



STATE OF NEW YORK DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

December 1, 2004

**RE: Misadministration Reporting Requirements and Quality Assurance Programs
for External Beam Therapy – Notice No. BERP 2004-1**

Dear Linear Accelerator Registrant:

During the past three years, in the course of conducting inspections at Radiation Oncology facilities, it has become apparent that many registrants have misinterpreted 10 NYCRR 16 (Part 16) requirements with respect to misadministration reporting, and have not fully implemented a quality assurance program. It is our intent with this letter to clarify these issues, as well as to make every facility aware of the need to operate an effective quality assurance program.

Misadministrations are defined in Section 16.25 of Part 16. Subsection (a)(1) states, “A radiopharmaceutical or radiation from a source other than the one ordered.” The source other than the one ordered includes the use of an incorrect energy, for both photon and electron beams. Subsection (a)(3) states, “A radiopharmaceutical or radiation by route of administration or to a part of the body other than that intended by the ordering physician.” The part of the body other than that intended by the ordering physician includes situations where the field size was incorrect and/or a failure to use a wedge or shielding block. Subsection (b)(2) requires the registrant to report such events to the Department.

Not all events that are defined by Part 16 as misadministrations result in harm to a patient. However, all occurrences do involve an error or errors in a patient’s treatment. It is our intent to analyze all reported events for causes and to look for any degree of commonality that we can share with all registrants. (Please note that no facility identifiers will appear on any such reports.) By sharing this information, we can help facilitate the establishment of effective prevention strategies.

During our review of Quality Assurance (QA) programs, we have identified deficiencies, which in some cases have caused major adverse events. Independent reviews by outside accrediting organizations have often identified the same issues.

Inspections have identified the following areas of concern:

- Quality Assurance policies and procedures must be developed for Record and Verify Systems which ensure that operating parameters are correctly entered into the system. Please note that the failure to program a wedge insertion, and the failure to perform a check of the operating parameters entered into a system, led to a patient receiving an orbital dose of 11,330 vs. the prescribed 3060 rads (cGy).

- Facilities must have a policy and procedure to verify function and calibration for diodes that are used for patient dosimetry. The failure to properly utilize a diode has resulted in a doubling of the planned daily dose. A prudent practitioner would use the diode on the first day of treatment, just as a film is used for port verification.
- Film processor sensitometry testing and measurement must be held to the same rigorous standards as would be applied to a diagnostic film processor. This is essential if film dosimetry is to be used for QA evaluations of Intensity Modulated Radiation Therapy (IMRT) treatments.
- Independent calculation checks must be done prior to initiating a single fraction prescription. Likewise, fractional doses that are greater than 300 cGy should be double-checked prior to the first treatment.
- When a patient is to receive hyper-fractionated treatment, weekly chart checks are insufficient. No more than five (5) treatments should be given between physics chart checks.
- Patient identification policies and procedures must be developed and strictly adhered to. Approximately 10% of the misadministrations reported to our office since January 2003 were the result of radiation administered to the wrong patient (10 NYCRR 16.25 (a)(2)).
- Quality control testing of all physical components of radiation oncology as required by 10 NYCRR 16.24 (a)(1)(i)(i, j) includes, but is not limited to, treatment planning equipment, Computed Tomography scanners/simulators, and ultrasound units. Please note that the failure to evaluate the performance of an ultrasound unit resulted in a systematic error in the administration of radioactive seeds to a number of patients with prostate cancer.
- The addition of IMRT capability requires a significant time commitment by medical physics staff in the treatment planning process. Staffing levels should be evaluated carefully by each registrant to ensure that coverage is sufficient to prevent the occurrence of treatment errors and misadministrations.
- IMRT treatments involve a greater number of monitor units or beam on time. Shielding calculations and measurements, for unrestricted and operator control areas, should be completed prior to commencement of an IMRT program.

You are not required to respond to this notice. However, we strongly urge you to carefully review this letter and ensure that these items are included in your Quality Assurance program.

If you have any questions or comments, or if we may be of assistance, please call John O'Connell, Janaki Krishnamoorthy, Ph.D., or me at (518) 402-7590, e-mail us at berp@health.state.ny.us or write to:

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Sincerely,

Robert E. Dansereau, Chief
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