

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Cancer Care Partners
301 E. Day Road
Mishawaka, Indiana 46545
REPORT NUMBER(S): 2011-001

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

3. DOCKET NUMBER(S)
030-38355

4. LICENSEE NUMBER(S)
13-32809-01

5. DATE(S) OF INSPECTION
Sept 1, 2011

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:

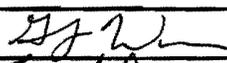
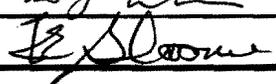
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

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		9/1/11
Branch Chief	Tamara E. Bloomer		9/19/11

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Cancer Care Partners Mishawaka, Indiana REPORT NUMBER(S) 2011-001	2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532
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3. DOCKET NUMBER(S) 030-38355	4. LICENSEE NUMBER(S) 13-32809-01	5. DATE(S) OF INSPECTION September 1, 2011
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6. INSPECTION PROCEDURES 87130, 87132	7. INSPECTION FOCUS AREAS 03.01 – 03.08, 03.01 – 03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02230	2. PRIORITY 2	3. LICENSEE CONTACT John Lowden, M.S., RSO	4. TELEPHONE NUMBER 574-201-7300
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|--|----------------------------------|
| <input checked="" type="checkbox"/> Main Office Inspection
<input type="checkbox"/> Field Office Inspection _____
<input type="checkbox"/> Temporary Job Site Inspection _____ | Next Inspection Date: Sept. 2013 |
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PROGRAM SCOPE

The licensee was a medical facility located in Mishawaka, Indiana, with authorization to use byproduct materials in Sections 35.100 and 35.200, as well as iridium-192 in a high dose rate (HDR) remote afterloader. Licensed activities were conducted only at the facility identified on the license. This was the initial inspection of activities performed under this license.

The PET/CT area was staffed with two full-time nuclear medicine technologists who performed approximately 25 diagnostic procedures monthly. Procedures were limited to PET/CT procedures using fluorine-18. The department received unit doses from a licensed radiopharmacy. All waste was held for decay in storage.

The licensee had acquired and sourced an HDR unit, but had not yet performed any procedures using it. One radiation oncologist, three physicists, and two dosimetrists would be involved in the procedures, which could start within two months. The physics and dosimetry staff also performed HDR procedures at Goshen Hospital. Licensee personnel expected that they would perform approximately 20 or 30 HDR fractions monthly. Licensee staff stated that they would train therapy staff on performing HDR procedures prior to treating the first patient, including multiple dry runs.

Performance Observations

No procedures involving licensed materials were performed during the inspection. Licensee personnel demonstrated daily checks of the HDR unit, dose calibrator constancy, wipe counter and survey meter QC, package receipt surveys, and diagnostic dose preparation, administration, and disposal. The physicist explained HDR planning and administration. The inspector noted no issues with these activities. The inspector reviewed HDR written directive forms and noted no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.