

Health Authority

January 9, 2012

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INFORMATIONAL BULLETIN 2012-01

To:

Medical Radioactive Materials Diagnostic and Therapy Licensees

X-Ray Machine Diagnostic and Therapeutic Registrants

From:

David M. Howe, Section Manager

Radiation Protection Services

RE:

Conference of Radiation Program Directors (CRCPD) Medical Event

Reporting System

The State of Oregon, Radiation Protection Services has been notified by the CRCPD that the Medical Event Reporting System has been developed and will be online starting January 1, 2012. The Medical Event Reporting System structure has been developed for reporting and data tracking for therapeutic and diagnostic radiation misadministration from radiation machines and byproduct materials used in diagnostic and therapeutic care. Data captured through the reporting system will be available for review through the CRCPD website at a future date.

The CRCPD has defined the criteria for reporting a medical event as the following:

Therapeutic radiation

- Involves the wrong patient, treatment modality or treatment site
- Weekly administered dose differs from the weekly prescribed dose by more than 30%
- Total administered dose differs from the total prescribed dose by more than 20%
- Dose differs by 50% or greater for any single fraction of a multi-fraction treatment
- Unusual event such as equipment failure, personnel error, or accident that could cause significant harm to the patient.

Diagnostic radiation

- Unintended dose to the skin greater than 2 Gy to the same area for a procedure or series
- Unintended dose greater than five times the facility's established protocol for a procedure and exceeds 0.5 Gy to an organ or 0.05 Gy total effective dose
- Wrong patient or treatment site for the entire diagnostic exam and exceeds 0.5 Gy to an organ or 0.05 Gy total effective dose for the procedure
- Unusual events such as equipment failure, personnel error, or accident with the administration of ionizing radiation that exceeds 0.05 Gy total effective dose

Reporting a medical event is voluntary other then where specified in the Oregon Administrative Rules. However, the State of Oregon, Radiation Protection Services recommends medical facilities to participate in the national database of radiation medical incidents in order to establish data on radiation machine events received from state radiation control programs that will identify states differences in laws and regulations regarding reporting and confidentiality and identify trends relating to patient safety and care.

The reporting form is attached for review and can be used as a model as an internal reporting tool.

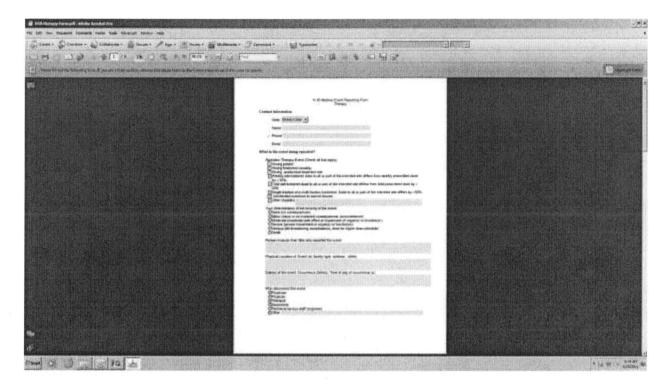
For further questions or when a medical event has been identified, The State of Oregon requests licensees and registrants to follow all Oregon Administrative Rules for reporting requirements and voluntary compliance with the CRCPD medical event reporting project by contacting:

Rick Wendt, Operations Program Manager State of Oregon Radiation Protection Services

Phone: 971-673-0505

Email @ Richard.a.wendt@state.or.us

Enclosure: Medical Event Reporting Form



Welcome to the Medical Event reporting form for Therapy. You can select or type your responses directly onto the form anywhere there is a blue highlight.

To submit the form, you must first save it to your computer. We ask that you use the following naming convention for any form you submit:

- 1. The 2 letter abbreviation for your state.
- 2. Dash (-)
- 3. The date of the incident in month-day-year.
- 4. Th (Therapy)
- 5. Dash(-)
- 6. Abbreviation of facility

An example would look like:

CA-1-10-2012Th-Mem (California, January 10, 2012, Therapy Event at Memorial Hospital)

This naming convention will allow us to keep submissions organized and allow quick entry into a database.

To submit your event form, attach it to an email directed to: bhirschler@crcpd.org

Please use the subject line: "H-38 Medical Event Report-Therapy "Thanks.

H-38 Medical Even't Reporting Form Therapy

Contact Information State Choose a State Name Phone **Email** What is the event being reported? 1. Radiation Therapy Event (Check all that apply) ☐ Wrong patient Wrong treatment modality Wrong anatomical treatment site Weekly administered dose to all or part of the intended site differs from weekly prescribed dose Total administered dose to all or part of the intended site differs from total prescribed dose by > 20% ☐ Single fraction of a multi fraction treatment. Dose to all or part of the intended site differs by >50% Unintended overdose to normal tissues Other (explain) 2. Summarize the incident in a single sentence headline: 3. Describe the details of the incident. Use language that would be understandable to an expert in another clinic: 4. Describe corrective action taken by the facility and/or the regulating body if reporting was required to prevent recurrence: 5. Your determination of the severity of the event: O None (no consequences) Minor (minor or no expected consequences, inconvenience) Moderate (moderate side effect or impairment of organ(s) or function(s)) O Severe (severe impairment or organ(s) or function(s)) O Serious (life-threatening complications, dose far higher than tolerable) O Death

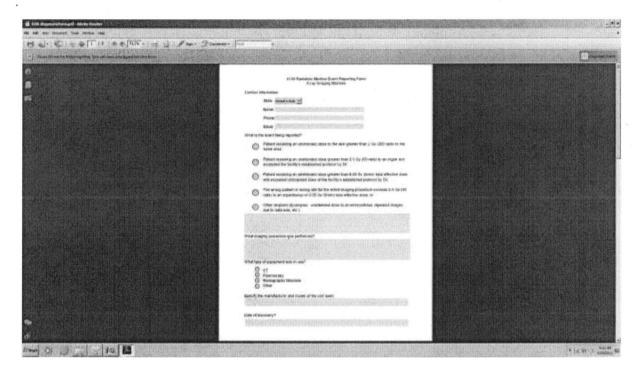
6. Person (Include their title) who reported the event:
7. Physical Location of Event (ie, facility type, address , state):
8. Date(s) of the event: Occurrence Date(s), Time of day of occurrence (s)
9. Who discovered the event OPhysician OPhysicist OTherapist ODosimetrist OTechnical service staff (engineer) OOther
10. How was it discovered? Chart Check In vivo dosimetry Portal Imaging Clinical Review of patient Equipment QC External Audit Olnternal Audit Other
11. When was error discovered: O Before patient's first treatment O At patient first treatment O After patient first treatment
12. Was more than one patient involved in the event? OYes ONo If Yes, please provide detail:
13. Equipment used: a. Machine(s)/Hardware involved (Manufacturer/Model/Version or SN):

b. Software Involved (Manufacturer/Model/Version):

	14. External Beam Technique (select all that apply) IMRT IGRT 3D conformal Modulated Arc Therapy Electons SRS SBRT Protons Other (specify)
	15. Type of error: OWrong patient Incorrect energy Incorrect field size Incorrect dose Incorrect treatment accessory (blocking, wedge, MLC pattern), etc. OGross Alignment Error Other
f y	16. Was any part of patient's treatment delivered incorrectly? O Yes O No Unknown es, number of fractions that delivered incorrect treatment:
	17. Dose deviation from intended: 0 0-5% 0 6-10% 0 11-20% 0 21-50% > 50%
	18. Provide the values for (1) Intended/Prescribed and (2)Delivered: Treatment site Daily dose received (Gy) Total Dose received (Gy) Field size Beam/Energy
	19. Causes/Contributing Factors (indicate all that apply): Inadequate Policy & Procedures Inadequate QA Inadequate Training Documentation & Communication (Records, Staff, Hardware/Software data flow) Therapist Error Physics/Dosimetry Error Physician Error Equipment Malfunction Other

Corrective action:

20. Was an intervention attempted in order to 'rescue' the patient, i.e., to prevent a minimize or reduharm? O Yes, O No, O Uknown
21. Were any additional tests or treatments required as a result of the incident? O Yes O No O Unknown
22. Did or will the incident result in an increased length of stay in the hospital ? OYes ONo OUnknown
23. After the discovery of the incident, was the patient, patient's family, or guardian notified ? O Yes O No O Unknown
24. Were the patient's primary care and other involved referring physicians notified? O Yes O No O Unknown
 25. Did the Radiation Safety Officer review the event? Yes No Unknown If Yes, summarize RSO's review:
26. If Equipment malfunction or defect is identified, have relevant state or national agency and manufacturers been informed? O Yes O No O Unknown



Welcome to the Medical Event reporting form for X-ray Imaging Machines. You can select or type your responses directly onto the form anywhere there is a blue highlight.

To submit the form, you must first save it to your computer. We ask that you use the following naming convention for any form you submit:

- 1. The 2 letter abbreviation for your state.
- 2. Dash (-)
- 3. The date of the incident in month-day-year.
- 4. X (X-ray Therapy)
- 5. Dash(-)
- 6. Abbreviation of facility

An example would look like:

CA-1-10-2012X-Mem (California, January 10, 2012, X-ray Imaging Event at Memorial Hospital)

This naming convention will allow us to keep submissions organized and allow quick entry into a database.

To submit your event form, attach it to an email directed to: bhirschler@crcpd.org

Please use the subject line: " H-38 Medical Event Report-X-ray " Thanks.

H-38 Radiation Medical Event Reporting Form X-ray Imaging Machine

Contact information			
	State Choose a State		
	Name		
	Phone		
	Email		
1. What is the event being reported?			
0	Patient receiving an unintended dose to the skin greater than 2 Gy (200 rads) to the same area;		
0	Patient receiving an unintended dose greater than 0.5 Gy (50 rads) to an organ and exceeded the facility's established protocol by 5X;		
0	Patient receiving an unintended dose greater than 0.05 Sv (5rem) total effective dose and exceeded anticipated dose of the facility's established protocol by 5X;		
	The wrong patient or wrong site for the entire imaging procedure exceeds 0.5 Gy (50 rads) to an organ/tissue or 0.05 Sv (5rem) total effective dose; or		
\bigcirc	Other (explain) (Examples: unintended dose to an embryo/fetus, repeated images due to data loss, etc.).		
e N			
2. What imaging procedure was performed?			
3. What type of equipment was in use?			
	CT Fluoroscopy Radiographic Machine Other		

4. Specify the manufacturer and model of the unit used:		
Date of discovery?		
Date reported to State Agency?		
5. Was the patient notified?		
○ Yes ○ No		
6. Who discovered the event?		
Other Physician-Specialty: Other Physician-Specialty: Medical Physicist Radiologic Technologist Nurse, Nurse Practitioner or Physician's Assistant Service Personnel Patient Other –please indicate:		
7. How was the event discovered?		
Clinical review of patient/patient record review Patient reported Quality control of equipment External audit Observation of machine output/technique parameters (Example: wrong technique used, etc.) Other-please describe		
8. What was the total estimated dose received in the event?		
9. Was more than one patient involved?		
O No O Yes If yes, how many?		

10. If more than one patient was involved what was the total dose received per patient in the event?
Patient #1:
Patient #2:
Patient #3:
11. What was/were the "Determined Cause(s)" of the event? (indicate all that apply) Equipment failure/software error Personnel error Accident Other unusual occurance, please describe:
12. Describe the event in detail:
13. Describe the cause(s) of the event. For example, equipment failure, personnel error, accident, other unusual occurrence, etc.
14. Describe any remedial actions taken by the facility to prevent recurrence of the event.
15. Describe any follow up actions taken by the facility.
16. Did the patient require any follow up care/treatment due to the event? Yes No If yes, please describe the follow up care/treatment:

Yes No	y Officer involved in the event/facility actions?
18. Were the event, cause Committee? Yes No	es and actions to avoid a recurrence reviewed by a Radiation Safety

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