09 AAPM Preliminary Draft of NCRP 2-3 TU-B-213A-1
Stephen Balter, Ph.D.

RADIATION DOSE MANAGEMENT FOR FLUOROSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES

NCRP Work-in-Progress
(Scientific Committee 2-3 Draft)

The current draft and recommendations have not been through the NCRP review process.
CHANGES ARE LIKELY

Stephen Balter, Ph.D.
(on behalf of the writing committee)
TU-B-213A-1 AAPM – July 2009

 Materials *not* reviewed by NCRP: *Changes are likely*

NOTICE

- The committee will meet 19-21 Aug to finalize the draft report.
- Comments and suggestions are both welcome and appreciated provided they are received no later than 10 Aug ! !
- Please email to sb2455@columbia.edu

 Materials *not* reviewed by NCRP: *Changes are likely*

Scope: Projection Fluoroscopy

- Addressed to policy makers.
- Not intended to be a complete how-to handbook.
- Critical background information and reference data will be included.

 Materials *not* reviewed by NCRP: *Changes are likely*

Key Participants

- Stephen Balter, Chair,
  Columbia University
- Beth A. Schueler, Vice Chair,
  Mayo Clinic
- Donald L. Miller, Vice Chair,
  USUHS

 Materials *not* reviewed by NCRP: *Changes are likely*

Organization

- General Concepts
- Fluoroscopic Equipment and Facilities
- Protection of the Patient
- Protection of Workers
- Administrative and Regulatory Considerations
- Appendices

 Materials *not* reviewed by NCRP: *Changes are likely*

Concepts

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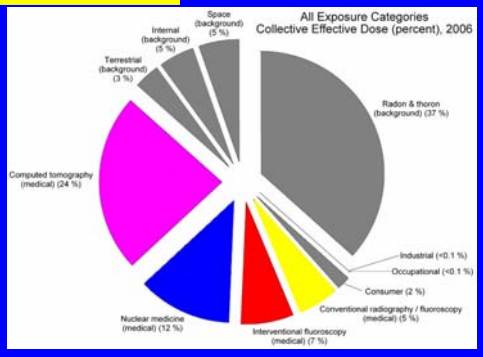
Definitions

- ***SHALL***
  a recommendation that is necessary to meet the currently accepted standards of radiation protection
- ***SHOULD***
  an advisory recommendation that is to be applied when practicable or practical (*e.g.*, cost effective)
- ***MAY***
  grants permission for its subject matter

Materials in yellow are not part of the report

 Materials *not* reviewed by NCRP: *Changes are likely*

NCRP 160: United States Population Dose



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Skin Reactions (In press)

PSD Band	Range Gy	Prompt < 14 d	Early 14 - 40 d	Mid Term 40 - 400 d	Late > 400 d
A1	< 2	- - - - - - - No effects expected - - - - - - -			
A2	2 - 5	Transient erythema	Transient hair thinning	Hair recovery	None expected
B	5 - 10	Transient erythema	Erythema, epilation	Recovery. At higher doses, prolonged erythema permanent epilation	Recovery. Skin changes at higher doses.
C	10 - 15	Transient erythema	Erythema, epilation, Possible dry or moist desquamation	Prolonged erythema permanent total epilation	Telangiectasia, induration, Skin likely to be weak.
D	> 15	Transient erythema with possible pain. Edema and acute ulceration at very high dose	Erythema, epilation, moist desquamation	Dermal atrophy, Secondary ulceration, Dermal necrosis	Dermal atrophy, induration, Late skin breakdown. Persistent wound. Surgical intervention likely.

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Extended ICRU Notation

- $K_{a,r}$ = Accumulated air kerma at a specified reference point
- P_{KA} = Air Kerma - Area Product
- $K_{a,i}$, $K_{a,e}$ = Incident & Entrance Skin Kerma
- $D_{skin,e}$ = Entrance Skin Dose
- $D_{tissue,max}$ = Peak Tissue Dose

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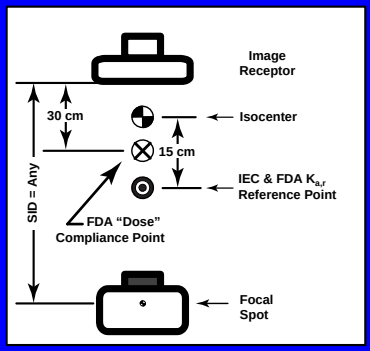
Reference Point Locations



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Risk

- Radiation ***shall*** be considered as only one of many risks of medical procedures.
- For pediatric patients, stochastic risk ***should*** be considered the higher radiation-risk priority.
- For adult patients, the likelihood of tissue reaction ***should*** be considered the higher radiation-risk priority.

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Dose Limit - Patient

- Dose limits ***shall not*** be applicable to patients undergoing fluoroscopically guided interventional procedures.
  - Joint Commission 15 Gy Sentinel Event is intended to trigger a root-cause investigation; it is not a dose limit.
  - Dose limits would often do more harm than good provided that the specific procedure has been justified and that doses are commensurate with the medical purpose.
- Any amount of radiation usage ***shall*** be justified for each procedure.
  - Responsible physician must have adequate knowledge!

 Materials *not* reviewed by NCRP: *Changes are likely*

Dose Limits - Staff

- Dose limits ***shall*** be applicable to staff participating in fluoroscopically guided interventional procedures.
- Doses ***shall*** be accurately estimated to avoid improperly limiting a worker's activities.

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Effective Dose

- Effective Dose (E) ***shall not*** be used for quantitative estimates of stochastic radiation risk for individual patients.
- E ***should not*** be used for quantitative risk estimates for patient groups.
- E ***may*** be used as a surrogate indicator of stochastic radiation risk for classifying different types of procedures into broad risk categories.
- E ***may*** be used by Institutional Review Boards to broadly estimate the stochastic risk associated with research procedures.

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Conversion factors (mSv/Gycm^2)

mSv / Gycm^2 - ICRP 60	Abdomen	Pelvis	Upper Leg
Centre 9	0.080	0.083	0.023
Centre 11	0.120	0.114	0.028
Centre 3	0.187	0.203	0.056
Centre 12	0.232	0.384	0.104

mSv / Gycm^2 - ICRP 103	Abdomen	Pelvis	Upper Leg
Centre 9	0.093	0.054	0.013
Centre 11	0.137	0.073	0.015
Centre 3	0.212	0.130	0.030
Centre 12	0.270	0.215	0.047

K. Smans, L. Struelens, et.al, A study of the correlation between dose area product and effective dose in vascular radiology, Radiat Prot Dosimetry, July 2008; 130: 300 - 308.

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Tissue Dose

- The measured dose quantities kerma area product (P_{KA}) and total air kerma at a reference point ($K_{a,r}$) **should** be used to compare similar procedures.
- Peak tissue dose ($D_{tissue,max}$) s***hall*** be used to estimate the possibility of deterministic injury.
- The risk of radiogenic injury of the lens of the eye ***may*** be greater than that indicated in current recommendations or regulations.

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Equipment and Facilities

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Equipment Features

- **The report will tabulate key equipment features on a risk stratified basis.**
- **Technology has reduced dose-rates by about two in the past 15 years.**
- **Total dose from diagnostic procedures has declined.**
- **Total dose from interventional procedures is stable or increasing.**

 Materials *not* reviewed by NCRP: *Changes are likely*

Potentially High-Radiation Procedures

- A procedure ***should*** be classified as potentially high-radiation if more than 5% of cases of that procedure result in a $K_{a,r}$ exceeding 3 Gy.
- Potentially high-radiation procedures ***should*** be performed using equipment complying with IEC 60601-2-43
- Non high-radiation procedures ***may*** be performed using equipment not complying with IEC 60601-2-43

 Materials *not* reviewed by NCRP: *Changes are likely*

Dose Awareness

- Equipment ***should*** provide real time dosimetric displays visible to the operator in the normal working position.
  - Fluoroscopic time ***should not*** be considered a dose display.

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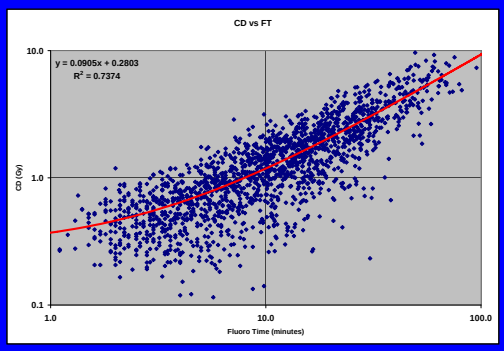
Fluoro time is a poor dose metric !



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Facility Shielding

- All spaces outside the procedure room (including control rooms) ***should*** be designed to limit full occupancy exposures to not more than 1 mSv/y.
- Spaces within laboratories intended exclusively for routine monitoring (or similar activities) ***should*** be shielded to limit exposure of individuals to not more than 1 mSv/y.

  Mobile or fixed shields

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Facility Radiation Safety

- Door interlocks that interrupt x-ray production ***shall not*** be permitted at the entrance to interventional fluoroscopy rooms.
- Caution lights indicating the [potential] production of X-rays ***shall*** be installed at each entry into a procedure room.
- Fluoroscopes used for interventional purposes ***shall*** be equipped with a specific safety switch that inhibits X-ray production without interfering with other uses of the equipment.

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Patients

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Pregnant Patients

- Pregnancy status ***shall*** be determined prior to an interventional procedure.
  - If pregnancy status is not established, the patient ***should*** be managed as if she were pregnant.
- When time permits, the mean absorbed dose to the conceptus ***should*** be prospectively estimated in consultation with a qualified medical physicist, to determine the potential risk and an appropriate benefit-risk evaluation made.
- Patients ***shall*** be informed of the expected benefits of the procedure and the potential risks to themselves and their conceptus.
  - The patient ***should*** understand whether or not some complication might result where the dose cannot be managed at low levels and the risk of this event made clear.

 Materials *not* reviewed by NCRP: *Changes are likely*

Dose records and their use

- Facilities ***should*** have a process to track the cumulative radiation doses and procedures for patients undergoing fluoro guided procedures.
- Dose records ***should*** include data on radiation therapy delivered to the same anatomical regions as fluoro guided procedures.
- Previous Interventional and radiotherapy dose data ***should*** be reviewed prior to any new fluoro guided or radiotherapeutic procedure.
- If there is a history of previous significant irradiation near a planned entrance beam site, the skin ***should*** be examined prior to starting a new procedure.

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Equipment Settings

- The system ***should*** be configured before placing the patient on the table.
  - The fluoroscopic system ***shall*** be checked for proper patient identification, procedural configuration, and adequate image storage space prior to starting a procedure.
  - The system ***shall*** be initially configured to provide the lowest dose rate to the patient consistent with the image quality requirements of the procedure.
- This ***should*** be verified as part of the pre-procedure time-out.

 Materials *not* reviewed by NCRP: *Changes are likely*

Dose monitoring

- Radiation dose accumulation ***shall*** be continuously monitored during a procedure.
  - Fluoroscopy time ***should not*** be used as the only dose indicator during high-dose procedures.
- Operators ***shall*** be responsible for patient radiation levels during interventional procedures.
- Support *staff* **should** assist in dose monitoring by providing appropriate information to the operator during the course of the procedure.

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Dose Documentation

- Patient dose data ***shall*** be recorded in the patient's medical record for all interventional procedures.
- A "significant dose" from one or more procedures performed on the same body part within a *six-month* period ***should*** be defined as a dose exceeding one or more of the thresholds shown in the report. (next slide)
- For significant dose procedures, the operator ***shall*** place a note in the medical record immediately after completing the procedure, explaining the need for the radiation dose used.

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Adult: Significant Dose Thresholds

- $D_{skin,max}$ = 3 Gy
- $K_{a,r}$ = 5 Gy
- P_{KA} = 500 Gycm^2
- Fluoro Time = 60 minutes

- Values ***may*** be locally adjusted
- These are SIR-CIRSE values

The operator should be notified twice before exceeding the relevant threshold. (e.g. 3 and 4 Gy for $K_{a,r}$)

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Patient Discharge and Follow-up

- Patients receiving a dose above the threshold for follow-up ***shall*** remain the responsibility of the operator until the likelihood of a reaction has passed.
  - Several months is appropriate
  - All relevant signs and symptoms ***shall*** be regarded as radiogenic unless an alternative diagnosis is unambiguously established.
- Patients, care givers, and responsible health-care professionals ***should*** be made aware of the possible radiologic etiology of relevant signs and symptoms.
- Prior to discharge, patients and caregivers ***should*** be appropriately informed about possible deterministic effects and the recommended follow-up.

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Patient Dose QA

- Patient radiation dose data ***shall*** be used for quality-assurance purposes as well as for individual patient management.
  - Individual and departmental radiation dose data ***should*** be compared to published guidance levels for similar procedures.
  - Radiation dose utilization ***should*** be discussed in departmental QA meetings.

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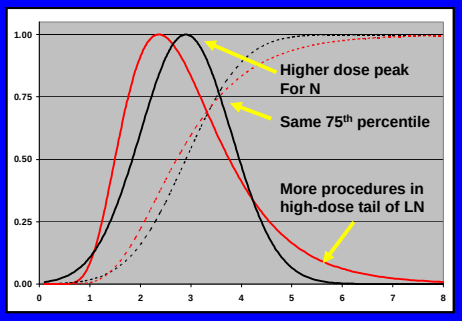
Normal (N) – LogNormal (LN) {cartoon}



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Workers

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Safety Hazards?

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Worker Radiation Safety

- Individuals responsible for oversight of radiation protection programs ***should*** be knowledgeable about the clinical aspects of interventional procedures.
- Each individual present in the room while a procedure is in progress ***shall*** have appropriate radiation protection training.
  - This requirement ***shall*** include all individuals who are only occasionally in the room while X-rays are being produced.
  - The level of training for different categories of workers ***should*** be risk-based.
- Concern for radiation effects on the fetus (below regulatory fetal dose limits) ***shall not*** be the only reason for excluding a woman from working in an interventional room.

Worker Radiation Protection

- Required minimum attenuation for radiation protective garments ***should*** be based on individual monitor readings.
  - Too much lead is also harmful.
- Individuals who are routinely "scrubbed" ***should*** use radiation protective eyewear.

Are thyroid shields of value for workers older than 30 – 40 ?

Occupational Dose Monitoring

- The occupational irradiation of a radiation worker ***shall*** be specified in terms of the effective dose (E) received by that individual.
  - Individual E is used here based on ICRP and NCRP usage.
- E and H_E ***should*** be determined using the methods supplied in NCRP Report 122
  - Goal is to avoid major overestimation.
  - The report will state a preferred method.
- In the absence of a central occupational dose data-base, individuals who work in more than one facility ***should*** track their personal cumulative radiation exposure.

  Unofficial version of "radiation passport" used in nuclear industry.
- Facilities ***may*** also track cumulative exposure of their workers.

Recommended Evaluation Models

Table 1 Recommended NCRP Evaluation Models

Dose Quantity[a] Being Estimated	Monitors Worn	Calculation Formula[b]	Resulting Estimate
$\underline{H}_E$	Single, neck	$\underline{H}_N/5.6$	$<3\ \underline{H}_E$
$\underline{H}_E$	Dual, waist or chest and neck	$1.5\ \underline{H}_W + 0.04\ \underline{H}_N$	0.97 to 1.72 $\underline{H}_E$
$\underline{E}$	Single, neck	$\underline{H}_N/21$	$<3.4\underline{E}$
Preferred Method $\underline{E}$	Dual, waist or chest and neck	$0.5\ \underline{H}_W + 0.025\ \underline{H}_N$	1.06 to 2.03 $\underline{E}$

[a] $\underline{H}_E$ = effective dose equivalent; $\underline{E}$ = effective dose.
[b] $\underline{H}_N$ = neck monitor personal dose equivalent [$\underline{H}_p(10)$] for strongly-penetrating radiation at a depth of 10 mm; $\underline{H}_W$ = waist or chest monitor $\underline{H}_p(10)$.

ICRP 60 weighting factors

Eye Dose

- A collar monitor ***may*** be used to estimate equivalent dose to the lens of the eye if a worker exclusively works with C-arms equipped with under-table x-ray tubes.
- An eye dose monitor ***should*** be placed within 5 cm of the lens of the eye if a worker uses systems with an over-table x-ray tube.
- If the lens of the eye is "shielded" then the effective attenuation factor for the shielding ***may*** be used in the estimate of equivalent dose.

  Perhaps a factor of three with side shields.

Investigations of occupational dose

- Investigational levels for groups that consistently utilize suitable radiation protective equipment ***should*** be set to appropriate levels.

  This is not the usual ALARA investigation of any worker with a reported dose above 10% or 30% of the MPD.
- Investigations ***should*** occur if an individual's readings are substantially above or below the expected range for that individual's duties.

  Unused badges need to be investigated.

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Administrative

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Requirements for Operators

- Policies and procedures ***shall*** assure that only specifically trained individuals are privileged to perform or supervise procedures.
- Clinical experience ***shall not*** be used as the only radiation safety credential.
- Radiation safety credentials ***shall*** include documentation of successful completion of appropriate initial and refresher training.
  - The operator ***shall*** possess both fundamental knowledge and machine-specific training.

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Risk Stratified Training

- **Individuals privileged to perform or clinically supervise potentially high-dose procedures.**
  - potentially high-radiation if more than 5% of cases of that procedure result in a $K_{a,r}$ exceeding 3 Gy.
- **Individuals privileged to perform or clinically supervise only non high-dose procedures.**
- **Individuals routinely in the room during the performance of FGI procedures.**
- **Individuals occasionally in a FGI room during or between procedures.**

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Equipment Performance and QA

- Clinical operators and qualified medical physicists ***should*** participate in the purchase and configuration process of new fluoroscopes.
- Acceptance and commissioning tests ***shall*** be performed by a qualified medical physicist before first clinical use.
- Periodic *acceptability* tests ***shall*** be performed by a qualified medical physicist on all fluoroscopes.
  - This ***may*** clear the equipment for unlimited use, for restricted use, or judge it unsuitable for any clinical use.

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Work is in Progress
your inputs are invited
by 10 Aug 2009
please email to:
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