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
James E. Cary Cancer Center 5985 Hospital Drive Hannibal, MO 63401 REPORT NUMBER(S) 2012-001	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
030-37750	24-32681-01	July 23-24, 2012

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)

One Severity Level IV violation was identified during this inspection. The violation is being cited because it was identified by the NRC.

Title 10 of the Code of Federal Regulations (CFR) 35.40(a) states, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

Contrary to the above, on April 20, 2012 and July 9, 2011, the licensee administered a therapeutic dose of radiation using a high dose rate remote afterloader, and the written directives for those administrations were not signed by an authorized user. (Continued on Part 2)

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	STEPHEN M. ROSE	S. M. Rose	8-9-2012
NRC INSPECTOR	Andrew Bramnik	Andrew M Bramnik	8/8/2012
BRANCH CHIEF	Tamara Bloomer	for	8/8/12

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(Continued)

The root cause was an oversight by the licensee's authorized user and authorized medical physicist. Specifically, the licensee completed an "HDR Treatment Record Summary" checklist for every treatment fraction, which included the written directive. The licensee implemented that checklist as written procedures to provide high confidence that each administration was in accordance with the written directive. For the two occasions listed above, the licensee completed all of the information on the checklist and the authorized user dated the written directive; however, the authorized user failed to sign the written directives before the administrations. The failures were isolated, did not represent a programmatic weakness in implementation, and did not result in a medical event. As corrective actions, the licensee developed more detailed written procedures to describe their process for completing written directives and providing high confidence that each administration is in accordance with the written directive. The licensee intended to complete these actions by August 10, 2012.

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87132	03.01 - 03.09

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Stephen Rose - AMP and RSO	(573) 406-5801

☑ Main Office Inspection Next Inspection Date: July 24, 2014

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a private medical practice that conducted therapeutic treatments using a High Dose Rate remote afterloader unit (HDR) in accordance with 10 CFR 35.600. The licensee had treated 16 patients since the previous inspection. Although five Authorized Users (AUs) and two Authorized Medical Physicists (AMPs) were listed on the NRC license, one primary AU and AMP usually planned and conducted treatments. The licensee conducted primarily breast treatment procedures using the HDR.

PERFORMANCE OBSERVATIONS

The AMP described or demonstrated the daily operations checks on the HDR and its associated equipment, including but not limited to: door interlocks, indicator lights, viewing and intercom systems, emergency response equipment, radiation monitors, and timers. The inspectors confirmed that these activities were routinely and successfully completed by reviewing selected records since the previous inspection, and also verified that the licensee's staff was familiar with the definition of a medical event.

The inspectors reviewed a selected sample of written directives and treatment case work since the previous inspection, as well as documentation from previous source exchanges and unit calibrations. Two written directives for treatment fractions had not been signed by an AU. This item is described in Parts 1 and 2; otherwise, no problems or inconsistencies were identified. The licensee's staff was routinely trained and familiar with procedures to follow in the event of an emergency, and emergency procedures were posted at the HDR unit console. The licensee possessed a radiation survey meter that was calibrated, operational, and performed comparably to readings from an NRC survey meter. Independent measurements did not identify any dose rates in excess of 10 CFR Part 20 limits in restricted or unrestricted areas. Personal whole body dosimetry badges were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the highest annual whole body reading since the previous inspection was 10 mrem.

One Severity Level IV violation for two examples of the licensee's failure to have an authorized user sign a written directive was identified during this inspection, and is described on Parts 1 and 2.