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
Goshen Health 200 High Park Ave Dept. of Nuclear Medicine Goshen, IN 46526 REPORT NUMBER(S) 2021001	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
030-14254	13-18845-01	8/2/21, with in-office review through 9/9/21

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	Jason D. Draper, Health Physicist	Jason D. Draper Digitally signed by Jason D. Draper Date: 2021.09.10 13:16:08 -05'00'	
BRANCH CHIEF	Michael A. Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.09.10 14:59:37 -05'00'	

From: Lowden, John
To: Draper, Jason
Subject: [External_Sender] RE: NRC 591M - Goshen Health
Date: Tuesday, September 14, 2021 7:57:22 AM
Attachments: image001.jpg

Thank you Jason, and it was a pleasure working with you.

The document has been received and signed.

John P. Lowden
Senior Medical Physicist | Goshen Health
(574) 364-2968
200 High Park Ave., Goshen, IN 46526
GoshenHealth.com

From: Draper, Jason <Jason.Draper@nrc.gov>
Sent: Monday, September 13, 2021 1:57 PM
To: Lowden, John <jlowden@goshenhealth.com>
Subject: NRC 591M - Goshen Health

Mr. Lowden,

As we discussed via telephone on September 9, 2021, attached is the inspection report for the routine NRC inspection that was performed for your facility in Goshen, Indiana on August 2, 2021. Please review and keep this document for your records. There is no response required, though I would appreciate an email confirming that you have received the document. Let me know if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Jason Draper
Health Physicist (Inspector)
NRC/RIII/DNMS/MIB
(630) 829-9839
jason.draper@nrc.gov

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Goshen Health	030-14254	13-18845-01

4. Report Number(s):	5. Date(s) of Inspection:
2021001	8/2/21 with in-office review through 9/9/21

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Draper	02230	2	IPs 87131, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
John P. Lowden, M.S., RSO	jlowden@goshenhealth.com	574-364-2538

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	08/02/2023 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a community hospital in Goshen, Indiana, authorized under its NRC license to use byproduct materials for medical uses permitted by 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 NMT assistant who administered approximately 250 diagnostic dosages monthly using a variety of radiopharmaceuticals in primarily unit dosages. The nuclear medicine staff also administered approximately 30 therapeutic dosages of Ra-223, Sm-153, and I-131 per year. The licensee's PET area was staffed with one NMT who performed approximately 60 PET scans per month using F-18. The licensee's radiation therapy department was staffed with three Authorized Users (AUs) and three Authorized Medical Physicists (AMPs). HDR procedures included gynecological, prostate, skin, bronchial, and other procedures totaling approximately 35 patients per year. The licensee also performed 2-4 Y-90 microsphere treatments per year. The licensee's site at the Retreat Women's Health Center used I-125 seeds for localization of non-palpable lesions on approximately 4 patients per week. The licensee's radiation safety committee met quarterly and the licensee retained a consulting physicist who audited the program quarterly.

Due to the Covid-19 public health emergency, the inspector contacted the licensee prior to the inspection to ensure an on-site inspection could be performed safely. During the inspection, the inspector toured the licensee's facilities, including the licensee's location at the Retreat Women's Health Center, in Goshen, Indiana, and performed independent surveys that provided readings consistent with licensee survey records and postings. On the day of the inspection, there were no HDR, Y-90 microsphere, or PET patients. The inspector observed the administration of one cardiac stress test and implantation of one I-125 localization seed. The inspector also observed an AMP demonstrate HDR spot checks and emergency procedures. The inspector interviewed a selection of licensee staff including the RSO, NMTs, AMPs, and other licensee staff with respect to material handling, material accountability, surveys, and emergency procedures. Through these observations and interviews, the inspector determined that licensee staff was knowledgeable of radiation safety concepts and procedures. The inspector also reviewed a selection of documents including: written directives, patient release records, source inventories, surveys, dosimetry, instrumentation calibrations, training records, and periodic program reviews.

The inspector performed an in-office review of the licensee's failure to acquire occupational dose records for licensee staff who had received occupational dose from previous employers, which is required by 10 CFR 20.2104 for individuals who are required to be monitored under 10 CFR 20.1502. Specifically, two of the licensee's

Materials Inspection Record (Continued)

interventional radiology physicians received occupational dose while concurrently working under another hospital system in northern Indiana, but at the time of the onsite inspection, the licensee was unaware how much occupational dose these individuals had received during the current and previous years. As a result of the inspectors questions, the licensee reached out to the other hospital system and was able to acquire the necessary occupational dose information and confirm the individuals had not exceeded any occupational dose limits.

No violations of more than minor significance were identified as a result of this inspection.