September 23, 2005

EA-05-128
NMED No. 050183

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $19,200 [NRC SPECIAL INSPECTION FOLLOW-UP TO TEAM FINDINGS AND INSPECTION REPORT NO. 030-13685/2005-002(DNMS)]

Dear Ms. Hellyer:

This refers to a Nuclear Regulatory Commission (NRC) Augmented Inspection Team (AIT) Inspection, conducted from March 30 to April 21, 2005, and a followup Special Inspection, conducted from May 23 to May 26, 2005, with continued in-office review through June 3, 2005, regarding activities at the Saint Joseph Regional Medical Center (SJRMC), South Bend, Indiana. The purpose of the inspections was to review the circumstances surrounding brachytheraphy treatments involving five patients who received unintended radiation doses to the skin of their thighs from cesium-137, NRC licensed material. The unintended radiation doses were received during brachytherapy treatments conducted from January 26 to March 22, 2004. Your staff reported the unintended radiation doses received by the patients to the NRC between March 30 and April 21, 2005. The results of the AIT and Special Inspection, including apparent violations associated with the unintended radiation doses, were provided to you on May 20, and June 24, 2005, respectively.

On July 27, 2005, a predecisional enforcement conference (PEC) was conducted in the NRC Region III office with you and members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions. You also described your corrective actions in letters to the NRC dated April 12 and June 2, 2005.

Based on the information developed during the Special Inspection, information that you provided in your April 12, and June 2, 2005, letters, and information that you provided during the PEC, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the Special Inspection report. In summary, an authorized user physician prepared written directives during the period of January 26 to March 22, 2004, prescribing low-dose-rate (LDR) gynecologic brachytherapy using cesium-137 sealed sources (NRC licensed material).

The written directives prescribed doses of 2,500 centigray (cGy) to 6,500 cGy to each of five female patients to be delivered using a Wang front-loading vaginal applicator. Instructions for the Wang applicator indicated that sources loaded into the tandem portion of the applicator were held in place by a compression spring and the sources should have a diameter of 2.8 to 3.1 millimeters (mm). However, the licensee's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not describe the gynecologic applicators used by the licensee and did not specify or limit the diameter of the cesium-137 sources that could be used in each applicator. The licensee maintained an inventory of cesium-137 sources, of different diameters (2.6 and 3.1 mm), that could be used in the different applicators utilized by the licensee as a part of its NRC-licensed brachytherapy program.

At the time of the brachytheraphy treatments, the contract medical physicist was not informed that the licensee maintained different diameter cesium-137 sources and was not informed of the source diameter limitations associated with the tandem portion of the Wang applicator. For each of the five brachytheraphy treatments associated with the unintended radiation doses, the medical physicist used the smaller (2.6 mm) diameter cesium-137 sources in the tandem portion of the Wang applicator instead of the larger (2.8 to 3.1 mm) diameter sources described in the instructions for the applicator. As a result, during the brachytheraphy treatments the cesium-137 sources loaded into the tandem portion of the applicator could have, and in some cases, did move from the location of the prescribed treatment to a position adjacent to the patients' thighs and caused the unintended radiation doses.

The NRC retained the services of a medical consultant to review the circumstances associated with the unintended radiation doses. Based on the NRC medical consultant's evaluation, two patients (identified as Patients Nos. 1 and 2 in the NRC medical consultant's report) may have received unintended radiation doses to their thighs that were estimated not to exceed 300 cGy. Two other patients (identified as Patients Nos. 3 and 5) received unintended doses of radiation to their thighs in the range of 1,800 cGy to 2,200 cGy, and a fifth patient (identified as Patient No. 4) received an unintended dose of radiation to the inner thigh in the range of 1,500 cGy to 2,000 cGy. According to the NRC medical consultant, Patients Nos. 1 and 2 did not demonstrate any signs or symptoms of a radiation injury to the thigh. Patients Nos. 3, 4, and 5 experienced moist desquamation to the skin of the thigh. The skin lesions experienced by Patients Nos. 3 and 4, as a result of the unintended radiation doses to their thighs, measured approximately 4 centimeters (cm) by 3 cm. The skin lesions experienced by Patient No. 5 measured approximately 5 cm by 4 cm. The extent of the injuries caused by the unintended radiation doses caused Patient No. 3 to seek reconstructive surgery and Patient No. 5 was treated in a hyperbaric chamber in an effort to stimulate healing and skin growth. The radiation induced wound to Patient No. 4 healed without extensive medical treatment.

The failure by SJRMC to develop written procedures to ensure that NRC-licensed material was administered in accordance with the authorized user physician's written directive and to instruct a contract medical physicist regarding its possession and use of different diameter cesium-137

sources and limitations associated with the tandem portion of the Wang applicator is a violation of 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," and a violation of 10 CFR 35.27(a), "Supervision." Because these violations directly contributed to significant health consequences for Patients Nos. 3, 4, and 5, each of those three events is categorized as a separate Severity Level II problem in accordance with the NRC Enforcement Policy (Violations I.A, I.B, and I.C). The events associated with Patients Nos. 1 and 2 are categorized as separate examples of a Severity Level IV problem in accordance with the NRC Enforcement Policy due to the more limited health consequences associated with these medical events. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov, select **What We Do, Enforcement**, then **Enforcement Policy**.

The medical events described in Violations I.A, I.B, and I.C of the enclosed Notice occurred during the period from February 23 to March 22, 2004, and came to the attention of your authorized user physician during April 2004. On May 24, 2004, the SJRMC Radiation Safety Committee (RSC) discussed the exposures to the patients' thighs and erroneously determined that NRC regulations did not require SJRMC to notify the NRC about the unintended radiation doses. Subsequently, SJRMC made reports to the NRC regarding the medical events on March 28, 2005 (Patients Nos. 3 and 4), and April 1, 2005 (Patient No. 5). The licensee also reported the unintended radiation doses associated with Patients Nos. 1 and 2 on April 5, 2005; however, the NRC did not determine that these unintended doses met the criteria for classification as medical events. The failure to notify the NRC Operations Center within one calendar day after discovering the medical events associated with Patients Nos. 3, 4, and 5 is a violation of 10 CFR 35.3045, "Report and Notification of a Medical Event." The licensee's failure to report the medical events was categorized as a Severity Level II violation (Violation I.D), in accordance with the NRC Enforcement Policy (Violation I.D), due to the significant potential and actual health consequences associated with the medical events, and the significant time between the licensee's identification of the potential need to report the medical events and its actual reporting of the medical events.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $4,800 is considered for a Severity Level II problem or violation occurring during the period February through May 2004.[1] The NRC considered whether credit was warranted for *Identification* and *Corrective Action* for the Severity Level II problems and violation in accordance with the civil penalty assessment process in Section VI.C.2 of the NRC Enforcement Policy. *Identification* credit was not warranted for the Severity Level II problems associated with the medical events since the issue was identified by the NRC. *Identification* credit was not warranted for the Severity Level II violation associated with the licensee's failure to report the medical events since the medical events were self-revealing as a result of the injuries received by the patients

[1] Effective November 3, 2000, the base civil penalty amount for a Severity Level II violation/problem was $4,800 (65 Federal Register (FR) 193, October 4, 2000, pages 59274-59275) and was increased to $5,200 effective November 26, 2004 (69 FR 206, October 26, 2004, pages 62485-62487).

and since the licensee had missed opportunities to report the medical events, including the May 2004 Radiation Safety Committee meeting. Credit was warranted for the *Corrective Action* factor for the Severity Level II problems and violation associated with medical events. Corrective actions consisted of, but were not limited to: (1) temporarily redirecting brachytherapy patients to other treatment facilities immediately after the issues surrounding the medical events were recognized; (2) revising the brachytherapy procedure to include details on different applicators, cautions, and source requirements; (3) creating guidelines for accepting new applicators that include a review of manufacturer product inserts, filming, dummy sources, sterilization, and staff education; (4) clarifying the written directive form to highlight both prescribed and actual dose used; (5) updating policy for reporting medical events and notice to hospitalization administration; (6) revising the policy and duties of radiation safety committee (RSC) members to include emergency committee meetings to determine the nature of a medical event; (7) developing a new orientation and training plan for medical physicists; and (8) developing an annual review of medical physicist competency.

In assessing the significance of the issues, the NRC recognized that the violations of 10 CFR 35.41(a) and 10 CFR 35.27(a) were closely related (*e.g.*, having a cause and effect relationship). However, the NRC considers the events associated with Patients Nos. 3, 4, and 5, to represent separate Severity Level II problems, because each treatment was independent of the others and represented a significant increase in the health risk to each of the patients due to the unintended radiation dosed received while undergoing medical treatment with NRC-licensed material. The events associated with Patients Nos. 1 and 2, although independent of each other, did not result in actual measurable consequences for either patient, and were treated as two examples of a single violation.

Therefore, to emphasize the importance of prompt identification and reporting of violations, the need to significantly improve performance, and the significance of the potential and actual health consequences to Patient Nos. 3, 4, and 5, I have been authorized, after consultation with the Director, Office of Enforcement (OE), to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the cumulative amount $19,200 for Violations I.A, I.B, I.C, and I.D. A civil penalty is not proposed for Violation II.A., associated with the unintended radiation doses to Patient Nos. 1 and 2, due to the more limited actual health consequences experienced by these two patients. In addition, the issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

Based on the results of the inspection, the NRC has also determined that two additional violations of NRC requirements occurred. From January 2004 to May 17, 2005, your Radiation Safety Officer (RSO) failed to provide adequate oversight of the brachytherapy program to

ensure that information about the Wang applicator and the instructions from the vendor were incorporated into written procedures, in violation of 10 CFR 35.24, “Authority and Responsibilities for the Radiation Protection Program” (Violation II.B). Also, SJRMC permitted a medical physicist to participate in intra-vascular brachytheraphy treatments from January 5, to April 12, 2005, without written licensee management approval in violation of 10 CFR 35.24 (Violation II.C). Violations II.B and II.C are categorized in accordance with the NRC Enforcement Policy at Severity Level IV.

Additional corrective actions implemented by the licensee, but not directly associated with the violations assessed a civil penalty, included: (1) requiring the RSC to meet monthly; (2) requiring the radiation safety officer (RSO) to make daily rounds in the radiation oncology department; (3) requiring weekly meetings between the RSO and hospital administrators; (4) revising the key for sources; and (5) developing a new policy to require RSC approval of new radioactive devices and radiopharmaceuticals. Additional corrective actions included plans to hire a new RSO and recruit an in-house medical physicist.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition, 45 CFR Part 61, “Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners,” requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services’ (HHS) Healthcare Integrity and Protection Data Bank. Since the HHS Data Bank requires information that the NRC does not normally collect, you are required to submit the following information with your response: Federal Employer Identification Number (FEIN), or Social Security Number (when it is used as a Taxpayer Identification Number (TIN)); the National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); the type of organization; and the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held. This information should be provided on a separate sheet of paper since it will not be publically released and should be marked, “Exempt From Disclosure, 10 CFR 2.390(a).” This enforcement action will not be closed until this information is received.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, except the HHS Data Base information, 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. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do**, **Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA by Geoffrey E. Grant for/

James L. Caldwell
Regional Administrator

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

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalties
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/encls: Richard Korman, General Counsel

FILE NAME: G:\EICS\C:\MyFiles\Roger\ML052690054.wpd
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OFFICE	RIII		RIII		OE/NMSS/OGC	RIII		RIII	
NAME	Weil		Reynolds		Nolan[1]	O'Brien		Grant for Caldwell	
DATE	9/22/05		9/22/05		9/22/05	09/22/05		09/22/05	

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[1]Concurrence from HQ in 9/22/05 e-mail from S. Merchant, OE, to Ken O'Brien, RIII

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Saint Joseph Regional Medical Center
South Bend, Indiana

Docket No. 030-13685
License No. 13-02650-02
EA-05-128

During an NRC inspection conducted from May 23 to May 26, 2005, with continued in-office review through June 3, 2005, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violations Assessed a Civil Penalty

A (1) 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, from January 26 to March 22, 2004, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not: 1) describe the different types of applicators used for brachytheraphy treatments; 2) reference the manufacturer's instructions for each of the applicators; 3) describe the two types of sealed sources, by different manufacturers, in the licensee's possession; 4) describe limitations regarding the use of either type of source with the different applicators; and 5) describe the methods the licensee relied upon to verify that byproduct material was administered in accordance with the written directive. As a result, on February 23 and February 24, 2004, the licensee delivered an unintended radiation dose of approximately 1800 to 2,200 centigray (cGy) to a patient's upper thigh, causing moist desquamation, measuring approximately 4 centimeters (cm) by 3cm, to the patient's upper thigh. The written directive, prepared by the licensee's authorized user physician, prescribed a radiation dose of 2,850 cGy be administered to the vagina of the patient.

A (2) 10 CFR 35.27(a)(1) requires, in part, a licensee that 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, NRC regulations, and license conditions with respect to the use of byproduct material. 10 CFR 35.27(a)(2) further requires, in part, that the supervised individual follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, NRC regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, between July 2003 and April 2005, the licensee did not specifically instruct a contract medical physicist in the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions with respect to the use of byproduct material. As a result, a contract medical physicist loaded a brachytheraphy applicator with under-sized cesium-137 sources and on February 23 and 24, 2004, the licensee administered a brachytherapy treatment to a patient during which the sources shifted inside the applicator causing an unintended radiation exposure to tissue other than the treatment site defined in the written directive.

This is a Severity Level II Problem (Supplement VI).
Civil Penalty - $4,800.

B (1) 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, from January 26 to March 22, 2004, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not: 1) describe the different types of applicators used for brachytheraphy treatments; 2) reference the manufacturer's instructions for each of the applicators; 3) describe the two types of sealed sources, by different manufacturers, in the licensee's possession; 4) describe limitations regarding the use of either type of source with the different applicators; and 5) describe the

methods the licensee relied upon to verify that byproduct material was administered in accordance with the written directive. As a result, on March 1 and March 2, 2004, the licensee administered an unintended radiation dose of approximately 1,500 to 2000 cGy to a patient's left thigh, causing moist desquamation, measuring approximately 4cm by 3cm, to the patient's upper left thigh. The written directive, prepared by the licensee's authorized user physician, prescribed a radiation dose of 2,850 cGy be administered to the vagina of the patient.

B (2) 10 CFR 35.27(a)(1) requires, in part, a licensee that 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, NRC regulations, and license conditions with respect to the use of byproduct material. 10 CFR 35.27(a)(2) further requires, in part, that the supervised individual follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, NRC regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, between July 2003 and April 2005, the licensee did not specifically instruct a contract medical physicist in the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions with respect to the use of byproduct material. As a result, a contract medical physicist loaded a brachytheraphy applicator with under-sized cesium-137 sources and on March 1, and 2, 2004, the licensee administered a brachytherapy treatment to a patient during which the sources shifted inside the applicator causing a radiation exposure to causing an unintended radiation exposure to tissue other than the treatment site defined in the written directive.

This is a Severity Level II Problem (Supplement VI).
Civil Penalty - $4,800.

C (1) 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, from January 26 to March 22, 2004, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not: 1) describe the different types of applicators used for brachytheraphy treatments; 2) reference the manufacturer's instructions for each of the applicators; 3) describe the two types of sealed sources, by different manufacturers, in the licensee's possession; 4) describe limitations regarding the use of either type of source with the different applicators; and 5) describe the methods the licensee relied upon to verify that byproduct material was administered in accordance with the written directive. As a result, from March 19 to March 22, 2004, the licensee administered an unintended radiation dose of approximately 1800 to 2,200 cGy to a patient's left thigh, causing moist desquamation, measuring approximately 5cm by 4cm, to the patient's upper left thigh. The written directive prepared by the licensee's authorized user physician prescribed a radiation dose of 6,500 cGy be administered to the vagina of the patient.

C (2) 10 CFR 35.27(a)(1) requires, in part, a licensee that 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, NRC regulations, and license conditions with respect to the use of byproduct material. 10 CFR 35.27(a)(2) further requires, in part, that the supervised individual follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, NRC regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, between July 2003 and April 2005, the licensee did not specifically instruct a contract medical physicist in the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions with respect to the use of byproduct material. As a result, a contract medical physicist loaded a brachytheraphy applicator with under-sized cesium-137 sources and from March 19 to March 22, 2004, the licensee administered a brachytherapy treatment to a patient during which the sources shifted inside the applicator causing an unintended radiation exposure to tissue other than the treatment site defined in the written directive.

This is a Severity Level II Problem (Supplement VI).
Civil Penalty - $4,800.

D. 10 CFR 35.3045(a)(3) requires, in part, that the licensee report any event 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.

Contrary to the above, on May 19, 2004, the licensee became aware that three medical events had occurred and did not notify the NRC of the events until more than one day after the medical events were discovered. Specifically, the three patients received radiation doses from byproduct material to the skin or organ or tissue, other than the treatment site, that were greater than 100 cGy and that were more than 50 percent of the dose expected from the administration defined in the written directives. The written directives prescribed radiation doses between 2850 cGy and 6500 cGy to the patents' vaginas. However, the patients received doses between 1500 cGy and approximately 2200 cGy to their thighs. The licensee reported two events on March 28, 2005, and one event on April 1, 2005.

This is a Severity Level II Violation (Supplement VI).
Civil Penalty - $4,800.

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, licensees develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

10 CFR 35.41(b), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

10 CFR 35.27(a)(1) requires, in part, a licensee that 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,

NRC regulations, and license conditions with respect to the use of byproduct material. 10 CFR 35.27(a)(2) further requires, in part, that the supervised individual follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, NRC regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, from January 26 to March 22, 2004, the licensee did not develop written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's written brachytherapy procedure, "Quality Management Program for Brachytherapy," did not: 1) describe the different types of applicators used for brachytheraphy treatments; 2) reference the manufacturer's instructions for each of the applicators; 3) describe the two types of sealed sources, by different manufacturers, in the licensee's possession; 4) describe limitations regarding the use of either type of source with the different applicators; and 5) describe the methods the licensee relied upon to verify that byproduct material was administered in accordance with the written directive. Additionally, the licensee did not specifically instruct a contract medical physicist in the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions with respect to the use of byproduct material. Specifically, the licensee prescribed a radiation dose of 2500 cGy and 6500 cGy to be administered to two patients respectively, by means of a brachytheraphy applicator that was loaded by a contract medical physicist with under-sized cesium-137 sources. The undersized sources may have shifted inside the applicator during treatment, and may have caused an unintended radiation dose to tissue other than the treatment site defined in the written directive.

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

B. 10 CFR 35.24(b) requires in part, 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.

Contrary to the above, between January 2004 and May 17, 2005, the licensee, through the Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the licensee's procedures and regulatory requirements. Specifically, the Radiation Safety Officer failed to provide adequate oversight of the brachytherapy program to ensure that a new applicator and vendor instructions were incorporated into the procedures and to ensure that the medical events were reported in accordance with regulatory requirements.

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

C. 10 CFR 35.24(a) requires, in part, 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.

Contrary to the above, from January 5, 2004, to April 12, 2005, the licensee'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 for intra-vascular brachytherapy on January 5, 2004, and the licensee did not approve the individual in writing until April 12, 2005, after requesting and receiving preceptor statements from those who were responsible for the individual's training.

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

Pursuant to the provisions of 10 CFR 2.201, Saint Joseph Regional Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation: EA-05-128" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) 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. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an Order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this

Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the civil penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234©) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Michael R. Johnson, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator and the Enforcement Officer, U.S. Nuclear Regulatory Commission, Region III.

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), 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. The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. 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 addition, 45 CFR Part 61, "Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers and Practitioners," requires Federal Agencies to report certain final adverse actions taken against healthcare providers, practitioners, and suppliers to the U.S. Department of Health and Human Services' (HHS) Healthcare Integrity and Protection Data Bank. Since the HHS Data Bank requires information that the NRC does

not normally collect, you are required to submit the following information with your response: Federal Employer Identification Number (FEIN), or Social Security Number (when it is used as a Taxpayer Identification Number (TIN)); the National Provider Identifier (NPI), when the NPI is issued by the Health Care Financing Administration (HCFA); the type of organization; and the State professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the State or territory in which the license is held. This information should be provided on a separate sheet of paper since it will not be publically released and should be marked, "Exempt From Disclosure, 10 CFR 2.390(a)." This enforcement action will not be closed until this information is received.

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

Dated this 23rd day of September 2005