



**SAINT JOSEPH**  
Regional Medical  
Center

South Bend • Mishawaka • Plymouth

October 21, 2005

Michael R. Johnson  
Director, Office of Enforcement  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD 20852-2738

**RE: Reply to a Notice of Violation: EA-05-128**

Dear Mr. Johnson:

This communication serves as Saint Joseph Regional Medical Center's ("SJRMCA") response to the United States Nuclear Regulatory Commission's ("NRC") Notice of Violation, which was received by SJRMCA on September 26, 2005.

I. Violations Assessed a Civil Penalty

A (1) 10 CFR 35.41 (a) (2), 10 CFR 35.41 (b), 10 CFR 35.41 (a):  
Written procedures in accordance with written directives and administration of byproduct materials in accordance with treatment plan.

- 1) SJRMCA accepts this violation.
- 2) Reason: Deficient oversight of Radiation Safety Officer ("RSO") and Radiation Oncology Department.
- 3) Corrective action taken:
  - a) Revised Brachytherapy Policy outlining the following:
    - 1) Types of applicators
    - 2) Manufacturer instructions
    - 3) Limitations and identification of sealed sources;
  - b) Revised the Written Directive form;
  - c) New Leadership in Radiation Oncology; and
  - d) Removed contract physicist group and secured-in-house physicist.
- 4) Future corrective action steps
  - a) New RSO by January 1, 2006 (Amendment submitted to NRC on 8/05).
- 5) Full Compliance Date: January 1, 2006.

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215 West 4th Street  
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C-1

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 4  
FOIA-2006-0119

*Attachment is exempt from disclosure, 10 CFR 2390 (b)*

A(2) 10 CFR 35.27 (a) (1), 10 CFR 35.27 (a) (2): Instruction of supervised individuals in written radiation protection procedures, written directive procedures, and NRC regulations and license conditions.

- 1) SJRMC accepts this violation.
- 2) Reason: Deficient oversight of RSO and Radiation Oncology department.
- 3) Corrective action taken:
  - a) Developed orientation/training plan for physicists;
  - b) Established annual competencies for physicists;
  - c) Established annual training for brachytherapy;
  - d) Established acceptance guidelines for approval of applicators and Radiation Safety Committee approval of new applicators; and
  - e) Suspended treatment of brachytherapy patients until corrective actions accepted by NRC.
- 4) Future Corrective actions steps: all steps completed.
- 5) Full Compliance Date: May 2005.

B(1) 10 CFR 35.41 (a) (2), 10 CFR 35.41 (b), 10 CFR 35.41 (a): Written procedures in accordance with written directives and administration of byproduct materials in accordance with treatment plan.

- 1) SJRMC accepts this violation.
- 2) Reason: Deficient oversight of RSO and Radiation Oncology Department.
- 3) Corrective action taken:
  - a) Revised Brachytherapy Policy outlining the following:
    - 1) Types of applicators
    - 2) Manufacturer instructions
    - 3) Limitations and identification of sealed sources;
  - b) Revised the Written Directive form;
  - c) New Leadership in Radiation Oncology Department;and
  - d) Removed contract physicist group and secured in-house physicist.
- 4) Future corrective action steps:

a) New RSO by January 1, 2006 (Amendment submitted to NRC on 8/05).

5) Full Compliance Date: January 1, 2006.

B(2) 10 CFR 35.27 (a) (1), 10 CFR 35.27 (a) (2): Instruction of supervised individuals in written radiation protection procedures, written directive procedure, and NRC regulations and license conditions.

1) SJRMC accepts this violation.

2) Reason: Deficient oversight of RSO and Radiation Oncology Department.

3) Corrective action taken:

- a) Developed orientation/training plan for physicists;
- b) Established annual competencies for physicists;
- c) Established annual training for brachytherapy;
- d) Established acceptance guidelines for approval of applicators and Radiation Safety Committee approval of new applicators; and
- e) Suspended treatment of brachytherapy patients until corrective actions accepted by NRC.

4) Future Corrective actions steps: all steps completed.

5) Full Compliance Date: May 2005.

C(1) 10 CFR 35.41 (a) (2), 10 CFR 35.41 (b), 10 CFR 35.41 (a): Written Procedures in accordance with written directives and administration of byproduct materials in accordance with treatment plan.

1) SJRMC accepts this violation.

2) Reason: Deficient oversight of RSO and Radiation Oncology Department.

3) Corrective action taken:

- a) Revised Brachytherapy Policy outlining the following:
  - 1) Types of applicators
  - 2) Manufacturer instructions
  - 3) Limitations and identification of sealed sources;
- b) Revised the Written Directive form;
- c) New Leadership in Radiation Oncology Department;

and

d) Removed contract physicist group and secured in-house physicist.

4) Future corrective action steps:

a) New RSO by January 1, 2006 (Amendment submitted to NRC on 8/05).

5) Full Compliance Date: January 1, 2006.

C(2) 10 CFR 35.27 (a) (1), 10 CFR 35.27 (a) (2): Instruction of supervised individuals in written radiation protection procedures, written directive procedures, and NRC regulations and license conditions.

1) SJRMC accepts this violation.

2) Reason: Deficient oversight of RSO and Radiation Oncology Department.

3) Corrective action taken:

- a) Developed orientation/training plan for physicists;
- b) Established annual competencies for physicists;
- c) Established annual training for brachytherapy;
- d) Established acceptance guidelines for approval of applicators and Radiation Safety Committee approval of new applicators; and
- e) Suspended treatment of brachytherapy patients until corrective actions accepted by NRC.

4) Future Corrective actions steps: all steps completed.

5) Full Compliance Date: May 2005.

(D) 10 CFR 35.3045 (a) (3), 10 CFR 35.3045 (c): Reporting

1) SJRMC accepts this violation.

2) Reason: Misinterpretation of NRC regulations.

3) Corrective action taken:

- a) Established daily rounds in Radiation Oncology by RSO;
- b) Increased Radiation Safety Committee meeting schedule to monthly;
- c) Established weekly meetings with RSO and SJRMC administration;
- d) RSO completion of radiation safety examination; and
- e) Annual audit by external radiation safety firm.

4) Future corrective action steps:

- a) Identification of new RSO;
- b) Completion of Radiation Safety policy review; and
- c) Completion of annual RSO training.

5) Full Compliance by January 1, 2006.

## II. Violations not assessed a civil penalty

- (A) 10 CFR 35.41 (a) (2), 10 CFR 35.41 (b), 10 CFR 35.41 (a):  
Written Procedures in accordance with written directives and  
administration of byproduct materials in accordance with  
treatment plan
- 1) SJRMC accepts this violation.
  - 2) Reason: Deficient oversight of RSO and Radiation Oncology  
Department.
  - 3) Corrective action taken:
    - a) Revised Brachytherapy Policy outlining the following:
      - 1) Types of applicators
      - 2) Manufacturer instructions
      - 3) Limitations and identification of sealed sources
    - b) Revised the Written Directive form;
    - c) New Leadership in Radiation Oncology; and
    - d) Removed contract physicist group and secured-in-  
house physicist.
  - 4) Future corrective action steps:
    - a) New RSO by January 1, 2006 (Amendment submitted  
to NRC on 8/05)
  - 5) Full Compliance Date: January 1, 2006.

10 CFR 35.27 (a)(1), 10 CFR 35.27 (a)(2): Instruction of  
supervised individuals in written radiation protection procedures,  
written directive procedures, and NRC regulations and license  
conditions.

- 1) SJRMC accepts this violation.
- 2) Reason: Deficient oversight of RSO and Radiation Oncology  
Department.
- 3) Corrective action taken:
  - a) Developed orientation/training plan for physicists;
  - b) Established annual competencies for physicists;
  - c) Established annual training for brachytherapy
  - d) Established acceptance guidelines for approval of  
applicators and radiation; and
  - e) Safety Committee approval of new applicators and  
suspended treatment of brachytherapy patients until  
corrective actions accepted by NRC.
- 4) Future Corrective actions steps: all steps completed.
- 5) Full Compliance Date: May 2005.

(B) 10 CFR 35.24 (b): Radiation Safety Officer

- 1) SJRMCM accepts this violation.
- 2) Reason: Lack of integration of RSO and Radiation Oncology Department.
- 3) Corrective action taken:
  - a) Established daily rounds in Radiation Oncology by RSO;
  - b) Increased RSC meeting to monthly;
  - c) Established weekly meetings with RSO and SJRMCM administration;
  - d) RSO completed Radiation Safety Examination; and
  - e) Annual audit by external Radiation Safety firm.
- 4) Future corrective Action steps:
  - a) Identification of new RSO;
  - b) Completion of Radiation Safety policy review; and
  - c) Completion of annual RSO training.
- 5) Full Compliance by January 1, 2006.

(C) 10 CFR 35.24 (a): Approval of authorized users.

- 1) SJRMCM accepts this violation.
- 2) Reason: Lack of integration of RSO and Radiation Oncology Department.
- 3) Corrective action taken:
  - a) Established daily rounds in Radiation Oncology by RSO;
  - b) Increased RSC meeting to monthly;
  - c) Established weekly meetings with RSO and SJRMCM administration;
  - d) RSO completed Radiation Safety Examination;
  - e) Annual audit by external Radiation Safety firm; and
  - f) Established policy for RSC approval of all new authorized users.
- 4) Future corrective Action steps:
  - a) Identification of new RSO;
  - b) Completion of Radiation Safety policy review; and
  - c) Completion of annual RSO training.
- 5) Full Compliance by January 1, 2006.

III. Payment of Fine

SJRMCM mailed a check made payable to the U.S. Nuclear Regulatory Commission in the amount of Nineteen Thousand Two Hundred and no/100 Dollars (\$19,200.00) on October 21, 2005.

IV. Healthcare Integrity and Protection Data Bank Information

Attached is a document requesting the required information which is exempt from disclosure pursuant to 10 CFR 2.390(a).

We will continue to work closely with the NRC to ensure the safety of all patients. If you have any question about this matter, please contact me at (574) 237-7982.

Sincerely,



Nancy R. Hallyer  
Chief Executive Officer  
Saint Joseph Regional Medical Center

Attachment

*Bcc Rick Korman  
Sent UPS 10-24-05*

~~EXEMPT FROM DISCLOSURE - 10 CFR 2.390(a)~~

Saint Joseph Regional Medical Center - South Bend Campus, Inc.

FEIN:

[ ]

Ex 4

NPI:

N/A

Type of Organization:

Non-profit Corporation

State Professional License:

Hospital

License Number:

05005012-1 (expires 12-31-05)

Field of License:

Acute Care

Name of State:

Indiana



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**Date:** 10/24/05  
**To:** JOHN MADERA  
**Fax:**  
**From:** Gary Percko  
**Phone:** 574-237-7320  
**Sender Fax:** 574-237-7077  
**# of pages:** 9, including cover page  
**Re:**

Here is the copy, per your  
request!

Jill for Gary Percko

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