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
Centerpoint Medical Center of Independence, LLC d/b/a Centerpoint Medical Center 19600 East 39th Street Independence, MO 64057 REPORT NUMBER(S) 2015-001	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
030-13994	24-18655-01	August 20, 2015

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 35.40(a), Centerpoint Medical Center of Independence, LLC performed an administration of 5.06 millicuries of I-131 sodium iodide using a written directive which had not first been signed and dated by an authorized user.

As corrective action, the licensee committed to revising its written directive template to include an additional line item to its pre-administration checklist, requiring a second individual to explicitly verify the presence of an authorized user's signature. The licensee also committed to discussing the change with staff members involved in the administration of therapeutic doses.

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	Linda Dunaway	Linda Dunaway	8/28/15
NRC INSPECTOR	Ryan Craffey	Ryan Craffey	8/28/15
BRANCH CHIEF	Aaron McCraw		8/28/15

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Centerpoint Medical Center of Independence, LLC d/b/a Centerpoint Medical Center 19600 East 39th Street Independence, MO 64057 REPORT NUMBER(S) 2015-001	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
030-13994	24-18655-01	August 20, 2015

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Linda Dunaway - Imaging Director	(816) 698-7132

☑ Main Office Inspection Next Inspection Date: 08/20/2017

☑ Field Office Inspection 19550 East 39th Street, Independence, MO

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a 220-bed hospital authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals, including Y-90 Sir-Spheres under 35.1000, at two locations on its campus in Independence, Missouri. At the time of the inspection, the licensee performed around 10 diagnostic administrations per day and four therapeutic administrations of I-131 per month at the hospital's nuclear medicine department, and up to four cardiac stress tests at a nuclear medicine department in the medical office building. The licensee also performed six SIR-Sphere treatments in 2013, twelve in 2014 and two in early 2015. The licensee retained the services of a medical physics consultant, and maintained a Radiation Safety Committee (RSC), which met quarterly.

PERFORMANCE OBSERVATIONS:

The inspector toured both nuclear medicine departments to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory surveys of the facilities, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed the preparation and administration of one hepatobility scan using Tc-99m, as well as demonstrations by licensee staff of package receipt, waste handling, area surveys, and spill response. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles, licensee procedures and regulatory requirements. The inspector reviewed a selection of I-131 and Y-90 written directives, and found that the licensee's procedures in general provided high confidence that each administration was in accordance with the written directive. The inspector also reviewed RSC meeting minutes, consultant audits, dosimetry reports, training records and other routine nuclear medicine documentation.

The inspector identified a violation of 10 CFR 35.40(a) for the licensee's administration of 5.06 millicuries of I-131 sodium iodide on 12/31/14 using a written directive which had not first been signed and dated by an authorized user. The inspector determined that the root cause of the violation was an oversight by the licensee. As corrective action, the licensee committed to revising its written directive template to include an additional line item to its pre-administration checklist, requiring a second individual to explicitly verify the presence of an authorized user's signature. The licensee also committed to discussing the change with staff members involved in the administration of therapeutic doses.