Clarian Arnett Health
Medical Group

October 31, 2007

U.S. Nuclear Regulatory Commission
Region III, Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

To Whom It May Concern:

On October 16, 2007, as part of an NRC inspection, an error in treatment was discovered. Upon review of the NRC, this error constituted a medical event under 10 CFR 35.3045(a) (2).

Please find attached the written report required by 10 CFR 35.3045(d) which describes this error and actions taken to prevent recurrence. The treating physician, Dr. Loubna Scally, has already seen this patient in follow-up care and discussed the treatment error with the patient. The physician found no adverse patient outcome.

I would like to note that this same report will be delivered to Dr. Leon McNealy, referring physician, by November 1, 2007. The report will include the patient name and patient identification number.

Please feel free to contact me with any questions at (765) 448-8151.

Thank you,

Dan Goodwin
Administrator, Division of Medical Specialties

cc: Bob Gattone (via fax)

DG/tc

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Report of Patient Treatment Error
August 14, August 28, and September 11, 2007
Oncology Institute of Greater Lafayette

On August 14, August 28, and September 11, 2007, a patient was treated at the Oncology Institute of Greater Lafayette (OIGL) under NRC Materials License number 13-32087-01. On October 16, 2007, as part of an NRC inspection, an error in treatment was discovered. Upon review by the NRC, it was determined that this error constituted a medical event under 10 CFR 35.3045(a)(2). This report is written to describe this error and actions taken to prevent recurrence as required by 10 CFR 35.3045(d).

The prescribing physician and Authorized User (AU) was Loubna Scally, M.D. The treatment was planned and the treatment machine operated by Phil H. Dittmer, Ph.D., who was acting both as Authorized Medical Physicist (AMP) and as Radiation Safety Officer (RSO). The institution as mentioned above was licensed as the Oncology Institute of Greater Lafayette (OIGL), but currently operates under the title of Clarian Arnett Cancer Care, which is used on most current forms and documents.

The physician planned a treatment course of three fractions of 700 cGy delivered to the vaginal wall at a depth of 0.5 cm. The patient was scheduled for treatment on the three days mentioned above. On the day of the first treatment, the patient arrived early and was already in the treatment room at 8 a.m. when the AMP arrived in the clinic. The applicator, a 4 cm diameter vaginal cylinder, was inserted in the patient and the patient was taken to the simulator. Orthogonal films were taken to localize the applicator, with dummy seeds inserted to indicate source dwell positions. While the patient was in the simulator, the AMP completed daily checks of the treatment machine, a Nucletron microSelectron HDR unit. The films were reviewed and it was determined that the applicator was in the correct position anatomically. However, the physician had inserted a rectal shield in the applicator that obscured the position of the dummy markers, so the shield was removed and the patient returned to the simulator and one of the films was retaken. After filming, care was taken to re-insert the rectal shield prior to treatment.

The AMP then began treatment planning on a Nucletron PLATO radiation treatment planning computer. The films were marked with the positions of bladder, rectum (as determined by a radiographically visible rectal marker), and ten points along the vaginal wall at a depth of 0.5 cm. The physician indicated the length along the applicator to be treated. Dwell positions as indicated by dummy markers were observed on one orthogonal film and marked on the second film at the corresponding coordinate position as measured from the coordinate axes on the film. The films were placed on the digitizer and dose points and dwell positions were entered into the treatment planning computer. A plan was prepared to deliver the intended dose of 700 cGy to the dose points. An attempt was made to export the plan to the treatment console of the HDR unit, but the software displayed the message "Error: Inaccurate catheter reconstruction. Export has been disabled!" and refused to export the treatment plan. The AMP could not find a fault in the plan, so he reviewed the films to make sure they were marked correctly, digitized

in (again) all of the points of interest, and repeated the planning process. The same message was displayed, along with the same refusal to transfer the plan.

The above steps, including two trips to the simulator, physicist completion of daily checks on the machine, and performing treatment planning twice, had taken over three hours. During this whole time the patient had a 4 cm diameter cylinder in the vagina and a stiff plastic marker in the rectum, and was complaining audibly (including moans or crying) of her discomfort. The planning station is near the treatment room, so the AMP was aware of this discomfort. The patient was so uncomfortable that she threatened to abort the procedure, but was dissuaded by the nurse.

The AMP printed scaled plots of the position of dose points and dwell positions and overlaid them on the film, and they corresponded very closely. He also noted that the length of the catheter in software was a fraction of a mm different from 70 mm, as would be expected for 15 potential dwell positions spaced by 5 mm (only 13 dwell positions were used in the final plan). He concluded that the report of inaccurate catheter reconstruction was an anomaly of the software or the digitizer and that treatment should go forward. Unable to transmit the plan to the treatment console electronically, he entered the values by hand. Prior to treatment, he asked the physician to complete a treatment prescription, which she did. He also used a spreadsheet to perform an independent calculation of dose as a function of coordinates of dose points and dwell positions and of dwell times and source strength, and found good agreement. He also called a colleague at his home institution (he regularly works at the Indiana University Medical Center, and works at OIGL under contract) and gave him important treatment parameters (source strength, treatment length, cylinder diameter, and depth), and his colleague performed an independent calculation and confirmed that the dwell times were correct within a few percent. Upon entering dwell times for treatment, the treatment machine console would not perform the treatment as originally planned because dwell times at some dwell positions exceeded 120 seconds. The AMP adjusted the optimization parameter in the plan so that the maximum dwell time would be less than 240 seconds and then divided all dwell times in the console by two. The patient was then treated twice to deliver the full dose.

On August 28, to spare the patient long delays and great discomfort, the AMP persuaded the AU to use the same plan developed previously. In the interim, he had contacted Nucletron and learned from them how to reset the maximum dwell time to 999 seconds so the full treatment could be delivered all at once. He performed calculations to verify that the dwell positions had all been adjusted correctly for source decay, and the treatment was administered. The patient was in the clinic less than an hour. A similar procedure was followed for the final treatment on September 11, 2007.

On October 16, 2007, as part of an NRC inspection, it was observed that the treatment record for all three treatments indicated that a dwell position spacing of 2.5 mm had been used. The treatment plan was performed for a dwell position spacing of 5 mm, so the treatment was delivered to a significantly shorter length than intended. A plan was created to reproduce the treatment as actually delivered, and it was found that while the

average dose to all dose points was 700 cGy as intended, the dose to points in the proximal vagina was as much as 30 percent greater than the original plan, and the dose to points in the distal vagina was low by an even larger percentage. The NRC notified the RSO on October 29, 2007 that it had determined this treatment error to be a medical event because of the magnitude of these local discrepancies.

The treatment error was reported to the NRC Operations Center as a probable medical event on October 17, 2007. The referring physician was notified the same day. The patient was contacted the same day and invited to come to the clinic the next day, where the physician told her of the treatment error. The physician had previously examined the patient and observed no symptoms from the treatment error (the patient reported some soreness, which is normal for a treatment of this kind).

The immediate cause of the treatment error was that when the AMP entered the plan into the treatment machine console, he failed to check and verify that the dwell position spacing agreed with the plan. Since this parameter is important in determining the geometry of the treatment, it may seem remarkable that this check was not performed. While there is no excuse, there is an explanation. The AMP has performed over 100 procedures of this kind using the same planning system and treatment machine at his home installation, and has always been able to transfer plan data electronically. When the network connection fails, a floppy disk is used. Because the treatment console corrects for source decay, part of this transfer is to always perform a decay calculation and to check that dwell times have been scaled accordingly. Plans are always performed with a dwell position spacing of 5 mm, and this parameter is always transferred correctly. In the case under discussion, the AMP carefully performed the checks that he is accustomed to doing and verified that dwell times were calculated correctly and entered correctly. However, feeling the pressure of patient delay and discomfort, he forgot that dwell position spacings other than 5 mm were available and did not check this parameter.

Upon discovery of the error by the NRC inspector, the AMP checked the treatment console and confirmed that the 2.5 mm spacing is not only available, but is also set as the default spacing. This default was immediately reset to 5 mm. In addition, procedures have been reviewed. Procedures previously developed for HDR treatments at OIGL explicitly include checking correct dwell position spacing, but these had not been carefully reviewed by the AMP prior to treatment because of extensive experience at his parent facility and familiarity with procedures developed and implemented there. He has revised and modified these procedures for OIGL, including specific mention of the source spacing parameter. Included is a list of parameters to be checked in the treatment console by a second staff member prior to treatment. A copy of these revised procedures is attached.

In addition to the immediate cause of the treatment error, there were several other factors that caused the procedure to go less smoothly and may therefore have contributed to the error made by the AMP. The most significant of these was the failure of the plan to transfer correctly to the treatment console. Following the NRC inspection, the AMP contacted the Nucletron service representative and reported anomalies in the planning

system or digitizer and asked him to come to check them. One anomaly is that the monitor often fails to wake up after automatic shut off, which added considerable delay and anxiety to the planning procedure the first time it occurred (this first occurrence may have been August 14, but the AMP does not recall for certain). Nucletron will send new hardware to correct this problem. The AMP also discussed the treatment plan transfer failure that led to the August 14 error and, at his suggestion, developed a completely new plan with the same result. After calling for software support (the service representative is a hardware specialist), the AMP discovered that the failure was caused by using the vertical coordinate on one film to determine the vertical coordinate of the dwell position on the second film, which produces discrepancies of a few mm if the points are a significant distance from isocenter in two dimensions, because of divergence of the x-ray beam from a point source. It appears that the coordinates in the plan were accurate, as verified by overlaying plan printout on the film as described above, but discrepancies in coordinates of the second film were larger than the software would accept. This can (and will) easily be avoided in the future by relying on guiding lines in the PLATO software that take beam divergence into account.

Other factors have also been reviewed and corrected which may have contributed to the August 14 error. The AMP has discussed scheduling with the nursing staff so that patients will not be placed in the room until after daily physics checkouts have been completed. Initial orthogonal simulator films will now be taken without shielding in place so correct dwell positions will be visible on both orthogonal films and added patient delay will be avoided. The rectal marker will be inserted for the simulator films but will be removed afterward to improve patient comfort. On August 14, planning was further delayed by the fact that while the scheduled treatment involved use of vaginal cylinders and the AMP had extensive experience with vaginal cylinder treatments, Nucletron has two different types of applicators of different geometry, and the applicator used August14 was unfamiliar to the AMP. Hence, after the treatment was completed and before the applicator set was wrapped and sterilized, the AMP took radiographic films of all applicators with dummies in so that the applicator set is now well characterized in the clinic and future planning can be performed with more speed and confidence.

One other factor indirectly contributing to the treatment error is the fact that the clinic in question if fairly busy with about thirty external beam patients per day, some treated with IMRT. The revival of a brachytherapy program, especially with physician, physics, and nursing staff learning to work together on different types of procedures for the first time, has added significantly to physics workload. The OIGL has recognized that current coverage at three days per week is inadequate to support this workload, and has requested full time coverage to begin some time in 2008. This will permit more thorough preparation work on procedures and equipment prior to treatments, and periodic independent review of the same to ensure compliance with all NRC regulations and to reduce the likelihood of unexpected events which may lead to errors and to improve the response to such events if they do occur.

This report was prepared by Phil H. Dittmer, Ph.D., RSO of OIGL.

Clarian Arnett Cancer Care
HDR Brachytherapy Procedures

I. Written Directive (Prescription)

A. Prior to initiation of an HDR treatment, a written directive (prescription) shall be dated and signed by an authorized user (AU). The written directive shall include the patient's name, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose.

B. A written revision to an existing written directive may be made if the revision is dated and signed by an AU before the administration of the HDR treatment.

C. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by an AU within 48 hours of the oral revision.

II. Patient Treatment Planning

A. Treatment plans shall be reviewed by a qualified staff member (e.g. a trained authorized user/staff physician, dosimetrist, or physicist) who did not complete the original plan to verify that the plan is in accordance with the written directive. This will include use of an independent means to verify that doses are calculated accurately (this portion of the review may be performed by the staff member who prepared the original plan). This review shall be completed before the treatment is initiated.

B. Following the review described in Paragraph IIA, the treatment plan is transferred to the treatment unit control console. At this time, the treatment parameters transferred to the control console shall be reviewed to verify agreement with the written directive and the treatment plan. Where possible, this review will be performed both by the staff member who prepared the plan and the one who reviewed it as described in Paragraph IIA. Treatment parameters to be verified shall include radioisotope, source positions, source position separation, indexer length, dwell times, and the total dose for the fraction. Treatment parameters shall be checked by comparing the printout from the console of the HDR unit to the final plan generated by the treatment planning computer, with dwell times corrected for source decay when applicable.

C. Acceptance testing for accuracy of dose calculation and treatment planning software will be performed on all computers used for this purpose.

III. Implantation of Sources

A. Before any source is implanted into patient, spot check measurements shall be performed in accordance with 10 CFR 35.643.

B. Before any source is inserted into a patient, the patient's identity shall be verified by two methods (i.e., by asking the patient his/her name, comparison of patient to face photo in chart, comparison of name in chart to hospital wristband, or any other appropriate method).

C. Before any source is inserted into a patient, the position of any catheters or fixed geometry applicators used will be radiographically verified. The radiograph shall be initialed by an authorized user/staff physician to indicate approval of the catheter or fixed geometry applicator positioning. The physician shall also verify that the treatment configuration will allow for expeditious removal of a decoupled or jammed source.

D. Before any source is inserted into a patient, the qualified staff member administering the patient treatment shall verify that the treatment to be provided is in accordance with the written directive and treatment plan, as described in Paragraph IIB above.

E. Before the treatment has been performed, an authorized user/staff physician shall sign and date the printout from the HDR console to indicate that the treatment is to be performed according to the written directive and treatment plan.
F. An authorized medical physicist (AMP) and an AU shall be physically present at the time of initiation of treatment. The AMP and the AU or another trained physician shall continue to be present for the duration of treatment.
G. Upon completion of treatment, the AMP shall survey the patient and the HDR unit to confirm that the source has been removed from the patient and returned to the safe shielded position. This survey shall be performed using a survey instrument calibrated within the past year in accordance with 10 CFR 35.61.
H. A qualified staff member administering radiation shall record the radiation dose delivered and the date.

IV. Full Calibrations
A. Whenever an HDR source is replaced or a major repair of the HDR unit is performed, full calibrations measurements shall be performed on the HDR unit in accordance with 10 CFR 35.633. These measurements shall include source output calibration to within ±5 percent using dosimetry equipment that has received an NIST-traceable calibration in the past two years in accordance with 10 CFR 35.630.
B. Source output shall be corrected for physical decay of the source when performing calculations to verify dwell times or point doses, as described in Paragraphs IIB and IIID above.

V. Clarifications of Written Directives and Record Keeping
A. Any individual involved in the administration of an HDR treatment who does not understand the written directive or how to carry out a treatment plan shall seek clarification from an AROP or a member of the physics staff.
B. Each written directive and a record of administered dose to patients shall be kept for three years.

VI. Chart Checking
A. Any identified unintended deviation from the written directive shall be immediately reported to an AROP.
B. If an unintended deviation from a written directive constitutes a medical event as defined in 10 CFR 35.3045, then all legally required actions shall be implemented.

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