UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 11, 2005

EA-05-128

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: PREDECISIONAL ENFORCEMENT CONFERENCE SUMMARY

Dear Ms. Hellyer:

On July 27, 2005, representatives of Saint Joseph Regional Medical Center met with NRC personnel in the Region III office located in Lisle, Illinois, to discuss the apparent violations identified in NRC Inspection Report No. 030-13685/05-002(DNMS). The predecisional enforcement conference was held at the request of Region III. The conference attendees are listed in Enclosure 1.

The NRC opened the conference with introductions, provided an overview of the Enforcement Policy, and presented the apparent violations (Enclosure 2). During the conference, you and your staff presented the root cause of the medical events, and your immediate and long term corrective actions as outlined in the enclosed presentation slides (Enclosure 3). Your corrective actions included, but were not limited to: (1) modification of the brachytherapy applicator involved in the medical events; (2) changes to brachytherapy procedures; (3) re-training radiation oncology staff; (4) heightened management oversight of the radiation oncology program, including weekly meetings with the Radiation Safety Officer; and (5) independent audits of the radiation safety program.

It is our understanding that you disagreed with the apparent violation involving failure to report medical events to the NRC. Your representatives stated that the medical events would not be reportable because these events were caused by patient intervention. Specifically, you indicated that the patients directly contributed to the exposures because the patients sat up in bed during treatment, causing the sources to migrate out of the intended position. In addition, your staff communicated their assessment that neither Patients 1 or 2 received any unintended exposures since there was no physical injury/symptoms for Patients 1 and 2. Therefore, these two cases were not considered to be medical events. Finally, you indicated that the authorized user physician determined that permanent functional damage did not occur to the skin of the thighs for Patients 3, 4, and 5.

NRC will continue its review of the apparent violations. Accordingly, no response to this letter is required. You will be informed of our final review on these issues in separate correspondence.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Gary L. Shear for

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Attendance List
2. NRC's Slide Presentation
3. Licensee's Slide Presentation

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Sincerely,

/RA by G. Shear Acting for/

Steven A. Reynolds, Director
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DATE	08/25/05		08/26/05		09/07/05		09/7/05	

OFFICE	RIII	
NAME	Reynolds GLS for	
DATE	09/11/05	

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List of Attendees
St. Joseph Regional Medical Center
Predecisional Enforcement Conference
Wednesday, July 27, 2005

Licensee
Nancy Hellyer, Chief Executive Officer
Carol Norris, Executive Director, Oncology Service Line
Gary Perecko, President, South Bend Campus
Christopher Karam, Senior Director, Clinical Services
John D. Schue, Ph.D., Radiation Safety Officer
Teresa Langley, Director, Radiation Oncology
Jon Frazier, MD, Medical Director, Radiation Oncology
Mike Stack, Public Relations Coordinator
Rich Korman, Esq., In House Counsel

Marty Malsch, Esq., Egan, Fitzpatrick, Malsch & Cynkar
Nathan Davis, M.S., Medical Physicist, Arete Medical Physics
Jeff Reed, M.S., Medical Physicist, Arete Medical Physics

Nuclear Regulatory Commission

Region III
Geoffrey E. Grant, Deputy Regional Administrator
Bruce Berson, Esq., Regional Counsel
Steven A. Reynolds, Director, Division of Nuclear Materials Safety
Gary L. Shear, Deputy Director, Division of Nuclear Materials Safety
John R. Madera, Chief, Materials Inspection Branch
Ronald E. Goans, Ph.D., M.D., M.P.H., Medical Consultant
Kenneth G. O'Brien, Enforcement/Investigations Officer
Kenneth J. Lambert, Senior Health Physicist
Deborah A. Piskura, Health Physicist

M. Christopher Nolan, Chief, Enforcement Policy & Program Oversight, Office of Enforcement
*Gregory Morell, Enforcement Coordinator, Office of Nuclear Materials Safety and Safeguards
*Thomas H. Essig, Acting Deputy Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards
*Audrey Hayes, Enforcement Specialist-Materials, Office of Enforcement
*Tyson Smith, Esq., Office of the General Counsel

*Participation by telephone

U. S. Nuclear Regulatory Commission
Region III
Lisle, Illinois

Predecisional Enforcement Conference
Wednesday, July 27, 2005

Saint Joseph Regional
Medical Center
South Bend Campus

Agenda

1. Welcome and Opening Remarks
2. Discussion of Enforcement Policy
3. Description of Apparent Violations
4. Licensee's Response to Apparent Violations
5. NRC Questions
6. NRC Caucus
7. NRC Clarifying Questions
8. Licensee Closing Remarks
9. Enforcement Process Next Steps
10. Summary
11. Closing Remarks

Apparent Violation No. 1

10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Apparent Violation No. 1 (con't)

As of May 26, 2005, the hospital did not develop written procedures to provide high confidence that each administration is in accordance with the written directive.

Specifically, the hospital's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not describe the different types of applicators used for treatments, or reference the manufacturer's instructions. Further the procedure did not describe the two types of sealed sources, by different manufacturers, that were possessed by the hospital, and the limitations of these sources in the different applicators.

Apparent Violation No. 2

10 CFR 35.27(a)(1) requires, in part, that the licensee who permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material.

Apparent Violation No. 2 (con't)

Between July 2003 and April 2005, the hospital did not instruct a contract medical physicist in the hospital's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material.

Specifically, the medical physicist did not receive specific instructions on radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions. Instead, the medical physicist only received limited instructions from the previous medical physicist on how the brachytherapy procedures were performed.

Apparent Violation No. 3

10 CFR Part 35.3045(a)(3), requires a licensee to report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

10 CFR 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.

Apparent Violation No. 3 (con't)

On May 19, 2004, the hospital became aware that five medical events had occurred, and the hospital failed to notify the NRC of two events until March 28, 2005, one event until April 1, 2005, and two events until April 5, 2005.

Specifically, radiation from byproduct material resulted in the skin of the inner thighs of five brachytherapy treatment patients receiving doses between 300 and 2000 rem and were greater than 50 percent of the dose expected from the administration defined in the written directive.

Apparent Violation No. 4

10 CFR 35.24(b) requires that the licensee, through the Radiation Safety Officer, ensures that radiation safety activities are being performed in accordance with licensee approved procedures and regulatory requirements.

Between January 2004 and May 17, 2005, the hospital, through the Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the hospital's procedures and regulatory requirements.

Specifically, the Radiation Safety Officer failed to provide adequate oversight of the brachytherapy program to ensure that the new applicator and vendor instructions were incorporated into the procedures and to ensure that the medical events were reported in accordance with regulatory requirements.

Apparent Violation No. 5

10 CFR 35.24(a)(2) requires that the licensee's management approve in writing any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist.

Fom January 5, 2004, to April 12, 2005, the hospital's management failed to approve in writing an individual before allowing that individual to work as an authorized medical physicist.

Specifically, the individual began work as an authorized medical physicist on January 5, 2004, and the licensee did not approve the individual until April 12, 2005, after requesting and receiving preceptor statements from those who were responsible for the individual's training.

Saint Joseph Regional Medical Center

NRC Region III

Enclosure (3)

I. Event Summary

A. General agreement with AIT

B. Clarifications

1. Authorized user physician did not determine that permanent functional damage to organ/system occurred in any patients
2. Cannot know if overexposure occurred in patients 1 & 2

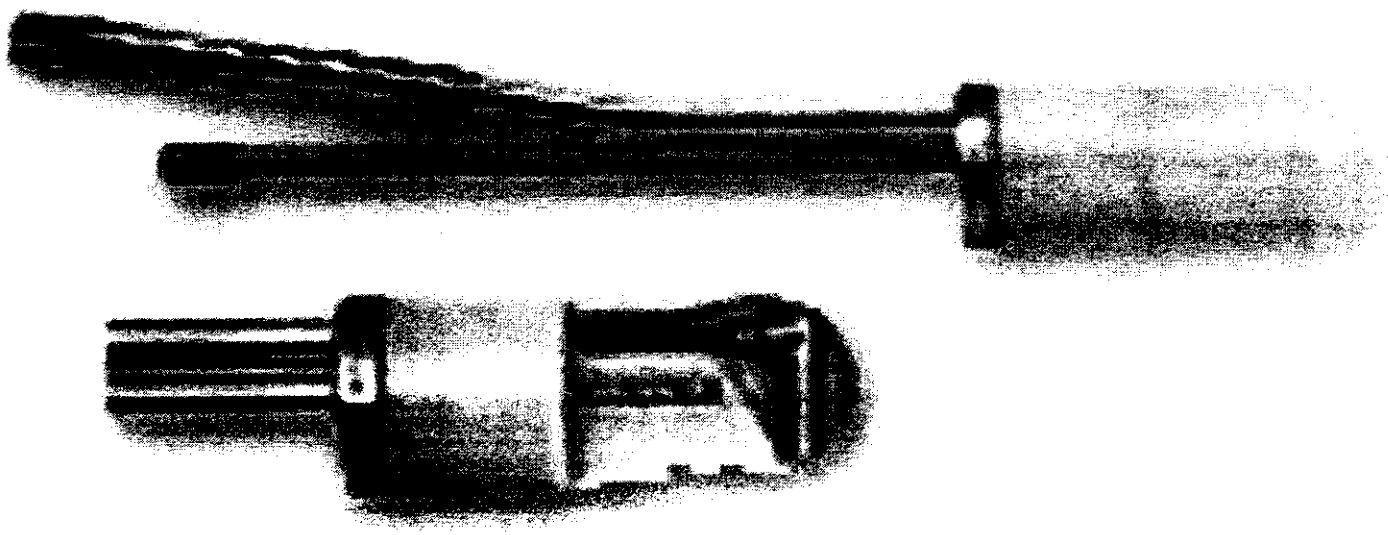
II. Effects on Patients

A. No permanent functional damage
B. Doses to whole body and treatment site as planned
C. Skin and soft tissues
D. Precautions and long-term follow-up

III. Root Cause

A. Partial agreement with AIT report regarding cause

B. Wang applicator



III. Root Cause continued

C. Causes

1. Failure of MP to recognize, a) source diameter was important for device; b) hospital had two sources with different diameters
2. Manufacturer's defect in spring
3. Insufficient procedures to alert MP to problems with device
4. Failure of oversight to assure adequate MP training and adequate procedures

III. Root Cause continued

D. Missed opportunities

1. Acceptance testing

2. Oversight of brachytherapy program

Corrective Actions Timeframe

A. Immediate Action
   - Device modification (April 2004)

B. Long Term
   - Began Developments (April 2005)
   - Final Revisions (July 2005)

IV. Corrective Actions Timeframe

- Appropriate RSC members participated in corrective action plan
- Timeframe for developing corrective action plan did not effect patient care

IV. Corrective Actions

B. Long Term

1. Procedural changes

a) Brachytherapy procedure includes details on different applicators, cautions, source requirements

b) Created Guidelines for Acceptance of New Applicators including review of inserts, filming, dummy sources, sterilization, staff education

c) Clarified Brachytherapy Prescription form to highlight both prescribed dose and actual dose used in patient

d) Established updated policy for reporting medical events and notice to administration

VI. Corrective Actions continued

e) Revised policy/duties of RSC members to include emergency RSC meeting to determine nature of medical event

f) New orientation/training plan for physicists

g) Annual competencies for physicists

2. RSC meets monthly
3. Weekly meetings between administration and RSO
4. RSO daily rounds in Radiation Oncology department
5. Revised source key
6. Voluntarily re-directing brachytherapy patients
7. Radiation Safety exam

IV. Corrective Actions continued

8. Developed new policy for Approval of New Radioactive Devices Radiopharmaceuticals by RSC

9. Recruitment of in-house medical physicist

10. New RSO

VI. Corrective Actions continued

11. Independent audit by ROR

- » Primary
- » Month follow-up (validate implementation)
- » Quarterly review (indefinitely)

Covered areas

- » Radiation safety
- » Regulatory issues
- » Inspections
- » Policies/procedures
- » Instrument quality control
- » In-services
- » Leak tests

IV. Corrective Actions continued

Recommendations for Nuclear Medicine:

- Depleted uranium in shielding of linear accelerator requires an address change
- Document check source activity on each survey meter
- The surveys of decay in storage waste should be recorded in mR/hr units
- The newest version of the guide indicates wipe test limits for unrestricted areas should be 1000 dpm/ 100 cm2 rather than 2000 dpm/100cm2.

IV. Corrective Actions continued

- The release calculations for patients containing I-131 after therapy should be completed for any patients above 33 mCi
- The linearity test on the dose calibrator should start with the highest activity given to a patient in this case 150mCi for some of the I-131 treatments.

IV. Corrective Actions continued

Recommendations for Radiation Oncology:

- Records of the removal and return of sources from the safe should include the name of the person or a list matching initials with names placed in the log book
- 4 cases in which the time of removal of the sources from the patient was not recorded. This information is needed to confirm that the survey was performed immediately after source removal and that the sources were promptly returned to the safe.

IV. Corrective Actions continued

- Document check source activity on each survey meter
- One patient room survey contained a decimal point error. Follow up should include review with the person who performed the survey.

IV. Corrective Actions continued

Audit conclusion

"Overall, I feel the program is run very well, and is in compliance with the NRC requirements."

Stan Buhr, Health Physics Consultant

Standard Nuclear Consultants

V. Violations

- Section 35.41 (a)
  - Agree
  - Contributor
  - Clear need for corrective action

V. Violations

- Section 35.24 (b)
  - Except for RSO role, not separate violation
  - RSO insufficient oversight of brachytherapy program
  - Possible violation, but NRC regulations and guidance unclear
  - Not fair contributor- proper focus is on section 35.41 (a)

V. Violations

- Section 35.27 (a) (1)

- Agree
- Can not violate 35.27 (a) (1) and 35.41 (a)
- Not a contributor

V. Violations

- Section 35.3045

- Disagree
- No evidence for patients 1 and 2
- Patient intervention for patients 3–5 (Part 35 preamble)
- No physician findings of permanent functional damage (35.3045 (b))

V. Violations

- Section 35.24 (a)
  - Agree
  - Not a contributor

V. Violations

- Enforcement Policy

  - Focus on contributing violations (35.41 (a))
  - Severity level (effects on patients)
  - Enforcement history (no prior escalated enforcement action)
  - No self identification of violations
  - Good root cause evaluation

V. Violations

- Enforcement Policy
  - Prompt and effective corrective action
  - Other NRC precedent (EA –04-093)
  - Discretion (manufacturer)