

August 15, 2007

Corey Elliott
Vice President, Ambulatory Services
SSM DePaul Health Center
12303 DePaul Drive
Bridgeton, MO 63044

SUBJECT: NRC INSPECTION REPORT 030-02308/07-01(DNMS) AND NOTICE OF
VIOLATION - SSM DEPAUL HEALTH CENTER

Dear Ms. Elliott:

This refers to the inspection conducted on July 23, 2007, at the SSM DePaul Health Center. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and members of your staff.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, 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.

The violation is cited in the enclosed Notice of Violation (Notice) and involves the failure to determine or verify that the total effective dose equivalent to any individual (e.g., a member of the public) from exposure to released patients administered with sodium iodine-131 would not likely exceed 0.5 rem. The violation is being cited in the Notice because it was identified by the NRC inspector.

During the inspection, the NRC inspector reviewed records for patients who were administered sodium iodine-131 in quantities greater than 33 millicuries. Based on interviews with members of your radiation oncology staff and review of patient records, the inspector determined that patients were released from the hospital on the basis of survey results. Survey readings were recorded at the surface of the patient's abdomen and at 1 meter from the patient; maximum survey readings were recorded as 2 to 4 roentgens per hour at the patient's abdomen and 100 to 400+ milliroentgens per hour at 1 meter. Your radiation oncology staff failed to determine the total effective dose equivalent (by calculations) to any other individuals (a member of the public) from exposure to these released patients would not likely exceed 0.5 rem as required by Section 35.75(a).

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 enclosure, 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.

Sincerely,

/RA/

John R. Madera, Chief
Materials Inspection Branch

Docket No. 030-02308
License No. 24-02490-03

Enclosure:
Notice of Violation

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NOTICE OF VIOLATION

SSM DePaul Health Center
Bridgeton, Missouri

Docket No. 030-02308
License No. 24-02490-03

During an NRC inspection conducted on July 23, 2007, a violation of NRC requirements was identified. In accordance with the Enforcement Policy, the violation is listed below:

10 CFR 35.75(a) states in part that a licensee may authorize the release from its control any individual who has been administered unsealed byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.

Contrary to the above, between November 28, 2005, and June 25, 2007, the licensee administered unsealed sodium iodine-131 to 12 patients in quantities ranging from 94.9 millicuries to 154.4 millicuries and released these individuals from its control without determining that the total effective dose equivalent to any other individual (members of the public) from exposure to the released individual is not likely to exceed 0.5 rem.

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

Pursuant to the provisions of 10 CFR 2.201, SSM DePaul Health Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, 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 2.790(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 15th day of August 2007