

UROLOGY

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Seconding the theme of his cardiologist counterparts, Dr. Keith Van Arsdalen indicated that most of his urologist colleagues would have no idea what amount of exposure they are subjecting themselves or their patients to from fluoroscopic procedures. He urged, however, that education, not regulation, be the primary way to address the problem. Most of the radiation exposure to patients associated with urologic practice emanates from extracorporeal shock wave lithotripsy (ESWL).

Common urological diagnostic studies include KUB, intravenous urography (IVU), and voiding cystourethrography (VCUG). Typical patient organ doses delivered with IVU (0.358 rad to the ovaries, 0.434 rad to the testes, 0.190 rad to the bone marrow) can vary by 200% with patient size and procedural factors. Sources of personnel exposure are the primary beam itself and scatter to the hands and eyes, but exposure to operators' gonads and thyroid is typically low. An over-the-table tube serves to increase radiation exposure to hands and torso and especially to the head and neck.

Interventional uroradiology encompasses such procedures as percutaneous nephrostolithotomy (PCNL), antegrade and retrograde pyelography, aspiration and drainage, sclerotherapy, angiographic/embolization procedures, and VCUG. PCNL takes about 24 minutes, 16 minutes to gain access to the stone and 8 minutes to remove it; reported radiation exposure to the urologist was 10 mR (range 1-38 mR) in one study and 2.5-3.7 mR (range 0.1-11.7 mR) in another. With a C-arm fluoroscope, a tube angle of 30 degrees increases scatter radiation to the urologist, compared to the vertical position. Among those in attendance, the urology resident sustains the greatest exposure at the hand and collar sites, while the radiology resident and staff sustain the higher belt doses. Personnel not directly involved in the procedure sustain low exposure, Dr. Van Arsdalen noted, adding that "very low dose" fluoroscopy is sufficient for imaging the upper and lower renal calyces. Limiting the number of yearly procedures to about 110 would be wise, he advised.

In ESWL, stones are localized with biplanar fluoroscopy; imaging methods include low- and high-dose fluoroscopy, snap shots, and in-bath radiographs. The fluoro operation utilizes an automatic brightness stabilization circuit set typically at 80-90 kVp/2.5-4.5 mA (range 40-120 kVp/0-6.0 mA). At 60 kVp/1 mA, radiation exposure would be 0.40 R/min; at 110 kVp/5 mA, it would be 7.83 R/min. A snap-shot operation utilizing a digital video image storage device would deliver 0.212 R per exposure at 50 kVp and 0.838 R per exposure at 70 kVp (at 125 mA/500 mSec). Depending on operator experience, radiation exposure in the typical ESWL is between 15 and 30 R. Other imaging variables include patient size, number and location of stones, opacity, retrograde catheter, distance from x-ray tube, ipsilateral vs. contralateral side, balloon inflation, image intensifier position, collimation, and operator technique preference.

In one report, average lithotripsy fluoro times over a two-year period went from 1.5 min in 1986 to 1.27 min one year later and then to 0.68 min by 1988, with corresponding patient entrance exposures of 6.75R, 5.63R, and 3.06R.

UROLOGY RADIATION DOSES
(mrad/procedure)

<u>Standard Studies</u>	<u>Patient Dose</u>	<u>Urologist Exposure</u>	
		<u>Eye</u>	<u>Hand</u>
KUB	1,000	0	0
IVP	4,000	0	0
Retrograde pyelogram	4,000	5	50
Cystourethrogram	1,000	3	30
Endourology			
Percutaneous nephrostolithotomy (20 min. fluoro time)	40,000- 60,000	27	136
Ureterorenoscopy (15 min. fluoro time)	30,000- 40,000	20	20

SELECTED RADIATION EXPOSURE DATA

<u>Procedure</u>	<u>Average Skin Dose (rem)</u>
Barium swallow	9.9
Barium enema	21.5
Lumbosacral spine	5.0
Cardiac catheterization	47.0
Plain film of kidneys, ureter, bladder	0.67
Excretory urogram 7 films	3.0
Percutaneous nephrostolithotomy	25.0
ESWL	10.1 (average per x-ray unit, or total of about 20 rem/case)

FLUOROSCOPIC USE IN ORTHOPEDIC SURGERY

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Testimony to the lack of radiation consciousness among orthopedic surgeons is the literature search undertaken by Dr. Lawrence S. Crossett that turned up only six studies since 1980 addressing the issue.

Orthopedic procedures that utilize fluoroscopy are on the upswing and include hip, femur, and tibia fractures; hip aspirations; biopsies; core decompression; and vascular fibular transplants. The surgeon's most vulnerable areas are hands, head, and neck.

Of those specialists who utilize fluoroscopy, however, the orthopedic surgeon is at relatively low risk of overexposure, assuming routine precautions are taken and the machinery used is appropriate. Average C-arm Fluoroscopy settings at the University of Pittsburgh Hospital, he noted, are 75 kV and 3 mA.

Maximum whole-body occupational exposure is set at 5 rem per year, a limit under which orthopedic surgeons easily fall. Average fluoro time for most procedures is 5 minutes or less with an average patient exposure of 344 mR and an average physician exposure at 61.2 mR (range 20-350 mR).

It would take an orthopedic surgeon between 2,000 and 8,000 procedures a year to reach "significant" exposure levels, Dr. Crossett said, noting that the literature indicates that a 0.5 mm lead-equivalent apron provides adequate protection. Radiation exposure levels vary with patient positioning and draping, he added.

Issues requiring more attention than they've received, he said, are surgeons' awareness of total exposure time, tissue tolerance to radiation exposure, the impact of beam direction, distance from the source and optimization of fluoroscopy equipment.

CONTROLLING PATIENT AND PERSONNEL FLUOROSCOPIC EXPOSURE LEVELS IN THE CLINICAL SETTING--ONE INSTITUTION'S EXPERIENCE

GARY T. BARNES, PH.D.

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If an institution is serious about minimizing radiation exposure without sacrificing image quality and sharpening fluoroscopic pictures without excessive dosage increases, it can do so.

At the University of Alabama, physicist Gary T. Barnes told workshop attendees, equipment specifications, quality control, and maintenance; fluoroscopy use guidelines; and meticulous attention to physician education, badge review, and protective devices have "markedly reduced" both the number of high film badge readings and patient radiation levels.

First, manufacturers supplying fluoroscopy equipment are asked to provide at least two fluoroscopic image intensifier input phosphor exposure rates, with the low dose mode the machine's automatic start-up. For a 9-inch image intensifier, the low dose rate would be 1.2 mR/min. and the standard dose rate would be 3.6 mR/min. Vendors should be required to provide operator-selectable low dose mode as well as standard and high level modes, Dr. Barnes said.

Second, high dose fluoro is limited to equipment designed for interventional radiology and to 20 R/min and requires an additional pedal to activate, thereby eliminating the former problem of inadvertent activation reported by cardiologists. High dose has been limited to the province of interventional angiography and cardiology. C-arms have been removed from orthopedic and urologic procedures, he added.

Third, real-time digital fluoroscopy is employed whenever possible, greatly enhancing image quality at low dose rates. The FDA, Dr. Barnes suggested, ought to focus more on this modality as a means to optimize image quality and lower radiation exposure.

Fourth, equipment should be designed to record and print out fluoroscopic techniques and times, especially useful in protracted electrophysiology procedures.

Regarding personnel requirements, the university's radiation safety committee conducts and documents interviews with individuals with high badge readings, issues recommendations, and has the authority to "remove from any service any careless person." Ergonomic shields and continuing education are also provided.

TRILEVEL DOSE OPTIONS

Low	1.2 mR/min	0.7 microR/frame
Standard	3.6 mR/min	2.0 microR/frame
High	11.0 mR/min	6.0 microR/frame

SESSION 3: QUESTIONS AND DISCUSSION PERIOD.

The ensuing discussion centered around radiation injuries to the patient and the issue of informed consent.

Though he'd indicated during his presentation that patient informed consent might well include radiation risks, Dr. Cardella noted that such information was "not currently incorporated" into the process at his institution.

The chance of dying from a contrast reaction ranges from 1/40,000 to 1/120,000, but the chances of radiation injury are less well pinpointed, he said, remarking that skin and hair damage appear to arise most frequently in neuroradiologic procedures but that adverse radiation effects are probably underreported. Considering that risk estimates are not reliable, patients could not be presented with more than a general statement along the lines of: "you may require high level fluoro and/or increased exposure time, and there may be a related radiation risk as a result."

Another participant commented that his "basic radiation protection lecture" to physicians at his institution includes the advice that potential radiation risk should be cited in consent procedures if fluoro time is anticipated to exceed two hours.

Remarking that erythema and epilation are not likely to show up on the table but perhaps a week later and that their existence or degree of severity cannot be predicted, an attendee asked whether it might not be wise to schedule routine re-examination 2-7 days after the procedure. Several participants commented that this did not appear to be current practice. It was also observed that erythema could arise within hours of a procedure and be gone within 24 hours, only to resurface perhaps three weeks later.

SESSION 4 - WORKSHOPS (DAY 1)

WORKGROUP SESSION

The participants were divided into four groups, each charged with addressing a set of questions related to a specific area of concern. Each group met for approximately three hours over the two-day period and then presented its recommendations at a final plenary session.

The workgroup topics were:

Group1	Radiation safety/risk management
Group2	Education/training
Group3	Technical aspects/improving performance
Group4	Fluoroscopy safety/regulatory issues

The questions posed to each group and their deliberations are given in the summary of session 6.

SESSION 5: UTILIZATION CONCERNS

RADIATION BIOEFFECTS AND FLUOROSCOPIC EXPOSURES

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In February 1896 William L. Dudley, Dean of the Vanderbilt University Medical School, got the bright idea to seek the help of physics professor John Daniel in establishing whether the machinery available in physics departments all over the country could help physicians see inside their patients. He had a patient, who had sustained a gunshot wound to the head, and Dr. Dudley wanted to know if the bullet could be located by x-ray. He had Daniel x-ray his own head which took about an hour. The film taken was a failure, but the report filed by Daniel prestaged the darker side of what eventually would be a boon to medical diagnostics. He wrote: "Dr. Wm. L. Dudley and I decided to make a preliminary test of photographing through the head....21 days after the experiment, all the hair came out over the space under the x-ray discharge."

"The acute radiation threshold for temporary epilation is about 3 Gy; it's about 7 Gy for permanent hair loss. The onset for both is about two weeks after exposure," Louis K. Wagner, Ph.D., told workshop participants, noting that a dose rate of 0.2 Gy/min. is the equivalent of 20 R/min., so that 5 minutes of HLC fluoro at 20 R/min would deliver 1 Gy.

There is still today, he said, some of the "obliviousness to potential harm" revealed in old photos showing physicians taking no precautions around imaging equipment. Overlapping fields of the x-ray beam are the areas of highest dose and can be minimized by manual collimation.

The basal cells of the epidermis are the target cells for most radiation-induced injuries. Skin and eye lens are the areas most vulnerable to deterministic radiation effects, or those that require a minimum dose and whose likelihood per year exposure limit should protect personnel from deterministic effects.

Radiation-induced basal and squamous cell skin cancers can be avoided "just by keeping your hands out of the beam," he exhorted, cautioning against a "false sense of protection" from wearing leaded gloves, especially single layer. "At 90 kVp," he said, "85% of the radiation gets through the first layer."

Moving to the eye, Dr. Wagner said that cataracts are caused in humans at thresholds of 2-5 Gy in a single dose, 10 Gy in a fractionated dose. It may take a year or more after exposure for the cataract to emerge, with latency inversely related to radiation dose and patient age.

Fluoroscopic monitoring of tuberculosis treatment and other practices that generated excessive chest exposure revealed the risk of radiation-induced breast cancer, reported in the mid-1960s. In 1979, the relationship between diagnostic dose and breast cancer was established. Latency period varies with the age of the individual at exposure: exposure before puberty is associated with a higher risk of breast cancer at around age 30, the age at which breast cancer risk emerges in the population in general; exposure later in life is associated with a shorter latency period. Susceptibility to radiation-induced breast cancer peaks in the teen years, Dr. Wagner said.

The lifetime risk of fatal cancer from a radiation exposure to the whole body of 10 mSv (or 1 rem) is 4/10,000 among radiation workers and 5/10,000 among the general population. Leukemia usually takes at least 2 years to emerge, with latency usually lasting for 12-15 years

and seldom beyond 25 years. Bone cancer follows a similar pattern. Other cancers typically reveal themselves about 5 years postexposure but may remain hidden for as many as 40 years, as has been shown to be the case among people in Hiroshima and Nagasaki.

Excess cancer mortality among radiologists has been documented for a variety of cancers, but the vulnerable sites after 1940 are different from those before that time. Radiologists had a higher risk of dying from leukemia, aplastic anemia, lymphoma, liver cancer, and skin cancer before 1940 but not after; they continue to demonstrate a higher risk of dying from oral and pharyngeal cancer; and they now appear at greater risk of lung cancer and multiple myeloma death than the general population, which was not the case before 1940. The improvements, Dr. Wagner speculated, could be due to better machine design and better shielding. The turns for the worse might be attributable to changed smoking habits, he added.

Table 1
SKIN EFFECTS AFTER ACUTE RADIATION

<u>EFFECT</u>	<u>THRESHOLD</u>	<u>ONSET</u>	<u>PEAK</u>	<u>COMMENT</u>
Erythema: early & transient	>2 Gy	few hours	~24 hr	later response
Main effect	>6 Gy	~10 days	~2 weeks	reddening, pigmentation; at 10 Gy, pigment may last weeks
Dry desquamation	>10 Gy	~4 weeks	~5 weeks	
Moist desquamation	>15 Gy	~4 weeks	~5 weeks	slow healing; late atrophy scarring
Secondary ulceration	>20 Gy	>6 weeks		
Dermal necrosis	>15 Gy	>10 weeks		
Dermal atrophy	>15 Gy	>26 weeks		
Telangiectasia	>12 Gy	>52 weeks		
Invasive fibrosis	>10 Gy			

FLUOROSCOPIC RADIATION SAFETY

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Providing the radiation safety officer perspective and the interventional radiologist perspective, respectively, Libby Brateman, Ph.D., and Victoria Marx, M.D., exhorted all fluoroscopy personnel to practice what is preached in ALARA philosophy and at all times deliberately act to keep radiation levels "as low as reasonably achievable."

It is not uncommon during neurologic embolization for 880 images to be generated by digital subtraction angiography (DSA) over an hour's fluoroscopy on-time, with the physician at the tableside for the duration--and sometimes without wearing a dosimeter, Dr. Brateman noted.

A review of what amounted to 93% of all fluoroscopic procedures performed in the vascular interventional suite over a 2-month period at the Univ. of Michigan showed that fluoroscopy time lasted from 1 to 89 minutes; of 30 fluoroscopy personnel responding to a questionnaire, 27 said they "always/frequently" (as opposed to "sometimes/rarely/never") hand-injected during DSA, and only half stood behind lead while doing it. Two-thirds were not using last-image hold--often because it wasn't available; high output fluoro was also largely unavailable.

It's the physician's obligation under ALARA guidelines--and in patient and self-interest--to minimize radiation dosage. Patient dosage can be reduced by decreasing fluoro time, field collimation, less use of magnification and high output modes, judicious use of filming and tube angulation, and increased use of last-image hold, especially, Dr. Marx said, "when you're ruminating over what to do next."

Operator dose can be decreased by decreasing patient dose, increasing distance from the patient, increasing shielding, and increasing the number of personnel to share the workload. The one circumstance where there's a conflict between operator and patient safety is when operator hand exposure would facilitate success and decrease fluoro time, as when the operator's hands enter the field to manipulate a catheter needle into a kidney during an abdominal intervention.

Particularly vulnerable is the anesthesiologist during an abdominal procedure--adjacent to the patient and the tube, not well protected and often not wearing a film badge. A short operator is also at a disadvantage when working at a high table and close to the image intensifier.

Dr. Marx reported the findings of a radiation dosimetry study involving 30 interventional radiologists that showed that caseload and lead apron thickness were the only two operator-controlled factors that influenced occupational radiation dose. It also showed that collar badge alone is not predictive of total body Effective Dose Equivalent (EDE).

The subjects wore unshielded collar badges and waist badges under apron for two months. The mean projected yearly over-lead dose was 49.1 mSv (1 mSv = 100 mrem), or about

5 rem (the current NCRP total body limit), with a range of 3.2 to 114.9 mSv. About half the study subjects had projected accumulated doses above the NCRP limit. Caseload of more than 1,000 a year was the one operator-controlled factor significantly associated with high dose. The collar dose "is essentially equal to head and neck dose" and is "high enough," Dr. Marx emphasized, "to warrant additional shielding to head and neck, especially the eyes." The mean projected yearly dose under apron was 0.9 mSv, with a range of 0.22 to 4.11 that varied with lead apron thickness (1.0 mm lead equivalent coverage in front was associated with a significantly lower dose than a 0.55 mm lead equivalent). The under apron doses, she observed, were well below the NCRP limit.

She recommended that full-time interventionalists wear custom-made aprons, collars, and glasses or use an external shield for head and neck. As had others, she advised that leaded gloves are less protective than many think.

Current regulatory dose limits are somewhat outdated and therefore inspire improper dosimeter usage by operators, Dr. Brateman said, noting that monitoring on the basis of effective dose equivalent (EDE) is on the horizon and should be more acceptable to angiographic and other interventional fluoroscopists.

Upcoming revisions to the Suggested State Regulations for Control of Radiation (SSRCR) are expected to include new Nuclear Regulatory Commission limits to specific organs, slated to be incorporated in 1994. Annual lens dose will change from 5 rem (50 mSv) to 15 rem (150 mSv). Other new limits are: extremities 50 rem (500 mSv), embryo/fetus 50 mrem (0.5 mSv) monthly and 500 mrem (5 mSv) throughout gestation.

A collar monitor can be used to estimate eye dose and EDE, although the latter will be an overestimate, Dr. Brateman said. A second monitor--a waist monitor under leaded apron--can help determine EDE more accurately with the following equation: $EDE = 0.04 C + 1.5 W$, where C is the unshielded collar reading and W is the shielded waist reading.

The waist monitor is particularly relevant in the event of pregnancy, known or otherwise, for monitoring conceptus dose. Personnel monitoring over a 4-year period at Shands Hospital at the University of Florida revealed that physicians are prone to shielded waist readings greater than 50 mrem in one month (unlike nursing personnel, who did not exceed 20 mrem in a month, or technologists, who registered no more than 30 mrem in any given month).

Other findings from this study, which covered 343 person-months, included: 40 monthly collar readings greater than 300 mrem, the institution's ALARA action level, and 26 were greater than 416 mrem, the annual equivalent of 5 rem. Applying a 0.3 weighting factor to the collar reading to estimate EDE, (as an overestimate), the number of exposures exceeding 300 mrem dropped from 40 to 7, and those exceeding 416 mrem dropped to 2. With the scientifically more correct two-badge equation (see above) for calculating EDE, only one exposure exceeded 300 mrem, and none went beyond 416 mrem, Dr. Brateman reported.

Collar badges for three physicians had readings greater than the annual equivalent of the upcoming eye dose limit of 15 rem, a signal of the need for leaded glasses--with side shields--or face shields. Many fluoroscopists, however, do not wear the glasses because they are heavy and uncomfortable or because prescription lenses are expensive, Dr. Brateman said.

Thyroid shields are also a useful adjunct, she said, covering some areas of exposed breast tissue and bone marrow in smaller individuals whose aprons have large neck openings. Aprons should be the wrap-around type to protect the back, and maternity aprons double-leaded at the abdomen are certainly advisable during pregnancy. But while regular aprons are available in six

different sizes, the double-leaded maternity apron is of the "one-size-fits-all" variety, making customization a necessity for many pregnant workers, Dr. Marx noted. At Shands Hospital, Dr. Brateman said, all fluoroscopists are required to use one badge, those who do special procedures are required to use two, and all residents and nurses rotating through special procedures use two. (Color coordination of the badges is necessary, she added, to facilitate proper monitoring. The badges could come in two varieties: "yellow belly" and "red neck," she explained.)

Drs. Brateman and Marx offered the following recommendations:

- * Educate special procedures personnel regarding their own and patients' exposure levels, emphasizing use of pulsed fluoroscopy, fewer images, collimation, shielding, and tube orientation. The X-ray tube orientation is a particularly important factor, because the backscattered X-ray beam intensity can be quite high; causing high personnel exposure.

- * Monitor cumulative fluoroscopy time and review excessively lengthy procedures.

- * Monitor extremities of angiographers/interventionalists; provide them with two, clearly identified, badges; encourage their use of shatterproof leaded glasses with side shields.

- * Provide wrap-around aprons of at least 0.5 mm lead equivalence for special procedures. Use thyroid shields to limit upper chest exposure. Provide maternity aprons for pregnant workers.

- * Be cautious in censuring personnel for high dosimetry values when they attempt to comply with ALARA guidelines, lest they refuse to wear dosimeters.

- * Measure the equipment, especially image intensifier input exposure requirements, automatic brightness control, and high level fluoroscopy exposure rates.

THE TRAINING AND CREDENTIALS OF FLUOROSCOPISTS

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The only "fluoroscopists" with formal training in radiation physics and safety are radiologists; the education of other physicians who do fluoroscopy is largely the informal "see one, do one, teach one" variety, said Stephen Balter, Ph.D., who made a plea for professional self-regulation and credentialing "before a well meaning government does it for us."

"I'm not interested in making orthopedic surgeons, for instance, into radiation physicists, only knowledgeable enough to know how to operate their system safely. Only then should physicians be granted fluoroscopic privileges," Dr. Balter proposed.

Privileges to perform fluoroscopic procedures would be granted by an institution's duly constituted radiation safety committee upon ascertaining that the physician had the requisite knowledge and skill. Professional societies could supply the knowledge--a short course to interested members already in practice that would cover such items as dose and image quality, field size effects, shielding, radiation physics, dosimetry concepts, and radiation output and radiation risks. They might enlist the services of medical physicists for such courses, Dr. Balter suggested, commenting that a "common curriculum developed by physicists could help avoid turf battles."

Formal hands-on instruction for each specific piece of equipment a physician intended to use, including a formal "check ride" to ensure proficiency, would complete the requirements for privileges, he said, adding that for physicians in training, such instruction and testing could be incorporated into the curriculum and medical boards.

The maximum 100-watt x-ray tube of the 1970s has been dwarfed by today's 2-3 kilowatt angiographic equipment; and numbers and length of procedures have soared. But operator knowledge has not kept pace, he said, displaying a photograph of a fluoroscopic procedure from a recent issue of a professional magazine in which both the pediatric radiologist and the nurse had their hands in the beam and were not wearing lead aprons.

He urged that physicians maintain personal dosimetry records and that patient and staff doses be monitored routinely.

HOSPITAL EXPERIENCES WITH CREDENTIALING AND TRAINING

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In Pennsylvania, New Jersey, and Delaware, any licensed practitioner may operate any x-ray equipment. A review of the procedures and practices in five hospitals in these three states was undertaken to find out how expertise to use such equipment is verified and ensured.

Two community hospitals, two university-affiliated hospitals, and a small pediatric hospital participated in the survey. Fluoroscopy in radiology, in cardiology, and in the operating room were targeted. All five hospitals followed the required JCAHO credentialing procedures for admission to the medical staff and for appointment to a specific department.

For a new attending radiologist, all hospitals first verified the individual's training and credentials, which determined their responsibilities in the department. The procedures followed to verify the new attending's expertise varied as follows among the five hospitals: Informal peer review, assuming competency based on training and credentials, proctoring for a designated period of time, or proceeding on an individual basis depending on the scope of the individual's credentials.

Use of fluoroscopy equipment by non-radiologists within the radiology department and the operating rooms was presented. There were no standard supervision procedures among the five hospitals for the non-radiologists using fluoroscopy equipment. For use within the radiology departments, the variations found included the following: Only the radiologist operated the fluoroscopy equipment with non-radiologists present, the non-radiologist operated the fluoroscope until the endoscope was in the duct and then the radiologist took the spot films, or the non-radiologist performed the entire procedure unassisted by the radiologist.

In the operating rooms, mobile C-arm fluoroscopes appear to be used most frequently by orthopedic surgeons and urologists. But all licensed physicians with operating room privileges can use the equipment. At the five hospitals, the following practices were followed: Either the physician or the technologist controlled the fluoroscopy foot pedal; radiology departments were responsible for providing a radiologic technologist and for equipment maintenance; radiology departments were not involved in the process of granting O.R. privileges to use fluoroscopy equipment. Radiology became involved if there were problems with use of the C-arm by the surgeon.

In the radiology and operating rooms surveyed, problems of equipment usage were usually identified by the x-ray technologist and reported to a supervisor or a medical physicist. Corrective actions included informal discussions and any needed additional training. Following this corrective action, if the physician continued to fail to correctly use the fluoroscopy equipment, C-arm privileges could be revoked.

One of the five hospitals' cardiology departments had a cardiac catheterization laboratory and offered angioplasty and electrophysiology studies. All cath. lab. cardiologists were board certified and had completed accredited fellowships. All new attending staff members are assigned a "big brother" for about 6 weeks to help them with the equipment and procedures followed at that institution.

Moore recommended sections of the joint American College of Cardiology and American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization

Laboratories as appropriate for all non-radiologists. The ACC/AHA guide stipulates that all cath. lab. physicians are to be trained in emergency care and radiation physics and are to be certified by the program director or institution. It also specifies that all cath. lab. physicians should participate in the lab's quality assurance program, which should include peer review. Moore suggested that the quality assurance program should also include routine radiation safety, physics and radiation biology lectures; review of monthly film badges with staff recording and review of patient's fluoro and cine times and, if possible, kVp and mAs. The fluoro/cine times and technique records are essential for accurate patient dosimetry and very helpful in the evaluation of staff exposure records.

PHYSICIAN CREDENTIALS AND PRIVILEGES

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All physicians should be trained and tested in safe fluoroscopy use, perhaps within the curriculum and examination context of each specialty.

Certification should be required for privileges and should be granted at two levels: "unrestricted" use for radiologists or the equivalent (100-300 hours of training and a radiation physics test) and "limited" use for those who operate within a single organ system or who have had limited training and require supervision by a radiation safety officer.

The Joint Commission on Accreditation of Hospital Organizations (JCAHO) ought to impose specific monitoring requirements, Dr. James Spies indicated in his recommendations for ensuring competent fluoroscopy use.

Currently, however, nonradiologists receive little if any fluoroscopy training. There is little oversight of users; hospital medical staffs generally do not regulate or privilege X-ray use outside the radiology department, and "it's hard to get the JCAHO to listen to suggestions," he said.

Certification could be conferred during relevant continuing medical education courses, by medical specialty societies, by individual states, as in California where the process appears to have been accepted by physicians and is working well, or by the federal government.

SESSION 6 WORKGROUP RECOMMENDATIONS

WORKGROUP 1: RADIATION SAFETY/RISK MANAGEMENT

Leaders: Beverly Wood M.D. and James Deye Ph.D.

Suggested topics of discussion:

1. How should the issue of acute patient radiation injury from interventional procedures be addressed?
2. What are the liability concerns for the facilities and individuals? What actions can be taken to reduce these?
3. Should there be action levels for fluoroscopy beam "on" time or total radiation exposure?
4. Should risk of radiation injury be on the Patient Consent Form?
5. What procedures should be followed for pregnant patients or staff?
6. How might one minimize patient and personnel radiation dose?
7. What can be done to assure adequate training of physicians and technical staff for operation of fluoroscopy equipment? For operation of equipment with high-level control (HLC)?
8. Role of the Radiation Safety Committee, Radiation Safety Officer, Quality Management Committee, Radiology Department, Cardiovascular Department, etc., in fluoroscopy radiation safety. What policies and procedures should be implemented to assure optimum safety and use?

Workgroup recommendations:

1. Informed Consent.

*Radiation risks related to fluoroscopic procedures should not be incorporated into written patient informed consent documents. Utilization is too broad, and such a requirement would undermine efforts to acquire and utilize data for improvements in equipment and technique

* However, radiation risks should be discussed with the patient. The physician must realize that radiation risks are a concern and must be sufficiently knowledgeable about such risks to adequately inform the patient.

2. Monitoring and Action Guidelines.

* ALARA is the underpinning of a risk management program. Adhering assiduously to the ALARA precept of keeping radiation levels "as low as reasonably achievable" precludes the need to set upper limits on exposure factors and allows for professional judgment.

* Procedure-specific action guidelines should be operative. Individual deviations from recommended levels should be reported and corrected by individualized education.

* A dose and time read-out should be visible to operators, and a confidential record should be maintained of examination type and factors used.

* Conscious observation of fluoroscopic techniques and habits should be integral to the daily routine, as should education and corrective action. Individual and procedural monitoring and record keeping can identify outliers and be used for educational purposes.

* Data collected should include equipment condition and uses, doses and exposure factors. Patient and physician information should be managed by confidential mechanisms.

3. Qualifications: Individuals, Procedures, Equipment.

* Individuals: A standard educational source or sources should be developed, complete with the necessary standardized testing mechanism and endorsed by all relevant specialty organizations. Proof of having met these educational requirements should be required by the medical staff credentials committee. (Workgroup 1 deferred to Workgroup 2 regarding the specifics of educational requirements.)

* Procedures: The Radiation Safety Committee should review the radiation safety factors attending all new procedures and institute and enforce staffing and equipment requirements.

* Equipment: Each piece of equipment should have its own standard for maintenance and appropriate staff training to use it. Each piece of equipment needs documentation from the manufacturer of radiation levels, potential risks, and appropriate safety measures.

4. Staff Considerations.

* It is the hospital's obligation to provide appropriate shielding, equipment monitoring (exposures and uses), and ongoing training and education of personnel using the equipment or involved in its use.

* Regarding pregnant staff, the hospital must meet necessary safety standards and should comply with Federal guidelines as provided in the Federal Register of Jan. 27, 1987 (52 FR 2522) on Radiation Protection Guidance to Federal Agencies for Occupational Exposure; Approval of Environmental Protection Agency Recommendations.

5. Pregnant Patients.

* ICRP recommendations regarding the pregnant patient apply. Medical urgency supersedes concerns over radiation exposure, but each department is responsible for notifying patients--either verbally or by highly visible posted signs--of potential radiation risks if they are pregnant and for requesting notification from patients of possible pregnancy.

WORKGROUP 2: EDUCATION/TRAINING

Leaders: Lewis Johnson M.D. and Joe Windham Ph.D.

Suggested Topics of Discussion:

1. What education is essential for physicians using fluoroscopy? HLC? For other technical staff?
2. What training is necessary for physicians? Technical staff?
3. Should there be special training for high level control fluoroscopy use or other unique modes?
4. How should the above education and training be provided and delivered?
5. Should there be hospital credentialing or granting of privileges for fluoroscopy use?
6. What should be the roles of federal, state, local, or professional organizations in assuring appropriate education and training for safe, efficient fluoroscopy use?
7. Would additional information provided to users on the magnitude of patient and personnel radiation dose be useful in influencing conduct to reduce exposure?
8. Are current users of fluoroscopy adequately trained? If not, what areas might be improved?
9. Can the ALARA concept be used for fluoroscopic studies? (i.e., noise-limited images for some of the study, image hold, etc.)

The Workgroup recommended that:

- 1) Educational and training programs be developed for physicians, physicists, and other allied health personnel associated with the utilization of fluoroscopic systems that can be used in a high dose mode. Allied health personnel include, but are not limited to, technologists and nurses.
- 2) A curriculum/syllabus and study guide in high dose fluoroscopy be developed for use in residency training programs, as well as by practicing physicians and physicists.
- 3) The American College of Radiology work with other specialties in developing their programs.
- 4) Means of credentialing and documentation be established to ensure that the education and training of those associated with the use of high dose fluoroscopy meet minimum requirements. For example, for physicians going through residency programs and physicists going through training programs, becoming board certified would be a minimum requirement. For practicing physicians and physicists, the acquisition of continuing medical education credits would be a minimum requirement.

5) Other professionals, including, but not limited to, chiropractors, dentists, gastroenterologists, surgeons and veterinarians, be encouraged to develop education and training programs in the use of fluoroscopy and HLC where applicable.

The Workgroup recommends the following **draft curriculum** within a residency training program. The relative weight given each topic is related to the amount of time that would be spent on that subject. The actual time would be determined by the different specialties.

DRAFT CURRICULUM PROGRAM

	<u>TOPIC</u>	<u>RELATIVE WEIGHT</u>
1.	X-ray Production	1
2.	Generator/Controls	1
3.	Equipment	1-4*
	Fluoroscopy	
	Fluorographic	
	Digital Imaging	
4.	Quality Control/Measurement	1-2*
5.	Film/Processing	1
6.	Image Quality	1
7.	Dosimetry Concepts	1
8.	Biological Effects/Risk	2
9.	Radiation Protection	2*
10.	Regulations and Recommendations	1
	Federal	
	State	
	National Council on Radiation Protection and Measurements	
	International Commission on Radiological Protection	

*Time allotted will necessarily vary with specialty needs.

NOTE:

The Workgroup proposes that for practicing physicians, an integrated overview of topics 1-5 and individual topics 6-10 contained in the proposed draft curriculum be covered in a continuing medical education course.

Following is a more detailed version of the draft curriculum:

DRAFT CURRICULUM
HIGH DOSE FLUOROSCOPY

1. X-Ray Production
 - X-Ray Tube
 - Electrical Quantities
 - X-Ray Generation
 - Bremsstrahlung
 - Characteristic Radiation
 - Efficiency
 - Efficacy (Output)
 - Heat Quantities
 - Focal Spot
 - Heat Limitations
 - Anode Capacity
 - Housing Capacity

2. Generator/Controls
 - Controls
 - Types
 - Kilovoltage Production
 - kV waveform
 - Tube Current
 - Timer
 - Quality Control Procedures

3. Equipment
 - Fluoroscopy
 - Intensifier Tube
 - Optical System
 - Image Formation
 - Video Principles
 - Video Image Quality
 - Fluorographic
 - Exposure Control
 - Receptor Sensitivity/Film Screen
 - Machine Output
 - Technique
 - Digital Imaging
 - Image Format
 - Digital Representation
 - Image Storage
 - Image Quality
 - Image Processing

4. Quality Control/Measurements

Generator

kVp/HVL

mA/mA Linearity/mA Consistency

Timer

Focal Spot Size/Resolution

Output/Exposure

Image Intensifier

Automatic Exposure Control

Video/Recording Devices

Film/Screen

Film Processing System

Image Quality

Mechanical

5. Screens/Film/Processing

Screens

Screen Design and Function

Screen Sensitivity (speed)

Effects on Image Detail

Cassettes

Film Changer

Film

Function

Optical Density

Film Structure

Photographic Process

Sensitivity

Contrast Transfer

Characteristic Curve

Factors that Alter Contrast

Processing

6. Image Formation/Image Quality

Image Contrast

Subject Contrast

Image Formation

Effect on Photon Energy

kV Selection

Visibility of Detail

Related Characteristics

Blurring

Motion

Focal Spot

Receptor

Image Quality

- Noise
 - Film
 - Intensifier Structure
 - Quantum
- Modulation Transfer Function (MTF)

7. Dosimetry Concepts

- Radiation
 - Types
 - Quantum Nature
- Radiation Quantities and Units
 - Unit Systems
 - Conventional
 - International System (SI)
- Quantities
 - Exposure
 - Absorbed Dose
 - Biological Impact
 - Relative Biological Effect (RBE)
 - RBE Dose
 - Dose Equivalent

8. Biological Effects/Risk

- Biological Effects (Acute/Chronic)
 - Concepts
 - Cancer
 - Mutation
 - Fetal Damage
 - Cataracts
- Risk
 - Exposure Limits
 - Source of Limits
 - Occupational Limits
 - Non-Occupational Limits
 - Patients
 - General Population
 - Fetus
 - Occupational Exposure
 - Exposure Quantities and Units
 - Exposure Sources
 - Patient Exposure
 - Exposure Pattern--Fluoroscopy
 - Radiation and Image Quality
 - Factors Affecting Exposure

9. Radiation Protection

Patient

- Exposure Factors
- Beam Limiting and Shielding
- Typical Exposure Value
- Determination of Exposure

Personnel

- Personnel Monitoring
- Radiation Surveys
- Factors Affecting Exposure
 - Time
 - Distance
 - Shielding

10. Regulations and Recommendations

Federal

State

National Council on Radiation Protection and Measurements

International Commission on Radiological Protection

WORKGROUP 3: TECHNICAL ASPECTS/IMPROVING PERFORMANCE

Leaders: Theron W. Ovitt M.D. and Larry Rothenberg Ph.D.

Suggested topics of discussion:

1. What changes in equipment design might be considered to improve image performance and/or radiation safety?
2. What features or accessories can equipment manufacturers provide that could help reduce patient and staff exposure? What is the cost impact of these features?
3. Is high level control mode needed? If so, should there be a limit imposed on radiation during activation? What should this limit be?
4. How should high level control mode be activated or its use indicated?
5. Changes to improve performance and to practice ALARA.
6. What testing should be performed on fluoro systems? How frequently? By whom?
7. When is a fluoro system too old or at what point should performance degradation warrant replacement?
8. What radiation measurements should be made for fluoro units? Who should make the measurements?
9. Should fluoro systems provide real-time display of cumulative patient exposure or an index related to patient exposure? Would such information influence users?
10. Are there modes or methods of digital image recording that are particularly efficient or inefficient regarding radiation exposure? Should standards (voluntary or regulatory) for radiation exposure during digital or analog recording be implemented?

Workgroup recommendations:

1. Fluoroscopy with automatic brightness control can be performed with no special indication at patient entrance exposure rates up to 10 R/min. (This is an increase from the previously mandated level of 5 R/min).
2. At exposure rates exceeding 10 R/min., there should be a blinking visual indicator at the television monitor assembly. With this visual indicator present, fluoroscopy can be performed at rates up to a maximum patient entrance exposure rate of 20 R/min.
3. The exposure rate measured at the entrance surface of the image intensifier (behind the grid) should be set at approximately 60 microR/sec for standard fluoroscopy in the 9-inch mode of the

image intensifier. There should also be the option for "low dose" fluoroscopy with an entrance exposure rate to the image intensifier of approximately 20 microR/sec.

4. All fluoroscopy should be performed with:

- a. A kVp setting of 70 kVp or higher, with override available to allow lower kVp settings for pediatric studies.
- b. A beam quality of half-value layer equal to 3.0 mm of aluminum or greater as measured at 80 kVp.
- c. It was the opinion of this Workgroup that, under these conditions and with the image intensifier exposure rate kept at 60 microR/sec, the patient entrance exposure rates will only very rarely exceed 10 R/min.

5. Pulsed progressive fluoroscopy and last image hold should be used wherever possible.

6. Visual indication of the following should be provided on the video monitor assembly:

- a. The previously mentioned flashing indicator when patient entrance exposure rates exceed 10 R/min.
- b. The total elapsed fluoro time. In addition, at the completion of each five-minute interval of fluoroscopy, there should be an audible alarm that lasts for five seconds.
- c. A "thermometer" type display of patient entrance exposure rate (from 0% to 100% at 10 R/min and to 200% at 20 R/min, with different colors available, if possible: green for the low zone, yellow for the intermediate zone, and red for the high zone. This indication should be proportional to $(kVp)^2 \times mA$).
- d. The total patient dose.
- e. Indication of $(kVp)^2 \times mA$ may be provided and should be provided for storage with all digital image data.

7. Grids for fluoroscopy should:

- a. Be readily removable
- b. Have high primary beam transmission and high scatter rejection (e.g., carbon fiber covers and interspace materials or better).

8. There should be an additional mode of fluoroscopy called "interventional mode" for which there is an image intensifier entrance exposure rate of approximately 180 microR/sec for the 9-inch mode. Interventional mode should:

- a. Be activated by a separate foot pedal and a switch on the operator console
- b. Run for a maximum time of 15 seconds
- c. Allow a maximum patient entrance exposure rate of 30 R/min, unless it can be shown that 20 R/min will be an adequate upper limit.

9. The Workgroup did not have sufficient time for an in-depth discussion of inspection frequency and test methods. It was felt that measurement of fluoroscopic exposure rates by qualified personnel should be done at least annually. Recommendations are supplied in:

- a. NCRP Report No. 99
- b. AAPM Reports No. 4, 12, 15, 25, and 31
- c. The ACR Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic and Fluoroscopic Equipment
- d. Individual manufacturers' recommendations.

10. The Workgroup recommends that algorithms be developed to provide optimum fluoroscopic performance for:

- a. Different image intensifier modes (i.e., an exposure rate increase by a factor of two when shifting from 9-inch to 6-inch mode, as currently practiced, may or may not be optimum) [The group considered this a new and significant recommendation.]
- b. Different types of examinations and applications.

11. Manufacturers of catheters, and other devices that must be visualized during fluoroscopy for interventional procedures, should be encouraged to construct these devices of more radio-opaque materials so that they may be more easily seen at lower fluoroscopic exposure rates.

12. A performance standard should be developed for image quality in fluoroscopy. A standard phantom that tests for high and low contrast performance should be specified.

13. Wherever appropriate and possible, the recommendations of this Workgroup should be applied by state and local regulatory agencies to existing fluoroscopic equipment.

WORKGROUP 4: FLUOROSCOPY SAFETY/REGULATORY ISSUES

Leaders: Warren Jacobi , Marilyn Wexler M.S. and Richard Geise Ph.D.

Suggested topics of discussion:

1. What is the states' role? Should physicians be regulated? What are the appropriate technical staff qualifications?
2. Are high level control limits needed? What might they be?
3. Should there be fluoro beam "on" time limits? What is acceptable patient radiation dose?
4. What is the federal role?
5. What is the manufacturer's role?
6. How can radiation safety be improved? Shielding/room designs?
7. Should radiation "dose integration" be built into equipment?
8. Who is responsible for a radiation safety program?
9. What is appropriate policy for pregnant patients and personnel?
10. What actions can be taken to reduce exposure from fluoroscopy procedures? What actions should be taken when personnel exposure approaches regulatory limits?
11. Should limits or guidelines be established for acceptable patient radiation exposure from specific procedures (or imaging modes)?
12. Should distinctions be made between diagnostic and interventional procedures regarding radiation safety measures or criteria?

Workgroup recommendations:

Workgroup 4 consisted of physicists from clinical facilities, representatives of several regulatory agencies and representatives of several X-ray manufacturers. Little time was wasted on general issues of whether more regulation was needed or which agency, in particular, should take the lead. Twenty three specific recommendations for future regulations came forth. Suggestions fell into three broad categories; those regulations that affected equipment design (manufacturers), those that affected the use of equipment (medical institutions) and those that involved operator training (physicians).

A number of recommendations were related to equipment design. Some were related to fluoroscopic equipment in general. There was unanimous agreement to require that cumulative fluoroscopy times be displayed on all fluoroscopy units. A majority felt this would allow the

elimination of the 5 minute elapsed timer, assuming that recording of total fluoroscopy time was required for all cases. Regulations requiring a continuous display of some sort of indicator of the accumulated radiation dose for all fluoroscopy units met with unanimous approval. The specific nature of the display was not discussed, and it was not agreed that display of the actual radiation dose to a particular point in the body was really necessary.

There was near unanimity for regulations that would require last image hold on all fluoroscopy units to discourage operators from using fluoroscopy for long periods when a single image would suffice for analysis and decision making. A strong majority recommended that all fluoroscopy units be designed so that the grids can be easily removed, that is, without the use of tools. A majority felt that the use of video recording (as opposed to film recording) as a provision for exceeding the maximum fluoroscopy exposure rate of 10 R/min should NOT be allowed and thus be excluded from the current regulations.

In general it was felt that methods should be sought to minimize the use of low energy radiation during fluoroscopy. Several recommendations addressed this. It was recommended that the minimum required filtration on fluoroscopy equipment be increased to provide a 3mm of Al half-value layer at 80 kVp. It was recommended that a minimum kVp be required for fluoroscopy use (in the 70-80 kVp range), provided there is an override for pediatric or special use. It was recommended that a limit be set on the image intensifier input exposure rate for all fluoroscopy units such that the lowest possible dose is used; consistent with an acceptable level of image noise. Similarly, it was recommended that a maximum limit for an entrance exposure rate to a standard phantom under standard operating conditions be established so that physicists in the field can test the dose efficiency of the fluoroscopy systems in a non-invasive manner. This last item was the most strongly approved from all of the recommendations.

Several equipment related recommendations applied specifically to equipment with high level control capability. Four recommendations received unanimous approval. It was recommended that regulations are needed to force manufacturers to standardize the terminology referring to high level control fluoroscopy conditions so as not to mislead the consumer into thinking that improved image quality can be achieved without an increase in radiation dose when high level mode is used. It was recommended that technique factors should change continuously rather than in a stepwise fashion when the operator switches from normal to high level mode fluoroscopy. It was recommended that a specific maximum exposure time be set for each activation of high level fluoroscopy. It was recommended that the high level control should not be allowed to be activated by simply depressing a single fluoroscopy "foot" switch farther than is required for normal fluoroscopy, but that a totally separate activation method must be available to use high level mode.

The recommendations to increase the maximum exposure rate for normal operation on systems with high level control from 5 to 10 R/min met with near unanimous approval. A small majority agreed that a maximum exposure rate should be set for high level control. This issue was hotly debated and no specific maximum value was agreed upon.

While the regulations recommended above, could be applied to both the equipment manufacturer and the source owner. Two recommendations for regulations specific to the source owner received unanimous approval. It was recommended that quality control be required at regular intervals for all fluoroscopy equipment. It was recommended that the source owner be required to record the fluoroscopy time of every fluoroscopy procedure for all patients.

A strong majority voted to recommend that the information needed to calculate the

radiation dose must be recorded for each patient undergoing a fluoroscopic procedure.

In a related matter it was recommended that the use of the Webster equation be allowed to be used to determine effective dose equivalent from film badge readings of persons performing fluoroscopic procedures.

The importance of education for users of X-ray sources was also considered. It was unanimously agreed and was recommended that physician education regarding radiation safety and the proper use of fluoroscopy must be required for all physicians using or directing the use of all fluoroscopy units. A three to one majority of the group felt regulations should specifically require physicians to pass a test before being allowed to operate or supervise operation of fluoroscopy equipment.

The votes on specific items are listed below:

To require that cumulative fluoroscopy times be displayed on all fluoroscopy units
17-0 in favor

To require the recording of "total" fluoroscopy times for all patients
16-0 in favor

To eliminate the 5 minute elapsed timer (assuming recording of total times)
11-4 in favor

To require the recording of radiation dose to all patients receiving fluoroscopy
9-3 in favor

To require physician education for all physicians using or directing the use of fluoroscopy
16-0 in favor

To require physicians to pass a test before being allowed to operate or supervise operation of fluoroscopy equipment
12-4 in favor

To require quality control at regular intervals for all fluoroscopy equipment
17-0 in favor

To require a continuous accumulative display of an indicator of the radiation dose (e.g. monitor units) on all fluoroscopy units
14-0 in favor

To establish a maximum limit for the entrance exposure rate for a standard phantom under standard conditions
13-1 in favor

To require last image hold on all fluoroscopy units
13-1 in favor

To increase the minimum required filtration to provide 3mm of Al half-value layer at 80 kVp
10-3 in favor

To set minimum kVp on fluoroscopy equipment (70-80 range) provided there is an override for pediatric or special use equipment
9-5 in favor

To require that all fluoroscopic units be outfitted with easily removable grids
11-2 in favor

To set a limit on image intensifier input exposure rate on all fluoroscopic units
11-4 in favor

To include the use of the Webster equation for determining effective dose equivalent from film badge readings in the regulations
8-2 in favor

To exclude the use of video recording as a provision for exceeding the maximum fluoroscopic exposure rate of 10 R/min
10-5 in favor

Manufacturers must use a standard means of referring to high level control conditions
14-0 in favor

When switching to HLC the dose levels must change continuously rather than stepwise
13-0 in favor

The maximum exposure rate for normal operation on systems with high level control should be raised from 5 to 10 R/min
15-1 in favor

The HLC can not be activated by simply depressing the fluoroscopy foot switch farther than required for normal fluoroscopy (a separate switch must be used)
17-0 in favor

A maximum exposure rate should be set for high level control (number not specified)
8-5 in favor

To limit the time of exposure under high level control mode
16-0 against

To make the spacer on mobile fluoroscopy systems non-removable
9-4 against

Speakers'
Submitted
Papers

The FDA's Role and Authorities
Regarding Fluoroscopy

Thomas B. Shope, Ph.D.

THE FDA'S ROLE AND AUTHORITIES REGARDING FLUOROSCOPY

Thomas B. Shope, Ph.D.
Office of Science and Technology
Center for Devices and Radiological Health
Food and Drug Administration

ABSTRACT

The purpose of this paper is to describe briefly the role of the Food and Drug Administration (FDA) with regard to fluoroscopy. The goals of this Workshop include the development of suggestions and recommendations regarding steps that might be taken to improve the use of fluoroscopy. Should some of these suggestions address the role of the FDA, it would be useful for participants have an understanding of the scope of FDA's authorities and responsibilities regarding x-ray equipment and other devices. The FDA proposal to limit the radiation output during high-level-control mode will also be described along with other FDA concerns regarding fluoroscopy. The discussion will close with a description of FDA's goals in participating in this Workshop.

LEGISLATIVE AUTHORITY

The activities any Government agency undertakes are those authorized by the legislation Congress passes and which are funded by the necessary appropriations. The Center for Devices and Radiological Health (CDRH) of the FDA carries out responsibilities derived from two mandates. The first is the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602) which requires an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. An essential component of FDA's radiation control program is the establishment and enforcement of performance standards for regulated products. Such standards are in place for a number of products such as televisions, microwave ovens, lasers, sunlamps and diagnostic x-ray systems. This legislation also authorizes other non-regulatory activities such as research, training and development of recommendations aimed at controlling radiation from electronic products. The second law implemented by FDA through CDRH is the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act (P.L. 94-295). These amendments were recently supplemented by additional amendments enacted in 1990 and 1992. These amendments require that the safety and effectiveness of all medical devices be assured through a variety of mechanisms.

Using a variety of procedures and processes, also specified in legislation or by regulation, the Executive Branch implements, through regulations, the programs required or authorized in the legislation established by Congress. In the case of medical devices, these regulations are extensive and are found in Title 21 of the Code of Federal Regulations, Subchapter H, Parts 800-895. The law and these regulations define a medical device quite broadly and the controls imposed by the regulations are directed toward the manufacturer and the device.

The 1990 amendments do establish, however, mandatory reporting requirements which require that certain facilities using devices report deaths, injuries or malfunctions associated with the use of a device.

MEDICAL DEVICE PROGRAM

A discussion of the complete medical device program is beyond the scope of this paper, but I will list the major elements of the program with a brief explanation of each. Additional information is available from the Center on the individual programs and requirements. These elements are:

- Classification - By regulation, all devices are classified into one of three classes based on the risk associated with the device and the controls necessary to assure safety.
 - Class I - Require only general controls.
 - Class II - Special controls (formerly performance standards) in addition to general controls.
 - Class III- Premarket approval required.

General Controls - All manufacturers must comply with these requirements.

Register manufacturing locations.

List marketed medical devices.

Manufacture in accordance with Good Manufacturing Practices (GMP) regulations.

Submit Premarket Notifications [510(k)] before marketing new or significantly modified devices.

Premarket Notification - Manufacturer must demonstrate that the device is substantially equivalent to a device which has been legally marketed in the United States.

Premarket Approval - For a new type of device, or a preamendments Class III device when required, the manufacturer must demonstrate safety and effectiveness of the device prior to being allowed to market the device.

Investigational Device Exemption (IDE) - Mechanism to permit limited use for investigating safety and effectiveness of new devices. For devices posing significant risk, FDA must review study plans.

Medical Device Reporting - Mandatory reporting by manufacturer and user facilities of deaths or injuries associated with use of a device, or malfunctions that might lead to serious injury or death if they recur.

Postmarket Surveillance - Required studies to evaluate performance of specific devices following approval to market. Protocol must be approved by FDA.

Labeling Requirements - Devices must be provided with adequate instructions and indications for use.

Performance Standards - Authorized to establish mandatory performance standards for devices.

Special Controls - Measures which can be used to assure safety and effectiveness of Class II devices, such as voluntary standards, special training or restrictions on sales.

These controls are thus directed primarily at the manufacturer and the device. Except for problem-reporting or involvement in studies under an investigational device exemption, or perhaps regarding use of an unapproved device, there is little impact or direct control by FDA over the use of devices or involvement by FDA in controlling this aspect of the practice of medicine.

RADIATION CONTROL PROGRAM

The regulations implementing the Radiation Control for Health and Safety Act are contained in Title 21 of the Code of Federal Regulations, Subchapter J, Parts 1000-1050. These regulations establish general requirements to control defective or dangerous electronic products that emit radiation. They also establish performance standards for certain radiation emitting electronic products. When standards have been established, manufacturers are required to establish testing programs and certify that products comply with the standard. The manufacturer must describe this testing program for each model of product before marketing begins. The FDA performs review of the testing programs and conducts product testing as required to assure compliance with the standard.

FLUOROSCOPIC SYSTEMS

Fluoroscopic x-ray systems are subject to the performance standard for diagnostic x-ray systems and their major components published in 1972 (21 CFR 1020.30-33). The performance standard became effective in 1974. The requirements in the standard for

fluoroscopic systems were based largely on recommendations of the National Council of Radiation Protection and Measurements (NCRP), primarily NCRP Report 33, and reflected the consensus on control of fluoroscopic system performance which existed in the late 1960s.

Under the Radiation Control for Health and Safety Act, the requirements of a standard must be performance-related, not design standards, and must address radiation safety. Under the Medical Device Amendments, standards could be broader in scope, including design, but this authority has yet to be used. In addition to the general requirements for all x-ray systems, the requirements of the standard for fluoroscopic systems address specific aspects of performance such as:

- Protective barriers and beam interlocks.
- X-ray beam control and collimation.
- Exposure rate limits for normal fluoroscopy.
- High-level-control mode activation and alarm.
- Exposure time indication.

The standard does not currently contain limits on exposure rate during high-level-control mode or during recording of images, nor does it contain any requirements regarding imaging performance. These omissions were due to a lack of consensus or technical basis regarding appropriate requirements at the time the standard was developed. There was an expectation at that time that these areas would be addressed later through amendments, as information on the necessary performance requirements and a consensus on appropriate controls were developed.

Suggestions for amendments began almost simultaneously with promulgation of the standard and several amendments dealing with fluoroscopy were implemented. These were primarily administrative or clarifying in nature and addressed spot-film devices and requirements for minimum field size and collimator adjustment. With regard to diagnostic x-ray systems in the late 1970s and early 1980s, the Agency's efforts were directed at implementing a compliance program and dealing with the challenges of concern over mammography, the development of computed tomography and magnetic resonance imaging, and the new responsibility to implement the medical device program. Considerable efforts were also directed toward describing and encouraging quality assurance activities in radiology and toward the development, for certain examinations, of criteria for ordering the x-ray examinations. These were seen as ways to reduce unnecessary exposures. Fluoroscopy did not receive the focus or attention it might have deserved.

Also during this time, the Center maintained a modest laboratory effort aimed at investigating methods for characterizing the performance of x-ray image intensifier tubes and other aspects of fluoroscopic system performance. The goal of this program is the development of consensus methods for evaluating the imaging performance as well as specifying the efficiency of exposure utilization by imaging systems. The ultimate goal of this activity is the development of quantitative methods, validated by inter-laboratory

comparisons, that provide methods for evaluating system performance in either laboratory or clinical settings. Progress has been made but much remains to be done to reach these goals. Our laboratory has been an active participant in the development of ANSI standards related to radiology. We frequently sit in as informal observers or participants with NEMA and IEC working groups, and we are among the principal active participants in a current ICRU committee working on a general approach to both laboratory and clinical assessment of diagnostic imaging systems. Major issues to be resolved include development of a consensus on imaging phantoms for evaluating specific diagnostic tasks and on human and machine reading of the resulting phantom images. Recent developments, both at CDRH and by other researchers, indicate an opportunity for significant progress toward this goal, especially for systems with digital imaging capability. We are optimistic that useful quantitative descriptions of performance, relatable to specific clinical tasks, are feasible and not too far away. We hope to continue a modest participation in these activities.

In the last few years, increasing attention has been given to fluoroscopy at the Center. There have been activities in dosimetry and organ dose estimation, efforts to assess the state of fluoroscopic system performance in the U.S. in order to identify problem areas and, recently, concerns over the trend toward increasing radiation output capability on some systems. This latter concern has resulted in a proposal to amend the standard to establish maximum exposure rate limits during high-level-control mode and during continuous recording of images. A draft of this proposal was circulated in 1990 and our advisory committee concurred with publication of the proposed amendments for public comment. We are currently awaiting publication of the proposal in the Federal Register. The proposed amendment would limit the maximum exposure rate during normal fluoroscopy to 10 R/min. During high-level-control mode or recording using continuous exposure the maximum exposure rate would be limited to 20 R/min.

In addition to this current proposal regarding maximum exposure rates during high-level-control mode, other equipment-related issues have been raised and may receive additional attention from FDA in conjunction with concerns regarding fluoroscopy. Among these are:

- * Exposure or exposure rate limits during recording of fluoroscopic images.
- * Requirements on imaging performance.
- * Increased labeling requirements concerning radiation exposures from different modes of operation.
- * Requirements concerning equipment features which would provide potential for exposure reduction, such as:
 - Easily removable grids.
 - Operator control of camera aperture.
 - Freeze frame or last image hold.

- Variable x-ray beam filtration.
- Efficiency of radiation usage during pulsed operation.
- Selectable AEC algorithms.
- Realtime display of patient exposure or an exposure index.

There are additional reasons for increasing our attention to fluoroscopy. Using the techniques recently described by Suleiman, *et al.* (Ref. 1) for determining organ doses from fluoroscopic procedures, it was recently possible to estimate roughly the radiation doses to the United States population from the upper gastrointestinal (UGI) examination and compare the estimated risks from this examination to those from chest x-rays and mammography. This comparison was presented at the Annual Meeting of the Conference of Radiation Control Directors in May of 1992 and details of the estimate will be published in the proceedings of this meeting (Ref. 2). The data on organ doses from the UGI examination were obtained from a limited number of procedures analyzed by Suleiman and co-workers at CDRH (Ref. 3). The results of this comparison are shown in the table below. This comparison indicates that, from the standpoint of public health impact, efforts to improve fluoroscopy deserve increased attention.

Estimates of Relative Risk
Due to the Annual Number of Selected Diagnostic Examinations Performed in the US

<u>Examination</u>	<u>Annual Number of Examinations</u>	<u>Relative Risk</u>
PA Chest (one film)	50 million	1
Mammography	12 million	1.9
UGI	10 million	36

There are also numerous indications that fluoroscopic systems frequently provide sub-optimum performance. This, coupled with the trends toward increased radiation output capability in some modes of operation and the increased use of fluoroscopy in interventional, therapeutic procedures with very long exposure times as compared to diagnostic procedures, indicates that the radiological community should give fluoroscopy increased attention and, if warranted, increased control. There also appear to be opportunities for equipment or technique modification or optimization that promise exposure reduction or improved imaging performance which deserve further study.

This Workshop provides a unique opportunity for many of the parties involved with fluoroscopy to explore these issues, to exchange data and opinions and to chart a course for recommended actions that can be undertaken to improve fluoroscopy. Fluoroscopic x-ray systems are clearly valuable imaging devices, but devices with the potential for harm if not used in a careful manner by knowledgeable practitioners. It seems especially important to factor consideration of risks from radiation into the risk-versus-benefit equation when fluoroscopy is used in therapeutic procedures, especially those of long duration. The CDRH looks forward to participating and assisting in these efforts. I encourage you to give this Workshop and the implementation of the recommendations developed here your best efforts and fullest cooperation.

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The Role of the States Regarding Fluoroscopy

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THE ROLE OF THE STATES
REGARDING FLUOROSCOPY REGULATION

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1. State Authority and Regulation

- a. State laws give authority to register and inspect x-ray facilities, and/or machines, and/or x-ray tubes.
- b. Regulations are written to implement those laws
 1. Based on CRCPD SSRs, NCRP, FDA regulations, with input from advisory committees, local professional associations such as AAPM, ACMP, etc.
- c. All state laws, regulations and procedures are not exactly the same even though the SSRs provide a common ground. Some differences include the areas of fees, inspection frequency, inspector experience/qualifications, state-employed or private contractor/consultant, content of the inspection, report and citation format, etc.
- d. State programs cover ALL x-ray facilities including veterinarians and industry and ALL X-ray machines whether they are certified or uncertified. In general, FDA covers only certified systems in medical and dental offices.
- e. State regulations can address USE of x-ray systems, i.e., who can operate them, who needs to be licensed, and the conditions under which a machine can be used. FDA covers the performance of the x-ray system.
- f. State inspections enforce compliance with rules to reduce patient exposure AND operator exposure. This two-pronged approach is characteristic of all regulations, state and federal. State regulations additionally address areas such as personnel monitoring, operator training/credentialing, film processing, and room shielding.

2. Current Suggested State Regulations.

The SSRs are model regulations that are designed as guidance for development and amendment of State radiation control regulations, to encourage more uniform regulations among the states, to complement Federal regulations, and to help states maintain regulations compatible with, identical to, or as effective as, Federal regulations. The SSRs were originally published in 1962 by the Council of State Governments with the assistance of the USAEC

(now NRC) and the US Public Health Service. In 1990, the CRCPD assumed the role (from FDA) of maintaining, coordinating and publishing the SSRCR. The 8th Edition was released in 1990. These are the subject highlights from the fluoroscopy part (Part F.5)

- a. Limitation of the Useful Beam
 1. Primary Barrier
 2. Alignment of fluoroscopic beam with image receptor.
 3. Spot Film alignment
- b. Activation of the Fluoro tube.
- c. Exposure rate limits.
 1. 5 R/min, 10 R/min, HLC, AEC/ABC
 2. Periodic measurement of the limits.
- d. Barrier transmission limits (2 mR/hour at 10 cm for every R per minute EER)
- e. Indication of tube potential and current (kVp and mA)
- f. Source to Skin distance limits.
- g. Fluoroscopic timer (max of 5 min and signal)
- h. Control of scatter.
- i. Therapy simulators.

3. Proposed Draft of Suggested State Regulations

- a. Improvements in scope and organization
- b. Typical entrance exposure rate shall be required (as well as maximum)

4. Results of State Surveys conducted in September, 1992 (survey form attached).

The following were **areas of concern** expressed by the states, and are presented here in bullet or capsule form:

- a. SSD and EER of C-arm fluoroscopes
- b. Use of fluoroscopy by chiropractors
- c. Use of hand-held fluoroscopes by podiatrists
- d. No limits to HLC
- e. Dose rates to children undergoing fluoroscopic procedures
- f. No limits for recording modes
- g. Assessing resolution
- h. Use of excessive long on-times by fluoroscopists
- i. technologists using fluoro on overhead remotes to position.
- j. Need for phantom for assessing typical EERS.
- k. Cardiologists using fluoroscopy
- l. Unqualified personnel using fluoroscopes
- m. Personnel using fluoroscopes without adequate instruction.
- n. Manufacturers designing equipment capable of extraordinarily high dose rates without adequate consideration to the need.
- o. Hooking up a simple VCR to a fluoroscope, thus turning it into "recording" mode and thus bypassing rate limits.
- p. Fluoroscopist ignoring some of the exposure reduction features of an imaging system
- q. High EERS