June 24, 2005

EA-05-128
NMED No. 050183

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 FOLLOWUP TO AUGMENTED INSPECTION TEAM FINDINGS AND INSPECTION REPORT 030-13685/2005-002(DNMS) SAINT JOSEPH REGIONAL MEDICAL CENTER SOUTH BEND CAMPUS

Dear Ms. Hellyer:

This refers to the special inspection conducted from May 23 through 26, 2005, at Saint Joseph Regional Medical Center in South Bend, Indiana, with continued in-office review through June 3, 2005. The purpose of the inspection was to follow up on the findings of the Augmented Inspection Team (AIT) inspection conducted from March 30 through April 21, 2005. The purpose of the AIT was to review the medical events involving five patients who received unintended radiation doses to the skin of the inner thighs from cesium-137 (NRC licensed material). The unintended skin doses were directly caused by the use of smaller diameter brachytherapy sources that migrated through the center of the spring intended to secure the sources within the applicator. As a result, the sources intermittently migrated through the spring and irradiated the patients' inner thighs. The findings of the AIT were transmitted to you in our May 20, 2005, letter. The enclosed report presents the results of this inspection. At the conclusion of the inspection, the findings were discussed with members of your staff.

Based on the results of this inspection, five apparent violations were identified and are being considered for escalated enforcement in accordance with the NRC Enforcement Policy. 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 violations include the failure to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (2) instruct a supervised individual on the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions; (3) report five medical events to the NRC by the next calendar day after discovery; (4) ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements; and (5) approve, in writing, an authorized medical physicist before allowing that individual to work as an authorized medical physicist. A Notice of Violation is not being issued for these inspection findings at this time because the NRC has not made a final determination in this matter. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open predecisional enforcement conference to discuss these apparent violations has been scheduled for July 27, 2005, at 1:00 p.m. (CDT) in the Region III office in Lisle, Illinois. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed opportunities to identify the medical events, corrective actions, significance of the issues, and the need for lasting and effective corrective action. During this conference, we also request that you discuss the seriousness of the injuries to the patients, including, but not limited to: (1) the potential for continuing medical issues to the skin from the radiation doses, for example, the recurrence of lesions, and the sensitivity to pain, sunlight, etc.; (2) the increased risk of cancer; and (3) the need for continuing patient follow up. In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on: 1) the severity of the violations; 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.C of the Enforcement Policy; and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your action will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 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,

/Gary L. Shear Acting for RA/
Marc L. Dapas, Director
Division of Nuclear Materials Safety

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

Enclosures: 1. Inspection Report 030-13685/2005-002(DNMS)
2. Excerpt from NRC Information Notice 96-28

cc w/encls: Gary L. Perecko, President South Bend Campus
John Schue, Ph.D., Radiation Safety Officer
See Attached Distribution

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REGION III

Docket No.:	030-13685
License No.:	13-02650-02
Report No.:	030-13685/2005-002 (DNMS)
Licensee:	Saint Joseph Regional Medical Center
Locations:	801 East LaSalle Street (main hospital) South Bend, Indiana Saint Joseph's Radiation Oncology Center 707 East Cedar Street, Suite 100 South Bend, Indiana
Date of Inspection:	May 23 through 26, 2005
Inspectors:	Kenneth J. Lambert, Senior Health Physicist Deborah A. Piskura, Health Physicist
Approved By:	John R. Madera, Chief Materials Inspection Branch

EXECUTIVE SUMMARY

Saint Joseph Regional Medical Center
South Bend, Indiana
Inspection Report No. 030-13685/2005-002 (DNMS)

This was a special inspection to followup on the findings of an Augmented Inspection Team (AIT) inspection conducted on March 30 through April 21, 2005. The AIT reviewed the circumstances surrounding five medical events that occurred between January and March 2004, involving unintended radiation doses to the skin of the patients' inner thighs from cesium-137 (NRC licensed material). The medical events were not reported to the NRC until March and April 2005, due to the licensee's misunderstanding of what constituted a medical event. Details of the AIT findings were described in the AIT Inspection Report 030-13685/2005-001(DNMS), transmitted May 20, 2005 (available in NRC Document System, ADAMS, ML051430221).

Based on the results of this inspection, five apparent violations were identified. The apparent violations include the failure to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (2) instruct a supervised individual on the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions; (3) report five medical events to the NRC by the next calendar day after discovery; 4) ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements; and (5) approve, in writing, an authorized medical physicist before allowing that individual to work as an authorized medical physicist.

The inspectors did not identify any additional medical events involving the licensee's brachytherapy program between January 2003 and May 2005. The licensee's assessment of the doses received to the inner upper thighs of the five patients was adequate and reasonable considering the lack of definite information on which to base the dose calculations. The licensee assigned doses to the skin of the thighs ranging from less than 1000 centigray to 2000 centigray (1000 rads to 2000 rads). The licensee appropriately followed up with the patients who continued to exhibit ulcerations on their thighs. The licensee provided specialized medical care to the patients including hyperbaric chamber treatments and skin grafts.

The root cause of the medical events was the licensee's use of sealed sources with a smaller diameter than the sources recommended by the manufacturer of the applicator, resulting in the sources moving within the spring that was used to hold the sources in place during the treatments. Contributing causes included the lack of appropriate training of the contract medical physicist on the licensee's procedures and the Mick Radio-Nuclear Instruments Model "Wang" front-loading vaginal applicator used in the treatments, and the licensee's lack of oversight of the brachytherapy program.

The licensee provided limited instruction to the medical physicist on the licensee's written radiation protection procedures, written directive procedures, NRC regulations, and license conditions. The licensee relied on the contract medical physicists to audit activities relative to the licensee's brachytherapy radiation safety program. The licensee did not conduct independent audits of the brachytherapy program. Therefore, the

licensee missed opportunities to identify deficiencies with the brachytherapy procedure such as the lack of references to: (1) the types of applicators used; (2) the applicator manufacturer's instructions; and (3) the types of sources possessed and their limitations for use in the different applicators.

The licensee implemented immediate corrective actions that included replacing the applicator spring with a plastic push rod to hold the tandem sources in position within the applicator. The licensee is continuing to develop and implement long-term corrective actions to prevent recurrence of the violations.

Report Details

1 Program Scope and Inspection History

Nuclear Regulatory Commission (NRC) License No. 13-02650-02 authorizes Saint Joseph Regional Medical Center (licensee) to use a variety of byproduct materials for diagnostic and therapeutic medical purposes. The therapeutic procedures include cesium-137 sealed sources in intracavity applicators for low-dose-rate gynecologic brachytherapy treatments. The licensee possessed two sets of brachytherapy sources, one manufactured by 3M Company (3M), the other by G.E. Healthcare (formerly known as Amersham) (Amersham). Typically, in one year, the licensee administers ten to fifteen gynecologic brachytherapy treatments utilizing various types of applicators, including the Mick Radio-Nuclear Instruments Model "Wang" front-loading vaginal applicator (Wang applicator). Other brachytherapy applications have included the use of strontium-90 sources in intravascular brachytherapy devices.

All gynecologic brachytherapy implants were performed at the main hospital located at 801 East LaSalle Street. Radiation therapy staff involved with brachytherapy procedures included three radiation oncologists (physicians), a contract medical physicist, and two dosimetrists. Brachytherapy procedures had been conducted under the direction and supervision of authorized users as defined in Title 10 Code of Federal Regulations (CFR) Part 35.2, and all three physicians were authorized by name on the NRC license. The licensee retained the services of a medical physics consulting group to provide clinical physics support to the radiation oncology department. The licensee established a Radiation Safety Committee (RSC) to provide oversight of the radiation safety program. The Radiation Safety Officer (RSO) was responsible for implementing the radiation protection program.

An Augmented Inspection Team inspection was conducted March 30 through April 21, 2005 to review five medical events involving unintended radiation doses to the skin of the patients' thighs. The two inspections of the licensee's facility prior to the AIT were conducted on January 14, 2002, and February 11, 2004. No violations of NRC regulatory requirements were identified during these inspections.

2 Summary of Events

2.1 Inspection Scope

The inspectors reviewed the time line and set of facts surrounding each of the five brachytherapy patients' treated between January and March 2004. The inspectors interviewed the authorized user, selected contract medical physicists, and the RSO.

2.2 Observations and Findings

The licensee used a Wang Applicator with cesium-137 sources to treat five patients between January 26 and March 22, 2004. As described in the AIT report (030-13685/2005-001(DNMS)), the Wang applicator design accommodated three cesium-137 sources manufactured by 3M. During treatments, one of the sources was placed into a hinged insert, referred to as a "bucket," and positioned within the Wang applicator perpendicular to the remaining two sources that were positioned in the

tandem portion of the applicator. The tandem sources were loaded into a flexible carrier tube and a spring was inserted into the tube to hold the sources in position. Once the Wang applicator had been inserted into the patient, the tube was placed into the applicator.

The licensee used the Wang applicator to treat Patients 1 and 2 from January 26 to 27, 2004, and February 18 to 21, 2004, respectively. Patients 1 and 2 did not exhibit observable effects as a result of the brachytherapy treatments.

The licensee used the Wang applicator to treat Patient 3 from February 23 to 24, 2004. On March 9, 2004, a nurse practitioner examined Patient 3 and observed moist desquamation (blister formation with drainage) on the patient's buttocks and upper thigh. The nurse practitioner suspected that the observed effects were dermatitis due to previous external beam treatments or contact dermatitis due to friction from the radiation implant brief worn by the patient to secure the applicator in position during the brachytherapy treatment. On March 18, 2004, the authorized user examined Patient 3 and observed dermatitis of the vagina and perineum. The authorized user also attributed the dermatitis to either the external beam treatments or contact dermatitis from the radiation implant brief. The authorized user requested the contract medical physicist to investigate the cause of these skin lesions.

In an effort to determine the cause of the patient's skin lesions, the contract medical physicist loaded the Wang applicator with 3M dummy sources and checked for any possible source movement. The physicist's trouble shooting consisted of tilting the applicator off level and listening for any movement/shifting of the dummy sources within the flexible tandem. The physicist noted no unusual observations and the sources remained secured in their intended position as he manipulated the Wang applicator. Based on these tests, the physicist initially concluded that the patient's injuries were not attributed to unintended radiation exposure during the brachytherapy treatments.

The licensee used the Wang applicator to treat Patient 4 from March 1 to 2, 2004. On March 22, 2004, the authorized user examined Patient 4 and observed moist desquamation on the medial aspect of the upper left thigh. He noted that the medial aspect of the upper left thigh was outside of the patient's external beam therapy treatment field. The authorized user attributed the abrasion to friction from the radiation implant brief worn by the patient during the treatment to hold the Wang applicator in position.

The licensee used the applicator to treat Patient 5 from March 19 to 22, 2004. During a routine follow-up on April 12, 2004, the authorized user examined the patient and observed moist desquamation on the medial aspects of both upper thighs, with each lesion measuring approximately 5 centimeters by 4 centimeters. He initially attributed these lesions to friction from the radiation implant brief.

On April 15, 2004, Patients 3 and 4 returned to the licensee's facility for routine follow-up examinations. Both patients continued to exhibit skin lesions. The authorized user concluded that the skin lesions on Patients 3 and 4 could not be attributed to external beam treatments because the skin lesions were outside of the treatment field. He further noted that the skin lesions could not be attributed to dermatitis from the radiation implant briefs because the lesions should have healed by that time. The authorized

user also recalled his recent examination of Patient 5 on April 12, 2004. Based on the clinical findings for Patients 3, 4, and 5, the authorized user suspected that the injuries to the patients' thighs were most likely radiation-induced, as a result of the brachytherapy treatments. The authorized user requested that the contract medical physicist further investigate the possible cause of the injuries.

The medical physicist, as part of his further investigation, reviewed the Wang applicator instructions and noted that the instructions specified the use of 3M sources. The physicist examined the licensee's brachytherapy sources and realized that the licensee possessed two sets which were marked differently. The "old" sources were color-coded and the "new" sources were etched with bands to designate the source strength. The physicist learned that the banded sources were manufactured by Amersham and the color-coded sources were manufactured by 3M. The physicist recognized that, contrary to the applicator instructions, he used Amersham sources in the applicator rather than the recommended 3M sources during the brachytherapy treatments for the five patients.

In order to mimic the actual source loading sequence for the patient treatments, the physicist loaded the Wang applicator with the Amersham sources. The physicist identified that the tandem sources slid down to the opposite end of the flexible carrier tube whenever he tilted the applicator more than 20 degrees off-level. The physicist concluded that the sources within the tandem migrated out of their intended position whenever a patient moved more than 20 degrees off-level (e.g., sat up in bed) during treatment, resulting in irradiation of the skin on the patients' thighs. The Amersham sources moved through the center of the applicator spring because the outer diameter of the source was smaller than the inner diameter of the spring.

The physicist and a senior medical physicist within the consulting group conducted a dose assessment for Patients 1 through 5 in April 2004. Although Patients 1 and 2 did not exhibit any skin lesions, the medical physicists conservatively estimated doses to the patients' thighs based on the possibility that the sources could have migrated through the applicator. The physicists based their dose assessments on patient follow-up photographs of the skin lesions observed for Patients 3, 4, and 5. The physicists compared the size and severity of the skin lesions with information contained in Gilbert H. Fletcher's "Textbook of Radiotherapy," to correlate the moist desquamation with an estimate of absorbed radiation dose as a means of determining the doses received by the patients' thighs. The physicists determined that Patients 1 and 2 received less than 1000 centigray (cGy) (1000 rads); Patient 4 received 1500 cGy (1500 rads); and Patients 3 and 5 received 2000 cGy (2000 rads). The NRC conducted an independent dose assessment of the patients. The NRC's dose assessments for patient 3, 4, and 5 agreed substantially with the licensee's assessment for these patients. For patients 1 and 2, the NRC estimated doses were less than 300 cGy, which is the threshold dose for the appearance of skin erythema.

Based on patient interviews, the physicists obtained information on the patients' leg positioning and the duration of these positions during the treatments. Based on the estimates of the radiation doses to the patients' thighs determined from the textbook, and the known dose rates at the surface of the applicator, the physicists determined the approximate time that the tandem sources were out of their intended position and estimated the doses to the intended treatment sites.

The physicists completed the dose assessments for Patients 1 through 5 in May 2004 and concluded that the greatest deviation from the prescribed dose was approximately 16 percent (Patient 5), and the smallest deviation from the prescribed dose was approximately 4 percent (Patient 2). The contract medical physicists determined that for Patients 1 through 5, the source in the bucket provided a significant portion of the dose to the treatment site. Movement of the tandem sources did not significantly impact the dose delivered to the intended treatment sites.

2.3 Conclusions

The licensee's assessment of the doses received to the inner upper thighs of the five patients was adequate and reasonable, considering the lack of definite information on which to base the dose calculations. The doses to the intended treatment sites were within 20 percent of the prescribed dose in the written directive.

3 Licensee Continued Patient Follow Up

3.1 Inspection Scope

The inspectors interviewed the RSO, the authorized user, and the director of the radiation oncology department regarding the current status of the five patients who received unintended radiation doses to the skin of the thighs.

3.2 Observations and Findings

During discussions with licensee staff, the inspectors learned that Patients 1 and 2 have not exhibited symptoms as a result of their treatments. Patient 4 initially had erythema of the skin and moist desquamation (blisters), which have subsequently healed without any recurrence to date. Patients 3 and 5 continued to exhibit ulcerations of the skin of the thighs. As a result of the serious injuries to the skin of the thighs, the licensee referred Patients 3 and 5 to another institution for continuing wound care. Patient 3 will be scheduled in the future to have surgery to remove the dead tissue surrounding the ulceration and a skin graft. Patient 5 is currently receiving hyperbaric chamber treatments in an effort to stimulate healing and skin growth.

3.3 Conclusions

The licensee continued to follow up with the patients who exhibited ulcerations on their thighs. The licensee referred Patients 3 and 5 to specialized medical care that included hyperbaric chamber treatments and skin grafts.

4 Program Oversight

4.1 Inspection Scope

The inspectors evaluated the licensee's oversight of the implementation of its brachytherapy program. The inspectors interviewed authorized users, selected contract medical physicists, the department director, and the RSO. The inspectors reviewed selected records, including RSC meeting minutes and radiation oncology departmental policies and procedures specific to brachytherapy.

4.2 Observations and Findings

The RSO's duties included a variety of radiation safety tasks. The RSO performed exposure-rate surveys in all areas adjacent to the brachytherapy source storage room quarterly, and areas adjacent to patient treatment rooms after sources had been implanted. Nursing staff, who attended to brachytherapy patients, were provided with personnel monitoring devices. The RSO also ensured that the source storage room and patient room doors were properly posted with caution radiation signs, emergency/notification procedures, and contacts (physicists and authorized users). Inventories and leak tests of the brachytherpay sources were conducted at the appropriate frequencies. The RSO, because he was not a medical physicist, limited his review of the brachytherapy administrations to reviewing the contract medical physicists' reports about the brachytherapy radiation safety program.

Although the contract medical physicists were responsible for the day-to-day implementation of the brachytherapy program, the licensee relied on the contract medical physicists to audit the brachytherapy radiation safety program. Contract medical physicists conducted quarterly audits of the implementation of the licensee's procedures to ensure that brachytherapy treatments were conducted in accordance with written directives. The audits included 100 percent of the cases completed during the audit period. The contract medical physicists' audits included treatment plan verification, patient identification verification, written directive completion, and nurse training completion. The contract medical physicists presented their audit findings and any problems or concerns associated with brachytherapy activities during quarterly RSC meetings. The licensee did not conduct any independent audits of the brachytherapy radiation safety program, either through the RSO, the RSC, or independent consultants.

The RSO did not conduct an independent assessment of the licensee's brachytherapy radiation safety program, or take other steps to validate the information provided by the contract medical physicists. The RSO did not review the brachytherapy procedures to ensure that the Wang applicator and manufacturer's instructions were incorporated into the procedures, or that the type of sources and their limitations with the different applicators were discussed in the procedures.

Title 10 CFR, Part 35.24(b) requires that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Between January 2004 and May 17, 2005, the licensee, through the RSO, did not ensure that radiation safety activities were being performed in accordance with the licensee's procedures and regulatory requirements. The RSO failed to provide adequate oversight of the brachytherapy program to ensure that the new applicator and manufacturer's instructions were incorporated into the procedures and to ensure that the medical events were reported in accordance with regulatory requirements.

4.3 Conclusions

The licensee relied on the contract medical physicists to audit activities relative to the licensee's brachytherapy radiation safety program, even though the contract medical physicists were delegated the responsibility for the day-to-day implementation of the program. The licensee did not conduct independent audits of the brachytherapy program. The inspectors identified an apparent violation of NRC requirements involving

the failure of the licensee, through the RSO, to ensure that radiation safety activities were being performed in accordance with the licensee's procedures and regulatory requirements.

5 Procedures for Brachytherapy Administrations

5.1 Inspection Scope

The inspectors reviewed selected licensee procedures for manual low-dose-rate brachytherapy, and evaluated their adequacy for routine and emergency conditions. The inspectors interviewed the RSO, the authorized user, the director of the radiation oncology department, and two contract medical physicists. The inspectors reviewed selected brachytherapy program procedures.

5.2 Observations and Findings

The licensee's procedures included receiving and handling radioactive material, management of patients containing radioactive material, and emergency procedures. These procedures provided adequate instruction and guidance to ensure radioactive material is handled appropriately and provided instructions to the nursing staff for patients receiving brachytherapy treatments. The licensee's emergency procedures for brachytherapy included actions to be taken in the event that the applicator moved or was removed by the patient during treatment.

At the time of the medical events, the licensee followed its procedure, "Quality Management Program for Brachytherapy," March 1999, for administrations requiring a written directive. The inspectors identified that the procedure referenced NRC regulatory requirements that were no longer in effect, since the NRC revised the requirements in 10 CFR Part 35 on April 24, 2002. Specifically, the licensee's procedures referenced terms that were no longer defined in 10 CFR Part 35.

The licensee's "Quality Management Program for Brachytherapy," also contained guidance intended to meet the requirements in 10 CFR 35.41(a)(2) for developing, implementing, and maintaining written procedures to provide high confidence that each administration is in accordance with the written directive. Item 1.G of the procedure stated that prior to the insertion of any byproduct material into the loading apparatus, the material is verified by the Medical Physicist or designee by either color coding, demarcation, or safe location. However, the licensee's procedure did not describe the specific applicators used by the licensee or require licensee staff to follow the manufacturer's instructions. In addition, the procedure did not describe the two types of cesium-137 sources, by different manufacturers (3M and Amersham), that were possessed by the licensee or the limitations of these sources in the different applicators. As a result, the licensee did not recognize, prior to the first use of the applicator, that sources manufactured by 3M were specified by the manufacturer of the Wang applicator and that the Amersham sources were not appropriate for use in the applicator without the use of other compensatory measures to prevent their movement during treatment.

Title 10 CFR Part 35.41(a) requires, in part, that for any administrations requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's failure to develop and implement adequate written procedures

to provide high confidence that each brachytherapy administration was in accordance with the written directive, constitutes an apparent violation of 10 CFR 35.41(a).

5.3 Conclusion

The licensee's "Quality Management Program for Brachytherapy," did not describe the types of applicators possessed by the licensee or reference the manufacturer's instructions. In addition, the procedure did not describe the types of sources possessed and their limitations in the different applicators. Finally, the procedure did not contain current references to 10 CFR Part 35. The NRC inspectors identified an apparent violation of NRC requirements involving the failure to adequately develop, implement, and maintain procedures for treatments requiring a written directive.

6 Medical Physicist Training

6.1 Inspection Scope

The inspectors reviewed the contract medical physicist's training provided by the licensee and former preceptors. The inspectors interviewed the RSO, the medical physicist, two preceptors (medical physicists who instructed the contract physicist), and an authorized user.

6.2 Observations and Findings

In July 2003, the consulting physics group hired the medical physicist with the intent this physicist would be permanently assigned to the licensee's institution. Between July and December 2003, the individual worked as a "junior" physicist half-time at two medical institutions in order to obtain the necessary working experience to satisfy the requirements of 10 CFR Part 35.961 for an authorized medical physicist. The licensee's former contract medical physicist provided initial and on-the-job training to the junior physicist.

The initial training included a tour of the brachytherapy source storage room and observations of the brachytherapy source inventory within the storage safe. The former consulting physicist pointed out the source strength differences between the "old" set and the "new" set of sources based on source activity. However, the junior physicist was not instructed on the differences in source manufacturers or physical dimensions. On-the-job training progressed from observations to active participation, with the former medical physicist, in treatment planning/patient calculations and preparing/loading sources for various brachytherapy treatments. The inspectors identified that the medical physicist did not receive specific instructions on radiation protection procedures, written directive procedures, regulations under 10 CFR Part 35, "Medical Use of Byproduct Material," and license conditions. Instead, the medical physicist only received limited instructions on how the brachytherapy procedures were performed from the previous medical physicist.

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

to instruct the contract medical physicist in its written radiation protection procedures, written directive procedures, regulations under 10 CFR Part 35, and license conditions with respect to the use of byproduct material constitutes an apparent violation of 10 CFR Part 35.27(a)(1).

In January 2004, the former medical physicist departed from the licensee's facility and the junior physicist, now qualified to work as an authorized medical physicist, assumed all medical physics support duties. At this time, an authorized user informed the newly trained medical physicist of a planned brachytherapy patient treatment, where the physician intended to use the Wang applicator, an applicator unfamiliar to the medical physicist. The medical physicist, unaware that the previous physicist had ordered and received this device on behalf of the licensee in September 2003, contacted the previous physicist to inquire about the Wang applicator. The authorized user relied on the medical physicist to self-instruct and familiarize himself with the applicator prior to the first use. The former physicist informed the medical physicist of the location of the Wang applicator within the radiation oncology department, described the source loading sequence, and informed him to read the device manufacturer's package insert/instruction pamphlet.

The medical physicist briefly reviewed the manufacturer's package instructions and focused his attention on the attached isodose curves and clinical studies. The medical physicist failed to note the specific references in the manufacturer's instructions that specified the use of 3M sources in the Wang applicator. Neither the former medical physicist nor the authorized user instructed the physicist to use 3M sources in the Wang applicator. In fact, neither the former medical physicist nor the authorized user had read the manufacturer's instructions for the Wang applicator. The Licensee possessed brachytherapy sources manfactured by 3M and Amersham, and, the former medical physicist and the authorized user were unaware of the differences in physical dimensions of the brachytherapy sources. This difference in physical dimensions, specifically the source diameter, was of significance regarding the technical limitations associated with the Wang Applicator.

Based on the inadequate instructions provided to the medical physicist, the physicist failed to recognize that 3M sources should be used in the Wang applicator and loaded Amersham sources. The medical physicist selected the Amersham sources, due to their higher source strength, to obtain the appropriate dose to the treatment site as prescribed in the written directives for the five patients involved in the medical events.

6.3 Conclusions

The licensee provided limited instruction to the medical physicist on the licensee's program including the use of the Wang applicator. The inspectors identified an apparent violation of NRC requirements involving the licensee's failure to instruct the contract medical physicist in its written radiation protection procedures, written directive procedures, regulations under 10 CFR Part 35, and license conditions.

7 Notifications and Reports

7.1 Inspection Scope

The inspectors interviewed the RSO, an authorized user, and selected contract medical physicists to verify that the licensee made the required notifications. In addition, the inspectors reviewed the written 15-day reports submitted to the NRC.

7.2 Observations and Findings

The licensee identified the unintended exposures to the patients' upper thighs in April 2004 during an investigation into the skin ulcerations of several patients treated January through March 2004. During a May 19, 2004, meeting, the Radiation Safety Committee discussed the exposures to the patients' thighs along with a discussion on whether the exposures were reportable to the NRC. The RSO informed the committee members, based on information form the contract medical physicists, that the events did not meet the criteria for a medical event and, therefore, were not reportable to the NRC.

The contract medical physicist misunderstood the reporting requirements in 10 CFR Part 35.3045(a)(3). This part 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 sievert (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. The contract medical physicists knew the doses to the patients' skin were greater than 0.5 Sv (50 rem); however, the physicists misunderstood the second part of the requirement as 50 percent or more of the prescribed dose to the treatment site and permanent functional damage to the skin.

The contract senior medical physicist recommended to the licensee on March 25, 2005, that Patients 3 and 4 be reported to the NRC as medical events. This recommendation was based on a further review of the reports, generated by the contract medical physicist assigned to the licensee's facility, that indicated the skin dose estimates to the skin of the thighs was greater than 50 percent of the dose administered to the prescribed location and permanent functional damage to the skin from the reoccurring lesions, as reported by the authorized physician user. The licensee reported these medical events to the NRC Operations Center on March 28, 2005. This delay was caused by the RSO waiting for a written report from the physician-authorized user describing the incident details as a means of assisting his communications of the medical events with the NRC.

The Augmented Inspection Team inspectors informed the licensee and medical physicists that the dose to the skin of the thighs was reportable if the dose to the skin was greater than 0.5 Sv (50 rem) and was 50 percent or more of the dose the skin was expected to receive from the correctly administered prescribed dose. Based on the inspectors' explanation, the licensee reported the medical event involving Patient 5 to the NRC Operations Center on April 1, 2005, and the medical events regarding Patients 1 and 2 to the NRC Operations Center on April 5, 2005.

Title 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. Title 10 CFR Part 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. The licensee's failure to notify the NRC of five medical events by the next calendar day after discovery of these medical events on May 19, 2004, constitutes an apparent violation of 10 CFR Part 35.3045(c).

The licensee submitted written reports on each medical event to the NRC as separate letters (five), dated April 6, 2005. The written reports included a description of the events, why the events occurred, the effects on the patients, immediate and long-term corrective actions, and when the patients and referring physicians were notified. The licensee provided an addendum to the written reports for Patients 3 and 5, dated April 14 and 15, 2005, respectively. The licensee provided additional information for Patient 3 in a letter, dated April 14, 2005, describing the clinical symptoms noted during a February 15, 2005, follow-up examination. In a letter, dated April 15, 2005, (for Patient 5) the licensee noted a corrected date of a follow-up examination. The reports and addendums included the information required by 10 CFR Part 35.3045(d).

7.3 Conclusions

The licensee's staff and the contract medical physicists misunderstood the NRC's definition of "medical event" and the related notification requirements. The inspectors identified an apparent violation of NRC requirements involving the licensee's failure to appropriately identify the five medical events and provide timely notification of the events to the NRC. The written reports and addendums included all of the required information.

8 Review of 10 CFR Part 35.400 Activities

8.1 Inspection Scope

The inspectors reviewed written directives, simulation films, and treatment plans for five selected low-dose-rate brachytherapy treatments, using the Wang applicator, that the licensee administered between January 2003 and April 2005. The inspectors interviewed two authorized users, the director of the radiation oncology department, selected contract medical physicists, and the RSO.

8.2 Observations and Findings

Prior to each brachytherapy treatment administration, an authorized user prepared a written directive. Each written directive included the patient's name, the radionuclide, treatment site, and dose. After implanting the applicator, but prior to implanting the radioactive sources, the licensee took simulation films with the dummy sources loaded in the applicator to verify the correct position of the applicator and the sources.

The licensee used simulation film data to enter three-dimensional data into its treatment planning computer. The treatment planning computer was used to generate the

treatment plan, and the treatment plan was reviewed and approved by the authorized user prior to treatment. After completion of the treatment plan, a second physicist or a dosimetrist independently verified that the data entry was accurate. In addition, the treatment plan calculations were verified by manually calculating the dose.

Prior to implanting the sources, the licensee staff verified patient identity by more than one method. Following implantation, but before source removal, the authorized user documented the prescribed dose to the treatment site, the total dose, and exposure time. The inspectors did not identify any medical events involving the five selected cases reviewed.

8.3 Conclusions

The licensee appropriately evaluated the completeness of the written directives, development of simulation films and treatment plans. The inspectors did not identify any additional examples of medical events during the review of treatments that occurred between January 2003 and April 2005.

9 Review of 10 CFR Part 35.1000 Activities

9.1 Inspection Scope

The inspectors interviewed the RSO, an authorized user, the director of the radiation oncology department, and selected contract medical physicists. The inspectors reviewed the medical physicist's training and qualifications along with the training for the licensee's staff who participated in intravascular brachytherapy(IVB) treatments. The inspectors reviewed written directives for six IVB treatments that the licensee administered between January 2004 and October 2004.

9.2 Observations and Findings

The licensee initiated IVB administrations in 2001 using the Novoste Model A1000 unit containing strontium-90 source trains. The hospital administered approximately 25 to 50 IVB treatments annually.

The device manufacturer provided initial training to the licensee staff who participated in the IVB treatments. A manufacturer's representative also proctored the first few cases to acquaint the staff with the use of the IVB unit. All IVB patient treatments were administered by an attending cardiologist, a radiation oncologist, and a medical physicist. All IVB procedures were conducted under the direction and supervision of two radiation oncologists, who were authorized by name on the NRC license. A contract medical physicist, whose training and experience met the requirements of 10 CFR Part 35.961, also participated in the treatment planning and administration of the IVB cases. The qualified contract medical physicist participated in IVB treatments between January and October 2004. However, the licensee had not approved the contract medical physicist, in writing, as an authorized medical physicist until April 12, 2005.

Title 10 CFR Part 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. The licensee's failure to

approve, in writing, a contract medical physicist who worked as an authorized medical physicist and participated in IVB treatments between January and October 2004, constitutes an apparent violation of 10 CFR 35.24(a).

Prior to each IVB treatment administration, an authorized user prepared a written directive. Each written directive included the patient's name, the radionuclide, treatment site, and dose. Prior to administration of the IVB treatment, the licensee staff verified patient identity by more than one method. The RSO reviewed all IVB treatment written directives every quarter and did not identify any medical events. The RSO reported these reviews to the radiation safety committee. The inspectors did not identify any IVB medical events involving the six selected IVB cases reviewed.

The hospital's use of its IVB units declined during the 2004 calendar year due to the experimental use of drug-coated stents. In October 2004, the hospital permanently ceased its use of the Novoste IVB unit. The licensee returned the unit and sources to the manufacturer for disposal on January 17, 2005.

9.3 Conclusions

The licensee appropriately conducted IVB treatments. The inspectors identified one apparent violation of NRC requirements involving the licensee's failure to approve, in writing, an authorized medical physicist before allowing that individual to work as an authorized medical physicist.

10 Licensee Corrective Actions

10.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions for the five medical events involving the unintended exposures to the skin of the patient's thighs. The review included interviews of selected licensee personnel.

10.2 Observations and Findings

In April 2004, immediately after the licensee identified that the Amersham sources could change position during brachytherapy treatments, the licensee initiated actions to prevent similar events. Based on a recommention from the senior consulting physicist, the licensee treated subsequent patients with the applicator using a plastic tandem and pusher rather than the spring to hold the sources in position. The solid, rigid plastic pusher ensured that the 3M and Amersham sources would remain in place within the applicator during treatments. The licensee promptly informed all applicable licensee staff about the use of the plastic tandem and pusher instead of the applicator spring.

On April 4, 2005, the senior consulting physicist initiated revisions to the licensee's written directive form for brachytherapy treatments and the licensee's procedures for ensuring that brachytherapy treatments were completed in accordance with written directives. The licensee revised the written directive form to include the prescribed dose prior to administration for cesium-137 brachytherapy treatments. The licensee revised the procedure for administrations requiring a written directive so that the procedure did not reference terms that were no longer defined in 10 CFR Part 35.

The licensee also revised its procedure for administrations requiring a written directive so that it included acceptance testing of new brachytherapy applicators. In addition, all applicable licensee staff were trained on the revised written directive and the revised procedure for ensuring that brachytherapy treatments were in accordance with written directives prior to the next brachytherapy treatment.

Although the licensee revised its procedure for administrations requiring a written directive, the revisions did not include: (1) a description of the applicators possessed by the licensee; (2) a reference to the manufacturer's instructions; and (3) a description of the brachytherapy sources possessed by the licensee and their limitations for use in different applicators.

The licensee formalized its training program for new employees. A training orientation checklist was developed and included competencies to be completed within 90 days of employment with the radiation oncology department. The competencies included, but were not limited to the hot lab, hot lab sources, and policy and procedures for brachytherapy treatments. The licensee also developed a training outline that provided details on the training to be provided for each of the competencies. The licensee also verfied that the contract medical physicist was qualified to participate in IVB treatments, and on April 12, 2005, approved the individual as an authorized medical physicist.

The licensee initiated long-term corrective actions on April 4, 2005. The licensee submitted its corrective action plan to the NRC on April 12, 2005. The plan included: (1) the need for a Root Cause Analysis Team to conduct a complete and thorough assessment of all precursor and current processes affecting patient outcomes as a means of identifying the root cause of the medical events; (2) enhancement of the licensee's audit program; (3) the need for the RSC to review educational needs, and problem identification and resolution techniques; and (4) notification of the NRC whenever an event involving unusual circumstances and/or outcomes occur.

On June 2, 2005, the licensee submitted a letter to the NRC describing additional corrective actions to be implemented including: (1) replacing the RSO; (2) conducting an independent audit of the radiation safety program before the end of June 2005; (3) reviewing radiation safety activities and holding radiation safety committee meetings monthly, until a new RSO is in place; and (4) auditing the radiation safety program annually by an independent contractor. In addition, the licensee is currently recruiting an in-house full-time medical physicist, rather than relying on contractor medical physicists.

10.3 Conclusions

The licensee implemented immediate corrective actions that included replacing the applicator spring with a plastic push rod to hold the tandem sources in position within the applicator. The licensee is continuing to develop and implement long term corrective actions to prevent recurrence of the violations.

11 Exit Meeting

At the completion of the onsite inspection, the inspectors conducted an exit meeting with licensee management and staff. The inspectors discussed the apparent violations, the root and contributing causes of the medical events, and the licensee's proposed corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Partial List of Persons Contacted

* 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 Langley, Director, Radiation Oncology
* Carol Norris, Executive Director, Oncology
* Gary L. Perecko, President, South Bend Campus
* John D. Schue, Ph.D., Radiation Safety Officer

Arete Medical Physics

Nathan Davis, M.S., Medical Physicist
Christopher Gouin, M.S., Medical Physicist (formerly with Arete)
Norm Lehto, M.S., Medical Physicist
* Brent Murphy, M.S., Senior Medical Physicist
Jennifer Sessions, M.S., Medical Physicist

* Individuals who participated in the onsite May 26, 2005, exit meeting