# Policy and Procedure Memorandum
# Radiation Oncology Department
# Medicine

***Clement J. Zablocki***
**VA Medical Center**
***Milwaukee, WI***

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## Medical, Sentinel, and Investigational Events

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| **Policy and Procedure** | : |
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| Title: Treatment Error Reporting | PP Number: RAD ONC - 01 |
| Division: Medicine | Effective Date: 7//04 |
| Department: Radiation Oncology | Date Revised: 3/12 |
| Rescission: None | Supersedes: 4/09 |

**I. PURPOSE:**

Establish a standard methodology to evaluate and report treatment deviations and/or errors in delivery of external beam radiation therapy.

**II. POLICY:**

Any treatment in which a deviation from the treatment plan has resulted in an error or misadministration of ionizing radiation shall be reported to the attending /covering physician. The event is to be evaluated in detail, the impact on treatment outcome assessed (on both toxicity and tumor control), a report written and a conclusion reached for necessary actions. The patient, and when appropriate his or her family, is informed about unanticipated outcomes of care, treatment, and /or services that are defined as treatment errors considered reviewable by this policy.

**III. PROCEDURES:**

A. Identify that an error has occurred in one of the following three categories:

1. Medical event: improper administration of external radiation that meets the definitions of the NHPP as outlined in Attachment 1.

2. Sentinel event: VHA Handbook 1050.1 provides requirements on the reporting of adverse events and sentinel events, as defined in the handbook

3. Investigational event- as defined by the Medical College of Wisconsin in Attachment 2 and adopted herein, namely, an event or treatment error

that does not qualify as a Medical or Sentinel event, but requires internal review to identify root cause and prevention of future re-occurrence.

B. After discovery of error further treatment will be held until notification of and approval by the attending Radiation Oncologist and Physics staff. Staff members involved will each write a report describing the incident from their perspective within 1 business day. The staff reports will be given to the Program Supervisor, the Lead Physician, and the Radiation Physicist. Depending upon the error, a VA Incident Report may need to be completed.

C. Based on the staff reports and analysis of the treatment record the physics staff will further investigate and document the nature, cause, and dosimetric impact of the error. Recommendations for further study and measures to prevent the error from re-occurring will be included in the report. This report and staff reports will be provided to the attending Radiation Oncologist in 1 business day.

D. The attending Radiation Oncologist will review and write a report that summarizes the error and the findings. A statement will be included regarding the possible medical impact of the error in terms of tumor control and risk additional toxicity. The summary report will suggest an appropriate classification level for the event and make recommendations for future follow-up actions. A recommendation for patient disclosure will also be made. This report will be submitted to the department Quality Assurance (QA) Committee.

E. The attending physician, physicist and department supervisor will:

1. Determine the severity of the error and define it as either a Medical, Sentinel or Investigational event.

2. Decide on the necessary steps to prevent a similar error from happening again, e.g., conduct Root Cause Analysis.

3. Take any necessary actions, e.g., education, training, etc., for involved staff.

4. If the error meets the definition of a Medical or Sentinel event, Physics will contact the hospital Radiation Safety officer immediately, who will report to the NHPP, Zablocki VA Performance Improvement, and/or Risk Management, if necessary, following the required processes.

5. Records of the error reports, subsequent root cause analyses, and follow-up monitors are to be maintained as privileged QA information in secure storage.

6. Follow-up steps should be taken to ensure all processes are in place to assure error will not be repeated and a presentation of the information will be discussed at the next available staff meeting.

7. If recommended, appropriate patient disclosure should be carried out.

8. Any changes in Policies and Procedure resulting from the analyses will be formally written up and reviewed/approved at the next available departmental staff and QA meetings.

**V. SCOPE:** Radiation Oncologists, Medical Physicists, Dosimetrist and Radiation Therapists.

**VI. DISTRIBUTION:** Policy and Procedure Manual

**VII: ATTACHMENTS:**

1. VHA Definitions of External Beam Treatment Errors
2. Medical College of Wisconsin, Department of Radiation Oncology Definitions of External Beam Treatment Errors
3. Error Log

Also See: *VHA Handbook 1200.5 and VHA Handbook 1058.1*.

**VIII. AUTHORIZATION/APPOVAL:**

**Recertification:** 3 years

**IX. APPROVED BY:**

_____ _____
Patrick Tripp, MD Date
Lead Physician, Radiation Oncology

_____ _____
Daniel Grimm, MS Date
Senior Radiation Physicist, Radiation Oncology

_____ _____
Carol Francis, RTT Date
Supervisor, Radiation Oncology

## ATTACHMENT 1.

### VHA Definitions of External Beam Treatment Errors

Currently, the VHA does not require reporting of misadministration of external beam irradiation (defined below and sometimes referred to as "Treatment Errors" or "Medical Events") to state governments since the VA falls under the jurisdiction of Federal law. The VA's National Health Physics Program (NHPP) currently has a voluntary reporting system of treatment errors, but this is temporary until the VHA completes an update of the VA Radiation Oncology Handbook. Once completed, reporting medical events to the NHPP will be mandatory and will use the following definitions of a misadministration and the thresholds for reporting them.

**A. Misadministration**. A misadministration of ionizing radiation is defined as:

1. An event, except for an event that results from intervention of a patient or human research subject, in which the administration of external beam radiation therapy results, or will result in unintended permanent functional damage to an organ or a physiological system as determined by a physician.
2. Other than events that result from intervention by a patient or human research subject, any event in which the administration of an external beam radiation therapy dose:
    a. Involves the wrong patient
    b. uses the wrong treatment modality,
    c. to an organ outside the intended treatment volume exceeds the expected dose to that organ by 0.5 Sv (50 rem or cGy) where the excess dose is greater than 50% of the expected dose to that organ
    d. Consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or
    e. The calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or
    f. The calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

c. Reporting requirements - Each VHA facility shall make notifications and reports of medical events and medical misadministrations to patients to the VHA National Health Physics Program (NHPP), as specified below.
    1. The facility shall notify the NHPP by telephone no later than the next calendar day after the discovery of a medical event or misadministration.
    2. The facility shall submit a written report to the NHPP within 15 days after the discovery of a medical event or misadministration. The written report must include:

a. The facility's name;
b. The name of the prescribing physician;
c. A brief description of the event or misadministration;
d. Why the event or misadministration occurred;
e. The effect, if any, on the individuals(s) who received the administration;
f. Actions, if any, that have been taken, or are planned to prevent recurrence;
g. Certification that the facility notified the individual (or the individual's responsible relative or guardian), or if not, why not.

3. The report may not contain the individual's name or any other information that could lead to the identification of the individual.
4. The facility shall provide notification of the event or misadministration to the referring physician and also notify the individual who is the subject of the event or misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The facility is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the facility shall notify the individual as soon as possible thereafter. The facility may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph the notification of the individual who is the subject of the event or misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made the facility shall inform the individual, or appropriate responsible relative or guardian that a written description of the event can be obtained from the facility upon request. The facility shall provide such a written description if requested.

## B. Disclosure and Reporting of Adverse Events

Disclosure of Adverse Events to Affected Patients: VHA facilities and individual VHA providers have an obligation to disclose adverse events to patients who have been harmed in the course of their care, including cases where the harm may not be obvious or severe, or where the harm may only be evident in the future. VHA Directive 2005-049 provides policy on the disclosure of adverse events related to clinical care to patients or their representatives.

Reporting of Adverse Events: Adverse Events and Sentinel Events shall be reported within the facility to the Patient Safety Manager (PSM), or designee. VHA Handbook 1050.1 provides requirements on the reporting of adverse events and sentinel events, as defined in the handbook, and on the performance of root cause analyses.

ATTACHMENT 2.

**Medical College of Wisconsin, Department of Radiation Oncology Definitions of External Beam Treatment Errors**

**A. Medical Event**

"Medical event" means an improper administration of radiation or radioactive material to a patient or human research subject that requires reporting to the Wisconsin Department of Health and Human Resources. The portions of the Wisconsin Administrative Code relative to external beam radiation therapy further defines medical events as incidences in which the radiation results in any of the following:

1. A dose that differs from the prescribed dose by more than 50 cGy (rem) to an organ or tissue and to which any of the following apply:
   a. The total dose delivered differs from the prescribed dose by 20% or more.
   b. The fractionated dose delivered differs from the prescribed dose, for a single fraction by 50% or more.

2 A dose that exceeds 50 Cgy (rem) to an organ or tissue from any of the following:
   a. An administration of a dose to the wrong patient or human research subject.
   b. An administration of a dose delivered by the wrong mode of treatment.

3. A dose to an organ outside the intended treatment volume that exceeds the expected dose to that organ by 50 cGy (50 rem) in which the excess dose is greater than 50% of the expected dose to that organ.

**B. Radiation Therapy Sentinel Event** (defined by Joint Commission):

Any delivery of radiotherapy to the wrong region or > 25% above the planned dose.

**C. Investigational Event:** defined by MCW Dept of Radiation Oncology as events that require internal review

Any delivery of radiotherapy to the wrong patient, or any improper administration of radiation that results in errors equal or greater than the half of the threshold as defined for the "Medical Events", e.g.:

1. A dose that differs from the prescribed dose by more than 25 cGy (rem) to an organ or tissue and to which any of the following apply:

a. The total dose delivered differs from the prescribed dose by 10% or more.

b. The fractionated dose delivered differs from the prescribed dose, for a single fraction by 25% or more.

2. A dose that exceeds 25 cGy (rem) to an organ or tissue from any of the following:

a. An administration of a dose to the wrong patient or human research subject.

b. An administration of a dose delivered by the wrong mode of treatment.

3. A dose to an organ outside the intended treatment volume that exceeds the expected dose to that organ by 25 cGy (50 rem) in which the excess dose is greater than 25% of the expected dose to that organ.

## D. Disclosure and Reporting of Medical Events and Sentinel Events

1. Medical Events: The reporting of medical events is governed by WI Administrative Code Part 157.72. The following are excerpts of the Code pertinent to the reporting of medical events:

*157.72 (1)(c) A licensee shall notify the department by telephone no later than the next calendar day after discovery of the medical event.*
*(d) 1. A licensee shall submit a written report to the department within 15 working days after discovery of the medical event.*

*2. The written report shall include all the following:*

*a. The licensee's name.*
*b. The name of the prescribing physician.*
*c. A brief description of the event.*
*d. Why the event occurred.*
*e. Any effect on the person who received the administration.*
*f. Any actions that have been taken or are planned to prevent recurrence.*
*g. Whether the licensee notified the person or the person's responsible relative or guardian and if not, why not.*
*h. If there was notification, what information was provided.*

*3. The report may not contain the affected individual's name or any other information that could lead to identification of the person.*

*(e) A licensee shall notify the referring physician of the event and also notify the person who is the subject of the medical event no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that the physician will inform the person or that, based on medical judgement, telling the person would be harmful. A licensee is not required to notify the person without first consulting the referring physician. If the referring physician or the affected person cannot be reached*

*within 24 hours, a licensee shall notify the person as soon as possible thereafter. A licensee may not delay any appropriate medical care for the person, including any necessary remedial care resulting from the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the person who is the subject of the medical event may be made instead to that person's responsible relative or guardian. If a verbal notification is made, a licensee shall inform the person or appropriate responsible relative or guardian that a written description of the event may be obtained from the licensee upon request. A licensee shall provide the written description if requested.*
*(f) If the person who is the subject of the medical event was notified under par. (d), a licensee shall also furnish within 30 days after discovery of the medical event a written report to the person by sending either of the following:*
*1. A copy of the report that was submitted to the department.*
*2. A brief description of both the event and the consequences as they may affect the person.*
*(g) Aside from the notification requirement, nothing in this subsection affects any rights or duties of a licensee or physician in relation to each other, to any person affected by the medical event or to any individual's responsible relatives or guardians.*
*(h) A licensee shall retain a record of a medical event. A copy of the record required shall be provided to the referring physician, if other than the licensee, no later then 15 days after the discovery of the event.*

2. Sentinel Events: The reporting of sentinel events to Joint Commission

    1 is initiated by completing the forms at the website

    http://www.jointcommission.org/SentinelEvents/Forms

    2. Is described in the policy and procedure for sentinel events: http://www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf

    3. Relies on what is described as a "Root Cause Analysis" which "focuses primarily on systems and processes, not on individual performance." This is followed by an "Action Plan" which "identifies the strategies that the organization intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions."

    4. Note that whereas the Wisconsin Administrative Code requires that all persons involved be named (excepting the patient), the Sentinel Event Reporting specifically states to not name those involved.

## E. Internal Requirements and Procedures for Investigational Events

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1. All Investigational Events meeting the above definitions will be reported to the responsible Radiation Oncologist, the department Director, the Head of Medical Physics, and the institutional Radiation Safety Officer.
2. Investigational Events will undergo the following root cause analysis and reporting:
    a. Each treating therapists will independently write a report describing their experience with the event, how it happened, why they believe it happened, and propose steps for prevention of recurrence.
    b. The Medical Physicist will also analyze, using all relevant methods (treatment planning system, phantom measurements, hand calculations, etc) to determine the effect of the error on dose to the tumor and normal tissue, as well as assessment of cause and means for prevention from the Physics perspective.
    c. The responsible Radiation Oncologist will review these reports and in a separate report summarize the findings, conclude the root cause analysis, assess any additional risk to the patient regarding a negative impact on tumor control and/or acute/late side effects and make recommendations for corrective action and patient disclosure.
3. These final reports will be retained in a separate QA file and labeled as confidential QA documents. The patients name will not appear on these reports. Recommendations will be made for reporting the results to the institution's Radiation Safety committee and/or NHPP.
4. Findings will be discussed at next available departmental QA meeting and final recommendations made. These final recommendations will be discussed at the next available departmental staff meeting.
5. Any changes in policies and procedures resulting from the analyses will be formally written up and reviewed/approved at the next available departmental staff and QA meetings.