



MPPG 12 – Fluoroscopy Dose Management

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Medical Physics Practice Guidelines

TG 343: MPPG 12 – Fluoroscopy Dose Management

- Fluoroscopy has come under increasing regulatory oversight
 - The Joint Commission
 - Radiation Overdose Sentinel Event – 2005
 - Fluoroscopy Standards – 2019
 - CRCPD Suggested State Regulations
- There have been many publications in the fluoroscopy space, but nothing from AAPM
- “The charge of this Practice Guideline is to outline the role of the diagnostic medical physicist in practical patient dose management for fluoroscopy and provide a framework for meaningful collection and interpretation of fluoroscopic case data.”



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Physicist’s Role in Fluoroscopy

Big Picture

- Serious tissue reactions from FGI procedures are rare, but do happen
- Want to avoid, if at all possible
 - Equipment protocol optimization
 - Operator training & education
- Want to have appropriate policies in place
 - Patient consent
 - Appropriate follow-up
- Want to remain compliant with regulatory requirements
- Primary goal is to provide good patient care



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FGI Policies



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FGI Policies

QMP Responsibility

Report recommends policies that facilities should have in place, regardless of regulatory requirements, to increase stakeholder awareness and to help prevent, identify, and properly care for patients with tissue reactions due to high-dose FGI procedures:

- Pre-procedure screening and consent of the patient
- Intra-procedure monitoring and notifications
- Post-procedural patient follow-up

While QMPs are not typically involved in the day-to-day implementation of these policies and procedures, their expertise is critical in their development.

- Surveying available dose indices
- Harmonizing any built-in equipment notifications



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FGI Policies

Pre-procedure Consent

- Important to consent patients for possible radiogenic tissue effects
- Also important for those risks to be in perspective
 - Radiation risk typically much smaller than other procedural risks
 - Bleeding, infection, organ damage, anesthesia, etc.
- Can consent all FGI procedures, or only a subset classified as potentially high dose
- MPPG includes sample consent language



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FGI Policies

Intra-procedure Monitoring and Notifications

- Intra-procedural notifications regarding radiation dose levels allow the performing physician to gauge the benefit-risk ratio at each stage of an FGI procedure
- For the benefit-risk ratio to be meaningful, the physician needs to have an accurate understanding of radiation risk, the likelihood of tissue injury, and the associated dose-response relationship
- The QMP, as the subject matter experts in this area, can provide radiation protection planning knowledge to the team to help ensure that the benefit-risk ratio is formulated correctly
- The QMP must also understand the magnitude of radiation risk compared to other procedural risks
- Recommend clinical observation and instruction for QMPs



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FGI Policies

Establishing the SRDL and Post-Procedure Actions

Substantial Radiation Dose Level – biological threshold for radiation dose above which additional post-procedure actions should be taken.

MPPG recommends using 5 Gy $K_{a,r}$ or 3 Gy PSD as the SRDL

Provide patient follow up instructions in simple written language, including provider contact information

- Report includes sample discharge instructions

Follow-up – in person or via telemedicine

If there is a severe or prolonged tissue reaction, should be seen in person and referred to dermatology, wound care, radiation oncology or another appropriate specialty for further care.



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Peak Skin Dose Calculations

When Should They Be Done?

- Previously needed for Joint Commission Sentinel Event purposes
- PSD estimates may be useful to direct patient care
- MPPG recommends facilities should have formal process for requesting PSD estimates
 - New CPT code this year
 - Need to have some kind of “institutional threshold” that triggers evaluation
 - Could be dose index based, or triggered by observed tissue reaction
- PSD probably not necessary for every FGI case above the SRDL
- MPPG recommends that PSD estimates be reported as a range of possible values due to inherent uncertainties
 - “likely 13 Gy, but with a possible range of 8-18 Gy”



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Pediatric and Pregnant Patients

Special Considerations

Recommend QMP involvement in

- Protocol optimization
- Staff education on benefits and risks
- Directly counseling patient or guardians to address concerns
- Ensuring collection of data for fetal dose estimate



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Joint Commission Requirements

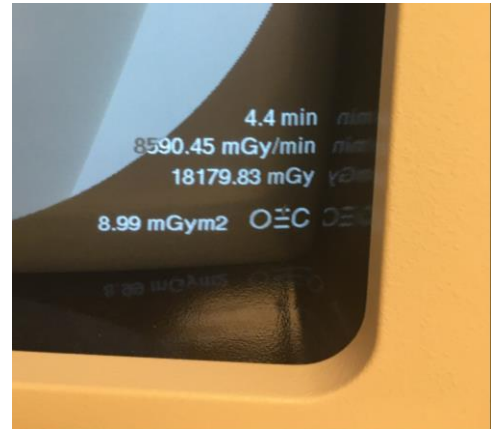


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The Joint Commission Fluoroscopy Requirements

Annual Equipment Evaluation

- TJC lists specific tests, but gives no pass/fail criteria
- Displayed dose index accuracy



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The Joint Commission Fluoroscopy Requirements

Dose Index Documentation

- Dose index documented in a retrievable format
- QMP usually responsible for helping set up documentation system
- Method will depend on fluoro equipment in use and resources & technology available
- Possible Solutions:
 - Manual / paper logs
 - Manual entry into digital systems
 - Automatic radiation dose index monitoring software
- Connectivity back to patient electronic medical records remains a challenge



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The Joint Commission Fluoroscopy Requirements

Radiation Exposure Thresholds

- Need to have a threshold that triggers further review or patient evaluation
- Need to review and analyze instances where it's exceeded
- Both are covered in the preceding policy recommendations



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The Joint Commission Fluoroscopy Requirements

Sentinel Event

“Prolonged fluoroscopy with cumulative dose > 15 Gy to a single field” summed over 6-12 months

- Practical implementation very difficult even 15 years later
- All other Sentinel Events were “Never” events
- 15+ Gy doesn't necessarily imply anything was done wrong
- Serious tissue effects can occur at 14.9 Gy
- PSD estimates fraught with uncertainty
- Required RCA involving hospital executive administration



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The Joint Commission Fluoroscopy Requirements



Sentinel Event – UPDATE!

“Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed.”

- Review triggered based on observed tissue reaction instead of PSD threshold
 - Accounts for individual radiosensitivity of patient
 - Avoids ambiguous time frame
 - Avoids uncertainties in PSD calculation
- Requires patient follow-up & review of cases leading to tissue reactions
- Allows for following the NCRP Statement 11 process



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NCRP Statement 11

Quality Assurance & Peer Review Program



- QA-PR Committee
 - Should include professional practitioners & QMP
 - Each service should have its own QA-PR committee, if feasible
- Committee evaluates cases where patient follow-up results in clinically important radiogenic tissue reaction
 - Clinical justification of the procedure
 - Proper pre-procedural review and evaluation of patient history
 - Proper informed consent
 - Appropriate use of radiation during procedure
 - Appropriate post-procedure patient follow-up



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NCRP Statement 11

Possible Outcomes

- The tissue reaction was detected through follow-up and likely unavoidable. No action required.
- Clinical or technical optimization might have reduced the severity or improved in the detection of the reaction, but overall practice criteria were met. Methods for optimization should be implemented.
- 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.

Root Cause Analysis only undertaken in the last case

Overall, new definition allows for lower-level review of cases prior to elevating to RCA

Avoids RCA for cases where proper care was delivered



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CRCPD Suggested State Regulations



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CRCPD Suggested State Regulations

Radiation Protocol Committee

Recommends creation of a "Radiation Protocol Committee" (RPC) including:

- Supervising FGI physician
- Lead technologist
- QMP

Responsible for establishing protocols and procedures:

- Authorized users of FGI equipment
- Intra-procedure patient radiation dose monitoring
- Dose notification levels
- Establishment of SRDL values
- Actions to be taken when a SRDL is exceeded

Meets at least annually



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CRCPD Suggested State Regulations

Radiation Protocol Committee MPPG Recommendations

Membership should include physician and technologist from each service (IR/Cardiology/Vascular Surgery)

For larger systems, one RPC with membership from each facility to help ensure consistent practice

RPC should include review and oversight of clinical data, including QA-PR functions

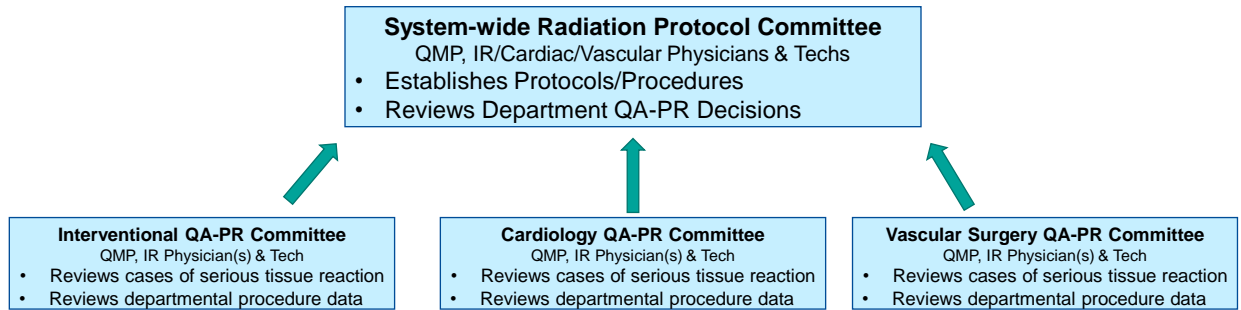
- QA-PR may best be initially handled by department level review
- Results of department level review sent to full RPC for final review and approval

Meeting frequency dependent on duties of committee and volume & complexity of FGI services



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FGI Committee Structure



Depending on system size, could combine committees
Individual department committees can include membership from various sites in larger enterprises



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Facility Dataset Review

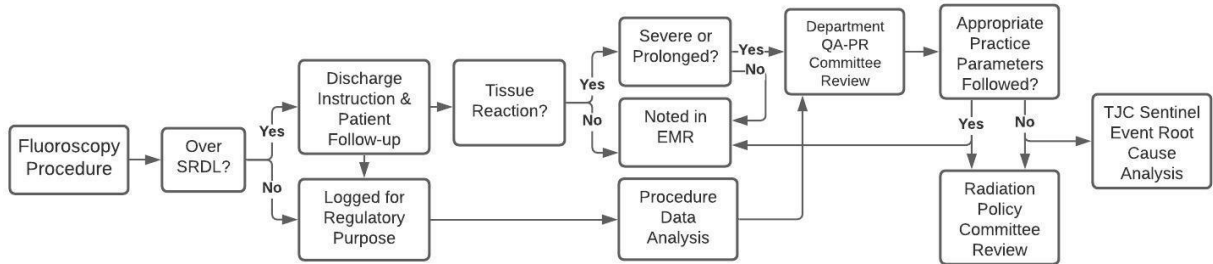
Improving Patient Care

- MPPG recommends that beyond regulatory requirements, FGI data be analyzed for quality improvement purposes
- Can compare practice across sites, equipment, and operators
 - $K_{a,r}$, AKAP, fluoro time, PSD, and/or occupational dosimetry
- Likely directed by QMP, and presented to operators or department chairs on a regular basis
- Can also compare to outside practice through ACR Fluoroscopy DIR



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FGI Procedure Workflow



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MPPG Odds & Ends

Document includes sections on other QMP duties related to fluoroscopy

- Training and Privileging Fluoroscopy Users
- Occupational Dose Monitoring
- Institutional Review Boards



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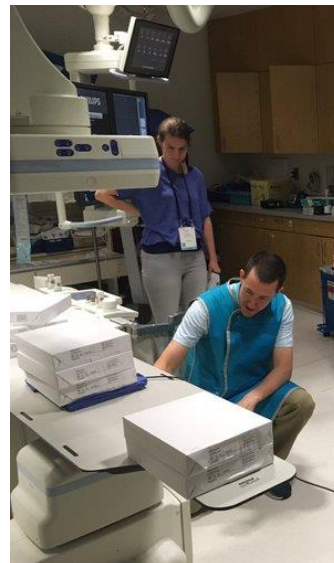
Conclusions

QMPs have a major role in helping manage modern FGI practices

Expertise related to:

- Equipment
- Radiation Biology
- Regulatory Environment

MPPG 12 helps outline these roles, and will (hopefully) be a valuable resource for the physics community



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