| NRC FORM 591M PART 1<br>(07-2012) U.S. NUCLEAR REGULATORY COMMISSION   |  |                        |   |                              |           |  |  |  |
|--|--|------------------------|---|------------------------------|-----------|--|--|--|
| 10 CFR 2.201 SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION  |  |                        |   |                              |           |  |  |  |
| 1. LICENSEE/LOCATIO<br>Indiana Universit   | N INSPECTED:<br>y Health Goshen Hospital   | 2. NRC/REGIONAL OFFICE |   |                              |           |  |  |  |
| Department of Nu   |  |                        | Region III<br>U. S. Nuclear Regulatory Commission |                              |           |  |  |  |
| 200 High Park Avenue   |  |                        | 2443 Warrenville Road, Suite 210                  |                              |           |  |  |  |
| Goshen, Indiana 46526  |  |                        | Lisle, IL 60532-4352                              |                              |           |  |  |  |
| REPORT NUMBER(S) 2015-001  |  |                        |   |                              |           |  |  |  |
| 3. DOCKET NUMBER(S)  | )  | 4. LICENSE NUMBE       | R(S)  | 5. DATE(S) OF INSPECTION     |           |  |  |  |
| 030-14254  |  | 13-18845-01            | 1/21/15   |                              | 5         |  |  |  |
| LICENSEE:<br>The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear<br>Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of<br>procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows: |  |                        |   |                              |           |  |  |  |
| 1. Based on  | 1. Based on the inspection findings, no violations were identified.  |                        |   |                              |           |  |  |  |
| 2. Previous  | 2. Previous violation(s) closed.   |                        |   |                              |           |  |  |  |
| non-repet  | <ol> <li>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.</li> </ol> |                        |   |                              |           |  |  |  |
|  | Non-cited violation(s) were discuss  | ed involving the fol   | lowing requirement(s):                            |                              |           |  |  |  |
| <ul> <li>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.<br/>(Violations and Corrective Actions)</li> </ul>  |  |                        |   |                              |           |  |  |  |
| 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   | eu, uniess specifically fequ | DATE      |  |  |  |
| LICENSEE'S   |  |                        | SIGNATORE   |                              |           |  |  |  |
| REPRESENTATIVE<br>NRC INSPECTOR  | Ken Lambert/Dennis O'Dowd  |                        | Kentembert  | Denii O'De                   | 1/1/21/15 |  |  |  |
| BRANCH CHIEF   | Aaron T. McCraw  |                        | AT M  |                              | 2/2/15    |  |  |  |
| NRC FORM 591M PART 1 (07-2012)   |  |                        |   |                              |           |  |  |  |

| NRC FORM 591M PART 3<br>(07-2012)  |             | U.S. NUCLEAR REGULATORY COMMISSION<br>Docket File Information |   |                          |  |  |  |  |
|--|-------------|---|---|--------------------------|--|--|--|--|
| 10 CFR 2.201<br>SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION   |             |   |   |                          |  |  |  |  |
| 1. LICENSEE/LOCATION INSPECTE  | ED:         | 2. NRC/REGIONAL OFFICE  |   |                          |  |  |  |  |
| Indiana University Health<br>Department of Nuclear Me<br>200 High Park Avenue<br>Goshen, Indiana 46526<br>REPORT NUMBER(S) 2015-0  | edicine     |   | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |                          |  |  |  |  |
| 3. DOCKET NUMBER(S)  |             | 4. LICENSE NUMBER(S   | S)  | 5. DATE(S) OF INSPECTION |  |  |  |  |
| 030-14254  |             | 13-18845-01   |   | 01/21/2015               |  |  |  |  |
| 6. INSPECTION PROCEDURES USE   | ΞD          | 7. INSPECTION FOCUS   | 7. INSPECTION FOCUS AREAS   |                          |  |  |  |  |
| 87131; 87132   |             | 03/01-03.08; 03.01-03.08                                      |   |                          |  |  |  |  |
| SUPPLEMENTAL INSPECTION INFORMATION  |             |   |   |                          |  |  |  |  |
| 1. PROGRAM CODE(S)   | 2. PRIORITY | 3. LICENSEE CONTAC  | 3. LICENSEE CONTACT 4. TELEPHONE NUM  |                          |  |  |  |  |
| 02240  | 2           | John Lowden, M  | I.S., RSO   | (574) 634-2538           |  |  |  |  |
| ✓ Main Office Inspection       Next Inspection Date:       01/21/2017         ☐ Field Office Inspection  |             |   |   |                          |  |  |  |  |
| Temporary Job Site Inspection  |             |   |   |                          |  |  |  |  |
| PROGRAM SCOPE  |             |   |   |                          |  |  |  |  |
| This was a routine inspection of a 125-bed hospital located in Goshen, Indiana, authorized for medical uses in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600 (Ir-192 in an HDR unit), 35.1000 (Y-90 microspheres and I-125 seeds for |             |   |   |                          |  |  |  |  |

35.100, 35.200, 35.300, 35.400, 35.600 (Ir-192 in an HDR unit), 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 technologists, who administered 200 diagnostic doses monthly, including the full spectrum of procedures using Tc-99m, In-111, Xe-133, and other isotopes. Therapy procedures included 25-30 I-131 treatments per year, including thyroid ablation, hyperthyroid treatments, and whole body scans, five Sm-153 treatments, and three treatments using Ra-223 Xofigo. The licensee's PET area was staffed with two technologists who performed whole body scans using F-18 FDG. The radiation therapy department was staffed with two physician authorized users, two (2) medical physicists. HDR procedures included breast, gynecological, prostate, bronchial, and other procedures. The licensee performs about ten Y-90 SirSphere treatments per year. In addition, the therapy department oversees the use of I-125 seeds for localization of non-palpable lesions, of which 68 have been performed since the implementation of the program in 2014.

## PERFORMANCE OBSERVATIONS

Licensee personnel discussed/demonstrated and the inspectors reviewed dose calibrator daily constancy checks; package receipt procedures and surveys; daily/weekly surveys; HDR daily checks and calibrations; nuclear medicine waste disposal; radiation safety committee meeting minutes; health physics consultant audits. The inspectors observed an HDR procedure, including HDR daily checks, and reviewed written directives and treatment plans for nine selected treatments. The inspectors also reviewed written directives for radiopharmaceutical therapies, and microspheres procedures. The inspectors identified no concerns in any of these areas. The inspectors also observed a Tc-99m and Xe-133 administration, including dose preparation and disposal. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Dosimetry records indicated no exposures of regulatory concern. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

No violations of regulatory requirement were identified.