
Outline of Administrative Policies for Quality Assurance and Peer Review of Tissue Reactions Associated with Fluoroscopically-Guided Interventions

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Introduction

Some current recommendations for quality assurance and peer review (QA-PR) policies for tissue reactions due to fluoroscopically-guided interventional (FGI) procedures provide specific values of radiation dose metrics for investigation of apparent outlier cases. However, these recommendations do not provide a means for determining whether or not radiation use was appropriate. They also do not provide a means for QA-PR process and management of other FGI cases.

This Statement is intended to clarify recommendations given in the National Council on Radiation Protection and Measurements (NCRP) Report No. 168, *Radiation Dose Management for Fluoroscopically-Guided Interventional Medical Procedures* (NCRP, 2010). It provides detailed recommendations for a facility's QA-PR process and recommendations for administrative practices for the evaluation of known or suspected FGI radiation injuries. Facilities typically investigate and characterize all unusual medical events via a QA-PR committee composed of professional peers of the involved practitioner. Evaluating those radiation management processes and practices discussed in this Statement ***shall*** be a part of an interventional service's QA-PR program.¹

NCRP Report No. 168 emphasizes that the safe performance of FGI procedures requires controlling radiation dose in order to prevent unexpected or avoidable tissue reactions and to minimize the severity of medically unavoidable injuries. It also provides guidance for controlling dose and for patient post-procedure follow-up. Similar guidance has been provided by professional societies and by several national and international organizations (Chambers *et al.*, 2011; Gibson *et al.*, 2010; Hirshfeld *et al.*, 2004; IAEA, 2009; 2010; ICRP, 2000; 2010, 2013; NCI/SIR, 2005; Stecker *et al.*, 2009; WHO, 2000).

¹Three terms used in this Statement have a special meaning as indicated by the use of ***bold italics***:

- ***shall*** and ***shall not*** are used to indicate that adherence to the recommendation is considered necessary to meet accepted standards of protection;
- ***should*** and ***should not*** are used to indicate a prudent practice to which exceptions may occasionally be made in appropriate circumstances; and
- ***may*** and ***may not*** indicate a reasonable practice that is permissible.

Background

Definition of Fluoroscopically-Guided Interventional Procedures

The International Commission on Radiological Protection (ICRP) Publication 85 and NCRP Report No. 168 define FGI procedures as “procedures comprising guided therapeutic and diagnostic interventions, by a percutaneous or other access route, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy” (ICRP, 2000; NCRP, 2010). This Statement is focused on the FGI subset of potentially high-dose procedures.

Tissue Reactions

Radiation-induced hair loss and injuries of the skin and subcutaneous tissues, collectively termed “tissue reactions” (ICRP, 2011) are rare complications of FGI procedures (Frazier *et al.*, 2007; Freysz *et al.*, 2014; Giordano, 2010; Huda and Peters, 1994; Koenig *et al.*, 2001a; 2001b; Park *et al.*, 1996; Shope, 1996; Sovik *et al.*, 1996; Vance *et al.*, 2013). The range of tissue reactions due to FGI, and a process for FGI radiation dose management, are discussed in detail in NCRP Report No. 168 (NCRP, 2010). While only a small fraction of these complications are severe enough to result in serious long-term clinical consequences, the impact on the patient’s quality of life from severe injuries (*e.g.*, disfigurement, functional impairment, and chronic pain) can be devastating (Balter and Miller, 2014; ICRP, 2000; NCRP, 2010).

A clinically important radiogenic tissue reaction is one that requires active medical intervention. The boundaries between different grades of tissue reaction are influenced by biological variability (Balter *et al.*, 2010; NCRP, 2010). Grade 2 reactions may be clinically important. Grades 3 and 4 tissue reactions **shall** always be considered to be clinically important (Balter *et al.*, 2010).

Skin Dose Estimation

As of 2014, there are few available technologies (*e.g.*, film, arrays of dosimeters) that can provide a map of skin dose distribution for a single procedure. There are research projects (Bednarek *et al.*, 2011; Johnson *et al.*, 2011; Khodadadegan *et al.*, 2011) and very recent commercial offerings that provide real-time maps of estimated (calculated) skin dose distributions. Difficulties can be expected in developing skin dose mapping methods that account for cumulative skin doses from multiple procedures as well as mapping these cumulative skin dose distributions, particularly when these procedures are performed on the same patient at different times, using different fluoroscopes, or in different facilities.

Substantial Radiation Dose Level and Patient Management

NCRP Report No. 168 (NCRP, 2010) defines substantial radiation dose level (SRDL). Suggested values for a number of different dose metrics are provided in Table 1. The SRDL is a trigger level for certain processes and follow-up measures. It is not an indicator for tissue reactions or a predictor of the risk of stochastic effects. SRDLs are intended to alert operators and staff to the possibility of harm. A patient is unlikely to experience any clinically important skin reaction if one or more dose metrics minimally exceeds an SRDL. The facility **may** adopt other values if appropriate (see NCRP Report No. 168 for additional details).

TABLE 1—*Substantial radiation dose levels (NCRP, 2010).*^a

Dose Metric	SRDL Value ^b
Peak skin dose ($D_{\text{skin,max}}$ or PSD)	3 Gy
Cumulative air kerma at a reference point ($K_{a,r}$)	5 Gy
Air kerma-area product (P_{KA}) (assuming a 100 cm ² field at the reference point)	500 Gy cm ²
Fluoroscopy time (only if PSD, $K_{a,r}$, and P_{KA} are not available) ^c	60 min

^aThe radiation dose level that is intended to trigger follow-up for an FGI procedure, in order to ensure detection of any clinically-relevant injury in an average patient.

^bThese criteria apply to radiation dose values at the end of a procedure.

^cFacilities performing potentially high-dose FGI procedures **shall** measure dose metrics and **should not** rely on fluoroscopy time alone. NCRP Report No. 168 states that fluoroscopy time **should not** be used as the only dose indicator during potentially high-dose FGI procedures.

NCRP Report No. 168 recommends that certain activities take place whenever an FGI case results in any dose metric exceeding an SRDL threshold. Newer, more dose-efficient equipment may make fluoroscopy time less useful as an SRDL trigger. Each interventional service that performs FGI procedures **shall** have the following policies and processes in place (Table 2) to ensure that when an SRDL threshold is exceeded appropriate action is taken (further details of the follow-up process are provided in NCRP Report No. 168).

TABLE 2—*Policies and processes for services performing FGI procedures.*

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1. When appropriate, the informed consent process includes discussion and documentation of the potential for skin injury.
 2. A complete set of dose metrics is included in the report for every FGI procedure, in addition to inclusion in the medical record in any other locations that the facility deems appropriate.
 3. Upon procedure completion, the responsible physician documents, in the medical record, the clinical necessity for exceeding any SRDL.
 4. Patients are promptly informed when substantial amounts of radiation (Table 1) were used for their procedures, and why it was necessary.
 5. Patients receive follow-up, documented in the medical record, to determine whether tissue reactions occurred.
 6. The results of patient follow-up are reported to and reviewed by the interventional service's QA-PR committee.
 7. If a tissue reaction is identified, or suspected, the patient **shall** be referred to an appropriate provider for management.
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Quality Assurance-Peer Review

In any complex procedure-oriented area, it is essential to have a quality assurance program that incorporates quality improvement and provides ongoing feedback within an established infrastructure (Bashore *et al.*, 2012; Klein *et al.*, 2011). An interventional service customarily has an internal QA-PR committee charged with reviewing both unusual events and statistical trends relevant to its area of clinical responsibility. This committee includes interventionists who are privileged to perform procedures on that service. Other qualified individuals participate in the committee's work as needed. The committee **should** include a qualified medical physicist when radiation management issues are discussed. The committee is therefore competent to evaluate the clinical appropriateness and relevance of quality and safety matters brought to their attention. Facilities usually perform many additional quality assessment and risk management tasks to comply with regulatory and other oversight requirements.

The Joint Commission's Sentinel Event Approach

The Joint Commission (TJC) has defined a sentinel event as:

“An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase ‘or the risk thereof’ includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.”

TJC further notes that the terms “sentinel event” and “medical error” are not synonymous (*i.e.*, not all sentinel events occur because of an error and not all errors result in sentinel events) (TJC, 2014).

As of 2014, TJC defines a 15 Gy skin dose acquired over a period of time as a sentinel event. However, skin dose estimation is complex and subject to large uncertainties. Summing skin doses acquired from multiple procedures is subject to additional uncertainties. In addition, TJC's time interval for summing skin dose is vague. Finally, this approach does not incorporate any clinical considerations (TJC, 2006),

NCRP Recommended Approach to Investigating Clinically Important Tissue Reactions in Fluoroscopically-Guided Interventional Procedures

This Statement provides an administrative approach to managing radiation dose for FGI procedures. It provides a process for evaluating procedures that result in a clinically important tissue reaction. This could replace the TJC sentinel event process. **Compliance with institutional and regulatory requirements for reporting radiation levels or injuries is also required.**

Some high-dose FGI procedures produce prompt erythema within hours of the procedure. In most cases, this reaction subsides within a few days without any subsequent signs or symptoms. Main tissue reactions begin to become evident within a few weeks of the procedure. Virtually all of these reactions are visible by 30 d. Because of biological variability, NCRP recommends that patients be checked approximately two and four weeks after the procedure so that appropriate medical management can be started [NCRP, 2010 (Appendix K)]. However, medical oversight should start immediately for symptomatic patients (e.g., burning, itching and erythema).

When a tissue reaction occurs after an FGI procedure, dosimetric and clinical data from the procedure **shall** be evaluated together, as part of the interventional service's routine QA-PR process. Evaluation **should not** be based solely on a patient's radiation dose exceeding any specific value of a dose metric over an arbitrary period of time. The QA-PR process **shall** include a careful assessment of procedure justification, patient-specific factors, radiation dose optimization, the time course over which radiation doses were administered, disease severity, and procedure complexity.

NCRP **recommends** that, regardless of the PSD, a sentinel event **shall not** be considered to have occurred when a skin tissue reaction results from one or more FGI procedures, if all FGI procedures that irradiated the affected skin were performed in accordance with recognized practice parameters.

The evaluation process should consider that, after a single radiation dose, repair of damaged DNA is complete within ~24 h, and repopulation occurs within six months (Balter *et al.*, 2010). Despite repair and repopulation, radiation-damaged skin may be more susceptible to injury than nonirradiated skin (Balter *et al.*, 2010). For those procedures that resulted in clinical injury and, where available, data from previous procedures **shall** be used to estimate skin dose distributions (Jones and Pasciak, 2012). If there is an injury, these skin dose estimates can help in predicting the severity and course of the injury.

Process for Evaluating and Managing Radiation Use for Fluoroscopically-Guided Interventional Procedures

A QA-PR program is necessary to track and review radiation use for all FGI procedures and not just those procedures where the radiation dose exceeds an arbitrary threshold. The essential elements of a QA-PR program for FGI procedures are shown in Table 3.

TABLE 3—*Essential elements of a QA-PR program for managing radiation use in all FGI procedures.*

1. Each interventional service **shall** have its own QA-PR program, a component of which is the evaluation of radiation management for all FGI procedures (Jones and Pasciak, 2012; Stecker *et al.*, 2009).
2. All available metrics that describe the total radiation dose from the case **shall** be recorded in the procedure report and the patient's medical record for every procedure.
3. Radiation dose data **shall** be collected and tracked for all FGI procedures.
4. Interventional services **shall** have policies and processes to ensure that when an SRDL is exceeded, appropriate documentation and follow-up are provided.
5. The interventional service's summary patient radiation dose metrics for all cases of every FGI procedure **shall** be analyzed periodically and at least annually. These data **shall** be compared to current published data.
6. Patient follow-up **shall** be based on exceeding an SRDL.

A quality assurance program **should not** rely on dosimetric data alone as the only input for monitoring potential tissue reactions. Currently available summary radiation dose metrics are cumulative air kerma at a reference point ($K_{a,r}$), air kerma-area product (P_{KA}), and fluoroscopic time. None of these metrics is an accurate predictor of the maximum absorbed skin dose ($D_{skin,max}$, also known as the peak skin dose or PSD) for individual cases (Fletcher *et al.*, 2002; Jones and Pasciak, 2011; Kwon *et al.*, 2011; Miller *et al.*, 2003). Nevertheless, the routine collection and appropriate use of patient radiation dose data is a critical part of the evaluation process (Chambers *et al.*, 2011; Miller *et al.*, 2012; NCRP, 2010). An interventional service's quality management process **shall** ensure that all available radiation dose metrics that describe the total radiation dose from the procedure are recorded in the procedure report and the patient's medical record for every procedure (Chambers *et al.*, 2011; Miller *et al.*, 2012; NCRP 2010). Radiation dose structured reports for interventional procedures provide

both summary metrics and complete data on each fluoroscopy foot pedal actuation. If radiation dose structured reports are available, they **shall** be archived by the interventional service and subsequently analyzed.

QA-PR programs **shall** include the periodic review of radiation dose metrics for FGI procedures, using the methods described in NCRP Report No. 168 and Report No. 172 (NCRP, 2010; 2012).

A procedure meets recognized practice parameters if the criteria in Table 4 are met. These criteria are applicable only to patients with a known, clinically important radiation injury. For emergent procedures, omission or limitation of some of these steps may be within recognized practice parameters. The possible outcomes of this analysis are shown in Table 5. Inadequate radiation tracking or patient follow-up **shall** also be subject to analysis by the interventional service's QA-PR committee. The committee **may** also review procedures that resulted in a Grade 1 or Grade 2 tissue reaction. The interventional service **shall** implement corrective actions as appropriate.

TABLE 4—*Criteria for a QA-PR committee to determine whether a procedure with a clinically important tissue reaction meets recognized practice parameters for radiation management.^a*

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1. The procedure was justified clinically.
 2. When applicable, the timing of this procedure with respect to previous procedures was reviewed.
 3. When applicable, the pre-procedure physical examination included inspection of relevant areas of the patient skin for evidence of previous radiation injury.
 4. If a tissue reaction was considered possible, the potential for a tissue reaction was included as part of the informed consent process.
 5. Use of radiation during the procedure was appropriate.^b
 6. After the procedure, the patient was advised of possible tissue reactions; appropriate follow-up was arranged and performed (NCRP, 2010).
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^aFor procedures performed on an emergent basis, some or all of the pre-procedural steps may have been limited or omitted due to clinical necessity.

^bA qualified medical physicist should be consulted to analyze the distribution of radiation dose, contributing technical parameters, and related factors.

TABLE 5—*Possible outcomes of a QA-PR analysis of an FGI procedure that resulted in a clinically important tissue reaction.*

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1. The tissue reaction was detected and, likely, was unavoidable. No action required.
 2. While clinical or technical optimization might have reduced the severity or improved the detection of the tissue reaction, overall practice parameters were still met. Methods for optimization of radiation use are available and should be implemented.
 3. Radiation use did not meet recognized practice parameters. A clinically important tissue reaction was potentially avoidable, its severity could have been minimized, or it was not detected. Corrective action is required.
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Root cause analysis (RCA) is a formal process performed under the authority of the facility's management. The purpose of an RCA is to identify administrative, clinical or technical causes of avoidable patient mismanagement. Cases that resulted in a clinically important tissue reaction (Balter *et al.*, 2010; NCRP, 2010), and do not fulfill one or more of criteria two through six in Table 4, **shall** be subject to an RCA.

Conclusions

Though rare, severe tissue reactions resulting from FGI procedures can be devastating. All interventional services **shall** develop and use policies and processes that are designed to minimize the number and severity of radiation-induced injuries. Radiation dose thresholds are an essential part of managing FGI, but any QA-PR evaluation **shall** include a review of recognized practice parameters. The QA-PR process **shall** assess performance of the procedure, including justification, radiation dose optimization, the time course over which radiation doses were administered, and patient outcomes. The outcome of the process **shall** be identification and implementation of any appropriate improvements.

Glossary

clinically important radiation injury: An injury that requires active medical intervention.

emergent procedures: Procedures performed on patients who have life-threatening conditions that require immediate assessment and treatment. Any delay is harmful to the patient.

fluoroscopically-guided interventional (FGI) procedures: Procedures comprising guided therapeutic and diagnostic interventions, by a percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy (NCRP, 2010).

grades of tissue reactions: Skin damage may be divided into four grades of increasing severity (Balter *et al.*, 2010; NCI, 2010). Injury Grades 1 and 2 are likely to be self-limiting with conservative care. Grades 3 and 4 require increasingly intensive medical intervention.

interventional service: A generic term for clinical fluoroscopically-guided interventional services performed in radiology, cardiology, vascular surgery, or other areas of a health-care facility.

peak skin dose (PSD): The actual maximum dose (including scattered radiation) delivered to any portion of the patient's skin during a fluoroscopically-guided interventional procedure. The clinical extent of a skin injury is related to the PSD and the area of the affected skin.

potentially high-dose procedures: A fluoroscopically-guided interventional procedure for which >5 % of cases of that procedure result in cumulative air kerma at a reference point ($K_{a,r}$) exceeding 3 Gy or air kerma-area product (P_KA) exceeding 300 Gy cm² (NCRP, 2010).

practice parameter: Described recommended conduct in specific areas of clinical practice based on analysis of current literature, expert opinion, open forum commentary, and formal consensus. Practice parameters are not intended to be legal standards of care or conduct and may be modified as determined by individual circumstances and available resources.

qualified medical physicist: An individual who is competent to provide clinical professional services independently in diagnostic medical physics (AAPM, 2014).

quality assurance-peer review (QA-PR): An independent process used by an interventional service to determine whether or not appropriate medical care was rendered. It is the responsibility of the QA-PR committee to assure that proper data collection is undertaken and that appropriate quality indicators are addressed. The committee consists of peers of the clinician who performed the procedure and should include a qualified medical physicist when radiation management issues are discussed. The committee reviews data and then identifies appropriate actions or interventions.

radiation dose structured report: A report created by a fluoroscope or other imaging device to record the radiation dose metrics and related information from an imaging procedure, using a predefined standard structure. Radiation dose structured report generation is a process that is not dependent on image capture and storage.

root cause analysis (RCA): A collective term that describes a wide range of approaches, tools and techniques used to uncover causes of problems (ASQ, 2014).

substantial radiation dose level (SRDL): The radiation dose level which is intended to trigger follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

tissue reaction: Structural or functional damage to tissue caused by irradiation. The type and amount of tissue damage increases with dose once a threshold is passed. For example, skin damage may be divided into four grades of increasing severity (Balder *et al.*, 2010; NCI, 2009). Injury Grades 1 and 2 are likely to be self-limiting with conservative care. Grades 3 and 4 require increasingly intensive medical intervention.

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