

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

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| 1. LICENSEE/LOCATION INSPECTED: Hamilton Heat, Inc. 17525 River Road Noblesville, IN 46060 REPORT NUMBER(S) 08-01 | 2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351 |
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| 3. DOCKET NUMBER(S) : 030-35897 | 4. LICENSEE NUMBER(S) : 13-32363-01 | 5. DATE(S) OF INSPECTION : May 14, 2008 |
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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.

1 Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):
 10 CFR 35.67 requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed 6 months. Contrary to the above, the licensee's nominal 10 millicurie cobalt 57 sealed source was leak tested on December 21, 2006 and May 7, 2008, a period exceeding 6 months.

The licensee identified the violation during an audit of its program and implemented immediate correction action that included testing the source for leakage. Corrective actions to prevent recurrence included adding a review of leak testing status to the quarterly radiation safety committee meeting agenda

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.
 (Violations and Corrective Actions)

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 | TOM KIRBY | | 6/3/08 |
| NRC INSPECTOR | Ken Lambert | | 6/3/08 |

SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

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| 1. LICENSEE Hamilton Heart, Inc. REPORT NUMBER(S) 08-01 | | 2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532 | |
| 3. DOCKET NUMBER(S) 030-35897 | 4. LICENSE NUMBER(S) 13-32363-01 | 5. DATE(S) OF INSPECTION May 14, 2008 | |
| 6. INSPECTION PROCEDURES USED 87130 | 7. INSPECTION FOCUS AREAS 03.01-03.07 | | |

SUPPLEMENTAL INSPECTION INFORMATION

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| 1. PROGRAM CODE(S) 2201 | 2. PRIORITY 5 | 3. LICENSEE CONTACT Anthony Cossell, M.D., RSO | 4. TELEPHONE NUMBER 317/297-7700 |
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| <input checked="" type="checkbox"/> | Main Office Inspection | Next Inspection Date: May 2013 |
| <input type="checkbox"/> | Field Office | |
| <input type="checkbox"/> | Temporary Job Site Inspection | |

PROGRAM SCOPE

This active clinic performs three to five diagnostic cardiology procedures daily using Tc99m. One full-time technologist currently performs all patient procedures. Generators are not received and all material is obtained from an area nuclear pharmacy in the form of unit doses.

Performance Observations

Interviews conducted with the technologist revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, daily surveys, package receipt surveys, waste handling and disposal, and injection technique were successfully described or observed.

Licensed material was observed adequately secured in the hot lab door during the review and was not accessible to members of the general public.

The licensee exchanges personal dosimetry quarterly with a NVLAP approved vender. Records reviewed indicated whole-body readings for: 2005 of 843 mrem and 2670 mrem extremity; 2006 of 369 mrem WB and 1320 mrem extremity; 2007 of 426 mrem WB and 1650 extremity; and 2008 (as of 4/14/08) of 91 mrem WB and 460 mrem extremity.

Independent measurements taken indicated a maximum reading of 0.2mr/hr in the hot-lab area and essentially background (<0.02mr/hr) in the imaging and unrestricted areas.

The licensee informed the inspector of a missed leak test on the licensee's cobalt-57 sealed source. The licensee identified the violation during an audit of its program and implemented immediate correction action that included testing the source for leakage. Corrective actions to prevent recurrence included adding a review of leak testing status to the quarterly radiation safety committee meeting agenda. This violation was characterized as a non-cited violation, since it was licensee identified and corrected.