



## American Association of Physicists in Medicine

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By Electronic Transmission

**RE: Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Field Review: Candidate 2007 National Patient Safety Goals (NPSGs) and Requirements**

The American Association of Physicists in Medicine<sup>1</sup> (AAPM) welcomes the opportunity to comment on the “Candidate 2007 Hospital and Critical Access Hospital National Patient Safety Goals (NPSGs) and Requirements”. In particular we would like to offer comments on the “Hospitals’ National Patient Safety Goals Sentinel Event” Section, Sentinel Event Policy and Procedures Updated: June 2005”. Part IV Reviewable Sentinel Events lists 10 events that are reviewable even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition. The last event (actually two quite different event types) in the list involves application of ionizing radiation and falls under the responsibilities of Medical Physicists, and it is this on which we would like to comment.

The AAPM supports the general concept that “any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose” should appropriately result in a reviewable sentinel event. This language is similar to that found in some regulatory references, but lacks some of the supporting detail normally provided. In certain situations (particularly in internal radiotherapy using radioactive material) the simple descriptions of “25% above the planned radiotherapy dose”, or “wrong body region” can either be difficult to quantify or can apply to situations that occur routinely as an expected normal variant of the procedure. In fractionated radiotherapy, event descriptions such as the one above typically make an explicit reference to the entire course of radiotherapy rather than to a subset of fractions. At the minimum, the descriptions in the sentinel event listing will require either an explanatory footnote (similar to footnote 4 describing rape). An alternative would be to expand the text of the event description with more precise language. We note that the U. S. Nuclear Regulatory Commission (NRC) has similar language and is currently (after much work) revising the concepts under which an event becomes a Reportable Medical Event.

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<sup>1</sup> AAPM’s mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 5,000 medical physicists.

AAPM suggests the following language :

1. “The total dose delivered differs from the prescribed dose by 20 percent or more.” This is consistent with the current NRC requirement for reporting a medical event, and expands the JCAHO requirement to underdoses as well as overdoses.
2. Add a footnote to the “wrong body region” phrase: “Delivery of radiation dose to anatomic regions due to migration of implanted radioactive material or delivery of radiation dose to tissue adjacent to treatment volumes due to normal variations in the treatment process do not rise to the level of a reviewable sentinel event.”

AAPM is willing to further assist JCAHO in refining the language of this phrase so as to capture events that meet the letter and spirit of the definition of Sentinel Event in Part I of the Sentinel Event section, but avoid problems associated with establishing a reportable status for events that may occur routinely in the course of radiotherapy, or events that do not rise to the level of the definition.

The AAPM recognizes the patient safety issues that have arisen in association with the increasing use of ionizing radiation for complex diagnostic and interventional procedures. However, the phrase “Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field” is conceptually inconsistent with the definition of Sentinel Event and with the other events that are described in the list of 10 Reviewable events. The other events in the list are unexpected and undesired occurrences that (by implication) should have been prevented or would have been prevented if appropriate procedures had been in place. The application of ionizing radiation in either diagnostic radiology studies or in interventional radiology procedures is a necessary part of the process to acquire sufficient imaging information to provide a diagnosis or guide a therapeutic intervention. While entrance skin doses of greater than 1,500 rads are rare, one cannot *a priori* determine that the level is inappropriate or requires a root cause analysis (and inherent assumption that the event should not be repeated). It is no more appropriate to define a fixed radiation dose above which a Reviewable Sentinel Event occurs than to quantify the length of an appropriate surgical incision, or the duration of anesthesia for a procedure. The 1500 rad level (to a single skin port) is rarely seen even at institutions that serve as referral centers for complex interventional image guided procedures. The occurrence of a Reviewable Sentinel Event within a hospital triggers an intense process at the institution that is not an appropriate response for a procedure where the medical intervention was necessary and completed as intended. The proposed language poses the risks of inducing behavioral changes in practice at institutions that are inconsistent with the highest quality of patient care: The statement may encourage premature termination of an interventional procedure when some arbitrary dose limit is reached, thus compromising the quality of patient care. Further, the simple “1,500 rad” limit may discourage the efforts of the professional staff to enable the clinically relevant dose monitoring and recording guidelines (such as those recommended by the U.S. Food and Drug Administration (FDA) in favor of the administratively more simple “1,500 rad” flag.

AAPM strongly supports the necessity of accurate monitoring and recording of significant patient dose in high dose imaging (not just fluoroscopy) procedures, with appropriate medical follow-up. We support the FDA recommendations on this subject and have provided comment to FDA and others in this regard. We believe that JCAHO can provide an important patient safety service by a standard that clearly states the necessity of accurate monitoring, recording and, where appropriate, reduction in patient dose for high dose diagnostic and interventional

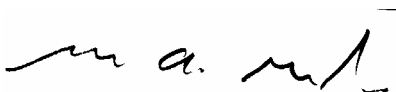
radiology procedures. The inclusion of the phrase “Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field” does not accomplish this goal.

AAPM recommends the following changes:

1. Modify the event description: “Prolonged high dose imaging procedure with an unanticipated cumulative dose >1,500 rads to a single field in a course of treatment.” This change allows for the planned medically appropriate delivery of such a dose, and further extends the integration time of the dose to account for situations where multiple procedures occur over the period of a few days during a course of treatment.
2. Add language elsewhere in the JCAHO publications that facilitates the effort to properly control patient safety in high dose imaging procedures (and thus avoiding procedure related radiation doses that result in unnecessary or unanticipated adverse skin damage)
  - 2.1. Reference the FDA recommendations for monitoring, recording and patient follow-up for high dose imaging procedures
  - 2.2. Recognize that measurements to achieve compliance with dose monitoring recommendations requires establishing appropriate measurement techniques by a qualified medical physicist to assure that the reported dose measurements correctly reflect the dose received by the patient
  - 2.3. Reinstate the previous JCAHO language regarding credentialing for medical practitioners who use fluoroscopy.

AAPM welcomes the opportunity to work with the JCAHO to find the appropriate language and location in the Standards to provide the intended outcome without compromising patient care. Please contact Lynne Fairbent, AAPM’s Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at [lynne@aapm.org](mailto:lynne@aapm.org).

Best Regards,



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Chair AAPM Professional Council

#### Selected consensus References:

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