

MEDICAL REPORTABLE EVENTS AND OTHER MEDICAL REPORTS FOR RADIATION-PRODUCING MACHINES (Used for Diagnostic, Interventional, and Therapy Procedures)

State regulations require that a licensee or registrant possessing a radiation-producing machine report to the Department of Environmental Protection's (DEP) Bureau of Radiation Protection all medical reportable events that occur during its therapeutic use. Other medical reports are also required when therapeutic or diagnostic use of a radiation-producing machine results in, or is the suspected cause of, an injury that was not an expected consequence when the procedure began. Injury is considered any condition that warrants medical intervention. DEP regulations require these notifications to be performed within certain specified time frames.

This fact sheet has been developed to assist with the notification process. It includes the addresses and telephone numbers of the regional offices requiring notification. It also includes responsibilities (see opposite page) for the licensee of therapy machines or the registrant of diagnostic machines to record important dates to be compliant with the time frame required by the regulations (25 Pa. Code, §§ 219.228 and 219.229).

The appropriate regional office and central office telephone numbers are provided below:

Region	Counties Served
EAST Southeast Regional Office 484-250-5950 2 East Main Street Norristown, PA 19401-4915	Bucks, Chester, Delaware, Montgomery, Philadelphia, Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Schuylkill, Susquehanna, Wayne, and Wyoming
CENTRAL South-central Regional Office 717-705-4700 909 Elmerton Avenue Harrisburg, PA 17110-8200	Adams, Bedford, Berks, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lancaster, Lebanon, Mifflin, Perry, York, Bradford, Cameron, Centre, Clearfield, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga, and Union
WEST Southwest Regional Office 412-442-4000 400 Waterfront Drive Pittsburgh, PA 15222-4745	Allegheny, Armstrong, Beaver, Cambria, Fayette, Greene, Indiana, Somerset, Washington, Westmoreland, Butler, Clarion, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango, and Warren
<p><i>Medical reportable event for radiation-producing diagnostic or interventional X-ray procedures</i>—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:</p> <ul style="list-style-type: none"> (i) An unintended peak skin dose to the same area in a single procedure greater than 1500 rad (15 Gy). (ii) An unintended dose, other than skin dose, in a single procedure exceeding five times the facility's established protocol and 50 rad (0.5 Gy) to any organ. (iii) A dose to the wrong patient, or wrong site for the entire procedure, and exceeding 50 rad (0.5 Gy) to any organ. (25 Pa. Code, § 219.3) 	
<p><i>Medical reportable event for radiation-producing machine therapy</i>—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:</p> <ul style="list-style-type: none"> (i) An administration of a therapeutic radiation dose to the wrong individual, wrong treatment site or using a treatment delivery intended for another individual. (ii) An administration of a dose for therapy identified in a written directive that differs from the prescribed dose for the treatment site or any other organ from the intended prescribed dose, by one of the following: <ul style="list-style-type: none"> (A) More than 20% of the total prescribed dose. (B) Exceeds 30% of the weekly prescribed dose. (C) Exceeds 50% of a single fraction dose of a multifraction plan. (25 Pa Code § 219.3) 	

Licensee Responsibilities for Therapy Machines

25 Pa. Code, § 219.228

- ✓ Notify DEP by telephone within 24 hours after discovery of the event. **§ 219.228(a)(1)**
Date of Event _____
Date and Time of Discovery of Event _____
Date and Time of Notification _____
- ✓ Submit a written report to DEP within 15 days after discovery of the event. **§ 219.228(a)(2)**
Date of Report _____
- ✓ Notify the referring physician within 24 hours after discovery of the event. **§ 219.228(a)(3)**
Date and Time of Notification _____
- ✓ Notify the patient within 24 hours after discovery of the event (provided there is concurrence by the referring physician). **§ 219.228(a)(3)**
Date and Time of Notification _____
- ✓ If the patient was notified, a written report to the patient must be submitted within 15 days. **§ 219.228(a)(4)**
Date of Report to Patient _____
- ✓ Retain a record of each medical reportable event for five years. **§ 219.228(b)**

Registrant Responsibilities for Diagnostic or Interventional Procedure Medical Reports

25 Pa. Code, § 219.229

Submit a written report to DEP within 30 days after determination by a physician of either actual or suspected acute or long-term functional damage to an organ or physiological system. **§ 219.229(a)**

Date of Report _____

Upon discovery of a medical reportable event:

- ✓ Notify DEP regarding the medical reportable event within one business day. **§ 219.229(b)(1)**
- ✓ Provide a written report, including analysis of the event, by the qualified medical physicist, to the DEP within 15 business days. **§ 219.229(b)(2)**
- ✓ Provide a clinical summary to the prescribing physician and patient within 15 business days. **§ 219.229(b)(3)**
- ✓ Retain a record of each medical reportable event for five years. **§ 219.229(a)**

For further guidance concerning programmatic questions, please call DEP's central office:

Department of Environmental Protection
Bureau of Radiation Protection
P.O. Box 8469
Harrisburg, PA 17105-8469
Phone: 717-787-3720
Fax: 717-783-8965

For more information, visit www.dep.pa.gov.