

May 30, 2008

Brian Hardesty, Manager
Radiopharmacy of Indianapolis
Corporate Center North II Bldg A
6538 Corporate Drive
Indianapolis, IN 46278

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-37428/08-01(DNMS) AND
NOTICE OF VIOLATION – RADIOPHARMACY OF INDIANAPOLIS

Dear Mr. Hardesty:

This refers to the inspection conducted on April 16, 2008, with continuing NRC review through May 5, 2008, at the Radiopharmacy of Indianapolis facility in Indianapolis, Indiana. The in-office review included additional follow up on your iodine-effluent monitoring and filtration system. This also refers to the telephonic exit meeting between yourself and Michael LaFranzo of my staff on May 5, 2008.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

The violation is cited in the enclosed Notice of Violation (Notice) and it pertains to your failure to equip the iodine fume hood with the required charcoal filtration system. The violation is being cited in the Notice because it was identified by the inspector.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

B. Hardesty

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We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Patrick L. Loudon, Chief
Materials Inspection Branch

Docket No. 030-37428
License No. 13-32637-01MD

Enclosures

1. Notice of Violation
2. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

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NOTICE OF VIOLATION

Radiopharmacy of Indianapolis
Indianapolis, Indiana

Docket No. 030-37428
License No. 13-32637-01MD

During an NRC inspection conducted on April 16, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 22 of License No. 13-32637-01MD states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in an application dated November 13, 2006.

Item 9 of application dated November 13, 2006, states, in part, that the licensee will equip the radioiodine hood with a charcoal filtration system consisting of two charcoal filters (1 foot by 1 foot by 1 inch) stacked one on top of the other.

Contrary to the above, as of April 16, 2008, the licensee's charcoal filtration system did not consist of two charcoal filters (1 foot by 1 foot by 1 inch) stacked one on top of the other. Specifically, the licensee removed approximately one third to one half of the charcoal from each of the two filters, such that the stacked filters contained a total of less than 2 inches of charcoal.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Radiopharmacy of Indianapolis is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, it should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then

please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 30th day of May 2008