NRC FORM 591M PART 1
(10-2003)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Capital Health System Trenton, New Jersey REPORT Nos 2009-001	**U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road King of Prussia, Pennsylvania 19406-1415**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03002441	29-01698-02	6/12/09 and 7/16/09; additional information received 8/7/09

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) was/were discussed involving the following requirement(s) and Corrective Action(s):

10 CFR 35.40(a) requires that a written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. An audit performed by the licensee in early 2008 revealed that written directives were not prepared for 5 patients at the Mercer campus who were administered diagnostic dosages of I-131 sodium iodide greater than 30 microcuries between 3/14/07 and 9/19/07. The licensee retrained staff members and no further instances have been identified.

☒ 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.

10 CFR 35.2075 requires, in part, that a licensee retain for 3 years a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75 if the total effective dose equivalent is calculated by using the effective half-life. For 15 administrations of I-131 greater than 33 millicuries at the Mercer campus between 1/24/07 and 4/8/09, the licensee did not create a record of the basis for authorizing the release of a patient in accordance with 10 CFR 35.75 when the total effective dose equivalent was calculated by using the effective half-life.

Prior to the conclusion of the inspection, the licensee retrained all staff members involved in I-131 treatments. It also updated procedures to: (a) require staff to confirm the presence of the record of the basis for authorizing the release of the patient before administering an outpatient dosage of greater than 33 millicuries of I-131, (b) require staff to file a copy of this record together with the written directive, and (c) include review of this record in the RSO's audit program.

Licensee's Statement of Corrective Actions for Item 4, above.

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	MARTIN HEMLEY	[signature]	8/10/09
NRC INSPECTOR	Sandra Gabriel	[signature]	8/8/09

SUNSI Review Completed By: /RA/ S. Gabriel ☒ Public ☒ Non-Sensitive