as iodine-125 (I-125) seeds for localization of non-palpable lesions under 35.1000. Licensed activities were conducted only at the facilities identified on the license. The nuclear medicine department was staffed with three full-time nuclear medicine technologists. The licensee's nuclear medicine staff typically administered 300 diagnostic doses monthly and three iodine-131 (I-131) therapy doses annually. The diagnostic procedures included a variety of imaging and uptake procedures. The department received daily unit doses and bulk technetium-99m from a licensed nuclear pharmacy. I-131 doses were received as capsules only. All waste was held for decay-in-storage (DIS).

The licensee performed around five I-125 seed implants monthly for the localization of non-palpable lesions in breast tissue. Seeds were implanted at the licensee's clinic at 844 Washington Ave. and explanted in an operating room at the main hospital. The seeds were removed from tissue samples by pathology staff and transferred to the control of nuclear medicine staff in the operating room. Unused and explanted seeds were held for DIS in the nuclear medicine area. One authorized user oversaw this program, though the licensee intended to add more authorized users soon.

Performance Observations: The inspector observed three diagnostic administrations of licensed material, including dose preparation and disposal. Licensee personnel demonstrated morning hot lab checks, package receipt surveys and wipes, and daily and weekly contamination surveys, and described iodine-131 therapy procedures, additional diagnostic procedures, and placement, removal, and tracking of iodine-125 seeds. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies and seed implants and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations of NRC requirements were identified as a result of this inspection.