



Event Reporting

Hani Abujudeh, MD *Massachusetts General Hospital, Boston, MA*

Patient injuries from fluoroscopic procedures should be reported in the same manner as other harmful events. Internal reporting structures vary by department or health care facility. Typically, reporting requirements are designed to meet certain standards of care that may be unique to that particular facility, but they are also designed to meet institutional external reporting requirements.

In some institutions the goal of collecting the data is to drive improvements; as such, those institutions may collect and report on data beyond what is required for reporting to outside entities. Health care providers should familiarize themselves with their institutional reporting structure and requirements, as well as those of external reports to state agencies.

External reporting can vary by state. The Joint Commission and the U.S Food and Drug Administration (FDA) also differ in their guidelines for reporting. The specific requirements for reporting fluoroscopic-related injuries will be discussed in this document.

In this document we use rules in the State of Massachusetts as an example. Although reporting requirements in other states may differ, familiarity with this state's rules may help the reader navigate through their own state's requirements [1].

The Massachusetts Department of Health and Human Services website provides information regarding X-ray imaging in "105 CMR 120.400: X-Rays in the Healing Arts" [2]. This document states that:

1. Each facility performing fluoroscopically-guided interventional and CT-guided procedures shall conduct patient dose evaluation for any procedure that has a reasonable probability of resulting in a deterministic injury as further defined in 105 CMR 120.405
2. Records documenting that policies and procedures have been developed to determine that those procedures that have a potential to result in patient doses exceeding the threshold for injury have

been established to reduce the probability of such exposures and that appropriate action occurs for patients receiving doses that warrant follow-up

3. The facility shall have procedures for patient dose-monitoring in place. When the fluoroscopy unit is equipped with an Air-Kerma dose readout, the recording of this value shall suffice as a patient dose record
4. The facility shall document in the patient's medical record an estimate of the absorbed dose to the skin
5. Any cumulative absorbed dose to the skin equal to or greater than 2Gy (200 rads) shall be noted in the patient's medical record and reviewed by the Radiation Safety Committee
6. Each facility that uses fluoroscopic x-ray systems shall maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name. The record shall be maintained for five years.

In our institution, we comply with these regulations by reporting weekly to the hospital radiation safety committee on all cases in which a patient receives a dose >2 Gy. We perform patient follow-up for all patients who receive a skin dose >5 Gy.

The Veteran's Administration (VA) requires reporting on doses >3 Gy: "If 3 Gy skin dose to single field is exceeded, estimated skin doses and locations must be recorded in the patient's medical record [3]."

In California, state law on CT and radiation therapy exams requires hospitals to report "Events" that fall into categories defined by the state (Section 115113). "CT of therapeutic exposure that results in unanticipated permanent functional damage to an organ or physiological system, hair loss, erythema, as determined by a qualified physician," but fluoroscopy is not mentioned specifically [4].

The Board of Registration in Medicine in the State of Massachusetts under section 243 CMR 3:08 requires that "Major Incidents" be reported by the health care facility to Board of Registration in Medicine. There are several general categories that define a "Major Incident" [5].

Although not specifically mentioned by name, a fluoroscopic injury may fall under the following category: “All deaths or major or permanent impairments of bodily functions that are not ordinarily expected as a result of the patient’s condition on presentation.” Reporting of such events is required.

The Massachusetts Department of Public Health (DPH) requires that hospitals must report serious injury resulting from accidental or unknown causes and other incidents that seriously affect the health and safety of patients. In this context, **“serious injury”** means injury that is life threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures. **“Accidents”** include falls, burns, electrocutions and other misadventures not related to patient treatment.

If the specific fluoroscopic injury does not fall into the above two categories, it may fit into **“Other serious incidents that seriously affect the health and safety of patients,”** which can result in a serious injury not anticipated in the normal course of events [6].

The Joint Commission classifies radiation overdose as a Reviewable Sentinel Event [7,8]. In regard to fluoroscopy, the Joint Commission considers a Sentinel Event to be “prolonged fluoroscopy with cumulative dose >1500 rads to a single field” and defines cumulative dose as a dose given within a period of six months to a year. The Joint Commission defines a “single field” as the location on the skin through which fluoroscopic beam is directed (which can be from different projections), in an attempt to assess the maximum or peak skin dose the patient received. If this threshold is exceeded, the health care organization is required to conduct a root cause analysis and is encouraged to voluntarily report the event to The Joint Commission, even though the outcome (harm to the patient) has not become evident [9].

Safe Medical Devices Act (FDA)

Health care providers are encouraged to file a voluntary report to the FDA through MedWatch if they suspect a problem with a fluoroscopic device or any event occurs that reasonably suggests a probability that a medical device has caused or contributed to the death, serious injury or serious illness of a patient. Such problems may include user error and device malfunction [10].

REFERENCES

1. Conference of Radiation Control Program Directors website. Available at: <http://www.crcpd.org/Map/default.aspx>. Accessed September 30, 2014.

2. Code of Massachusetts Regulations, 105 CMR 120.400: X-Rays in the Healing Arts, State of Massachusetts, Executive Office of Health and Human Services. Available at: <http://www.mass.gov/eohhs/docs/dph/regs/105cmr120-400.pdf>. Accessed September 30, 2014.
3. Veterans Health Administration Handook 1105.04: Fluoroscopy Safety. Available at: http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2764. Accessed September 30, 2014.
4. California Health and Safety Code: Section 115113. Available at: http://www.weblaws.org/california/codes/ca_health_and_safety_section_115113. Accessed September 30, 2014.
5. Code of Massachusetts Regulations, 243 CMR: Board of Registration in Medicine. Available at: <http://www.mass.gov/eohhs/docs/borim/reg-243-cmr-2.pdf>. Accessed September 30, 2014.
6. The Commonwealth of Massachusetts Circular Letter: DHCQ 07-02-474. Available at: <http://www.mass.gov/eohhs/docs/dph/quality/hcq-circular-letters/hospital-serious-incidents-0742474.pdf>. Accessed September 30, 2014.
7. The Joint Commission Radiation Overdose FAQs: available at http://www.jointcommission.org/Radiation_Overdose_FAQs/. Accessed September 30, 2014.
8. The Joint Commission FAQ page: available at <http://www.jointcommission.org/about/JointCommissionFaq.aspx>. Accessed September 30, 2014.
9. Shaqdan K, Aran S, Daftari BL, Abujudeh H, Root-cause analysis and health failure mode and effect analysis: two leading techniques in health care quality assessment. JACR, Jun 2014;11(6):572-9. Available at <http://www.sciencedirect.com/science/article/pii/S1546144013007230>. Accessed September 30, 2014.
10. United States Department of Health and Human Services, Food and Drug Administration, radiation emitting products. Available at http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115354.htm?KeepThis=true&TB_iframe=true&height=600&width=900. Accessed September 30, 2014.