



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 6, 2005

Nancy Hellyer, Chief Executive Officer
Trinity Health System
Saint Joseph Regional Medical Center
South Bend Campus
801 East LaSalle Street
South Bend, IN 46617-1935

**SUBJECT: NRC SPECIAL INSPECTION 030-13685/05-003(DNMS)
SAINT JOSEPH REGIONAL MEDICAL CENTER, SOUTH BEND CAMPUS**

Dear Ms Hellyer:

This refers to the special inspection conducted on November 16, 2005, at Saint Joseph Regional Medical Center in South Bend, Indiana. The purpose of this inspection was to review your corrective actions implemented in response to the findings identified during our March 30 through April 21, 2005, Augmented Inspection Team inspection and the violations identified during our May 23 through 25, 2005, special follow-up inspection.

This inspection was an examination of the corrective actions, described in your letters dated April 12, June 2, and October 21, 2005, that you implemented. Within this area, the inspection consisted of an examination of corrective action procedures and representative records, and interviews with personnel.

We have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter 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>

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Madera", written over a large, loopy scribble.

John R. Madera, Chief
Materials Inspection Branch

Docket No. 030-13685
License No. 13-02650-02

cc: Gary Perecko, President

December 6, 2005

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Sincerely,
/RA/

John R. Madera, Chief
Materials Inspection Branch

Docket No. 030-13685
License No. 13-02650-02

cc: Gary Perecko, President

See Attached Distribution

*See prior concurrence

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| | | | | |
|--------|-------------|----------|------|------|
| OFFICE | RIII | RIII | RIII | RIII |
| NAME | Piskura:jc* | Madera | | |
| DATE | 11/23/05 | 12/06/05 | | |

OFFICIAL RECORD COPY

N. Hellyer

-2-

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RIII Enf. Coordinator

ENCLOSURE 6

INSPECTION RECORD

Region III

Inspection Report No. 2005-003

License No. 13-02650-02

Licensee (Name and Address):

Docket No. 030-13685

Saint Joseph Regional Medical Center
South Bend Campus
Department of Nuclear Medicine
South Bend, IN 46617-1935

Location (Authorized Site) Being Inspected: St. Joseph Radiation Oncology Center, Suite 100, 707 East Cedar Street, South Bend, IN

Licensee Contact: Christopher Karam, Sr. Director, Clinical Services

Telephone No.
574.237.7723

Priority: 3 Program Code: 02120

Date of Last Inspection: 5/23-25/2005

Date of This Inspection: 11/16/2005

Type of Inspection: () Announced (X) Unannounced
() Routine (X) Special
() Initial

Next Inspection Date 02/2006 (X) Normal () Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:

- (X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or **regional letter issued**
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Followup on previous violations

Inspector(s) *D.A. Piskura*
Deborah A. Piskura

Date 11/23/05

Approved *J.R. Madera*
John R. Madera, Chief, MIB

Date 12/6/05

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

| <u>AMENDMENT #</u> | <u>DATE</u> | <u>SUBJECT</u> |
|--------------------|-------------|---|
| 35 | 5/25/05 | Delete authorization for Sr-90 IVB units/use Revise AUs authorization of RAM accordingly |

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

On March 30, 2005, the MIB dispatched an inspector to the licensee's facility to review the circumstances of two medical events which the licensee reported to the NRC on March 28, 2005. The hospital initially reported that two patients had received unintended radiation exposures to the skin of their upper thighs during brachytherapy treatments for endometrial cancer. The unintended exposures occurred when the brachytherapy sources shifted position within the applicator during treatment, resulting in the unintended radiation doses to the skin of the patients' thighs rather than the intended treatment site.

During the March 30th special inspection, the inspector identified an additional medical event in which the patient exhibited skin lesions. As a result of the additional medical event identified during the special inspection, the uncertainty of dose assessments for additional two patients who did not exhibit any skin injuries, and the complexity of the circumstances surrounding the patient treatments, the NRC elevated the special inspection to an Augmented Inspection Team (AIT) on March 31, 2005. The AIT inspection was conducted from March 30-April 21, 2005, and the inspection findings included: (1) skin exposures for the involved patients exceeded the expected doses from the respective treatments and the skin doses were greater than 50 rem; (2) the root cause of the medical events was the use of smaller diameter sources in the applicator than those specified by the applicator manufacturer; (3) numerous radiation safety program weaknesses.

Five apparent violations were identified during the special follow up inspection (to the AIT) between May 23-25, 2005, for failures to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive (e.g. that the correct size sources are used with the Wang brachytherapy applicator); (2) report three medical events to the NRC by the next calendar day after discovery (35.3045(a)(3)); (3) instruct supervised individuals on the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions (35.27 (a)); 4) ensure (thru the RSO) that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements (35.24(b)); (5) approve, in writing, an authorized medical physicist before allowing that individual to work as an authorized medical physicist (35.24(b)).

The licensee presented its corrective actions during the July 27, 2005, predecisional enforcement conference. On September 23, 2005, the agency issued

an NOV (EA-05-128) with a proposed civil penalty of \$19,200. In letter dated October 21, 2005, the licensee responded to the NOV and paid the civil penalty.

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.) **NONE**

According to the licensee representatives, there have been no events, incidents, or equipment failures since the last NRC inspection. The inspector confirmed this through a review of ADAMS and the events listed in the NMED database.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

This special inspection was conducted in accordance with MC2800 to review the licensee's corrective actions in response to the findings identified during the AIT and the violations identified during the May 2005 special follow up inspection. At the time of this inspection, the licensee voluntarily suspended its brachytherapy program since May 2005. The inspector reviewed the licensee's corrective actions, the licensee's updated brachytherapy procedures and policies, and department personnel training records. The licensee's corrective actions were described in detail in letters dated April 12, 2005, June 2, 2005, and the licensee's reply to the NOV in letter dated October 21, 2005. The inspector also interviewed the proposed new RSO/medical physicist. The medical physicist informed the inspector that the hospital had been working closely with the applicator manufacturer to re-design the "spring" within the applicator and to revise the user instructions in the manufacturer's package insert. These interviews included lengthy discussions on the proposed revisions of the manufacturer's insert for the Wang applicator.

According to the licensee representatives, the hospital expected to resume its brachytherapy activities in early 2006. In addition, the hospital anticipated expanding its radiation oncology program to include additional treatment modalities (HDR). No violations were identified during this inspection. All corrective actions were deemed acceptable.

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED: **87132**

INSPECTION FOCUS AREAS: **03.01, 03.02, 03.04, 03.05, 03.06, and 03.07**

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

None. At the time of this inspection, the licensee voluntarily suspended its brachytherapy program.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

No violations were identified during this inspection. The Region issued a “clear” letter to the licensee, indicating that all violations are considered “closed” and the corrective actions were determined to be acceptable.

5. PERSONNEL CONTACTED:
[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

Jon Frazier, M.D., Authorized User Physician, Radiation Oncologist
***#Christopher Karam, Senior Director, Clinical Services**
Guy Kedziora, M.D., Authorized User Physician, Radiation Oncologist
***#Teresa Langlely, Director, Radiation Oncology**
***#Carol Norris, Executive Director, Oncology**
***#Gary L. Perecko, President, South Bend Campus**
***#Jeff Reed, M.S., Medical Physicist**
***#John D. Schue, Ph.D., Radiation Safety Officer**

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting