

FOOD AND DRUG ADMINISTRATION

IMPORTANT INFORMATION FOR PHYSICIANS  
AND OTHER HEALTH CARE PROFESSIONALS

September 9, 1994

**AVOIDANCE OF SERIOUS X-RAY-INDUCED SKIN INJURIES TO  
PATIENTS DURING FLUOROSCOPICALLY-GUIDED  
PROCEDURES**

**WARNING - FDA has reports of occasional but at times severe radiation-induced burns to patients from fluoroscopically-guided, invasive procedures. This communication describes the nature of these injuries and provides recommendations for avoiding them.**

**PROCEDURES RESULTING IN INJURIES**

An increasing number of invasive procedures, primarily therapeutic in nature and involving use of devices under fluoroscopic guidance, are becoming accepted medical practice. Examples of such procedures are listed in Table I. These procedures are performed by a variety of medical specialists and may provide significant advantages over alternative therapies in terms of improved clinical outcome and reduced overall patient risk. However, physicians performing these procedures should be aware of the potential for serious radiation-induced skin injury caused by long periods of fluoroscopy occurring with some of these procedures. Such injuries have recently been reported as a result of radiation exposure during some of these procedures (Ref. 1-3) due to long fluoroscopic exposure times, high dose rates or both.

**TYPES OF INJURIES**

The types of injuries to skin and adjacent tissues which result from x-ray radiation are summarized in Table II along with the typical absorbed dose in the skin required to produce the injury. (See below for a discussion of radiation quantities and units.) Each of these injuries has recently been observed as a result of fluoroscopically guided

---

Table I. Procedures typically involving extended fluoroscopic exposure time

Radiofrequency cardiac catheter ablation  
Percutaneous transluminal angioplasty (Coronary and other vessels)  
Vascular embolization  
Stent and filter placement  
Thrombolytic and fibrinolytic procedures  
Percutaneous transhepatic cholangiography  
Endoscopic retrograde cholangiopancreatography  
Transjugular intrahepatic portosystemic shunt  
Percutaneous nephrostomy, biliary drainage or urinary/biliary stone removal

---

procedures. These "threshold doses" are typical of the absorbed dose in skin required to cause the effect, since appearance of the injury is dependent on a number of variables other than the cumulative dose in the skin, such as: the rate of delivery of the radiation; the fractionation of the absorbed dose; the age and characteristics of the person exposed; and the site on the skin of the exposure.

Table II. Radiation-Induced Skin Injuries

Effect	Typical Threshold Absorbed Dose (Gy)*	Hours of Fluoroscopic "On Time" to Reach Threshold* at:		Time to Onset of Effect**
		Usual Fluoro. Dose Rate of 0.02 Gy/min (2 rad/min)	High-Level Dose Rate of 0.2 Gy/min (20 rad/min)	
Early transient erythema	2	1.7	0.17	hours
Temporary epilation	3	2.5	0.25	3 wk
Main erythema	6	5.0	0.50	10 d
Permanent epilation	7	5.8	0.58	3 wk
Dry desquamation	10	8.3	0.83	4 wk
Invasive fibrosis	10	8.3	0.83	
Dermal atrophy	11	9.2	0.92	>14 wk
Telangiectasis	12	10.0	1.00	>52 wk
Moist desquamation	15	12.5	1.25	4 wk
Late erythema	15	12.5	1.25	6-10 wk
Dermal necrosis	18	15.0	1.50	>10 wk
Secondary ulceration	20	16.7	1.67	>6 wk

\* The unit for absorbed dose is the gray (Gy) in the International System of units. One Gy is equivalent to 100 rad in the traditional system of radiation units.

\* Time required to deliver the typical threshold dose at the specified dose rate.

\*\* Time after single irradiation to observation of effect.

(Table adapted from Ref. 4.)

## ABSORBED DOSES TO SKIN FROM FLUOROSCOPY

The absorbed dose rate in the skin from the direct beam of a fluoroscopic x-ray system is typically between 0.02 and 0.05 Gy/min (2 and 5 rad/min), but may range from 0.01 to more than 0.5 Gy/min, depending on the mode in which the fluoroscopic equipment is operated and the size of the patient. The times required to deliver the typical "threshold doses" shown in Table II are for fluoroscopic dose rates of 0.02 Gy/min (third column) and 0.2 Gy/min (fourth column) in that portion of the skin irradiated by a stationary, continuous fluoroscopic x-ray

beam. These dose rates are, respectively, the usual or typical dose rate for normal fluoroscopy for an average-size patient and a dose rate near the maximum which will be permitted for high-level control mode of operation under a recently established Federal limit (See Ref. 7). **Thus, even typical dose rates can result in skin injury after less than one hour of fluoroscopy.** For comparison, the absorbed dose to the skin from a typical diagnostic x-ray examination is hundreds to thousands of times smaller than the threshold doses for skin injuries given in Table II.

It should be noted that many fluoroscopic x-ray systems used for invasive procedures have modes of operation which result in dose rates which significantly exceed the usual dose rate of 0.02 Gy/min used as an example in Table II. Many systems currently in use are capable of dose rates which are higher than 0.2 Gy/min. In addition, many fluoroscopically guided procedures involve image recording (fluorography) using film or digital means to permanently record images. **The recording modes typically involve much higher dose rates than fluoroscopy and the contributions from fluorography must also be included in assessing total absorbed dose to the skin.** Fluoroscopic systems which are improperly adjusted or have dose rates increased to compensate for degraded performance can also result in unnecessarily high absorbed dose and consequent injury from very long exposure times.

#### OTHER RISKS

Procedures of the type described here may also increase the risk for late effects such as radiation-induced cancers in other tissues and organs. The potential for such late effects should not be disregarded in risk/benefit considerations, especially for individuals with many decades of expected life remaining, such as pediatric and young adult patients, or for procedures involving absorbed dose to radiosensitive tissues such as the breast. These interventional procedures can also result in increased occupational exposure to physicians and staff, and efforts to reduce the exposure to patients will result in reductions in the exposure to those conducting the procedures.

#### DELAYED SYMPTOMS

Complicating the assessment of the magnitude of the problem of injuries from fluoroscopy is the fact that the injuries are not immediately apparent. Typical times to onset or appearance of the effect are given in Table II. Other than the mildest symptoms, such as transient erythema, the effects of the radiation may not appear until weeks following the exposure. Physicians performing these procedures may not be in direct contact with the patients following the procedure and may not observe the symptoms when they occur. Missing the milder symptoms in some patients can lead to surprise at the magnitude of the absorbed doses delivered to the skin of other patients when more serious symptoms appear. For this reason, it is recommended that information be recorded in the patient's record which permits estimation of the absorbed dose to the skin. This is especially important for patients who may receive a significant fraction of a threshold dose, such as from an hour of fluoroscopy or from a large

number of recorded images, or who may be subject to repeated treatments using fluoroscopy. Consideration should be given to counseling such patients on the possible symptoms and risks from these procedures.

Because of these concerns and reported injuries, the following advice is provided for physicians performing fluoroscopically guided procedures. The goal is to avoid such injuries without adversely affecting the clinical objectives of the procedure.

#### **GENERAL PRINCIPLES AND RECOMMENDATIONS FOR FACILITIES IN WHICH INVASIVE PROCEDURES ARE PERFORMED**

1. Establish standard operating procedures and clinical protocols for each specific type of procedure performed. The protocols should address all aspects of the procedure such as patient selection, normal conduct of the procedure, actions in response to complications and consideration of limits on fluoroscopy exposure time.
  - ◆ Include all fluoroscopic system modes of operation used, including image recording.
  - ◆ Strive for clinically adequate images with minimum fluoroscopic exposure.
  - ◆ Assure appropriate credentials and training for physicians performing fluoroscopy.
  - ◆ Minimize exposure duration.
  - ◆ Collimate the radiation beam.
  - ◆ Communicate and enforce protocols.
2. Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol.
  - ◆ All operators of the system must be trained and understand system operation, including the implications for radiation exposure from each mode of operation.
  - ◆ Have a quality assurance program for the x-ray system supervised by a qualified medical physicist.
  - ◆ Calibrate and document radiation output.
  - ◆ Record information permitting estimation of the absorbed dose to skin in the patient's medical record.
3. Assess the impact of each procedure's protocol on the potential for radiation injury to the patient.
  - ◆ Facilities should ensure that physicians performing fluoroscopic procedures have education so they may, on a case-by-case basis, assess risks and benefits for individual patients, considering variables such as age, beam location and direction, tissues in the beam and previous fluoroscopic procedures or radiation therapy.
  - ◆ Counsel patients regarding the symptoms and risks of large radiation exposures and address risks from radiation in the consent form.

- ◆ Justify and limit the use of high dose rate modes of operation.
4. Modify the protocol, as appropriate, to limit the cumulative absorbed dose to any irradiated area of skin to the minimum necessary for the clinical tasks, and particularly to avoid approaching cumulative doses that would induce unacceptable adverse effects. Use equipment which aids in minimizing absorbed dose with such features as:
    - ◆ Indication of cumulative fluoroscopic exposure time.
    - ◆ Indication of cumulative absorbed dose to the skin or a related quantity such as dose-area product.
    - ◆ Real-time indication of dose rate or related quantity.
    - ◆ "Last image hold" or "freeze frame" image display.
    - ◆ Optimum beam filtration, removable grids, variable optical aperture, and radiation efficient automatic brightness control algorithms.
  5. Enlist a qualified medical physicist to assist in implementing these principles in such a manner as not to adversely affect the clinical objectives of the procedure.

### REPORTING REQUIREMENTS

Healthcare practitioners who are aware of fluoroscopy or radiation related deaths or injuries are asked to notify FDA. The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other facilities to report death, serious illness and serious injury associated with the use of medical devices. The reporting procedures established by each medical facility to comply with the mandatory reporting requirements should be used. Practitioners who become aware of any medical device related adverse event or product problem/malfunction should inform their designated Medical Device User Facility reporter. To reinforce the point that second degree burns requiring medical treatment, along with other serious injuries, resulting from use of a medical device are reportable under the SMDA, the FDA is considering a proposal to make this requirement explicit in the medical device user facility reporting regulations. FDA encourages these reports now. In addition, any issues concerning the quality or performance of a medical device can be reported directly to the MedWatch program. Anonymous reports are accepted. Please submit your reports to MedWatch, the Medical Product Reporting Program, by phone at 1-800-FDA-1088 (you may also use this number to request MedWatch information); by FAX at 1-800-FDA-0178; by modem at 1-800-FDA-7737; or by mail to MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

### RADIATION QUANTITIES AND UNITS

The quantity which is used to assess the energy deposited in tissue from radiation is absorbed dose. In the current International System the unit of absorbed dose is the joule/kilogram with the special name of gray (Gy) (in honor of the radiobiologist L. H. Gray). An absorbed dose

of one Gy is 100 times the magnitude of the older unit of absorbed dose, the rad. Thus, a dose rate to skin of 0.02 Gy/min is equivalent to 2 rad/min.

#### REFERENCES

1. Food and Drug Administration Mandatory Device Reporting System. Report Nos. 241641, 275018, 275019, 298419, 298423, 487999.
2. Private communication, L.G. Smith, May 16, 1994.
3. Davidson County Circuit Court, Nashville, Tennessee. Case No. 93C-1916, 1993.
4. Wagner LK, Eifel PJ, Geise RA. Potential Biological Effects Following High X-ray Dose Interventional Procedures. *Journal of Vascular and Interventional Radiology* 1994; 5:71-84.
5. National Council on Radiation Protection and Measurements. Quality assurance for diagnostic imaging equipment. NCRP Report No. 99, Bethesda, MD, 1988.
6. American College of Radiology. Proceedings of the ACR/FDA Workshop on Fluoroscopy: Strategies for Improvement in Performance, Radiation Safety and Control, October 16 and 17, 1992, Washington, D.C.
7. FEDERAL REGISTER, Vol. 59, No. 96, pp 26402-26405, May 19, 1994.