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
Good Samaritan Hospital 520 S 7th St. Vincennes, IN 47591 REPORT NUMBER(S) 202101	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
030-01600	13-01787-01	August 17, 2021

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)

Contrary to 10 CFR 35.643(a) and 35.643(d)(6), on May 26 and May 28, 2021, the licensee failed to spot-check the high dose-rate remote afterloader (HDR) unit to assure proper operation of the timer accuracy before the first use of the HDR.

As corrective action, on September 2, 2021, the licensee updated its HDR start-up procedure and daily quality assurance checklist to include a timer accuracy test.

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	Mark Beanblossom	Mark Beanblossom	9-20-21
NRC INSPECTOR	Luis Nieves Folch	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2021.09.13 07:15:56 -05'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2021.09.13 07:39:32 -05'00'	

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Good Samaritan Hospital	030-01600	13-01787-01

4. Report Number(s):	5. Date(s) of Inspection:
2021001	August 17, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Luis Nieves	02230	2	87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Mark Beanblossom, RSO	m.beanblossom@ampmedicalphysics.com	812-882-5220

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☑ Main Office ☐ Field Office	August 17, 2023
☑ Routine ☑ Announced	☐ Temporary Job Site ☐ Remote	☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced		☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced, routine inspection of a hospital authorized by its NRC license to use unsealed byproduct material for diagnostic and therapeutic procedures under 10 CFR 35.100, 200, 300, 400, and 600. At the time of the inspection, the licensee performed a comprehensive spectrum of diagnostic procedures. The nuclear medicine department was staffed with three full-time nuclear medicine technologists (NMTs) who performed approximately 30 diagnostic nuclear medicine procedures per week. The licensee has one hot lab at the hospital that works from Mondays to Fridays. The licensee performed one Xofigo treatment in the last year. No manual brachytherapy had been perform since the last inspection. In the HDR suite, only one patient was treated in 2020 and one in 2021, both vaginal cylinders. The licensee retains a consultant health physicist to perform annual audits of the radiation safety program and calibrations.

PERFOMANCE OBSERVATIONS

The inspector conducted a tour of the nuclear medicine hot labs at the main hospital and at the PET location and discussed with the NMT package receipt, surveys, and instrument quality control checks. The inspector observed the preparation and administration of one heart rest test. The NMTs demonstrated adequate knowledge of radiation safety principles and practices through interviews. The inspector reviewed audit reports, instrument quality control, safety committee minutes, written directives, inventory, dose calibrator linearity and accuracy, leak tests, and training. The inspector also reviewed monthly dosimetry reports which indicated annual whole-body and extremity doses were below regulatory limits.

In the oncology suite, the inspector reviewed written directives, quarterly QC, daily QC, emergency procedures, emergency equipment, security of the material, and annual training.

One violation was identified during this inspection: the inspector identified that the licensee failed to spot-check the timer accuracy of the high dose-rate remote afterloader (HRD) unit before first use of the unit to treat a patient on May 26 and May 28, 2021. This failure was a violation of the requirements for periodic spot-checks for remote after loaders units in 10 CFR 35.643(a) and 35.643(d)(6).

As corrective action, on September 2, 2021, the licensee updated its HDR start-up procedure and daily quality assurance checklist to include a timer accuracy test.