

Controlling Patient and Personnel  
Fluoroscopic Exposure Levels in  
the Clinical Setting - One  
Institution's Experience

Gary T. Barnes, Ph.D.

## MEETING THE CLINICAL NEEDS IN FLUOROSCOPY: THE UAB EXPERIENCE

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### ABSTRACT

Briefly reviewed are the factors that affect fluoroscopic exposure and the trade-off between exposure and image quality. Fluoroscopic image quality is directly related to patient radiation levels. Increasing the patient dose level results in the detection of more quanta per unit time and a quieter image, i.e., less scintillation noise. This trade-off and the desire, if not the need, for physicians to see greater detail often drive up fluoroscopic exposure rates. Offsetting this tendency are the availability of image intensifiers with improved performance and advances in real time digital fluoroscopy. Incorporating these advances allows one to simultaneously improve image quality and reduce patient exposure rates. Another factor that can be exploited to reduce radiation levels is that the fluoroscopic image quality needed clinically is variable. Tube placements and routine GI exams are not overly demanding; whereas, the requirements for interventional angiography and cardiology are more stringent. Also during a procedure the requirements vary. It has been our experience that high personnel radiation levels are generally experienced by interventional radiologists and cardiologists and also by cardiologists performing electrophysiology and alcohol or RF ablation studies. The steps taken at UAB to control patient and personnel radiation levels in these and other areas are presented and discussed. Equipment related steps are: 1) Vendors supplying equipment to UAB are requested to provide two or more fluoroscopic image intensifier input phosphor exposure rates that can be conveniently selected by the operator. When a machine is turned on it comes up normally in the low dose mode and reverts to the low dose mode after a predetermined time. For a 9" image intensifier the standard and low dose selections correspond to input phosphor exposure rates of 3.6 mR/min (2  $\mu$ R/frame) and 1.2 mR/min (0.7  $\mu$ R/frame), respectively; 2) Real time digital fluoroscopic enhancement is employed whenever possible. With this technology excellent image quality can often be obtained at a very low dose rate. (Furthermore, major improvements in this area are anticipated); 3) A comprehensive equipment acceptance testing, QC and maintenance program is in place and is constantly being improved. This program ensures that quality imaging chains are installed initially, the image intensifier input phosphor exposure rates are set up according to UAB specs, and imaging chain performance is monitored and the necessary steps are taken (other than to increase the dose rate) when performance is subpar; 4) Limit high dose fluoro to interventional radiology and cardiology and also limit the associated maximum table top exposure rate to 20 R/min. These steps in conjunction with the availability of ergonomic shields, review of high film badge readings and continuing education has markedly reduced the number of high film badge readings and patient radiation levels. Based on our experience high dose fluoro should be limited to 20 R/min and to equipment designed for interventional procedures. Equipment manufacturers should be required to provide low as well as standard dose fluoroscopy. Equipment should also be designed to record and to print out fluoro techniques and times. Furthermore, the FDA should invest time and money in understanding the potential of real time digital fluoroscopy in improving image quality and reducing radiation levels.

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## OUTLINE

- I. Factors Affecting Fluoroscopic Exposure
  - A. Exam and degree of difficulty
  - B. Operator training
  - C. Equipment performance
- II. Equipment and Fluoroscopic Exposure
  - A. II input phosphor exposure rate
  - B. ABC algorithm and patient thickness
  - C. Max exposure rate
- III. Image Quality and Exposure
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- IV. UAB Philosophy
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  - D. Purchase ergonomic shielding devices when feasible
  - E. Design and build specialized shielding devices
- V. Program Implementation—Equipment
  - F. Comprehensive equipment acceptance testing, QC and maintenance program
    - A. Require equipment vendors to provide operator selectable low and standard dose fluoro
    - B. Employ real-time digital processing
    - C. Limit high dose fluoro to interventional angiography and cardiology
    - D. Limit high dose fluoro to 20 R/min
    - E. Employ second or additional foot pedal for high dose fluoro

Radiation Bioeffects and  
Fluoroscopic Exposures

Louis K. Wagner, Ph.D.

## SESSION V: UTILIZATION CONCERNS

### RADIATION BIOEFFECTS AND FLUOROSCOPIC EXPOSURES: Louis K. Wagner, Ph.D., Professor, University of Texas Medical School, Houston, Texas

In the April 10, 1896 issue of Science, Professor John Daniel of Vanderbilt University reported on a failed attempt to acquire a radiograph of the head of Dr. William L. Dudley, Dean of the Medical School:

"Dr. William 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."

This is one of the first reports in the scientific literature of an x-ray induced effect. After acute irradiation, the threshold for temporary epilation is about 3 Gy; it's approximately 7 Gy for permanent hair loss. The onset of epilation is about two weeks after exposure and new hair growth will be thinner than before.

In the early history of radiography, there are many interesting anecdotes about radiation effects, some of which are tragic. Within the first year following Röntgen's discovery, there were many reports of burns that were said to have been caused by the X rays. Many did not believe that the X rays were responsible for the burns and felt that they may be due to some other phenomena, such as electrical discharge. Elihu Thomson decided to do a test by exposing a finger at close proximity to the source for 30 minutes. He reported his results in the Boston Medical and Surgical Journal of December 10, 1896:

"Hearing of the effects of x-rays..., I was determined to find out what foundation the statements had by exposing a single finger to the rays...For about nine days very little effect was noticed, then the finger became hypersensitive...,dark red,...and...began to blister...the whole epidermis is off the back of the finger...the tissue even under the nail is whitened, and probably dead, ready to be cast off."

A summary of some skin effects is given in Table 1. The basal cells of the epidermis are the target cells for most radiation-induced injuries to the skin. The actual response will depend on several factors which include the amount of ultraviolet radiation to which the skin is exposed, the pigmentation of the skin, the age of the individual, the location of the skin on the body, medications, and more.

Table 1  
SKIN EFFECTS AFTER ACUTE IRRADIATION

EFFECT	THRESHOLD	ONSET	PEAK	COMMENT
Erythema: early & transient	≥ 2 Gy	hours	~24 hr	reddening → pigmentation; at 10 Gy, pigment may last weeks
Erythema: main effect	≥ 6 Gy	~10 days	~2 weeks	
Dry desquamation	≥ 10 Gy	~ 4 weeks	~5 weeks	slow healing; late atrophy scarring
Moist desquamation	≥ 15 Gy	~ 4 weeks	~5 weeks	
Secondary ulceration	≥ 20 Gy	>6 weeks		
Dermal necrosis	≥15 Gy	>10 weeks		
Dermal atrophy	≥ 11 Gy	> 14 weeks		
Telangiectasia	≥ 12 Gy	> 52 weeks		
Invasive fibrosis	≥ 10 Gy			

The risks for radiation-induced basal and squamous cell cancers are summarized in Table 2. These risks appear to be small, but are a concern to both the patient and occupational personnel, especially physicians who experience direct exposure of their hands. However, for occupational risks, the recommendations for exposure limitation by the International Commission on Radiological Protection (ICRP) state that the principal concerns are long-term deterministic effects of radiation rather than stochastic effects. Since the threshold for dermal atrophy and telangiectasia five years after a protracted exposure to radiation is approximately 30 Gy, adherence to the 0.5 Gy per year exposure limit to any square centimeter of the skin should be adequate to protect personnel from deterministic skin effects. These risks are best minimized by physicians diligently keeping their hands out of the direct beam. Wearing surgical leaded gloves to protect the hands from radiation is questionably cost effective (Kelsey and Mettler) because of their expense and because a large percentage (60% - 85%) of the radiation penetrates the gloves to expose the hands. Worse yet may be the false sense of security that one may more frequently place one's hands in the beam because one is wearing the minimally protective gloves.

Table 2

### RADIATION-INDUCED SKIN CANCER<sup>a</sup>

- 1) Primarily squamous & basal cell; evidence for melanoma is weak, but small excesses have been observed.
- 2) The ratio of induced basal cell carcinoma to squamous cell carcinoma is approximately 5:1, the x-ray induced ratio may be as high as 10:1.
- 3) Basal cell carcinoma mortality is less than 0.1% and squamous cell carcinoma mortality is less than 1%.
- 4) X rays and ultraviolet radiation are synergistic.
- 5) For a 100<sup>2</sup> cm area of ultraviolet exposed skin, the risk of skin cancer increases by about 2% per Gy.
- 6) Pigmentation is a major factor and blacks are far less susceptible than whites.

<sup>a</sup> Adapted from ICRP Publication #59, 1992.

The threshold for radiation-induced cataract has been quoted at approximately 1 Gy. Vision impairing cataracts probably have a threshold of about 5 Gy when delivered in a single dose. The threshold after protracted exposure is approximately 10 Gy. It generally takes a year or more after exposure for the cataract to emerge, with the latency inversely related to dose and patient age.

Between the 1930s and 1950s, fluoroscopy was used to monitor the treatment of pulmonary tuberculosis. The treatment involved an artificially induced pneumothorax and the adequacy of the treatment was monitored under fluoroscopy. In many cases, the patients directly faced the X-ray beam so that the chest received the highest fluoroscopic dose. Some patients underwent many such monitoring episodes and the doses accumulated over the course of the treatment were quite high, frequently in excess of many gray. In 1965, MacKenzie reported that women who underwent these procedures appeared to be at higher risk for breast cancer. Radiation was thought to be the likely causal agent, and the relationship between radiation exposure and the higher incidence of breast cancer was later confirmed (Boice et al.). This experience indicates the need to make concerted efforts to reduce radiation exposures to levels as low as possible without compromising the intended medical benefits of the procedures.

The lifetime risk of radiation-induced fatal cancer following a 10 millisievert (1 rem) whole-body equivalent dose is 4 per 10,000 among radiation workers and about 5 per 10,000 in the general population (ICRP). Leukemia takes a minimum of two years before progressing to a diagnostic stage with latency usually

lasting 12-15 years, but seldom beyond 25 years. Most other cancers typically require at least five years post-exposure to reveal themselves, but may not become apparent for as many as forty or more years, as has been shown to be the case among those exposed to atomic bomb radiation.

Excess cancer mortality among radiologists has been documented for a variety of cancers (Matanoski), but the types of cancers for individuals entering the field after 1940 are different from those in radiologists who entered the field prior to that time. Radiologists going into the field prior to 1940 had a higher risk of dying from leukemia, aplastic anemia, lymphoma, liver cancer, and skin cancer, but those who entered after 1940 did not. For all radiologists there appears to be a higher risk of mortality from oral and pharyngeal cancers. Radiologists entering the field after 1940 appeared to be at greater risk of death from lung cancer and multiple myeloma, which was not the case prior to 1940. The decreased risks are due to better technology, better shielding, and better attention to radiation safety habits. The role that a change in smoking habits may have played in increased susceptibility for oral and lung cancers has not been fully investigated.

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(WASH ACR TALK)

# Fluoroscopic Radiation Safety

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and

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## Fluoroscopic Radiation Safety

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### I. The Radiation Safety Officer Point of View (Brateman)

Patient and personnel doses from angiographic and interventional procedures follow the same principles as doses from routine x-ray procedures; the major differences lie in the unusual variability of the primary beam orientation(s) and the duration of the procedures, with regard to the total fluoroscopic time (or mA-minutes) as well as the number of fluorographic or radiographic exposures (mAs) used in the procedure. When many images are made, the patient and operator doses can be quite large. For most studies, personnel are in the room and exposed to scatter radiation only for the fluoroscopic portion of the study; however, some studies require that an interventionalist stand by the patient for an entire procedure when manual injections are required.

The equipment is frequently a C-arm or U-arm fluoroscope, which allows continuous variability in the beam orientation, and which necessitates special considerations with regard to operator safety. In addition to rotation about the long axis of the patient, cardiology units also offer a cranial-caudal tilting option. In general, the highest scatter dose to the operator occurs when the x-ray tube is near the operator's face, because the primary beam intensity is greatest and there is no attenuation by the patient of the backscattered beam. The proximity of the angiographer depends on the relative distance between the puncture site on the patient and the radiation field, because the operator is standing closest to the puncture site. Distance also plays a large part in the working field intensity, and short personnel have their faces closer to the radiation source than taller individuals. When the individual is close to the table, frequently the best rule is simply to take a step back, unless the image intensifier serves as a better barrier when the operator is immediately next to it. The radiation field intensity in which the angiographer is immersed, therefore, depends on the relative positions of the primary beam, the x-ray tube, the patient, other absorbing objects and the operator, and of course the total dose depends on the duration of the procedure.

### Personnel Dosimetry and Dose Limits

Current regulatory limits in the states are based on the outdated concept of the critical organ dose from the Nuclear Regulatory Commission (NRC) and the Conference of Radiation Control Program Directors' Suggested State Regulations for Control of Radiation (SSRCR), even though international and national recommendations were changed to the concept of effective dose equivalent (EDE) more than a decade ago. The current regulations have fostered a situation among angiographers and interventionalists in which the operators are unable to wear their dosimeters properly and remain within the regulatory limits, primarily because the annual lens dose is limited to 5 rem (50 mSv). Upcoming revisions to the SSRCR, upon which most state

regulations are based, will reflect new limits from the NRC, and it is hoped that an existing proposal to include the monitoring of EDE for fluoroscopists will also be accepted, because the current lifetime limit of 5(N-18) rem will be eliminated, and because the definition of whole body will be changed to include the dose to one upper arm. New limits to specific organs, such as the thyroid, and the extremities (50 rem or 500 mSv), lens (15 rem or 150 mSv) and embryo/fetus (500 mrem or 5 mSv during gestation and 50 mrem or 0.5 mSv in one month) will be incorporated in 1994, as well as the requirement for monitoring when the possibility exists of an individual receiving a dose of 10% of the applicable limits.

It is an unfortunate fact that, under the present regulations, many personnel in Special Procedures who receive high doses do not comply with the existing requirements that they wear their dosimeters. With the incorporation of the increased eye dose limit, and with a change to monitoring EDE for fluoroscopists, it is expected that personnel behaviors would change for the better, as the regulations would be likely to be perceived as being sufficient without being overly restrictive. The collar monitor which is currently required by the SSRCR can be used to estimate eye dose, and the same monitor can be used with a 0.3 weighting factor to estimate EDE. However, this estimate is an overestimate, which may be burdensome for some personnel. A second monitor underneath the protective apron can be used to determine the EDE of the worker more accurately with the use of the following relationship:  $EDE = 0.04 C + 1.5 W$ , where C and W refer to the unshielded collar and shielded waist monitors, respectively. Wearing the second monitor has the added benefit of monitoring a conceptus of a pregnant or potentially-pregnant worker simultaneously; however, the added cost and potential for confusion must be considered.

EDEs were calculated according to the above procedure for personnel monitoring data from Shands Hospital at the University of Florida over a four-year period for Special Procedures personnel (physicians, technologists and nurses) who wore two personnel monitors. Of 343 person-months, 40 had monthly collar exposures greater than 300 mrem (the institution's ALARA action level), and 26 of these were greater than 416 mrem (which annualizes to 5 rem or 50 mSv). With the use of the 0.3 factor applied to the collar monitor to determine the (overestimated) EDE from one film badge, the number of exposures exceeding 300 mrem was reduced to 7, and the number exceeding 416 was reduced to 2. With the use of the two-badge method of determining the EDE, which is more scientifically correct, only one exposure exceeded 300 mrem, and none exceeded 416. Waist badges were found not to exceed 20 mrem in one month for nursing personnel or 30 mrem in one month for technologists. However, physicians did receive shielded waist values greater than 50 mrem in one month, which is of consideration for personnel with declared pregnancy.

Of the 26 collar badges which exceeded 416 mrem in a month,

collar badges for three physicians indicated values greater than 1250 mrem, which annualizes to the upcoming limit for eye dose. Since many angiographers and interventionalists who perform Special Procedures receive doses to the eyes which are greater than 5 rem (0.05 Sv) per year, the new limit of 15 rem (0.15 Sv) will reduce the number of incidents in which personnel are cited for violations. Personnel who are likely to exceed this limit can wear protective eyewear, but no reasonable method currently exists to monitor the lens dose directly, except when face shields are worn.

#### Personnel Shielding

Many structural barriers are available to shield the operator from the radiation field, and some individuals are in the habit of using them when the clinical procedures allow their use. Many personal shielding devices are also available. NCRP Report No. 102 requires at least 0.5 mm lead equivalent aprons. Aprons should be the wraparound type for personnel who may have their backs to the beam; this recommendation becomes a necessity when effective dose equivalents (EDEs) are determined from two personnel dosimeters, and a protective half-apron worn at the back is insufficient. Maternity aprons are available which have a wide wrap and a double thickness of lead over the abdomen. Lead glasses are available in prescription glass, and it is important to use the type with side shields in order to protect the eyes properly. Other devices may be worn which shield the entire head. Because the angiographer/interventionalist is looking through the shield, cleanliness and freedom from scratches and image distortions are a necessity. Because the lens dose will be limited to 15 rem (150 mSv), it is unlikely that the thyroid dose will approach the limiting level of 50 rem (500 mSv). However, thyroid shields serve two even more useful purposes: they customize the neck of the apron, thereby shielding some breast tissues and bone marrow in small individuals who wear aprons with large neck openings; and they also serve as a convenient place to wear a neck radiation dosimeter. Some leaded surgical gloves are available; however, their attenuation factor is low, and they are somewhat expensive. After the reduced regulations revisions, personnel who receive monthly hand doses of more than 4 rem (40 mSv) may need to explore this option.

Recommendations for ALARA

1. Educate special procedures personnel, particularly with regard to the exposure levels that they are working in and the levels to which they are exposing their patients. Stress the use of pulsed fluoroscopy and minimization of the number of images. Demonstrate the effects of collimation, shielding by structural barriers and personal shielding equipment, and tube orientation in the work environment.
2. Monitor cumulative fluoroscopy time (or mA-minutes) and review excessively lengthy procedures after determining what the expected procedures should be.
3. Monitor extremities of angiographers/interventionalists.
4. Provide two monitors for angiographers/interventionalists. Identify badges clearly to minimize administrative chaos.
5. Provide wraparound aprons of at least 0.5 mm lead equivalence for personnel in special procedures. Use thyroid shields to limit upper chest exposure by customizing the neck.
6. Provide maternity aprons after declaration of pregnancy.
7. Recommend protective eyewear for angiographers/interventionalists. Leaded glasses should have side shields and be shatterproof.
8. Be cautious in censuring personnel for high dosimetry values. If they are doing all that they can to maintain ALARA, you will succeed only in having them refuse to wear their dosimeters, which will not be helpful.
9. Measure the equipment, particularly the image intensifier input exposure requirements, the automatic brightness control system and high level fluoroscopy exposure rates.

## **Fluoroscopy Radiation Safety: the Physician Point of View.**

M. Victoria Marx, MD. Vascular / Interventional Radiology. University of Michigan

### **1. Role of the Physician.**

The physician performing fluoroscopically-guided procedures has several goals - which may or may not be at odds with each other. The first goal is to complete the task (i.e. - the arteriogram, angioplasty, or biliary tube change) successfully. An accompanying goal is to avoid procedure-related complications. Achievement of these aims requires individual skill and training, appropriate support personnel, the right tools, and high quality imaging.

A second set of goals is to accomplish the above within the ALARA guidelines - with respect to both patient and operator exposure. Factors which decrease patient dose include: minimizing fluoroscopy time, collimation of the field, avoiding the magnification mode, avoiding the high output mode, minimizing tube angulation, and increasing use of last image hold. Techniques which increase patient dose should be used only when not using them will increase the fluoroscopy time, decrease the likelihood of technical success, and/or increase the risk of technical complication.

With regard to operator exposure, most things that reduce patient dose will reduce operator dose. The exception to this general rule is operator hand exposure - on occasion, the operator will put his/her hands in the field in order to accomplish a task. Doing this can increase the likelihood of technical success, decrease the risk of complication to the patient, and decrease the fluoroscopy time (and with it the patient dose) required to complete the goal. Operator threshold for doing this varies. Other factors which decrease operator exposure include increasing distance from the patient, increasing shielding, and increasing the number of personnel doing the procedures.

### **2. Radiation Safety Practices.**

All fluoroscopists wear lead aprons - although the type may vary. Use of collars, glasses, gloves, and ceiling or floor mount shields varies with operator preference and perception of need. Full time interventionalists should wear custom made aprons, collars and glasses or should use an external shield for the head and neck. Protection provided by leaded gloves is questionable. More attention needs to be paid to shielding and education of support

personnel - technologists, nurses, anesthesiology personnel. The latter, in particular are in close proximity to the patient throughout lengthy procedures.

Fluoroscopy habits and shielding habits vary widely from individual to individual and from institution to institution. Factors which affect both fluoroscopy habits and protection habits are education, personal perception of risk, and institutional example. People tend to imitate their teachers. Good radiation safety habits are most likely to develop if senior physicians set a good example, if senior physicians actively remind and encourage good habits, if the radiation safety officer is actively involved in the department, and if the institution/department treats radiation safety as a priority by investing in proper equipment and shielding for personnel.

### 3. Radiation Dosimetry Project. (1)

This study investigated the occupational radiation dose to interventional radiologists and the operator-controlled factors possibly affecting dose. Thirty interventional radiologists wore radiation badges over-lead and under-lead for two months and answered a questionnaire. Projected yearly doses under and over lead were calculated. The relationships between dose and case-load, case mix, experience, fluoroscopy features, lead apron thickness, and addition lead shielding were evaluated.

#### Radiation Dosimetry Results

Dosimeter Position	Radiation Dose (mSv) - Mean (Range)	
	Monthly Dose	Projected Yearly Dose
Collar over-lead (N=29)	4.6 (0.3-10.9)	49.1 (3.2-114.9)
Waist under-lead (N=29)	0.09 (0.02-0.39)	0.9 (0.22-4.11)

The mean projected yearly dose over-lead was 49.1 mSv (1 mSv = 100 mrem). This is essentially equal to head and neck dose. The only operator - controlled factor to have a statistically significant relationship with over-lead dose was case load (p=0.027). The mean projected yearly over-lead dose for persons doing more than 1000 cases/year was

66.6 mSv. The mean projected yearly over-lead dose for persons doing less than 1000 cases/year was 31.0 mSv. Over-lead dose per case was approximately 0.06 mSv. Experience level was related to over-lead dose but the relationship was not statistically significant in this small sample.

The mean projected yearly dose under-lead was 0.9 mSv. There is some uncertainty to this number because 14/30 subjects had "minimal" dose readings which were arbitrarily assigned a value of 0.05 mSv. The only operator-controlled factor to have a statistically significant relationship with under-lead dose was lead apron thickness ( $p=0.002$ ). Mean projected yearly dose for persons with 0.5 mm Pb equivalent coverage in front was 1.3 mSv. Mean projected yearly dose for persons with 1.0 mm Pb equivalent coverage in front was 0.4 mSv.

Applying the method of Webster (2), the average yearly Effective Dose for study group members wearing 0.5 mm lead aprons was 4.29 mSv. The ED for persons wearing 1 mm thick lead aprons would be lower but a formula has not been derived for its calculation.

Conclusions of this study are that, of the variables examined, case-load and apron thickness are the primary determinants of interventional radiologists' total body occupational radiation dose. In addition, the over-lead dose is high enough to warrant additional shielding to the head and neck (especially the eyes). Finally, the large difference between under-lead and over-lead doses indicates that use of a collar badge alone for monitoring purposes is not predictive of total body Effective Dose for this group of radiation workers.

#### **4. Conclusions.**

Fluoroscopically-guided procedures provide a valuable patient care service and are thus proliferating. Radiation risk must be weighed against the risk of not doing the procedure. Increasing attention must be paid to both patient and operator radiation safety issues. Doses are high enough to warrant changes in radiation safety and monitoring practices.

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The Training and Credentials of  
Fluoroscopists

Stephen Balter, Ph.D.

## The Training and Credentials of Fluoroscopists

Stephen Balter, Ph.D., FACR  
New York City

October 1992

The variety of clinically useful fluoroscopic procedures continues to increase. Fluoroscopic and fluorographic doses increase as these procedures become more complicated and hence longer. The number of procedures is also increasing. Equipment capability has co-evolved with clinical demand. Physicians with a wide variety of backgrounds used fluoroscopy in their practices. Problems occur when relatively untrained physicians use technological wizardry to produce clinical miracles. The inappropriate use of radiation may produce severe adverse health effects in both patients and staff.

The objectives of my presentation are to:

1. Informally review the background and training of those physicians who work with fluoroscopic and fluorographic systems.
2. Discuss some sources of information available to these physicians.
3. Sketch some topics of which all fluoroscopists should be aware.
4. Propose a voluntary program which might fill the existing knowledge gap.

Physicians with increasingly diverse backgrounds depend upon fluoroscopy and fluorography in their clinical practices. There is a wide variation in the nature of their basic radiological training. Radiologists are examined in this subject as part of their board certification process. Other medical specialty boards ask their candidates little or nothing about these topics. Time constraints result in the allocation of few resources to non-board related material. Professional societies make some additional radiological education available to their members. The resulting uneven degree of basic knowledge and understanding is not surprising.

Systematic practical training of fluoroscopic operators in the actual operation of their imaging systems is also important. Equipment manufacturers offer help in the form of operators' manuals, audio-visual training materials, and live instructors. However, even well done self-study materials do not always command top priority. Instructor's visits are often difficult to integrate into busy clinical schedules. Thus practical instruction is commonly reduced to little more than the *see one, do one, teach one* method. The inquiring student usually obtains additional information from radiological technologists, service engineers, and even the occasional odd medical physicist. The lack of practical training may result in sub-optimal or inappropriate equipment use.

What is needed is a process that provides:

1. A basic store of knowledge for all fluoroscopists.
2. Practical training in the actual use of individual pieces of equipment.
3. Means for assuring the qualifications of equipment operators.

Appropriate educational experiences should be included in the training programs of residents and fellows. This will require action by relevant specialty boards. However, all fluoroscopists need to be brought up to a realistic standard of proficiency without undue interference with clinical practice. A proposed standard is that the physician should have the technical and radiobiological knowledge needed to avoid inappropriate radiation exposure.

Professional societies can start the process by offering appropriate short courses to their members. Such courses will most likely have a duration of a day or two. The medical physics community is a source of qualified instructors for many topics. Next, a physician who would like to use a specific piece of equipment would receive brief but formal instruction on its use. Such instruction could be given by the chief technologist, medical physicist, or other qualified individual. Finally, institutional radiation safety, risk management, or quality assurance committees should grant fluoroscopic privileges only to qualified individuals. This voluntary program, even with its own bureaucracy, is probably a better method of reaching our goal than the external imposition of new layers of legal or regulatory requirements. The choice is still available!

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## **Training and Supervision of Fluoroscopists**

**ACR - CDRH  
Workshop on Fluoroscopy**

**Stephen Balter, Ph.D., F.A.C.R.  
October 1992**

SB P9210 - 1

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## **Outline**

**FLUOROSCOPISTS  
INSTRUCTORS  
KNOWLEDGE  
CREDENTIALS**

SB P9210 - 2

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## **Physicians**

**Cardiologists  
Gastroenterologists  
Orthopedic Surgeons  
Radiologists \*  
Urologists  
Others**

SB P9210 - 3

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## **Others**

**Laboratory Technologists  
Nurses  
Physicians Assistants  
Radiological Technologists \*  
Technical Staff**

SB P9210 - 4

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## **Academic**

**General Education  
Pre - Boards  
Medical Meetings  
Continuing Education**

SB P9210 - 5

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## **Self Help**

**Instruction Manuals  
Video Instruction  
Manufacturers' Literature  
Government Publications**

SB P9210 - 6

## Peers

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**See One  
Do One  
Teach One**

SB P9210 - 7

## Applications Specialists

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**New equipment  
Scheduling problems  
Little follow up**

SB P9210 - 8

## Technical Specialists

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**(Provide most of the actual training)**

**Hospital Technical Staff  
Service Engineers  
Medical Physicists**

SB P9210 - 9

## Knowledge

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**Equipment  
Radiation Physics  
Radiation Risk**

SB P9210 - 10

## Knowledge

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**Fluoroscopists should  
know enough to operate  
their systems in a safe  
and effective manner.**

SB P9210 - 11

## Equipment

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**Production and control of  
radiation  
Dose and image quality  
Field size effects  
Radiation shielding**

SB P9210 - 12

## **Dose and image quality**

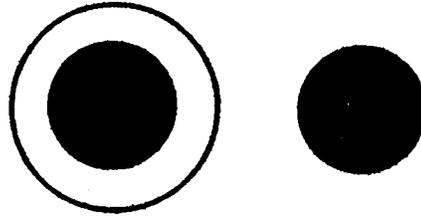
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**DSA Clinical Images 250:1**

SB P9210 - 13

## **Field size effects**

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SB P9210 - 14

## **Radiation shielding**

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**Intrinsic  
Fixed  
Personal**

SB P9210 - 15

## **Radiation Physics**

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**Dosimetry concepts  
Description of output  
Spatial distribution of  
radiation**

SB P9210 - 16

## **Dosimetry Concepts**

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**Exposure  
Dose  
Integral Dose  
Dose Equivalent**

SB P9210 - 17

## **Description of Output**

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**Electrical (KV, MA, S)  
In air  
Patient entrance  
Image Intensifier**

SB P9210 - 18

## Spatial distribution of radiation

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**Drawing of Asymmetric Scatter**

SB P9210 - 19

## Radiation risk

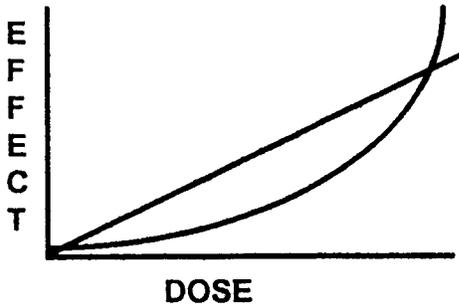
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**Deterministic  
Stochastic  
Fetal  
Legal**

SB P9210 - 20

## Stochastic

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SB P9210 - 21

## Legal

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**International  
Federal  
State**

SB P9210 - 22

## Legal

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**Accreditation  
Reimbursement**

SB P9210 - 23

## Credentials

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**Licences  
Boards  
Voluntary  
Privileges**

SB P9210 - 24

## What was covered

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**FLUOROSCOPISTS  
INSTRUCTORS  
KNOWLEDGE  
CREDENTIALS**

SB P9210 - 25

## The problem

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**More cases  
Longer cases  
Increasing instrument  
capabilities  
Decreasing operator  
knowledge**

SB P9210 - 26

## What can be done

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**Legal  
Boards  
Voluntary  
Privileges**

SB P9210 - 27

## Important

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**The profession should  
take responsibility  
and avoid unnecessary  
bureaucracy !**

SB P9210 - 28

## Bureaucracy

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**State licences  
Federal licences  
Manufacturers' labeling of  
approved use  
Mandatory dosimetry in  
patients' charts**

SB P9210 - 29

## Boards

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**Boards are for newcomers  
  
Practicing physicians  
are a problem  
Evolving medical care  
is a problem**

SB P9210 - 30

## **Boards**

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**Academic training  
Practical experience  
Individual dosimetry log  
Formal examinations**

SB P9210 - 31

## **Voluntary**

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**Academic training by  
professional societies  
Formal "check ride"  
before using system  
Monitor patient dose  
Monitor staff dose**

SB P9210 - 32

## **Voluntary**

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**Patients look for certificate  
(ACR Mammography)**

SB P9210 - 33

## **Privileges**

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**Institutions should regard  
the use of ionizing  
radiation to be a privilege  
granted only to those  
with appropriate training  
and experience.**

SB P9210 - 34

## **Qualifications for privileges**

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**Evidence of academic or  
postgraduate training  
  
Completion of "check ride"  
  
Ongoing dosimetry (?)**

SB P9210 - 35

## **End Note**

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**It is much better to  
protect our patients and  
ourselves by our own  
efforts than to have a well  
meaning government do  
it for us !**

SB P9210 - 36

Physician's Credentials and  
Privileges for Use of Fluoroscopy

James B. Spies, M.D.

## Physician's Credentials and Privileges for Use of Fluoroscopy

James B. Spies M.D., Society of Cardiovascular and Interventional Radiology

Given the serious potential hazards associated with the use of fluoroscopic equipment, training of all individuals operating such equipment is essential. Unlike other types of radiographic examinations, physicians are the primary operators of fluoroscopes. As a result, they control the duration of exposure, as well as other exposure factors, and thus control the radiation dose.

There is no universal requirement for training or regulating physician users of fluoroscopic equipment. Only the American Board of Radiology requires the training and testing of physician candidates in radiation physics and radiation safety prior to board certification. No other medical specialties train or test their physician trainees routinely. In addition, there are few states that regulate the operators of fluoroscopic equipment and hospitals generally do not require radiation safety training prior to granting privileges for fluoroscopy.

There are several potential means of improving the safety of operators. These include voluntary education standards, mandatory training standards, certification of operators by specialties or regulatory agencies, or by having hospitals require certification prior to granting or renewing privileges for fluoroscopic equipment use.

Because the radiation risk varies with each specialties' needs, developing universally acceptable standards for training and testing in radiation physics and safety is difficult. For instance, a radiologist performs many fluoroscopically-guided procedures, in different organ systems, and for both diagnostic and therapeutic purposes. In addition, a radiologist often must assume responsibility for overseeing the purchase, use and maintenance of radiographic equipment in both outpatient and inpatient facilities. This level of responsibility requires extensive training in radiation physics, principles of equipment design and function, and radiation safety. An orthopedic surgeon, on the other hand, has limited need for fluoroscopic guidance, generally during reduction of fractures or in joint replacement. Thus the use of the fluoroscope is limited to occasional use and a single organ system. The level of fluoroscopic use is greater for invasive cardiologists and urologists who perform fluoroscopically guided procedures and therefore so is the need

for training .

The best solution is to require training for all physicians who wish to operate fluoroscopic equipment, with certification required prior to receiving privileges. The certification could 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. The requirement for each specialty should vary (10-50 hours training with subsequent testing), depending on the use associated with each specialty. Thus, the requirement for orthopedists might be considerably less than that for invasive cardiologists, interventional gastroenterologists or other heavy users of fluoroscopy. Such a limited permit would require supervision by the radiation safety officer at the facility. The requirements of the curriculum could be tailored for each specialty. The training necessary could be provided during residency or fellowship or through CME courses for those who have completed their formal training programs.

The ideal means of enforcing such a system is via the JCAHO ( Joint Commission for the Accreditation of Health Organizations). If the JCAHO were to require certification as outlined above, each health facility would have to see that their staffs complied. Since all health facilities require accreditation by the JCAHO in order to receive Medicare and Medicaid funds, adding a requirement for fluoroscopy certification would in essence be self-enforcing by the individual facilities. The alternative of federal or state regulation would be expensive and the relevant agencies in the government already have very few resources for enforcement.

# Appendix

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The following proposed rule was published in the  
FEDERAL REGISTER / Vol. 58, No. 83 / Monday, May 3, 1993,  
beginning on page 26407.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 1020

[DOCKET NO. 92N-0108]

FEDERAL PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS AND THEIR  
MAJOR COMPONENTS

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing amendments to the Federal performance standard for diagnostic X-ray systems and their major components (the performance standard), amendments to which are published elsewhere in this issue of the FEDERAL REGISTER as a final rule. The proposed amendments revise the limits established for maximum radiation emissions for fluoroscopic X-ray systems during high-level control and other modes of operation. The revisions are being proposed due to concerns regarding excessively high radiation exposure levels on some fluoroscopy systems.

DATES: Comments by August 2, 1993. FDA proposes that any final rule based on this proposed rule become effective 1 year after the date of its publication in the FEDERAL REGISTER.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan,  
Center for Devices and Radiological Health (HFZ-84),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-443-4874.

## SUPPLEMENTARY INFORMATION:

## I. BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as amended, FDA is proposing to amend the performance standard for diagnostic X-ray systems and their major components in § 1020.32 (21 CFR 1020.32), by revising the limits established for maximum radiation emissions for fluoroscopic X-ray systems during high-level control and other modes of operation. In the FEDERAL REGISTER of August 15, 1972 (37 FR 16461), the performance standard was published as a final rule, which became effective on August 1, 1974. Since that time, there have been several amendments to the performance standard. These amendments take into account new technology, clarify misinterpreted provisions, or incorporate additional requirements determined to be necessary to provide for adequate radiation safety of diagnostic X-ray systems. (See, e.g., those published October 7, 1974 (39 FR 36008); February 25, 1977 (42 FR 10983); September 2, 1977 (42 FR 44230); November 8, 1977 (42 FR 58167); May 22, 1979 (44 FR 29653); August 24, 1979 (44 FR 49667); November 30, 1979 (44 FR 68822); April 25, 1980 (45 FR 27927); and August 31, 1984 (49 FR 34698 at 34712)). FDA also proposed amendments to the performance standard in the FEDERAL REGISTER of October 17, 1989 (54 FR 42674), corrected January 16, 1990 (55 FR 1472), and is publishing a final rule amending the standard elsewhere in this issue of the FEDERAL REGISTER.

In § 1020.32(d) of the performance standard, limits on the entrance exposure rate for fluoroscopic systems are specified. These requirements limit the maximum entrance exposure rate to which a patient may be exposed during normal fluoroscopy. (In this discussion, normal fluoroscopy refers to fluoroscopy without activation of the high-level control mode or recording of images.) The current performance standard does not impose entrance exposure rate limits for fluoroscopic systems when they are operated in an optional high-level exposure mode or when fluoroscopic images are recorded. In the performance standard, FDA provided for the optional high-level mode of operation to permit increased radiation output over that normally necessary for fluoroscopic imaging, for situations involving very large patients or for special imaging requirements. By creating an exemption from the entrance exposure rate limits for normal fluoroscopy for the period during recording of images, FDA recognized the higher exposure rates used when recording fluoroscopic images on film.

When these requirements limiting entrance exposure rates were originally developed and proposed, there was a lack of consensus as to appropriate entrance exposure rate limits during high-level control or during recording of images. This lack of consensus was due to the fact that the exposure rate necessary is determined by the quality of the image required to accomplish the clinical task,

and no quantitative or standard description of the required image quality was possible. In view of this lack of consensus as to appropriate entrance exposure rate limits during high-level mode or during recording of images, no limits were established, and the question of appropriate limits was left for further study and possible future amendments.

In addition, when the requirements of § 1020.32(d) were developed, due to the increasing use of fluoroscopic systems that provided automatic exposure rate control, there was some controversy as to the appropriate entrance exposure rate limits during normal fluoroscopy. FDA originally proposed a limit of 5 roentgens per minute (R/min) on the entrance exposure rate during normal fluoroscopy, based on voluntary recommendations regarding equipment performance from the National Council on Radiation Protection and Measurements (NCRP). Some concern was raised in the comments on the proposed standard that a limit of 5 R/min would limit the capabilities of some newly introduced fluoroscopic systems, which provided automatic exposure rate control during fluoroscopy. It was argued that to operate effectively, these systems required exposure capabilities exceeding 5 R/min.

To accommodate these systems, the performance standard, as finally published, established two limits on entrance exposure rate for systems providing automatic exposure rate control, depending on whether or not the system provided a high-level mode of operation. For systems with automatic exposure rate control which do not provide high-level control, the limit on entrance exposure rate was set at 10 R/min during normal fluoroscopy. For automatic exposure rate control systems provided with a capability for high-level mode operation, the entrance exposure rate was set at 5 R/min unless the high-level control was activated. When the high-level control is activated, there is no limit on entrance exposure rate.

Recent testing of fluoroscopic X-ray systems and reviews of the operational capabilities of some systems by FDA and others have raised concerns regarding the potential for unnecessary radiation exposures to patients from some current system designs. These concerns arise from two aspects of the current performance standard and the increased radiation output capability of some recently introduced fluoroscopic X-ray systems. First, the lack of a limit on radiation emission during high-level control mode of operation has allowed systems to be marketed which have unlimited entrance exposure rates during high-level mode. These exposure rates are many times greater than the maximum rates allowed during normal fluoroscopy. The clinical need for such high radiation output has not been demonstrated.

Second, the current requirements for systems with automatic exposure rate control can result in increased use of the high-level control mode for systems limited to 5 R/min during normal fluoroscopy. For those imaging situations when entrance exposure

rates greater than 5 R/min might be required, the operator is forced to use the high-level mode, which, due to the lack of a limit on exposure rate during high-level mode, may result in significantly higher exposures than necessary. Rather than operating at exposure rates of 6 or 7 R/min, the system may operate in the range of 10 to 20 R/min or higher, depending on the system adjustment for the high-level mode.

In view of these concerns, FDA discussed proposed draft amendments to the performance standard during a public meeting of the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC) on November 14, 1990. TEPRSSC is a statutory advisory committee (21 U.S.C. 360kk(f)(1)(A)) that FDA is required to consult before it may prescribe any electronic product performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602). TEPRSSC approved the content of the proposed amendments and concurred with publication of them for public comment (Ref. 1). Accordingly, FDA is proposing to amend the performance standard as indicated below.

## II. PROPOSED AMENDMENTS TO THE PERFORMANCE STANDARD FOR DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

### A. Change in Unit for the Quantity Exposure

Elsewhere in this issue of the FEDERAL REGISTER, the agency is setting forth a policy to implement the International System of Units (SI) throughout the performance standard. FDA proposes to change the units used in the performance standard for the quantity exposure from the current unit of roentgen (R) to the SI units of coulomb per kilogram (C/kg). The new units will be followed in the amended standard by its equivalent in roentgens in parentheses to assist in the transition to the new unit.

FDA notes that adoption of the SI system of units by the radiation protection field is resulting in a period of transition for the unit used for the quantity exposure and the instrumentation used to measure this quantity and its calibration. The previously used unit for exposure, the roentgen, is not a unit consistent with the SI system.

Use of the SI units for the quantity exposure, the C/kg, results in numerical quantities that are somewhat awkward compared to previous values encountered in radiation protection activities and used in the performance standard. (Compare 5 R to its equivalent of  $1.29 \times 10^{-3}$  C/kg.) The use of the quantity exposure in radiation protection activities is gradually being phased out, and the quantity air kerma is being adopted as the quantity to describe the intensity of an X-ray or gamma-ray field in many circumstances.

This change can also lead to values for limits which appear awkward when the limits, formerly expressed as integer values in R, are expressed using equivalent limits of the air kerma and its SI unit, the gray (Gy). For example, a limit of 10 R on exposure would be equivalent to a limit of 8.7 centigray (cGy), or 87 milligray (Mgy), when expressed as the quantity air kerma.

In this proposal, which primarily deals with fluoroscopic entrance exposure rate limits, FDA is not proposing to adopt the quantity air kerma for use in the performance standard. FDA does invite comment on the approach which should be taken in the entire performance standard for diagnostic X-ray systems regarding the quantities and units to describe the intensity of the X-ray field. Adoption of the quantity air kerma and the description of limits as integer values, a desirable approach for ease of use, could require changes in the present regulatory limits. For example, an exposure rate limit of 10 R/min expressed as an air kerma rate limit of 100 Mgy/min would involve an effective increase in the limit of about fifteen percent. Recent revision of NCRP recommendations were published as NCRP Report 102, entitled "Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies Up to 50 MeV" (Ref. 2). This report adopted the use of air kerma as the quantity to describe the radiation field, used integer values for the recommended limits, and effectively increased previous NCRP recommended limits by about 15 percent.

#### B. Entrance Exposure Rate Limit During Normal Fluoroscopy

FDA proposes to replace the current two-tier system of limits on entrance exposure rate during normal fluoroscopy with automatic exposure rate control (AERC), contained in § 1020.32(d), with a single limit of 10 R/min on the entrance exposure rate. The current standard has limits of 5 or 10 R/min on the entrance exposure rate during normal fluoroscopy, depending on whether or not the system has a high-level control. This change increases the limit on entrance exposure rate during normal fluoroscopy for systems having AERC and high-level control from the current value of 5 to 10 R/min. In the revised standard, this limit would be expressed in SI units as a limit of  $2.58 \times 10^{-3}$  C/kg per minute followed by the limit in the older units in parentheses expressed as (10 R/min).

The current requirement of § 1020.32(d)(1) limits the output, during normal fluoroscopy, of systems with a high-level control to less than 5 R/min. For examinations where system output levels of slightly more than 5 R/min are required for the diagnostic task, these systems must be operated in the high-level mode. In this case, instead of the output being that needed for the examination, say in the range of 5 to 10 R/min, the output characteristic of

high-level control is delivered. For many systems, the maximum output in high-level mode is considerably greater than 10 R/min.

This change will affect the small portion of fluoroscopic systems which have high-level controls and AERC. The impact will be to increase the range of patient sizes which can be accommodated in normal fluoroscopy without having to resort to high-level control. It will also bring the performance standard into closer agreement with the recommendations in NCRP Report 102 (Ref. 2), which uses "should" for the 5 cGy/min limit and "shall" for the 10 cGy/min limit on recommended entrance kerma rates.

### C. Entrance Exposure Rate During High-Level Fluoroscopy

FDA proposes to establish a limit on the maximum patient entrance exposure rate permitted during high-level control mode of fluoroscopy. The limit proposed is 20 R/min, which is twice the maximum entrance exposure rate of 10 R/min, which would be allowed during normal fluoroscopy.

The current standard places no limit on system output or entrance exposure rate during the high-level control mode of fluoroscopic imaging. Only a small fraction of fluoroscopic systems are provided with the high-level control capability. Of these systems, a majority operate with the maximum entrance exposure rate during high-level control limited to values less than 20 R/min. However, because there is no upper limit, some systems are adjusted such that the entrance exposure rate during high-level control is considerably greater than 20 R/min. FDA testing has revealed systems with maximum entrance exposure rates during high-level control in the range of 40 to 70 R/min. Reports of systems with outputs exceeding 100 R/min have been received. The clinical justification for such high radiation output has not been established.

In response to a request for comments on a preliminary draft of these proposed amendments made available to a number of professional organizations, manufacturers, and others, a comment was received from a medical physicist at a large medical institution. This comment made the observation that, at his facility, none of the 65 fluoroscopic systems was equipped with the optional high-level control, and he questioned the need for a high-level control. He described his facility as doing the full range of fluoroscopic and special procedures, including interventional procedures, without the need for high-level control. He described other steps which could be taken using modern equipment to enable adequate imaging of large patients without subjecting them to the radiation exposure associated with high-level control mode of operation. Among these suggestions were imaging without using a grid or adjusting the iris in front of the television camera. In view of these comments, FDA solicits

comments specifically on the need for a high-level control mode and whether such a mode should be allowed by the performance standard, as well as comments on the proposed limit for exposure rate during high-level control operation.

#### D. Requirement for Automatic Exposure Rate Control

FDA proposes that any fluoroscopic system capable of operating at greater than 5 R/min entrance exposure rate must be provided with an AERC mode of operation. Except for a few examinations with special imaging requirements not accommodated under AERC, the preferred mode of operation of a fluoroscopic X-ray system is with AERC. This frees the physician to concentrate on the clinical aspects of the examination, without concern for equipment technique factors during the examination, and generally results in images of appropriate brightness or density. Establishing the requirement for the provision of AERC at an entrance exposure rate greater than 5 R/min will permit currently marketed "manual only" systems to continue to be marketed, while requiring that AERC be available on any systems with output capability above 5 R/min for normal and high-level fluoroscopy.

#### E. Limit on Entrance Exposure Rate During Recording of Continuous Fluoroscopy

FDA proposes to apply the entrance exposure rate limits during the continuous recording of dynamic fluoroscopic images with a video tape recorder or similar device. Currently, the performance standard places no limit on the radiation output during recording of the fluoroscopic image. This exemption has been interpreted to apply when the video signal from the video camera is recorded with a video tape recorder. The result is that the limit on radiation output during normal fluoroscopy (and during high-level control under the changes proposed here) is negated by simply attaching a video tape recorder to the system. This practice can be used to bypass the limit on entrance exposure rate during fluoroscopy, regardless of whether the recorded video images are used.

The appropriate controls or entrance exposure rate limits for video recording using a sequence of pulsed radiation exposures, such as with progressively scanned cameras, or for digital recording, such as digital subtraction procedures, needs further study to determine appropriate limits. Thus, the exemption to the entrance exposure rate limits would continue to apply during these other means of recording images. Furthermore, any recording that requires pulsed exposure (pulsed tube current), such as cinefluorography or photospot filming, would still be exempted from the entrance exposure rate limits.

F. No Intended Effect On Already-Existing X-ray Systems Or Their Major Components

These amendments are not intended to impose any new requirements on X-ray systems or their major components manufactured before (insert date of publication in the FEDERAL REGISTER).

III. REFERENCES

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. to 4 p.m., Monday through Friday.

1. Agenda and Background Information, 21st meeting, Technical Electronic Product Radiation Safety Standards Committee, Center for Devices and Radiological Health, June 22 and 23, 1987.

2. National Council on Radiation Protection and Measurement, Report No. 102, "Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV," June 30, 1989.

IV. ENVIRONMENTAL IMPACT

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. ECONOMIC IMPACT

FDA has identified three types of potential costs that might be associated with implementation of the proposed amendment. These are: (1) Costs to manufacturers resulting from changes in system design and installation procedures required to meet the new requirements; (2) costs to Federal and State regulatory programs to implement and enforce the new requirements; and (3) costs to X-ray facilities to conduct quality assurance evaluations of X-ray systems. The costs to Federal and State regulatory agencies and to X-ray facilities are not anticipated to be significant. The testing required to ensure compliance with the performance standard and quality assurance requirements can easily be included in current testing programs with minimal additional costs. The total costs to manufacturers to meet the new requirements are estimated

to be \$760,000, based on estimated labor and materials costs of \$362,000 (\$1,000 per system with high-level control mode for an estimated 362 systems), and estimated overhead costs associated with implementation of \$400,000 (\$50,000 per manufacturer for eight manufactures). This proposal establishes a maximum entrance exposure rate to which a patient can be exposed when fluoroscopic systems are operated in high-level control mode. The proposal also revises the maximum limit for entrance exposure rate during normal fluoroscopy, which should reduce the need for use of high-level control mode, with its attendant higher exposure rates. These actions offer a significant public health benefit by reducing the potential for unnecessary radiation exposure of patients and staff. After consideration of the economic consequences of the proposed amendments, FDA certifies that this proposal requires neither a regulatory impact analysis, as specified in Executive Order 12291, nor a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (5 U.S.C. 601-612). A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (address above) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

#### VI. COMMENTS

Interested persons may, on or before August 2, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1020 be amended as follows:

#### PART 1020--PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. The authority citation for 21 CFR part 1020 continues to read as follows:

AUTHORITY: Secs. 501, 502, 515-520, 530-542, 701, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e-360j, 360gg-360ss, 371, 381).

2. Section 1020.30 is amended in paragraph (b) by alphabetically adding a new definition for "Pulsed mode" to read as follows:

§ 1020.30 Diagnostic X-ray systems and their major components.

\* \* \* \* \*

(b) Definitions. \* \* \*

\* \* \* \* \*

Pulsed mode means operation of the X-ray system such that the X-ray tube current is pulsed by the X-ray control to produce one or more exposure intervals of duration less than one-half second.

\* \* \* \* \*

3. Section 1020.32 is amended by revising paragraph (d), by redesignating paragraphs (e) through (h) as paragraphs (f) through (i) respectively, and by adding new paragraph (e) to read as follows:

§ 1020.32 Fluoroscopic equipment.

\* \* \* \* \*

(d) Entrance exposure rates. For fluoroscopic equipment manufactured before (insert date 1 year after date of publication of the final rule in the FEDERAL REGISTER), the following requirements apply:

(1) Equipment with automatic exposure rate control (AERC). Fluoroscopic equipment which is provided with AERC shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $2.58 \times 10^{-3}$  coulomb per kilogram (C/kg) per minute (10 roentgens per minute (R/min)) at the point where the center of the useful beam enters the patient, except:

- (i) During recording of fluoroscopic images, or
- (ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $1.29 \times 10^{-3}$  C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) Equipment without AERC (manual mode). Fluoroscopic equipment which is not provided with AERC shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $1.29 \times 10^{-3}$  C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, except:

- (i) During recording of fluoroscopic images, or
  - (ii) When an optional high-level control is activated.
- Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) Equipment with both an AERC mode and a manual mode. Fluoroscopic equipment which is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $2.58 \times 10^{-3}$  C/kg per minute (10 R/min) in either mode at the point where the center of the useful beam enters the patient, except:

- (i) During recording of fluoroscopic images, or
- (ii) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $1.29 \times 10^{-3}$  C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level is being employed.

(4) Measuring compliance. Compliance with paragraph (d) of this section shall be determined as follows:

- (i) If the source is below the X-ray table, the exposure rate shall be measured at 1 centimeter above the tabletop or cradle.
- (ii) If the source is above the X-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- (iii) In a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the imaging assembly.

(iv) In a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source, with the

end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

(5) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (d) of this section.

(e) Entrance exposure rate limits. For fluoroscopic equipment manufactured on and after (insert date 1 year after date of publication of the final rule in the FEDERAL REGISTER), the following requirements apply:

(1) Fluoroscopic equipment operable at any combination of tube potential and current which results in an exposure rate greater than  $1.29 \times 10^{-3}$  C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with automatic exposure rate control. Provision for manual selection of technique factors may be provided.

(2) Fluoroscopic equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $2.58 \times 10^{-3}$  C/kg per minute (10 R/min) at the point where the center of the useful beam enters the patient, except:

(i) During the recording of images from an X-ray image intensifier tube using photographic film or a video camera when the X-ray source is operated in a pulsed mode.

(ii) When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of  $5.16 \times 10^{-3}$  C/kg per minute (20 R/min) at the point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) Measuring compliance. Compliance with paragraph (e) of this section shall be determined as follows:

(i) If the source is below the X-ray table, the exposure rate shall be measured at 10 millimeters above the tabletop or cradle.

(ii) If the source is above the X-ray table, the exposure rate shall be measured at 300 millimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured at 300 millimeters from the input surface of the

fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 300 millimeters from the input surface of the fluoroscopic imaging assembly.

(iv) In a lateral type of fluoroscope, the exposure rate shall be measured at a point 150 millimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 150 millimeters to the centerline of the X-ray table.

(4) Exemptions. Fluoroscopic radiation therapy simulation systems are exempt from the requirement set forth in paragraph (e) of this section.

\* \* \* \* \*

Dated: April 21, 1993.

/Signed/  
Michael R. Taylor  
Deputy Commissioner for Policy