Interventional Fluoroscopy Patient and Staff Safety


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Minneapolis - 2007

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Procedures

- Numbers of procedures will continue to increase
  - Growing older population segment
  - Variety of procedures is increasing
- Average dose per procedure may increase
  - Increasing patient weight
  - Increasingly complex procedures
- Radiation management should focus on high dose procedures

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Safety objectives

- Protect workers
  - Both from radiogenic and non radiogenic risks
  - Non-scrubbed staff
  - Scrubbed staff
- Minimize the unnecessary use of radiation on patients

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Medical physics tasks

- Risk based strategy
  - Equipment
  - Sensitive Procedures
- QA on what you have
  - Including built in or add-on “dose” display
- Educate, Educate, Educate
  - Patients
  - Physicians
  - Physicists

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Ethics

- Patients should be irradiated only when a net medical benefit is anticipated.
- Staff do not receive medical benefits when they are irradiated.
- Health care workers have a long tradition of accepting personal risks if these are believed to be a necessary part of optimally caring for their patients.

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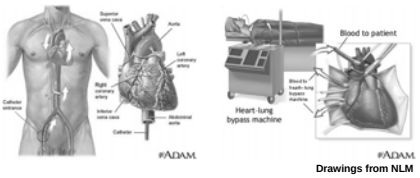
Comparative patient risks



Drawings from NLM

Estimated Risks: Treatment Modality	Multi vessel PCI	Multi vessel bypass surgery
Death	0.5 %	1.5 %
Major Stroke	<0.1 %	1.0 %
Major Wound Infection	<0.1 %	2.0 %

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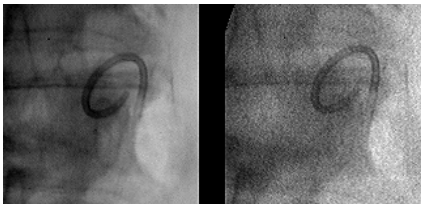
How much radiation is needed?

- Image frequency must be high enough to minimize motion uncertainty.
- Imaged volume must cover clinical ROI.
- Single image dose should be sufficient to reduce noise to a clinically acceptable level



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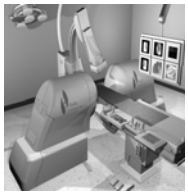
Staff Safety

- Infection control
- Lead garments
- Interlocks
- Mechanical
- Reboot time
- Radiation
- *Magnetic*



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Any safety issues here?

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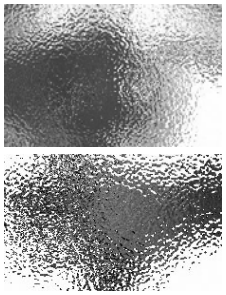
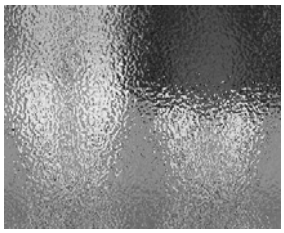
Modern operator injuries





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Enhanced radiation safety basics

- Time
- Distance
- Shielding
- Personnel monitoring
- Situational awareness
- Mode and dose rate selection

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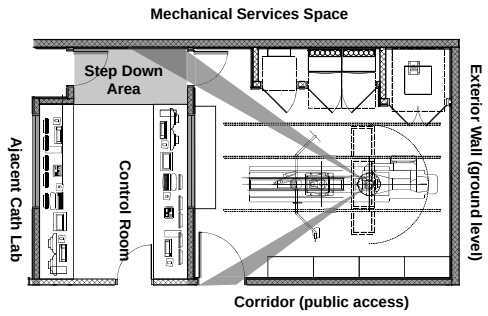
Typical interventional lab



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Mobile shielding

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Personal shielding

- Garments
  - Well tailored apron
  - Thyroid collar
  - Eye protection ?
- Inspection
  - Every 6 months
  - Few unnoticed failures significantly reduce shielding value

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Radiation monitoring

- For the benefit of the wearer
  Access to reports
- Readings should correlate with workload
- OUTSIDE LEAD – Left collar (1 or 2)
- INSIDE LEAD – Chest – Waist (2)

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Dose evaluation

- Personnel monitors report deep dose equivalent (DDE) based on their local irradiation.
- NCRP states whole body MPD in terms of effective dose (E)
- E is estimated from one or two DDEs.
  - ED(2) = 1.5 x Inner + 0.04 Outer
  - ED(1) = Outer / 3
  - Both methods overestimate E (NCRP122)

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Risk optimization

- Many (if not most) interventionalists develop spinal injuries attributable to their working conditions.
- Reducing the 'lead' weight often relives symptoms and slows the injury progression.
- It may be appropriate to reduce personal shielding. This reduces orthopedic risk at the cost of increasing radiation risk.
  - This will often increase the ALARA level.
  - Dual badge monitoring is necessary.
  - Individual informed consent is essential.

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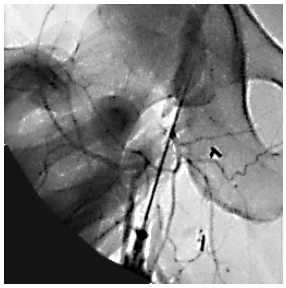
Situational awareness



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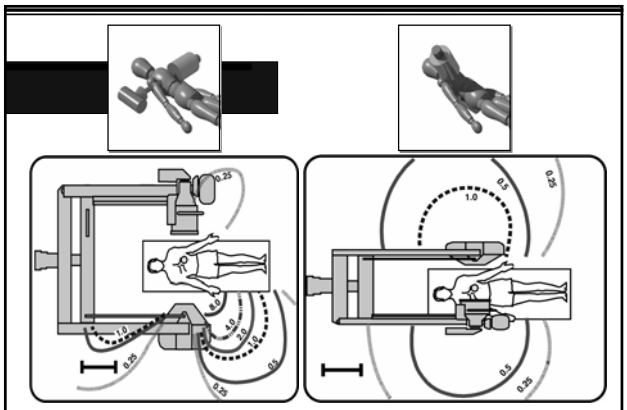

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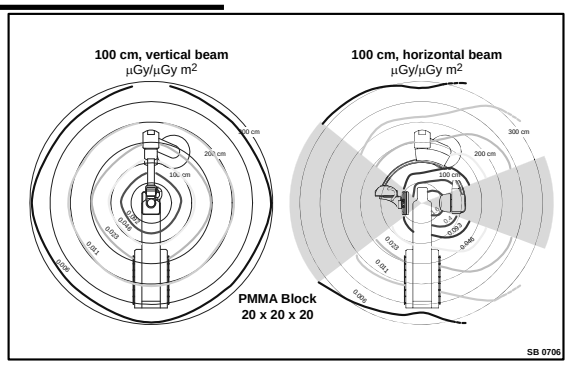
Typical IFU Scatter Map



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Pregnancy

- Fetal limit 5 mSv for pregnancy
- Operational limit 0.5 mSv/month
- Monitor with under-lead badge
  - Low probability of stochastic effects
  - Well below deterministic effect threshold
  - Nurses expected to be 'Minimum'
  - Assistant (>0.05 mSv/m)
- Worker and health-care providers must aware of the 5% natural incidence of congenital abnormalities

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ALARA (support staff)

As Low As Reasonably Achievable

- Radiation risk similar to other 'normal' risks (e.g. where to live).
- Effective Dose
  (E) < Variations in background

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'Burns are Back§' c 1997

Estimated frequencies

Approx 2 million interventions per year in the US
Less than 10 injuries per year reported to FDA

PROCEDURE DEPENDENT:

Frequency of significant radiation injury is probably between 1/20,000 and 1/200,000

Frequency of significant non-radiation interventional complications is much higher (Death ≈ 1/1000)

USA Today November 20, 2000

§ Audience Comment Dublin

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An older viewpoint

- We may safely expect that damage suits for Roentgen-ray burns caused during diagnostic exposures will become more and more infrequent. But with the employment of the rays for therapeutic purposes burns have now become a rather common accident . . . .
- Where cosmetic considerations alone are concerned, such heroic therapy is injudicious.'

1907 Kassabian

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Actual and potential toxicity

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Focus of this section

- Minimizing and managing patient deterministic radiation injury in interventional fluoroscopy
- Not Discussed
  - Patient radiation stochastic risks
  - Pregnancy risks

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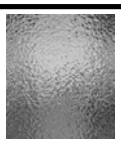
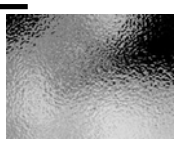
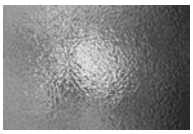
Deterministic injuries



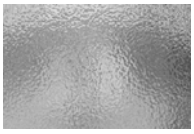
Coronary Angioplasty
Mettler



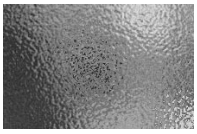
Cardiac Ablation
F. Wong



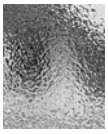
TIPS placement
Nahass



Uterine embolization
Shope



Renal angioplasty
Dandurand



Neuroembolization
Miller

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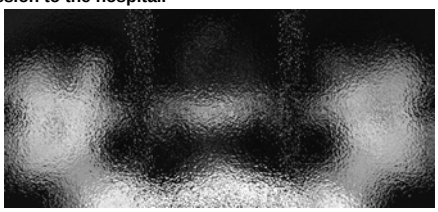
CT fluoro

"Bandage-shaped hair loss (53-year-old woman with subarachnoid hemorrhage). Temporary bandage-shaped hair loss, which lasted for 51 days, was seen on day 37 after the first perfusion study of the head with MDCT. In this patient, four perfusion studies of the head with MDCT and two angiographies of the head had been performed within the first 15 days of admission to the hospital."



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Time sequence

2 months | 6 months | 2 years

Source: FDA/CDRH

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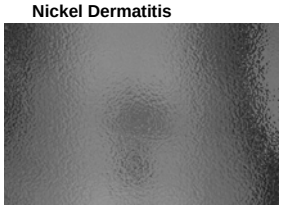
Non radiation injuries

Nickel Dermatitis



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Deterministic patient injury

- Hair loss starting at a few gray (Gy).
- Skin injury when peak skin dose (PSD) exceeds several gray (Gy).
- Major skin injuries usually occur above 10 – 15 Gy PSD.

Effects are first seen hours – weeks after injury.

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Radiation injuries are not thermal burns

Substantial amounts of deposited thermal energy are needed to cause noticeable thermal burn.	Minute amounts of deposited X-ray energy will cause a severe radiation injury.
Heat is sensed by the patient before injury occurs.	X-ray damage is not sensed
Signs of injury are prompt and progress quickly. The extent of the injury can be assessed in hours.	Signs and symptoms are usually delayed by weeks to months. The injury may take a year or more to fully evolve.
Response to treatment is apparent in a matter of days.	Treatment is often ineffective until the latent injury is fully expressed.

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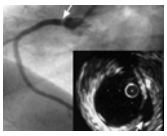
Patient risk management goals

- Maximize patient benefit against risk.
- No ***unintended*** deterministic injuries.
- Medically ***unavoidable*** deterministic injuries should be as infrequent as possible.

REQUIREMENT:
ADEQUATE REAL-TIME DOSE MONITORING

- - - - - - - - - -



- Stochastic risk considered
- Careful management of fetal risk

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FDA 1994 advisory

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.

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ICRP 85: Interventional Procedures

Used by an increasing number of clinicians not adequately trained in radiation safety or radiobiology.

Operators not aware of the potential for injury or the simple methods for decreasing their incidence.

Patients are not counseled on the radiation risks, or followed up when radiation doses from difficult procedures may lead to injury.

Some patients suffer radiation-induced skin injuries and younger patients may face an increased risk of future cancer.

In some procedures, skin doses to patients *approach* [exceed] those experienced in *some* [most] cancer radiotherapy *fractions* [courses].

Skin injuries are occurring due to inappropriate equipment and, more often, due to poor operational technique.

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JC(AHO): Reviewable Sentinel Events

2006 Sentinel Event list includes:

- Surgery on the wrong individual or wrong body part.
- Unintended retention of a foreign object in an individual after surgery or other procedure.
- [Unintended] Prolonged fluoroscopy with cumulative dose >1500 rads (15 Gy) to a single field, or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

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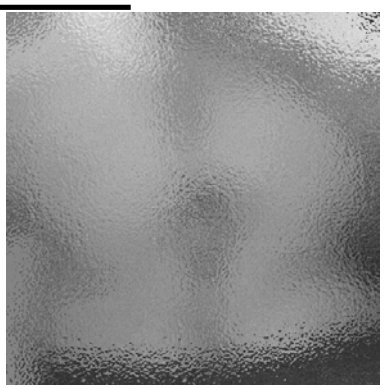
Sentinel event?



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Deterministic injury decisions

- There is no regulatory maximum dose!
- Operator must have sufficient real time information to reevaluate radiation risk against patient benefits of continuing
- Almost always avoidable
- Should never be a post-procedure surprise !

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Causes of deterministic injuries

- Defective, inappropriate, or inadequate equipment

± High dose rate technique

+ Long and complex procedures

(medical complications and emergencies)

+ Multiple procedures

(staged)

+ Long beam paths

(heavy patients & compound angles)

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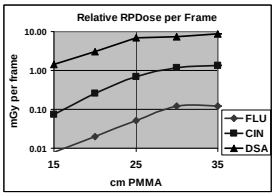
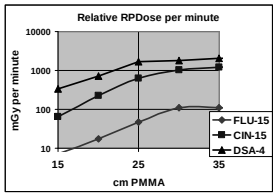
Dose rates





CUMC - 06

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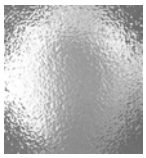
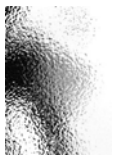
Unnecessary body part in beam



Wagner – Archer, Minimizing Risks from Fluoroscopic X Rays, 3rd ed, 2000



3 W

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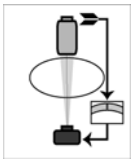
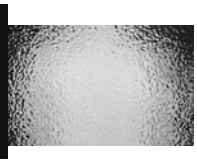
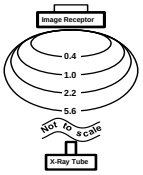
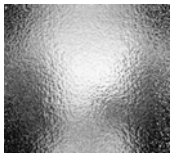
Long path lengths





14 months
51 min fluoro
? Cine
Wolff D, Heinrich KW. 1993





Different Patient

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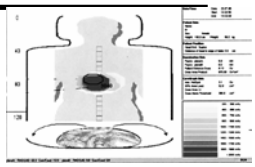
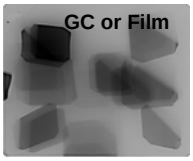
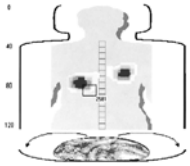
Skin dose maps

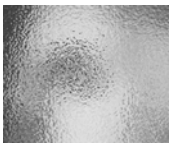




Vano



CareGraph
Siemens



All different cases

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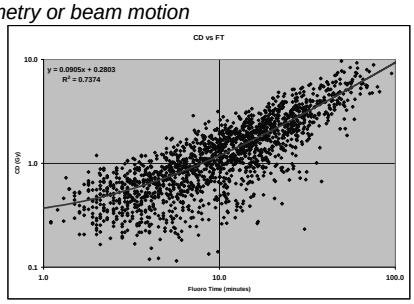
~~Fluoroscopy time~~

Does not reflect patient size, mode selection, beam geometry or beam motion



Source: CUMC Cardiac

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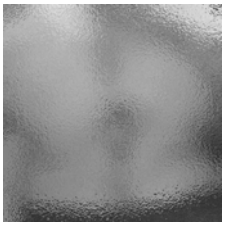
MedPhys List – May 2007

- **"A facility without a full-time physicist needs a quick, easy number that they can refer to, so we use fluoro time, as archaic and inaccurate as it might be.**
- **If you want to know if your patient received more than the threshold for skin injuries, look at the patient's skin, not the KAP meter or fluoro time!"**



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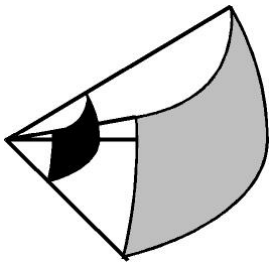
Kerma Area Product

Does not reflect field size, beam geometry, or beam motion



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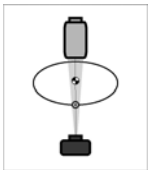
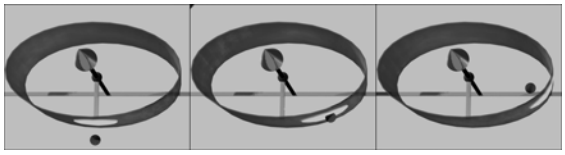
RPDose

Labeled mGy on most systems





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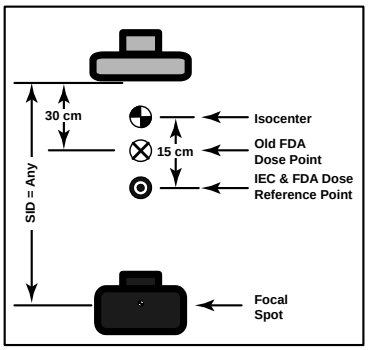
Reference points



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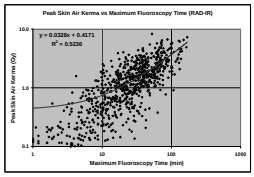
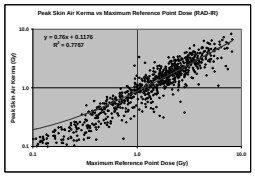
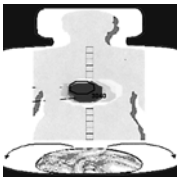
PSAK vs. Fluoro time and RPDose







RADIR: 709 Cases

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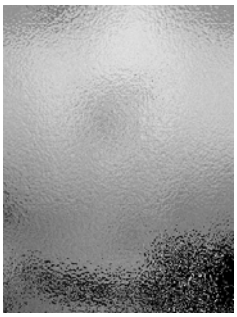
Biological Dosimetry?

- Only the most severe injuries will produce signs or symptoms before the patient leaves the hospital.
- Interventionalists seldom have any contact with their patients post discharge.
- Almost all patients and most of the medical community are unaware of radiation skin injuries.
- Dosimetry during a procedure can be a major factor in ongoing benefit-risk assessment.



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Columbia Clinical Dose Management

- Before the Procedure
  - Radiation Risk Evaluation
  - Appropriate Consent
- While the Procedure is in Progress
  - Continual Risk – Benefit Evaluation
  - Radiation similar to contrast (Iodine) management
- After the Procedure
  - Documentation
  - Patient Discussion
  - Follow – Up
- Clinical Quality Assurance

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Significant Dose

- Threshold value used to trigger extended post-procedure education and clinical follow-up
- Almost no injuries should be observed below the significant dose
- Major injuries may occur well above the significant dose
- RPDose = 5,000 mGy for patients without radiation risk factors (cardiac)

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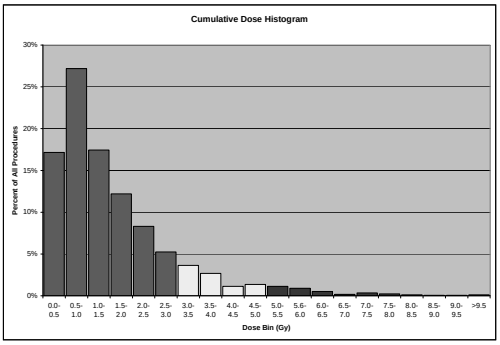
Extremes are clinically important



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Before the procedure

- Radiation Injury Risk Factors
  - Weight > 150 kG
  - Planned procedure
  - Radiation history
    - Previous angioplasty
    - Previous or planned RT to chest
    - Examine patient's back !
- Potential Significant Dose Patient
  - Appropriate additional discussion of injury risk as part of consent process
  - Reduce Significant Dose trigger based on radiation history.

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Patient radiation risk factors

- Over 150 kg
- Planned complex procedure
- Positive radiation history
  - Previous PCI
  - Previous or planned RT to region.
  - Examine back of all positive patients before the patient goes to the lab

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Possible patient risk topics

A slightly elevated risk for cancer several years later in life. This risk is typically low in comparison to the normal incidence of human cancer.

Hair loss occurs in many patients following complex neurointerventional procedures. This is usually temporary; regrowth of hair may be incomplete.

Skin rashes occur infrequently; on very rare occasions may result in tissue breakdown and possibly severe ulcers. The likelihood of this occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease, or genetic conditions.

Cataracts are rarely induced following neurointerventional procedures. This can be avoided in most cases.

Based on Wagner (AAPM SS 02)

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While the procedure is in progress

- Process
  - Continual Risk – Benefit Evaluation
  - Radiation similar to contrast (Iodine) management
- Questions
  - Has the beam moved?
  - Are you using a lot of cine?

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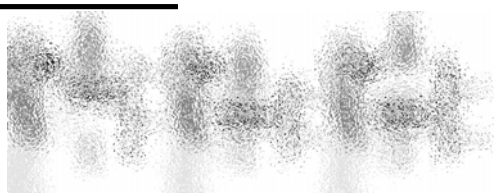
Imaging geometry



L Wagner

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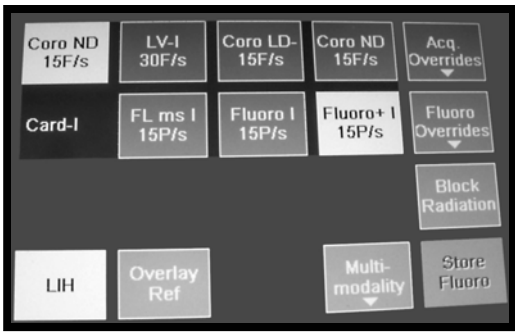
Operator options



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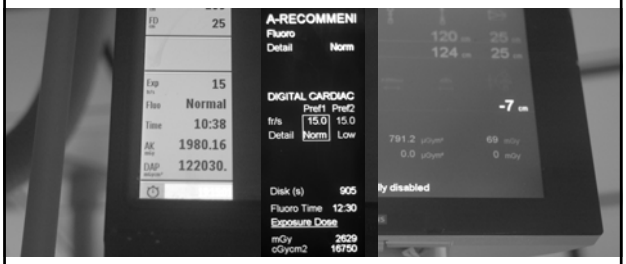
In lab dose displays



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Physician Take Away

Manage Radiation as responsibly as you manage dye

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After the procedure

- Documentation
- Patient Discussion
- Carefully examine the back of a symptomatic patient before discharge.
- Follow – Up

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Follow-up

- All suspicious injuries are considered radiogenic until proven otherwise.
  - Red patch (sunburn) on back about the size of a hand
- Pre-discharge: Patient complaints about localized redness, ± blisters, ± itch; need immediate evaluation
  - Reference Point Dose > 10,000 mGy
  - Frequent flier or post RT
  - This is a very important sign

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Repeat procedures

- Radiation damaged skin will heal after an injury.
- The repair process often damages the skin's microvasculature.
- Suggested delay between procedures
  - 1 month for a different vessel (different angles)
  - 2 months for the same vessel (same angles)

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Quality program

- X-ray equipment and its calibration
- Collect dose data on all procedures
- Benchmark against national and international standards
- Review all significant dose procedures
- Review all positive injury reports

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Physics QA reports – US practice

- FDA reference point may be further from focus than the patient's skin
- Maximum fluoro output is always tested
- Maximum acquisition output is seldom tested
- Typical outputs are still based on 38 mm Al attenuation in most States
  - Too often reported by the physicist as the actual patient skin dose rate.
  - For a modern system this is 10 – 20 % of max
  - NY requires 38Al + 2 mm Cu (approx 50% of max)
  - Given patient size, it is prudent to assume that the system is at maximum output

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Measure maximums!

Dose Rate Ratio Cine/Fluoro			
	38 mm Al +.5 mm Cu	38 mm Al +2 mm Cu	Maximum Output
Average	7.9	8.8	18.7
StDev	2.2	2.4	3.7

CUMC-Cath: 6 Labs 25 data sets
Smallest available FOV

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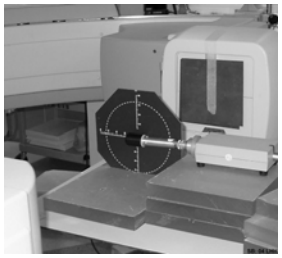
Calibration, Attenuation, and Backscatter

- Present practice is to calibrate instruments to read correctly when 'free in air'.
- Measurements made at the patient's skin are always higher than 'free in air' measurements due to backscatter
- Beams are attenuated when they traverse table tops and mattresses.



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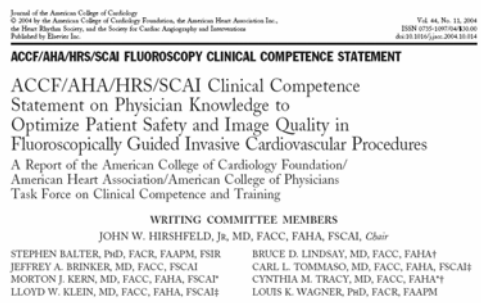
TEXTBOOK - Standard of Care



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ACCF/AHA/HRS/SCAI FLUOROSCOPY CLINICAL COMPETENCE STATEMENT

ACCF/AHA/HRS/SCAI Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety and Image Quality in Fluoroscopically Guided Invasive Cardiovascular Procedures

A Report of the American College of Cardiology Foundation/ American Heart Association/American College of Physicians Task Force on Clinical Competence and Training

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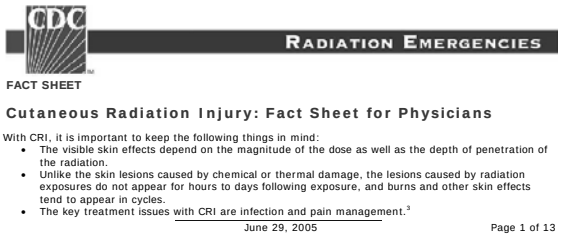
Cutaneous radiation injury



CDC RADIATION EMERGENCIES

FACT SHEET

Cutaneous Radiation Injury: Fact Sheet for Physicians

With CRI, it is important to keep the following things in mind:

- The visible skin effects depend on the magnitude of the dose as well as the depth of penetration of the radiation.
- Unlike the skin lesions caused by chemical or thermal damage, the lesions caused by radiation exposures do not appear for hours to days following exposure, and burns and other skin effects tend to appear in cycles.
- The key treatment issues with CRI are infection and pain management.[3]

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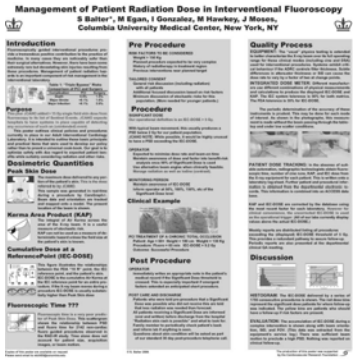

Management of Patient Radiation Dose in Interventional Fluoroscopy

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Columbia University Medical Center, New York, NY

Introduction
Purpose
Dosimetric Quantities
Peak Skin Dose
Kerma Area Product (KAP)
Cumulative Dose at a ReferencePoint (IEC-DOSE)
Fluoroscopic Time ???
Pre Procedure
Procedure
Clinical Example
Post Procedure
Quality Process
Discussion

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