STATE OF NEW YORK
DEPARTMENT OF HEALTH
Flanigan Square 547 River Street Troy, New York 12180-2216

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

April 6, 2010

RE: Misadministrations – Event Summaries and Preventive Strategies
Notice No. BERP 2010-1

Dear Medical Therapy Accelerator Registrant:

The issue of radiation therapy misadministrations/errors has recently received significant attention at the national level. As you undoubtedly know, the New York Times published a series of articles on this subject, and the Subcommittee on Health of the United States House Energy and Commerce Committee held a hearing on "Medical Radiation: An Overview of the Issues", on February 26, 2010.

In December 2004 the Department released a notice (BERP-2004-1) to registrants in regard to Misadministration Reporting Requirements and Quality Assurance Programs for External Beam Therapy (copy enclosed). The notice also informed registrants that it was our intent to analyze all reported events for causes and to look for any degree of commonality that we could share with all registrants. That information has been collected and analyzed, and a summary of misadministrations and brief descriptions of select events, is presented in Attachment A. In addition, registrants' corrective actions to prevent recurrence have also been analyzed. A summary of the registrants' strategies and the Department's recommendations are presented in Attachment B.

Although the vast majority of patients receive the intended treatment, significant events occur, some causing permanent damage or death. The Department shares a common goal with registrants to ensure that patients receive accurate and precise treatments as prescribed by their radiation oncologist. Consistent with this goal, we strongly urge you to carefully review this notice and ensure that you incorporate the preventive strategies, as well as the recommendations in this and the previous notice, into your Quality Assurance and training programs.

You are not required to respond to this notice. If you have any questions, or you have any additional preventive strategies, including those you implemented following a "near miss" situation, that would be helpful for other registrants, you are encouraged to contact this office. Janaki Krishnamoorty, Ph.D., DABR is the point of contact for this notice and inquiries.

Dr. Krishnamoorty can be contacted at (518) 402-7590, e-mail us at berp@health.state.ny.us or:

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Sincerely,

Robert E. Dansereau, Assistant Director
Bureau of Environmental Radiation Protection

Enclosures: As stated

BERP 2010-1, Attachment A

Summary of event types

Statistics of event causes for the 230 medical therapy accelerator misadministrations reported for the period of 1/1/2001 through 12/31/2009 are presented below. The total number of accelerators was 112 at the beginning of the period and 162 at the end. Please note that more than one cause/contributing factor is seen for each event. Error prevention strategies are necessary for all aspects of radiation therapy, including staffing/tasks at each level, starting with the physician's prescription/directives to each dose delivery. Comprehensive QA and the team approach can't be stressed enough.

Therapist error. While about 84% had therapist error as a contributing factor, almost 62% had therapist error as the primary cause/contributing factor. Providing sufficient support to therapists by way of adequate staffing levels (e.g. having 2 therapists on each machine at all times) would help reduce this rate.

Failure to follow existing policies and procedures (P&P) contributed to 63% of the events.

Incorrect body part treated (most often setup error) was the leading type of error at 46%.

Physics/Dosimetry error was seen in 26.5% of the events with physics as the primary contribution in 10.4% of events.

The wrong patient was treated in 19% of the events.

Inadequate P&P was found in 16% of the events. This finding points to the importance of establishing and adhering to P&P without fail, for ***each*** treatment field of ***each*** fraction for ***every*** patient. (See NYSSIPP http://www.nyhealth.gov/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/nyssipp_faq.htm)

Radiation oncologist error contributed to 12% of the events.

Misadministration examples and preventive measures/corrective actions

Wrong patient. The wrong patient was treated due to failure to follow patient identification in a non-routine situation; specifically in this case, not following the patient schedule.
One patient received the IMRT treatment intended for another patient (both were prostate cases and both had IMRT plans). Patient C was scheduled for treatment at 10:00 AM and patient A was scheduled for treatment at 10:15 AM. The ultrasound system equipment vendor was present that day and was to demonstrate the system's localizing capabilities. When questioned, the physicist stated that they wanted to treat Patient A first because the requirement of a full bladder for a good demonstration of the ultrasound system led them to choose Patient A, as he usually had a full bladder. With that in mind, rather than following the appointment schedule, they retrieved patient A's electronic chart and called patient A from the waiting room. Patient A had not arrived so they called patient C but they did not retrieve his treatment plan. Consequently patient C was treated using patient A's treatment plan.
Preventive measures. They are enforcing their patient identification policy more rigorously. One therapist will escort the patient from the waiting room to the console and the second therapist will retrieve the chart in the record and verify (R&V) system. Together the two therapists will match the patient to the patient's photograph and the treatment record that has been retrieved. They are also using a TIME OUT step prior to treatment. This step involves reading out loud the patient's name along with treatment parameters and this will be simultaneously compared to the hard copy chart.

Wrong energy. An error in the transmission of data from the treatment planning system to the R&V system resulted in the use of the wrong energy for one field.
A patient that was undergoing AP & PA treatments for a lung tumor received 28 fractions without incident. The 29th through 33rd fractions were to be given as a boost dose. The energy prescribed and entered into the treatment planning system was 18MV for left posterior oblique (LPO) field and 6MV for a right anterior oblique (RAO) field. However a data transmission error during transfer from the treatment planning system to the record and verify system resulted in treatment of both field with the 18 MV x-rays. The facility had noted that they encountered intermittent problems with such data transfers. The physicist stated that he exported data from the treatment planning system to IMPAC (R&V) on the first day of treatment, as part of the set up routine. The transfer was successful for the LPO field, however when he set up for the RAO field there was a fault condition. The fault condition was cleared but in doing so the parameters automatically switched back to the default 18 MV x-ray energy.
Preventive measures included implementation of a policy that requires treatment parameter verification before initiating treatment. A patch to the software that was involved with the data transfer has been installed and tested. In addition, the Department strongly recommends a TIME OUT following any computer crash or error messages to verify all treatment parameters before initiating treatment

Physician error. A patient's left thigh was treated instead of the right thigh (laterality).
A 77-year-old male, with recurrent melanoma to the right thigh, was instead simulated and treated with 9 MeV electrons to the left thigh with 3 fractional treatments of 600 cGy per treatment. The radiation oncologist discovered the error during a weekly follow-up with the patient. The facility reported that the patient was in pain during the simulation and it appears that things were rushed in order to complete the procedure quickly, which likely caused or contributed to the error.
Preventive measures implemented by the facility include a requirement for the simulation technologist to verify the correct body part by comparing physician's prescription with the information in the chart, and the physician will verify correct body part at the time of the simulation.

Therapist error. Incorrect patient set-up resulted in treating the wrong area. Two therapists were involved in setting up a patient for image guided radiotherapy treatment to treat prostate cancer. One read the couch longitudinal position as 150.6 cm to the therapist that was setting the position, but that therapist heard it as 156 cm and set it up accordingly. They obtained an image prior to treatment, as required by their policy. One therapist thought the image did not look right and the other therapist thought it looked okay. Despite this, they treated the patient. The radiation oncologist that reviewed the image later that day discovered the setup error and determined that the patient had been treated 5.4cm inferior to the intended area.
Preventive measures included counseling the therapists that any discrepancy in positioning must be resolved by a physician before treatment and positions adjustments will be made with numbers written on a piece of paper and handed to the therapist at the imaging computer.

Medical Physicist error. The wrong dose was delivered due to a calculation error.
The facility discovered a calculation error after the patient received a single fraction AP/PA treatment to the hip to prevent heterotopic ossification. During a post therapy chart check, it was discovered that the dose delivered was 20% less than the prescribed dose. The initial calculation was double checked by a second member of the physics staff, however the fact that the tissue maximum ratio (TMR) was left out of the calculation was not discovered until days after the treatment, during a treatment completion chart check. The second check done prior to treatment delivery appears not to have been done using a sufficiently independent method, as the 20 % discrepancy was not identified.
For preventive measures they will use 2 different, independent methods to calculate monitor units.

BERP 2010-1, Attachment B

Preventive Measures

Our bureau has reviewed reports of misadministrations involving medical accelerators and brachytherapy procedures for the period of over the past 9 years. Following is a list of effective prevention strategies. We encourage you to go over this list and make changes to your facility's P&P as appropriate.

ERROR/Situation	Preventive Measures
Wrong number of fractions/fractionation	Highlight chart/R&V (Ex: BID, dose change after a few treatments etc), ensure patient/family education/understanding.
Wrong patient treated	Match the patient and treatment record at the console just before the patient is escorted into the linac vault, use a Picture ID or wristband, TIME OUT. *
Errors in calculation (dose, energy or other parameter)	No treatment allowed before a double-check if dose > 300 cGy. Install software interlock to prevent treatment if double check has not been entered in R&V. Require 2 different (independent) ways to calculate monitor units.
Wrong body part (Set up/shift error, wrong side)	Indexed couches, Shift data highlighted, Old/New tattoos clearly marked in pictures and on mask/skin. Document Right/Left laterality confirmation in the simulation/planning sheet. Require port film (image) approval by MD prior to treatment. Tighten tolerance on couch position parameters as appropriate. TIME OUT.
Wrong device (block, compensator, wedge, bolus or other)	Highlight accessory in the chart or R&V, TIME OUT, Label accessories clearly with patient's name, field, orientation, etc.
Machine failure during treatment	Mandate that 2 therapists are assigned to each accelerator for all IMRT or IGRT treatments and for any doses larger than 300 cGy per fraction.
Any Error	"DO NOT DISTURB/TREATMENT IN PROGRESS" Sign by Console. "TIME OUT" Sign by console. Monitor adherence to P&P by therapists. Document all orientation and training of staff, including temporary staff. It is essential that all temporary as well as new staff receive proper and thorough orientation and are credentialed. Repeat/supplement training as necessary. No treatment before completing acceptance tests for new software/hardware.
Calibration	Require an independent confirmation by the Radiological Physics Center or equivalent entity.
Disruption in staff's routine during setup	TIME OUT, recheck patient identity, match patient to treatment plan in treatment console.
Computer/Network Crash/Power interruption	TIME OUT, require data validation prior to treatment.
System override	Limit override privileges via software interlock.

Discrepancy or unclear orders directions	TIME OUT, require verification/clarification of treatment parameters.
Data entry error	Data input verified by a second person (RTT or medical physicist)

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*TIME-OUT Protocol

A “time-out” in the context of radiation therapy is a pause immediately prior to initiation of patient treatment, and at any time that a question or potential discrepancy is noted.

The time-out generally consists of:
1. Patient identification by 2 means;
2. Identification of the correct treatment site
3. Verification of the treatment parameters (energy, collimation, beam modifiers and treatment aids, etc.);
4. Patient positioning: and
5. Verification of monitor units

In September 2006 the Department’s Office of Health Systems Management, Division of Primary and Acute Care Services released the Surgical and Invasive Procedure Protocol (attached) that is designed to prevent wrong patient, wrong site, wrong side and wrong procedure errors for surgery. The basic principles outlined in that document, specifically time-out, are germane to radiation therapy treatment. This protocol is attached and it is available at: http://www.nyhealth.gov/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf

The Joint Commission likewise developed a Universal Protocol to prevent such surgical errors. That protocol and supporting documentation can be accessed at: http://www.jointcommission.org/PatientSafety/UniversalProtocol/