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

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

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.

Key Participants

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

Organization

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

Concepts

This material has not been through the NCRP review process.

CHANGES ARE LIKELY
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

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Skin Reactions (In press)

<table>
<thead>
<tr>
<th>PSD Band</th>
<th>Range Gy</th>
<th>Prompt</th>
<th>Early</th>
<th>Mid Term</th>
<th>Late</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1 &lt; 2</td>
<td>&lt; 14 d</td>
<td></td>
<td>- - -</td>
<td>No effects expected - - -</td>
<td></td>
</tr>
<tr>
<td>A2 2 - 5</td>
<td>14 - 40 d</td>
<td>Transient erythema, transient hair thinning</td>
<td>Recovery, At higher doses, prolonged erythema, permanent epilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B 5 - 10</td>
<td>40 - 400 d</td>
<td>Transient erythema, possible dry or moist desquamation</td>
<td>Prolonged erythema, permanent total epilation, telangiectasia, induration, skin likely to be weak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C 10 - 15</td>
<td>&gt; 400 d</td>
<td>Transient erythema, possible dry or moist desquamation</td>
<td>Telangiectasia, induration, skin likely to be weak</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Skin changes at higher doses.

- Erythema, epilation, possible dry or moist desquamation
- Prolonged erythema, permanent total epilation, telangiectasia, induration, skin likely to be weak

Extended ICRU Notation

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

Reference Point Locations

- 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.
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!

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.

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.

Conversion factors (mSv/Gycm²)

<table>
<thead>
<tr>
<th>Conversion factor (mSv/Gycm²)</th>
<th>ICRP 60</th>
<th>ICRP 103</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centre 9</td>
<td>0.080</td>
<td>0.083</td>
</tr>
<tr>
<td>Centre 11</td>
<td>0.120</td>
<td>0.114</td>
</tr>
<tr>
<td>Centre 3</td>
<td>0.187</td>
<td>0.203</td>
</tr>
<tr>
<td>Centre 12</td>
<td>0.232</td>
<td>0.304</td>
</tr>
<tr>
<td>Pelvis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centre 9</td>
<td>0.093</td>
<td>0.054</td>
</tr>
<tr>
<td>Centre 11</td>
<td>0.137</td>
<td>0.073</td>
</tr>
<tr>
<td>Centre 3</td>
<td>0.212</td>
<td>0.130</td>
</tr>
<tr>
<td>Centre 12</td>
<td>0.270</td>
<td>0.215</td>
</tr>
<tr>
<td>Upper Leg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Centre 9</td>
<td>0.013</td>
<td>0.013</td>
</tr>
<tr>
<td>Centre 11</td>
<td>0.073</td>
<td>0.073</td>
</tr>
<tr>
<td>Centre 3</td>
<td>0.130</td>
<td>0.130</td>
</tr>
<tr>
<td>Centre 12</td>
<td>0.187</td>
<td>0.187</td>
</tr>
</tbody>
</table>


Equipment and Facilities

- The measured dose quantities kerma area product (P_{K_a}) and total air kerma at a reference point (K_{ref}) **should be** used to compare similar procedures.
- Peak tissue dose (D_{tissue,max}) **shall 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.

This material has not been through the NCRP review process. **CHANGES ARE LIKELY**
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.

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

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.

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

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.

Fluoro time is a poor dose metric!

$$y = 0.0905x + 0.2803$$

$R^2 = 0.7374$
Patients

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.

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.

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.

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.

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

**Adult: Significant Dose Thresholds**
- \( D_{\text{skin,max}} = 3 \text{ Gy} \)
- \( K_{\text{ar}} = 5 \text{ Gy} \)
- \( P_{\text{KA}} = 500 \text{ Gycm}^2 \)
- 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 \( K_{\text{ar}} \)).

**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.

**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.

**Normal (N) – LogNormal (LN) {cartoon}**
- Same 75th percentile
- More procedures in high-dose tail of LN
- Higher dose peak
- For N

**Safety Hazards?**

This material has not been through the NCRP review process.

*CHANGES ARE LIKELY*
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 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>
<thead>
<tr>
<th>Dose Quantity</th>
<th>Monitors Worn</th>
<th>Calculation Formula</th>
<th>Resulting Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>Single, neck</td>
<td>H / 5.6</td>
<td>&lt;3 E</td>
</tr>
<tr>
<td>E</td>
<td>Dual, waist or chest and neck</td>
<td>1.5 H_w + 0.04 H_n</td>
<td>0.97 to 1.72 E</td>
</tr>
<tr>
<td>E</td>
<td>Single, neck</td>
<td>H / 21</td>
<td>&lt;3.4E</td>
</tr>
<tr>
<td>Preferred Method</td>
<td>Dual, waist or chest and neck</td>
<td>0.5 H_w + 0.025 H_n</td>
<td>1.06 to 2.03 E</td>
</tr>
</tbody>
</table>

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.
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.

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 $K_{n}$ 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.

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.

Work is in Progress
Your inputs are invited
by 10 Aug 2009
please email to:
sb2455@columbia.edu

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