

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Goshen Health 200 High Park Ave. Dept. of Nuclear Medicine Goshen, IN 46526</p> <p>REPORT NUMBER(S) 2018001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-14254</p>	<p>4. LICENSE NUMBER(S)</p> <p>13-18845-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>10/24/2018</p>
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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	Dennis P. O'Dowd	<i>Dennis P. O'Dowd</i>	10/24/18
BRANCH CHIEF	Aaron T. McCraw	<i>A T McCraw</i>	11/15/18

Docket File Information

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<p>6. INSPECTION PROCEDURES USED</p> <p>87131, 87132</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>All</p>	

SUPPLEMENTAL INSPECTION INFORMATION

<p>1. PROGRAM CODE(S)</p> <p>02230, 02240, 02120</p>	<p>2. PRIORITY</p> <p>2</p>	<p>3. LICENSEE CONTACT</p> <p>John P. Lowden, M.S., RSO</p>	<p>4. TELEPHONE NUMBER</p> <p>(574) 533-2141</p>
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Main Office Inspection Next Inspection Date: 10/24/2020

Field Office Inspection 1135 Professional Dr., Goshen, Indiana

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a 125-bed hospital and health system located in Goshen, Indiana, authorized for medical uses under 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 (Ir-192 in an HDR unit), and 35.1000 (Y-90 microspheres and I-125 seeds for localization of non-palpable lesions). Although authorized to perform brachytherapy procedures under 35.400, the licensee had not performed any such procedures in several years and had no plans to reactivate the program. The nuclear medicine department was staffed with 4 full-time nuclear medicine technologists (NMTs) and one part-time NMT, who administered over 200 diagnostic doses monthly, including the full spectrum of procedures using Tc-99m, In-111, Xe-133, and other isotopes. The NMT staff received unit doses only from an area pharmacy. Therapy procedures included approximately 25 I-131 treatments per year, including thyroid ablation, hyperthyroid treatments, and whole body scans; 1 Sm-153 treatment per year; and 5-7 Ra-223 Xofigo treatments per year. The licensee's PET area was staffed with one NMT who performed 3-4 scans per day using F-18 FDG. The radiation therapy department was staffed with two physician authorized users and two medical physicists. HDR procedures included breast, gynecological, prostate, skin, bronchial, and other procedures, totaling approximately 100 treatment fractions per year. The licensee performed 3-5 Y-90 SirSphere treatments per year. The licensee's site at the Retreat Women's Health Center used I-125 seeds for localization of non-palpable lesions, of which more than 100 were performed per year. The licensee has an active RSC, and retained a consulting physicist who audited the licensee's program on a quarterly basis.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's facilities, including the licensee's location at the Retreat Women's Health Center on Professional Dr., in Goshen, Indiana. In the nuclear medicine department, the inspector observed the preparation and administration of two cardiac stress tests and the preparation and administration of I-131 for a whole body scan (4 mCi) during the inspection. These observations, combined with interviews with available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques. Licensee staff successfully demonstrated routine equipment QA/QC checks, daily package receiving and check-in procedures, daily and

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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, 02240, 02120	2. PRIORITY 2	3. LICENSEE CONTACT John P. Lowden, M.S., RSO	4. TELEPHONE NUMBER (574) 533-2141
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Field Office Inspection 1135 Professional Dr., Goshen, Indiana

Temporary Job Site Inspection _____

PROGRAM SCOPE

(cont'd. from previous page)

weekly area surveys, and waste handling and disposal procedures. The inspector noted no concerns with these activities. No therapeutic administrations, including HDR and Y-90, were scheduled on the date of the inspection. Licensee medical physics staff demonstrated/discussed, HDR daily and monthly checks, source exchanges, and emergency procedures. Staff involved in preparations and administrations of Y-90 treatments were not available on the date of the inspection. The inspector also reviewed written directives, and other relevant records and procedures, for radiopharmaceutical therapies, Ir-192 HDR, and microspheres procedures. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of licensee dosimetry and survey records indicated no concerns with exposures to radiation workers or general public. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector reviewed a violation (SLIV) cited during an inspection on February 15, 2017, (ML17072A468). The violation involved the licensee's failure to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and not in storage; specifically, a 10 mCi dose of F-18 was left in the hot lab with the hot lab door open, and the NMT was not maintaining constant surveillance and control during that time. The inspector determined that the licensee's corrective actions were completed as described in the report, and that the violation had not recurred. Based on this, this violation is closed.

No violations of NRC requirements were identified during this inspection.