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Technical White Paper: Monitoring and Tracking of Fluoroscopic Dose

Developed by CRCPD's H-31 Task Force for Monitoring Patient Dose during Fluoroscopy

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EXECUTIVE SUMMARY

Monitoring and tracking of fluoroscopic dose has been an issue since the mid-1990s when the FDA issued a health advisory entitled "Avoidance of Serious X-ray Skin Injuries to Patients during Fluoroscopically Guided Procedures." The advisory provided guidance for monitoring and tracking radiation doses from fluoroscopic procedures. But to date, only a few state radiation programs have mandated such actions. Radiation dose to patients and staff is an increasing concern today as reliance on radiological procedures for medical diagnoses continues to increase globally.

This paper discusses deterministic injuries that can be caused by radiation from fluoroscopic procedures, methods available to monitor fluoroscopic dose, recommendations on recording and tracking dose, and patient follow-up. Other discussions include staff education and methods to reduce fluoroscopic dose.

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*Note: Monitoring and Tracking of Fluoroscopic Dose, a four page **handout**, CRCPD Pub. E-10-8, is also available from CRCPD.*

MONITORING AND TRACKING OF FLUOROSCOPIC DOSE

In 1994, the Food and Drug Administration (FDA) issued a health advisory entitled "Avoidance of Serious X-ray Skin Injuries to Patients during Fluoroscopically Guided Procedures." Within this advisory the FDA reported the "*occasional but at times severe radiation induced burns to patients from fluoroscopically guided procedures*." The complexity of interventional procedures has led to increasingly longer procedure times that require significant fluoroscopic use. This in turn has led to higher radiation dose to both patients and staff involved with the procedures. With the awareness of this type of injury, the medical physics and regulatory communities began to evaluate the risks of these procedures and to develop methods to monitor and ultimately reduce radiation dose to patients.

In 2000, the International Commission on Radiological Protection (ICRP) issued Publication 85 entitled "Avoidance of Radiation Injuries from Medical Interventional Procedures." In this report the Commission made recommendations on methods to monitor and track radiation dose to the patient, as well as methods to reduce radiation dose during fluoroscopic procedures. To further address this problem the FDA made additions to their regulations entitled "Performance Standard for Diagnostic X-ray Systems and their Major Components." The additions required that fluoroscopic equipment manufactured after June 10, 2006, display air kerma rate and cumulative air kerma. This was mandated to give the fluoroscopist real time patient radiation dose data, with the intent that having this information would result in improved fluoroscopic performance and reduced radiation dose.

While this new standard has helped simplify monitoring of radiation dose, a major challenge still exists in determining patient dose from machines manufactured prior to this standard. There are several direct and indirect methods of radiation dose monitoring available. It should be noted that no commercially available product provides precise real-time skin-dose data; however, they can be used to estimate the likelihood of potential radiation injury. Using these estimates, the operator will have increased dose awareness during the procedure and if necessary can then initiate proper medical follow-up care at the end of the case. With the knowledge of increasing fluoroscopic dose and with injuries apparent, the need for monitoring and tracking of patient dose is a necessary portion of an effective radiation safety program.

Fluoroscopic Exams and Potential Doses from Procedures

The following chart is a representation of a typical patient dose for a selected sample of interventional fluoroscopic procedures. The list is not inclusive of all interventional procedures currently being performed in the medical community. It is meant to give some insight into typical radiation doses.

Table 1. Typical patient dose for a selected sample of interventional fluoroscopic procedures

Procedure	Skin Dose	Author/Year/Journal
TIPS	~2,168 mGy (217 rad)	Miller et al., 2003, JVIR
Nephrostomy	~258 mGy (25.8 rad)	Miller et al., 2003, JVIR
Neuroembolization—Head (all types)	~1,977 mGy (198 rad)	Miller et al., 2003, JVIR
Neuroembolization—Spine (all types)	~3,739 mGy (374 rad)	Miller et al., 2003, JVIR
IVC Filter Placement	~193 mGy (19.3 rad)	Miller et al., 2003, JVIR
Biliary Drainage	~781 mGy (78.1 rad)	Miller et al., 2003, JVIR
Hepatic Embolization	~1,959 mGy (196 rad)	Dauer et al., 2009, JVIR
Percutaneous Coronary Intervention	~2 Gy (200 rad)	Suzuki et al., 2006, Circulation Journal
PTCA & CA	~1,407 mGy (141 rad)	Balter, et al., 2008, Medical Physics

Dose Monitoring Methods

Methods for dose monitoring during fluoroscopy fall under two categories, direct or indirect. Direct methods usually record dose at a specific location and require placement of a dosimeter, or dosimeters, on a specific area of the patient. The exact location of maximum skin dose is typically not known ahead of time; therefore multiple dosimeters can be used to calculate the dose over a specific area. The second method is indirect and requires more effort to extract estimates of skin dose based on radiation measurements of the beam and technical factors.

Direct measurement of skin dose can be performed using electronic dosimeters, photographic film, and thermoluminescent dosimeters (TLD). Several types of electronic dosimeters are commercially available. These dosimeters typically employ very small photodiodes or field effect transistors and like TLDs are used to acquire exposure data at a specific point. It is most common to use multiple TLDs or electronic dosimeters in order to acquire data over a broader area of

the skin. A disadvantage of electronic dosimeters is the visibility of the detectors and connecting leads in the image fields. The primary disadvantage of TLDs, though, is that you will not get a dose estimate until after the procedure—TLDs cannot be read until the end of the procedure. Although dosimeters can be very accurate, it is ultimately dependant upon proper placement.

Radiographic film is another direct method and it can be used over a broad area. Film darkens in proportion to dose and optical results can be measured. A densitometer is used to measure the optical density of the film, which can then be related to patient dose. Radiographic film is only useful for doses up to approximately 2 Gy (200 rad) and thus is not practical for higher dose fluoroscopic procedures. Disadvantages to this method are that it only provides information post procedurally and that an increasing number of facilities lack the availability of film processors due to conversion to digital radiography. Radiochromic film (e.g., Gafchromic) is being used more frequently and is better suited for higher dose fluoroscopy than traditional x-ray film—it requires no wet processing and is less sensitive. This method only provides dose data post procedurally and therefore, this method may be more advantageous when used with other monitoring methods to better determine the actual area of exposure. The advantages are relative low cost and simple analysis.

Indirect dose monitoring methods include live display of dose rate and cumulative dose (air kerma), dose-area product, manual recording of fluoroscopic time, and dose mapping. Cumulative dose is accumulated at a specific point in space relative to the gantry, also known as the interventional reference point. FDA regulations enacted on June 10, 2006, require all new fluoroscopy equipment to be equipped with this capability through a dosimeter that is integrated in the unit. Cumulative dose does not reflect beam motion and only approximates total radiation to the skin; therefore it tends to overestimate skin dose. Despite these drawbacks, cumulative dose is a good indicator of potential deterministic risk.

Dose-area product (DAP), also referred to as kerma-area product (KAP), is a measure of the total radiation emitted from the fluoroscopic system entering the patient. The DAP meter is a transmission type air ionization chamber mounted on the face of the x-ray tube collimator, which integrates the dose over the entire image field. DAP meters are widely available and can be installed on older equipment. Unfortunately, DAP meters do not account for patient size, mode selection, beam geometry, or motion, but rather provide an average of patient dose, which does not correlate directly with skin dose. A DAP measured for a large dose over a small area will be the same as a small dose

over a large area, therefore underestimating dose. DAP measurements are a better measure of stochastic risk and are not a good indicator of deterministic risk.

Manual recording of fluoroscopic time and number of image frames does not measure dose directly; therefore, it is insufficient to determine patient dose alone. Although this method is used widely, it does not account for patient size, mode selection, beam geometry or motion. Dose estimates based on fluoroscopic time alone can over or under estimate the cumulative dose by as much as a factor of 10.

Skin dose mapping shows the overlapping fields and can determine exactly what the peak skin dose measurement is, which in turn indicates the highest dose at any point on the patient's skin. This method utilizes computers to track where the beam is located on the patient as well as radiation output data to determine the skin dose to locations on the patient's body. A few older interventional fluoroscopes were equipped with such a system. While potentially useful, there are no such systems currently on the market. It is likely that they will become available in the next few years.

Most all dose monitoring methods have many factors that must be correlated for more accurate skin dose estimates. Key factors in calculating or estimating dose to the patient include patient size, beam position, technical factors, source-to-image distance and source-to-skin distance. Backscatter and equipment capabilities can also influence dose calculations.

Currently there is no perfect system available for monitoring patient dose. However, each facility should use the best indicator available to them. The decision for the best method of monitoring should be made with the guidance of a qualified medical physicist. This will provide each facility with the best indicator of deterministic injury. With monitoring comes awareness, and with awareness, radiation dose can be reduced.

Radiation Dose Management

Displaying the radiation dose as a "real time" value is only part of the solution to preventing serious radiation skin injuries during fluoroscopically guided medical procedures. A comprehensive program for radiation dose management should address training for the fluoroscopist and other staff and should include various dose monitoring and tracking procedures. The following are some recommendations and points to consider when developing a comprehensive radiation dose management program.

A. Training of Fluoroscopist and Staff

Initial and refresher training in radiological protection for patients and staff should be an integral part of the education for the fluoroscopist and staff performing interventional fluoroscopic procedures. A thorough understanding of radiobiological effects is paramount since there is a potential to deliver doses high enough to cause serious deterministic effects. Each facility should develop a training program in radiation management that is specific to their facility, which would include but not be limited to the following:

- Biological effects of ionizing radiation
- Radiation protection of the patient and support staff
- Use of personal protective equipment (i.e., shields, aprons, etc.)
- Personnel dose monitoring
- Threshold action levels

An orientation/certification system also should be utilized for any newly employed fluoroscopist to ensure proficient skill in the safe operation of each fluoroscopic system. This should be completed before the operator is given privileges to conduct procedures and use the system without supervision. Established operators should be oriented when new equipment installations occur, as "buttonology" may be different. Maintenance of such operator skills requires a minimum level of activity as deemed necessary by the radiation safety committee/officer. Annual refresher training in radiation safety is recommended for the fluoroscopist and staff.

B. Monitoring and Tracking of Fluoroscopic Dose

Machines manufactured after June 2006 include a dose display system that indicates dose in units of air kerma rate and cumulative air kerma. This system approximates the point at which the x-ray beam enters the skin and displays the dose. FDA regulations allow ±35% accuracy for such dose monitor systems. It is understood that these systems do not accurately predict actual skin dose; however, these are very useful indicators of potential deterministic risk.

The FDA does not have any requirements for dose monitoring devices to be installed on x-ray equipment manufactured prior to June 2006. However, it is recommended that some method be utilized to monitor patient dose. There are a number of after market devices available that can be implemented to monitor radiation dose. To reiterate the point, considering the methods of dose monitoring discussed previously in this paper, the best dose monitoring

method available to the facility should be determined and implemented through consultation with a qualified medical physicist.

The dose data should be used during fluoroscopic procedures to help the fluoroscopist to adequately monitor radiation dose without compromising medical treatment. Assistants should be prepared to alert the fluoroscopist at the dose levels defined here:

Table 2. Summary of radiation monitoring dose notification thresholds

Parameter	First Notification	Subsequent Notifications
PSD	2000 mGy (200 rad)	500 mGy (50 rad)
$K_{a,r}$	3000 mGy (300 rad)	1000 mGy (100 rad)
P_{KA}	300 Gy·cm² *	100 Gy·cm² *
FT	30 min	15 min

***** Assuming a 100 cm² field at the patient's skin. The value should be adjusted to the actual procedural field size.

Summary of radiation monitoring dose notification thresholds reprinted with permission: Stecker, Michael S., M.D., S Balter, Ph.D., et al. Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology (2009) 20: pp S263-S273.

All available dose data should be recorded for every fluoroscopic procedure. This information should be immediately reviewed to determine if the patient is at risk for potential deterministic effects. The entire data log should be periodically reviewed as part of the facility's quality management program.

Currently only a few states have implemented regulations that require fluoroscopic dose determination and tracking. Dose threshold values at which tracking and patient follow-up are required range from 1 Gy (100 rad) to 6 Gy (600 rad) for states that have regulations in place. In 1995, the FDA recommended that procedures resulting in an absorbed dose to the skin of 1 Gy (100 rad) be recorded in the patient's medical record. In 2000, the ICRP in Publication 85 recommended that a threshold dose for action was 3 Gy (300 rad) or 1 Gy (100 rad) if the procedure was likely to be repeated.

The ACR has suggested that skin doses that exceed 2 Gy should be tracked. The Society of Interventional Radiology (SIR) has made recommendations that fluoroscopists be promptly notified if any of the following occur: the peak skin dose exceeds 3,000 mGy (300 rad), the reference point air kerma exceeds 5,000 mGy (500 rad), the kerma air product exceeds 500 Gy/cm², or the fluoroscopy time exceeds 60 minutes. The dose is to be recorded in the patient's medical record and the patient should be closely monitored for any deterministic injury. It also has been recommended that any procedures performed subsequently in

the next 60 days should be considered additive to the dose already received. While the regulatory dose threshold value continues to be debated, it is apparent that the value that is selected will help the fluoroscopist and the facilities achieve a higher level of awareness of patient dose. This should allow the facility to improve medical care and reduce radiation dose.

C. Patient Follow-up

The list below is a chart of deterministic effects. This chart includes the approximate threshold dose to produce the effects and the typical time to the onset of symptoms.

Table 3. Effects of radiation on skin and hair

Single-site Skin Dose Range (Gy)	Prompt < 14 days	Early 14 – 40 days	Mid term 40 – 400 days	Long term > 400 days
0-2	No observable effects expected			
2-5	Transient erythema	Transient hair thinning	Hair recovery	None expected
5-10	Transient erythema	Erythema, epilation	Recovery from previous effects; at higher doses, possible prolonged erythema. Permanent partial epilation	Recovery, with possible permanent skin changes at higher doses in this range.
10-15	Transient erythema	Epilation, erythema. Possible moist desquamation at higher doses, with subsequent healing	Permanent total epilation. Prolonged erythema	Telangiectasia, induration. Skin likely to be weak and more susceptible to secondary injury.
> 15 *	Transient erythema and possibly pain. Edema and acute ulceration after very high doses (> 80 Gy)	Epilation, erythema, moist desquamation. Possible healing of acute ulceration.	Dermal atrophy. Secondary ulceration in areas of prolonged moist desquamation after higher doses. Dermal necrosis. Surgical intervention likely required; should be delayed until viable tissues are defined.	Telangiectasia, dermal atrophy/induration. Depending on dose and patient characteristics, any persistent wound might progress into a deeper lesion. Healing in absence of surgical correction likely to result in some or all of the following: scarred tissues, weak skin susceptible to injury, skin breakdown reoccurring at later dates.

* Some effects may occur sooner than noted and be more pronounced as dose increases above 20 Gy.
Adapted from Balter et.al – Radiology in Press

Radiation risks associated with fluoroscopic procedures should be discussed with the patient as part of the pre-procedure patient consent process. Fluoroscopic procedures where the radiation dose potentially may be high should be discussed with the patient, and the patient should be informed of the possible deterministic risks.

Once any threshold level shown in the following table has been exceeded, notification should be made to the patient, the interventional physician, and the radiation safety committee/officer. The interventional physician should be directly involved in this notification process with the patient. This notification, at a minimum, should include potential deterministic effects. The patient should be informed of what symptoms to look for and to notify his/her primary care physician as well as the facility if any are observed. Facilities should follow up by telephone approximately three weeks after the procedure to ascertain whether there is any evidence of a radiation induced injury. This will assure that prompt medical care will be delivered if necessary. Some deterministic injuries may take several months to manifest. The patient should be made aware of this fact during the three week follow-up, and the patient should be advised to report any symptoms that may occur later.

Table 4. Thresholds for patient follow-up

Parameter	Threshold
PSD	3000 mGy
$K_{a,r}$	5000 mGy
P_{KA}	500 Gy·cm^2
FT	60 min

It is recommended that the facility radiation safety committee/officer take an active role in reviewing all cases that meet or exceed the dose threshold level. The committee should review the cases to ensure that appropriate notification has occurred and that medical follow-up has been pursued. It is also required by the Safe Medical Devices Act 1990 that any serious injuries associated with the use of medical devices be reported to the FDA. This includes radiation burns and other deterministic injuries. Additionally, the radiation safety committee/officer should monitor all recorded fluoroscopic doses for trends among current operators.

Methods should be employed to help minimize radiation dose during fluoroscopic procedures. These include but are not limited to the following:

- Minimize x-ray beam on time

- Vary the site of the entrance port on the patient as clinically possible
- Optimal collimation
- Use the least amount of machine magnification possible
- Position the x-ray source and image receptor optimally
- Understand and utilize machine dose reduction features
    - Last image hold feature
    - Pulsed fluoroscopy
- Maintain equipment in good repair and calibration

CONCLUSION

All machines manufactured after June 2006 have the ability to track and display patient dose both in real time and cumulatively. Facilities are encouraged to make efforts to incorporate dose display features into fluoroscopic equipment manufactured prior to June 2006. Each facility will have to decide which method of dose tracking is best. This decision should be made with consultation with a qualified medical physicist. The patient dose information and other suggested procedures will help fluoroscopists and facility staff to have a better understanding of the potential risks associated with interventional fluoroscopic examinations. Additionally, they will be able to further strengthen their radiation safety programs, and with this increased knowledge be able to better manage radiation dose and reduce deterministic risks. This in turn benefits both patients and staff.

It should be noted that radiation dose from medical exams is not solely a fluoroscopic issue. All medical radiation doses should be tracked and considered to determine if an increased deterministic risk exists. Radiation dose from computed tomography, diagnostic x-ray, therapy, and other sources of dose should be considered pre-procedurally. Patient disease conditions that may increase radiosensitivity should also be part of the pre-procedure preparation and evaluation. Quoting from noted medical physicist Dr. Stephen Balter, Ph.D. "…*Deterministic effects should never be a post procedure surprise*." Ultimately the risk to benefit decision is the physician's responsibility and the patient's overall medical outcome must take precedence over radiation risk. However, with better education and training of fluoroscopic staff, and with the monitoring tools now available, physicians and facilities will be better prepared to manage and address this problem.

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