

PROCEEDINGS OF THE  
ACR/FDA WORKSHOP  
ON FLUOROSCOPY

STRATEGIES FOR IMPROVEMENT IN  
PERFORMANCE, RADIATION SAFETY  
AND CONTROL

DULLES HYATT HOTEL  
WASHINGTON, D.C.  
OCTOBER 16 AND 17, 1992

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## ACKNOWLEDGMENTS

Of the many people involved in the realization of this Workshop on fluoroscopy, three deserve special mention. Otha Linton of the American College of Radiology (ACR) first suggested that a multi-medical specialty forum be used to address and discuss issues of high exposure rate fluoroscopy. To this end he helped facilitate the ACR Grant proposal to seek FDA funding and summon ACR support. Rebecca Kupper and Phyllis Martzke of the ACR Government Relations Department deserve recognition for all of their time and effort in putting together the ACR Grant and providing ACR logistics support for the workshop. Finally, Tom Shope of the FDA, worked diligently in the planning of the workshop. Thanks are also due to all of the speakers and workgroup leaders whose knowledge, concern and efforts made this workshop possible.

The opinions and statements contained in these proceedings are those of the authors and participants and may not reflect the views of the American College of Radiology or the Center for Devices and Radiological Health, Food and Drug Administration. The mention of commercial products is not to be construed as either an actual or implied endorsement of such products by the above organizations.

## Preface

In 1990, the Food and Drug Administration circulated a draft of a proposed amendment to the Federal radiation safety performance standard for diagnostic x-ray systems. This proposed amendment would establish a maximum limit on patient entrance exposure rate for fluoroscopic x-ray systems when operated in the high level control mode. The American Collage of Radiology commented on this draft proposed amendment and suggested that additional discussion of the clinical impact of the proposal was required. The ACR suggested that a meeting or workshop to provide a forum for discussions of a number of issues related to fluoroscopy would be useful to foster improved usage and control of fluoroscopy.

The impetus for the workshop was further driven by growing concerns over the trend toward fluoroscopic x-ray systems with greatly increased radiation output capability and the potential for inappropriate use of such capabilities. Also of concern was the increased use of fluoroscopy in therapeutic interventional procedures leading to marked increases in fluoroscopic "beam on" time.

Mid-year 1992, a Conference Grant was awarded to the American College of Radiology by the Food and Drug Administration to hold a two day Fluoroscopy Workshop. The grant provided partial funding to hold the conference and produce proceedings of the conference. The Workshop was attended by invited participants and included invited physician users, medical physicists, Federal and State regulators and representatives of industry. In particular, the following specialty societies and organizations were represented:

- American College of Cardiology
- American Academy of Orthopedic Surgeons
- American College of Radiology
- American Association of Physicists in Medicine
- American Urological Association
- Society for Cardiac Angiography and Interventions
- Conference of Radiation Control Program Directors
- Center for Devices and Radiological Health
- National Electrical Manufactures Association
- Society of Cardiovascular and Interventional Radiology
- National Council of Radiation Protection and Measurements

The Fluoroscopy Workshop was held Oct.16-17,1992 at the Dulles Hyatt Hotel, Washington D.C. Approximately, 125 persons participated. Participants were divided into four groups for the Workshop sessions. The proceedings are divided into two sections. Section one consists of a synopsis of all the presentations as recorded by a science writer. It also includes summaries of the discussions among attendees which occurred following sections of the program. Also, at the end of Section One are the recommendations of the four Workgroups which developed recommendations regarding specific issues posed to the Workgroups.

Section two consists of papers submitted by the presenters (not all presenters submitted papers). There are also selected references and a copy of the FDA's proposed rule concerning high level control fluoroscopy published in the Federal Register, Vol. 58, No. 83, May 3, 1993. The workshop was well received and should stimulate further work.

Chairperson: J. Thomas Payne PhD ACR

## FINAL PROGRAM

Workshop on Fluoroscopy  
October 16 and 17, 1992  
Strategies for Improvements in Performance, Radiation Safety and Control

### October 16, 1992 (Day 1)

7:00 -8:00 a.m.      Registration

#### Session 1- Introduction

- 8:00 - 8:05 a.m.      Welcome and discussion of meeting format and logistics - J. Thomas Payne, Ph.D.
- 8:05 - 8:15 a.m.      Opening Remarks - The ACR Perspective of Fluoroscopy - J. Thomas Payne, Ph.D.
- 8:15 - 8:25 a.m.      Opening Remarks - The FDA Perspective of Fluoroscopy - Elizabeth Jacobson, Ph.D..
- 8:25 - 8:45 a.m.      The FDA's Role and Authorities Regarding Fluoroscopy - Thomas B. Shope, Ph.D.
- 8:45 - 9:05 a.m.      The Role of the States Regarding Fluoroscopy - Michael A. Odlaug, M.S., M.P.H.
- 9:05 - 9:15 a.m.      Questions and Discussion

#### Session 2 - Fluoroscopy Systems

- 9:15 - 9:45 a.m.      Review of Fluoroscopy Equipment Operation and Performance - Paul Lin, Ph.D.
- 9:45 - 10:15 a.m.      Engineering Considerations for Fluoroscopic Systems - Mel Siedband, P.E.
- 10:15 - 10:30 a.m.      Coffee Break
- 10:30 - 11:00 a.m.      Fluoroscopic Systems Control, Evaluation and Performance - Joel Gray, Ph.D.
- 11:00 - 11:15 a.m.      Questions and Discussion
- 11:15 - 11:35 a.m.      Evaluation of Systems with High Level Control Mode - Christopher Cagnon, B.A.
- 11:35 - 11:55 a.m.      Assessment of Fluoroscopic System Performance - Orhan Suleiman, Ph.D.

11:55 - 12:15 p.m. The NEMA Perspective on Fluoroscopy - Robert G. Britain,  
Vice President, Medical Products, National Electrical  
Manufacturers Association

12:15 - 12:30 p.m. Questions and Discussion

12:30 - 1:30 p.m. Lunch Break

**Session 3 - Clinical Perspectives of Fluoroscopy**

1:30 - 1:45 p.m. General/Gastrointestinal Radiology - David W. Gelfand,  
M.D.

1:45 - 2:00 p.m. Interventional Radiology - John Cardella, M.D.

2:00 - 2:15 p.m. Cardiovascular - Diagnosis - Jeffrey Brinker, M.D.

2:15 - 2:35 p.m. Cardiovascular - Interventional - Malcolm Bell, M.D.

2:35 - 2:50 p.m. Urology - Keith VanArsdalen, M.D.

2:50 - 3:05 p.m. Orthopaedic Radiology - Larry Crossett, M.D.

3:05 - 3:35 p.m. Controlling Patient and Personnel Fluoroscopic Exposure  
Levels in the Clinical Setting - One Institution's Experience  
- Gary T. Barnes, Ph.D.

3:35 - 3:50 Questions and Discussion

3:50 - 4:05 p.m. Organize Workshop Groups

4:05 - 4:30 p.m. Break

**Session 4 - Workshops**

4:30 - 5:30 p.m. Workshop Groups Meet to Discuss Assigned Topics

5:30 - 7:30 p.m. Dinner Break

7:30 - 9:00 p.m. Informal Workshop Group Discussions

**October 17, 1992 (Day 2)**

**Session 5 - Utilization Concerns**

7:00 - 8:00 a.m. Continental Breakfast

8:00 - 8:45 a.m. Radiation Bioeffects and Fluoroscopic Exposures - Louis K.  
Wagner, Ph.D.

8:45 - 9:30 a.m. Fluoroscopic Radiation Safety - Libby F. Brateman, Ph.D.  
and Victoria Marx, M.D.

- 9:30 - 9:45 a.m. Questions and Discussion
- 9:45 - 10:15 a.m.. The Training and Credentials of Fluoroscopists -  
Stephen Balter, Ph.D.
- 10:15 - 10:30 a.m. Hospital Experiences with Credentialing and Training -  
Mary E. Moore, M.Ed., M.S.
- 10:30 - 10:45 a.m. Physician Credentials and Privileges - James B. Spies, M.D.
- 10:45 - 11:00 a.m. Questions and Discussion
- 11:00 - 11:30 a.m. Break
- Session 6 - Workshop Deliberations and Recommendations**
- 11:30 - 1:00 p.m. Workshop groups meet with working lunch
- 1:00 - 1:30 p.m. Break
- 1:30 - 2:30 p.m. Presentation of Workshop Results (15 minutes per group  
including discussion).
- 2:30 - 3:00 p.m. Discussion of recommendations and summary
- 3:00 p.m. Adjournment

**ACR/FDA WORKSHOP ON FLUOROSCOPY  
STRATEGIES FOR IMPROVEMENTS  
IN PERFORMANCE, RADIATION SAFETY, AND CONTROL**

**OCTOBER 16 AND 17, 1992**

**SESSION 1: INTRODUCTION**

**THE ACR PERSPECTIVE ON FLUOROSCOPY**

**J. THOMAS PAYNE, PH.D.**

CHAIRMAN, AMERICAN COLLEGE OF RADIOLOGY COMMISSION ON PHYSICS AND RADIATION SAFETY, AND MEDICAL PHYSICIST, ABBOTT-NORTHWESTERN HOSPITAL, MINNEAPOLIS, MINNESOTA.

When the X-ray Equipment Standards were adopted by the Food and Drug Administration in 1974, an interesting category of fluoroscopy performance was created: the High Level Control (HLC) mode. In this mode there is no upper limit to the table-top radiation exposure rate. The only requirements in HLC mode are that there is a continuous manual activation exposure switch and that there is a continuous audible signal. Since 1974, dramatic advances in X-ray tube technology have taken place. With these new "turbocharged" systems, it is possible to obtain fluoroscopic table-top exposure rates of 20-120 R/min in HLC. Diagnostic fluoroscopes are now capable of operating at radiation therapy dose rates.

Another trend is the development of vascular interventional procedures which require long fluoroscopy times (beam "on" times of 60 minutes or more). Often these procedures are performed by physicians with little or NO training in radiation safety. This can lead to significant radiation risks to both patients and personnel. Recently, an interventional procedure was performed at a hospital using a fluoroscope in HLC mode in which the patient received a severe radiation skin burn. The total fluoroscopy beam "on-time" was approximately 100 minutes. The estimated patient entrance exposure rate was about 20 R/min. Thus, the resultant skin exposure was 1000-2000 Roentgens. This is unfortunate and should be avoided.

Thus, the following questions have been raised and are the backdrop for this workshop. Should long fluoroscopy procedures be performed in High Level Mode (i.e., is it a good thing to engage a high-level system for 100 minutes at 20 R/min for a 2000 R skin exposure)? Should there be maximum output limits to HLC? Is it okay to hook a VCR to a fluoroscope to bypass the normal table-top limits when one goes into a recording mode? What about education and training in the use of fluoroscopy? What is the role of risk management in fluoroscopy? How can we optimize equipment performance? And finally, how can we do better?

## THE FDA PERSPECTIVE ON FLUOROSCOPY

ELIZABETH JACOBSON, PH.D.

DEPUTY DIRECTOR FOR SCIENCE AND TECHNOLOGY, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA.

Good morning. On behalf of the FDA's Center for Devices and Radiological Health, I would like to welcome you to this most important workshop. I am Liz Jacobson, Deputy Director for Science at FDA's Center for Devices and Radiological Health. I am pleased to have been asked to give the FDA perspective on fluoroscopy. Let me give you the bottom line first. We are concerned-- very concerned-- about high radiation output in high output modes and in interventional procedures.

We have some regulatory tools with which to approach this problem, but the problem is much broader, and will require the interaction of government, industry and the clinical community to fully address it. Dr. Shope, who will speak to you after me, will give you a rather complete discussion of FDA's role and the authorities that we have to deal with fluoroscopy.

Let me just say, that for those of you who may not be familiar with the Radiological Health part of the FDA, our mandate is to protect the public from unnecessary radiation exposure which dates back to the 1960's. As Dr. Payne indicated, we do have a mandatory performance standard for diagnostic X-ray systems and their major components which became effective in 1974. Dr. Shope will discuss the requirements in that standard that pertain to fluoroscopy and the rationale for those requirements. Suffice it to say that right now the standard does not contain limits on exposure rate during high-level-control mode (HLC) or during recording of images, nor does it contain any requirements regarding imaging performance. We have become very concerned about the recent trend towards equipment with increased radiation exposure capability (>100 R/min ) and increased exposure times (greater than 100 minutes of beam "on" time) associated with complex procedures. There have been reports of situations where patients have suffered acute radiation injury (skin burns, hair loss and tissue damage).

Now it is conceivable, I suppose, that there could be situations where the benefit of the procedure outweighs the radiation risk to the patient, but the public health concern is very real. We need to assure that users of fluoroscopy systems are cognizant of the potential for high radiation exposure from the procedure, especially interventional procedures. Which brings me to the genesis of this conference. A couple of years ago, we in the FDA drafted and presented to our advisory committee a proposal to amend the diagnostic x-ray equipment standard to limit the entrance exposure rate in HLC. The ACR's reaction to that was that we needed input from across the various disciplines in the clinical community before reaching a decision on this proposal, i.e., that high radiation exposures may partly be a result of the lack of information and awareness by users. Today's session is the result of the ACR's suggestion.

It's an exciting meeting--I think a landmark meeting--with people here from industry, government and a broad array of clinical specialties. The agenda includes tough fluoroscopy issues beyond the performance standard--issues such as training, design, use and control of fluoroscopy. It is vital for the medical professions to play an active role in tackling this problem. Problems such as this, which are at the interface of technology and the user, are difficult to approach with traditional FDA authorities, although we do have some which Dr. Shope will get into, and which we are prepared to use. Our mutual goal is to have all patients receive appropriate, safe and effective fluoroscopic diagnosis or treatment--to reach that goal, we have to

work cooperatively. We have a proud history in CDRH of working cooperatively with the medical profession on a wide range of radiation issues. We certainly have many valuable collaborations with ACR under our belt. Let me mention just one aspect where your contribution could be immediate and that is by reporting any patient problems from large radiation exposure from fluoroscopy. Under our new law of 1990, user facilities are required to report adverse incidents--manufacturers have been required to report these for quite a few years now--since 1984, I think. Facilities are required to report device-related deaths to FDA within 10 working days, and device-related serious injuries or illnesses to the manufacturers within 10 working days. This includes incidents caused by misuse or error. By reporting incidents, you will be contributing to a much needed database on high radiation exposure incidents. I think, too, that reports would be an incentive for manufacturers to change the design or labeling of their devices-- they need information on over-exposures to help provide a solution.

I would like to close by encouraging all of you to get involved in developing a solution to high exposures and other problems concerning fluoroscopy. I would also like to thank the ACR for their leadership role in sponsoring this workshop. The workshop agenda is an ambitious one, but the issue is a very important one, and I wish you the best of meetings. The FDA staff here today are very committed to working with you to improve the use of fluoroscopy. Thank you.

**THE FDA'S ROLE AND AUTHORITIES REGARDING FLUOROSCOPY**  
**THOMAS B. SHOPE, PH.D.**  
OFFICE OF SCIENCE AND TECHNOLOGY, CENTER FOR DEVICES AND  
RADIOLOGICAL HEALTH, FDA.

The absence of rate limits and imaging performance requirements in the Federal standard for fluoroscopic X-ray systems reflects the lack of consensus at the time the regulations were devised. Moreover, the demands of CT, mammography, MRI, and the medical device amendments have diverted our attention from fluoroscopy.

FDA is now focusing its attention on HLC fluoroscopy, including digital imaging systems and recording modes, with a view toward taking some first step to limit HLC and nonpulsed recording, possibly to 20 R/min, with specific activation and audible alarm requirements. "Normal" fluoroscopy would be defined at 10 R/min maximum.

A draft proposal on these issues has been circulating since 1990 and should soon see the light of day in the Federal Register. Note see section two for this proposal that was published May 3, 1993.

The two legislative mandates underpinning FDA's role in this realm are the Medical Device Amendments of 1976 (and the 1990 and 1992 updates), providing for FDA review of device safety and effectiveness prior to marketing approval, and the Radiation Control for Health and Safety Act of 1968, which covers all electronic products that emit radiation.

Devices are classified by risk and control levels. Class I devices are subject to general controls including good manufacturing practices; Class II are subject to additional special controls; Class I and Class II devices must be shown to be substantially equivalent to a device previously marketed; and Class III devices require premarket approval based on demonstrated safety and efficacy.

A reportable event under the Safe Medical Devices Act of 1990 includes any device-related death or injury or malfunction that results in a life-threatening situation, permanent impairment, or damage. Device failure can refer to user error or incorrect device maintenance leading to death or injury.

Performance standards for radiation-emitting products require that the manufacturer test and certify that the equipment complies with the standards.

FDA, Dr. Shope said, would like workshop participants to address recording mode exposure levels; imaging performance and labeling; and features to reduce radiation exposure levels, such as removable grid mechanisms, freeze-frame or last-image hold, and running tallies of patient exposure. The agency would also appreciate user perspective on the notion of High Level Output and its clinical necessity, or lack thereof.

That fluoroscopy is an area ripe for risk assessment and risk reduction, he observed, is brought home by calculations of the relative risks of fatal cancer induction related to various diagnostic tests. Measured against a relative risk of 1.0 for chest films (50 million of which are performed annually in this country), mammography (about 12 million a year) carries a relative risk of 1.9 and upper gastrointestinal fluoroscopic exam (about 10 million a year) carries a relative risk of 36.

## THE ROLE OF THE STATES REGARDING FLUOROSCOPY

MICHAEL ODLAUG M.S., M.P.H.

MANAGER, X-RAY CONTROL DIVISION, WASHINGTON STATE DEPARTMENT OF HEALTH, AND CHAIRPERSON, SUGGESTED STATE REGULATIONS COMMITTEE IN DIAGNOSTIC X-RAY FOR THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, SEATTLE, WASHINGTON.

While FDA covers machine performance, state regulations focus on machine use: who can operate them, who needs to be licensed, and conditions of use. State programs cover all x-ray facilities and entail inspection of both certified and uncertified machines, with the aim of reducing occupational, patient, and public exposure. State regs must be in synch with federal standards.

Current state regulations differ from one another in such items as fee and fine impositions, inspection frequency, inspection content, and report and citation format.

A questionnaire sent to all state radiation control agencies--specifically in preparation for this workshop--reveals that most states do not license or credential fluoroscope users, though California and some others have the authority to do so.

Personnel exposure limits of 5 rem/year, complete with requisite on-body monitoring device, are fairly universal, but only 10 or so states reported specifying a limit on the "typical" patient exposure.

Suggested state regulations for the control of radiation (SSRCR) are model regulations to guide states in such areas as: limitation of useful beam, fluoro tube activation, exposure rate limits, barrier transmission limits, tube potential and current, source to skin distance (SSD) limits, fluoroscopic timer, scatter control, and therapy simulators. All these issues, Odlaug said, are on the table.

The state survey was conducted in September 1992; responses from 45 had been received and tabulated at the time of the workshop. Two sources of pervasive concern were user qualifications and overexposure potential. In the first category were fluoroscopy use by unqualified, inadequately trained, or insufficiently cautious personnel, as well as by chiropractors and cardiologists.

Overexposure issues included high entrance exposure rates, the lack of HLC and recording mode limits, rate limit bypassing via VCR-fluoroscope hook-up into "recording" mode, too long on-times, and equipment designed to generate "extraordinarily high dose rates."

Odlaug said that the survey showed the inability of responders to pinpoint how many HLC systems were in their state. And the guesstimates that were offered were suspect, since larger and smaller states came up with similar system tallies and incongruous numbers of overexposures. Asked how many patient or personnel overexposures had occurred between January and September 1992, some larger states answered "zero," while some smaller ones reported double digits. "It just doesn't jive," Odlaug commented. "Obviously, these incidents aren't being reported." The new medical device reporting regs, he said, might help in this regard.

The "most outstanding" finding, he said, was cardiologists accounted for about 99% of reported occupational overexposures. "If we can solve your problem," he remarked to any cardiologists who might be present, "we may have most of the problems licked."

**STATE FLUOROSCOPY SURVEY, SEPTEMBER 1992**  
(45 states reporting)

Issue of Concern	Number of States
Rate limits	24
High level control	21
Occupational exposure	20
Training and user authorization	18
Remote/special procedures	18
Mobile C-arms	9
Stationary C-arms	8
Other	8

**STATE FLUOROSCOPY SURVEY/OVEREXPOSURE INCIDENTS,**  
**JANUARY-SEPTEMBER 1992**  
(45 states reporting)

State	Number	Type of Incidents
Michigan	40	
	28	cardiac catheterization
	12	general radiology
Mississippi	24	all fluoroscopy
Texas	19	special procedures
Illinois	15	interventional radiology (e.g., cardiac cath)
Wisconsin	12	cardiac catheterization
Los Angeles (county)	11	cardiology
Florida	8	special procedures
South Carolina	6	cardiac cath/special procedures
Georgia	4	cardiac cath/orthopedist (1)
Kansas	3	cardiac cath/special procedures
Nebraska	3	cardiac cath
Colorado	3	---
Washington	3	cardiac cath
Indiana	2	cardiac cath
Arkansas	1	radiology
West Virginia	1	cardiac cath
Utah	1	cardiac cath
North Carolina	1	fluoroscopy tech
New Jersey	1	cath lab
Maine	1	cardiac cath

**The following 25 jurisdictions reported no reported overexposures: Pennsylvania, Arizona, Tennessee, Oklahoma, Massachusetts, Rhode Island, Alabama, Nevada, Idaho, Oregon, Missouri, Kentucky, Alaska, Connecticut, Iowa, New York City, New York State, Montana, New Hampshire, Hawaii, Vermont, Virginia, North Dakota, South Dakota, New Mexico.**

**A sampler of written survey comments:**

"We are concerned about the lack of standards or limits in the recording of cine. Some of the units can give up to 300 R/min exposures....We are especially concerned about the possible high exposure of infants and children during special procedures."

"I strongly believe FDA needs to establish table top exposure limits for HLC in both the manual and the automatic modes....As state regulators, we can establish standards requiring the user to record fluoroscopic on-time. To set fluoroscopy time limits or examination time limits, we would be guilty of not allowing the physician to practice medicine. As regulators, we would be overstepping our authority if we get into this area."

"Do you suppose we can have a [rate] limit to prevent erythema in patients?....How can we get manufacturers to stop making high capability equipment that does not adequately consider/address patient dose?"

"Most operators appear to not be aware of fluoro rates or cumulative dose to patients....Units that operate in high level mode (over 10 R/min) should have a requirement to record total time of use and calculate dose to patient. This should be in the patient record and also in a log of exposure by exam type."

"Considering the length of some of these procedures [mobile C-arm] and the lack of formal training for these individuals, more emphasis should be placed in this area. Physicians are observed not wearing their monitoring devices quite often during fluoroscopic procedures....Several maximum (HLC) measurements have been taken which exceeded 40 R/min on mobile C-arm equipment, which tend to have the least trained individuals operating the equipment. The recent limit for this mode of operation, i.e., 25 R/min, does not appear to be totally adequate."

"The statute states the fluoroscope can be operated by a 'licensed practitioner.' The meaning of 'licensed practitioner' and requirements are not specific.... We have no means to determine an accurate or rough count of high level control-capable fluoroscopic systems operating [in the state].... We have no means to determine an overexposure due to fluoroscopy."

"It concerns me that nonradiologists are operating cath lab equipment. I don't believe that cardiologists have the healthy respect for radiation that a radiologist does. This is probably why most of or 'true' overexposures are in cath labs."

"Almost all valid overexposures are to cardiologists."

"We had one at 123 R/min!! And we all too often see 30-40 R/min. I think the limit should be 15 R/min....Rate limits--all they have to do is hook up a \$200 VCR and now they're recording and none of the maximum exposure rates apply--that needs to change! I would also suggest deleting the 5 R/min maximum for units with high level, as it only encourages them to use high level."

"Minimum SSD of 30 cm ignored, in some cases, by design of new equipment....Fluoroscopist training--too many with heavy feet."

**THE NEMA (NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION)  
PERSPECTIVE ON FLUOROSCOPY**

**ROBERT G. BRITAIN M.S.**

VICE PRESIDENT, MEDICAL PRODUCTS, NEMA, WASHINGTON, D.C.

NEMA, whose members represent 95% of domestic sales of fluoroscopic equipment, hopes to improve machine performance and radiation safety, but there is no consensus in the industry on strategies to encourage users to use dose-reducing features with fluoroscopic equipment nor on ways to improve education and training.

Dose reducing features are available from manufacturers. These include such items as last image hold and pulsed X-ray options. Manufacturers provide information about each feature offered.

NEMA proposes the following for guidance:

**For equipment with automatic exposure rate control (AERC), provide:**

For fluoroscopy systems with high level control (HLC), state the technique factors that produce an entrance exposure rate (EER) of 20 cGy/min, the maximum EER and the techniques that produce this maximum EER.

For non-pulsed fluoroscopy systems during the recording of fluoroscopy images, state the EER to a typical patient and the technique factors that produce this EER for each recording mode. State the maximum EER and the technique factors that produce this maximum EER for each recording mode.

For pulsed fluoroscopy systems during the recording of fluoroscopy images, state the entrance exposure per frame to a typical patient and the technique factors that produce this entrance exposure per frame for each recording mode. State the maximum entrance exposure per frame and the technique factors that produce this maximum entrance exposure per frame for each recording mode.

**For equipment without AERC, provide:**

For fluoroscopy systems with high level control (HLC), state the technique factors that produce an entrance exposure rate (EER) of 20 cGy/min, the maximum EER and the techniques that produce this maximum EER for each recording mode.

For non-pulsed fluoroscopy systems during the recording of fluoroscopy images, state the EER to a typical patient and the technique factors that produce this EER for each recording mode. State the maximum EER and the technique factors that produce this maximum EER for each recording mode.

For pulsed fluoroscopy systems during the recording of fluoroscopy images, state the entrance exposure per frame to a typical patient and the technique factors that produce this entrance exposure per frame for each recording mode. For the purposes of this policy, a typical patient is a phantom that intercepts the entire useful beam and is equivalent to 9 inches of water or 7 7/8 inches of acrylic.

## SESSION 1: QUESTIONS AND DISCUSSION PERIOD.

Among the points made during the comment period were the following:

- \* It's a false distinction between pulsed and nonpulsed recording modes, since "it's the same radiation, just applied in a different way."

- \* Immediate reporting of adverse effects may not be possible when fluoroscopic overexposure may not manifest itself for several weeks, as with some skin burns. "Is this the sort of serious injury that requires reporting?" asked one attendee. The FDA's Dr. Shope replied that, in general, FDA does not want to hear about "minor" events. "My feeling," he said, "is that if action is required to avoid permanent damage, that's a reportable event."

- \* Several participants commented that skin burns and hair loss are not rare events following high-dose procedures. And one advocated the establishment of a national registry, especially to document cardiac catheterization complications. "Late vascular complications are very poorly reported. If it doesn't happen at the time, in the lab, it tends not to get reported," he said.

- \* Exposure limits must be discussed in the context of imaging performance criteria, especially in interventional radiology, or the procedure will lose the clinical utility that called it into action in the first place. System designs ought to be optimized to achieve the best image at the lowest exposure.

- \* Audible beeps alerting the user that HLC has been activated are not always audible; the user may be unaware that he or she has exerted that extra pressure on the foot switch to move into a higher level; even when the auditory or visual alert is adequate, the significance of the higher dose level may not have been adequately conveyed at some institutions.

- \* Despite occasional turf protectionism, an institution's radiation safety officer, often a medical physicist, has the authority to move across departmental lines--and should--to educate fluoroscopy users and review procedures and equipment. Local medical societies are usually more than willing to facilitate the process.

## SESSION 2: FLUOROSCOPY SYSTEMS

### **REVIEW OF FLUOROSCOPY EQUIPMENT OPERATION AND PERFORMANCE**

**PEI-JAN PAUL LIN, PH.D.**

CHAIRMAN, DIAGNOSTIC X-RAY IMAGING COMMITTEE, AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE; AND NORTHWESTERN UNIVERSITY MEDICAL SCHOOL, CHICAGO, ILLINOIS.

"It's the physicist who should determine how a system operates," Paul Lin, Ph.D., advised, offering his own rule-of-thumb: "For most high-level mode equipment, I simply set the maximum level to 15 R/min; for cardiology, it's 20 R/min."

That said, Dr. Lin presented the basics of fluoroscopic technology by which radiation input, output and patient exposure are controlled and modulated to match clinical needs. (He put in a side plea to FDA to develop and encourage adoption of uniform terminology, the lack of which was evident, he said, in the terminology used for the abstracts of this workshop.)

Fluoroscopy comes in four standard packages: conventional, or under-table; remote control, or over-table; C-arm/U-arm, including mobile C-arm and special angiographic equipment; and special purpose, including urology/cystoscopy and lithotripter.

Image quality and patient exposure are both largely dependent on the amount of radiation penetrating the input phosphor of the image intensifier, calculated as the image intensifier input exposure level (IIEL). To maintain image quality with a smaller image intensifier, the IIEL must be increased, but not necessarily by increasing the amount of x-rays, per se, Dr. Lin said. Increasing the x-ray tube potential (kVp) will increase the penetration ability of the x-rays without a commensurate increase in patient exposure level (patient exposure level is proportional to tube potential squared, while x-ray penetration power is proportional to tube potential raised to the third to fifth powers.)

Calibrating the IIEL for normal fluoroscopy use is aimed at limiting radiation output to a maximum patient entrance exposure rate of 10 R/min. Automatic exposure control (AEC) circuits, usually referred to as automatic brightness control (ABC) in fluoroscopy systems, are based either on tube potential (kVp) in conjunction with fixed or automatic tube current (mA) values or on tube current in conjunction with automatic or fixed kVp.

High level output fluoroscopy is needed when low contrast objects are the imaging targets, as in lithotripsy procedures--but "12-13 R/min is really all that's needed here," Dr. Lin commented. At extreme viewing angles for thick body parts, as in cardiac catheterization, you may need an extra boost to 20 R/min. Also, in electrophysiology labs, when a fine catheter is used and a higher signal-to-noise ratio is needed; one may need a high level boost of short duration.

But, Dr. Lin emphasized, there should be an upper limit to high level output fluoroscopy, and 20 R/min should do it; lowered to 15 R/min or less in most cases for mobile C-arm. As to recording mode, only when recorded images are used to establish diagnosis should high level output be necessary. Personnel should be familiar with equipment design and the operation of automatic control circuits. For instance, one piece of equipment can have eight default settings under high level control and patient exposure can be altered dramatically by decreasing the distance from the patient to the image receptor.

**TYPICAL IMAGE INTENSIFIER INPUT EXPOSURE LEVEL(IIEL) VALUES AND  
TYPICAL PATIENT ENTRANCE EXPOSURE  
FOR 9" IMAGE INTENSIFIER INPUT PHOSPHOR SIZE**

<b>IMAGING MODE</b>	<b>IIEL</b>	<b>EXPOSURE</b>
<b>Fluoroscopy</b>	<b>75-100 microR/sec</b>	<b>2-3 R/min</b>
<b>100 mm photospot camera</b>	<b>100 microR/frame</b>	<b>75-100 mR/frame</b>
<b>35 mm cine camera</b>	<b>10-15 microR/frame</b>	<b>10-15 mR/frame</b>
<b>Digital fluoroscopy</b>	<b>75-100 microR/sec</b>	<b>&lt; 2-3 R/min</b>
<b>Digital spot imaging</b>	<b>75-100 microR/frame</b>	<b>50-100 mR/frame</b>
<b>Digital cine angiography</b>	<b>10-15 microR/frame</b>	<b>10-15 mR/frame</b>
<b>Digital subtraction angiography</b>	<b>50-1000 microR/frame</b>	<b>350-500 mR/frame</b>

## ENGINEERING CONSIDERATIONS FOR FLUOROSCOPIC SYSTEMS

MELVIN P. SIEDBAND, P.E.

UNIVERSITY OF WISCONSIN, MADISON, WISCONSIN.

The good news is that x-ray tube potential (kVp), filtration, and lens settings can (and must) be optimized for each varying degree of patient thickness and type of imaging. "The physics has always been there to do this; it just hasn't been done much," Melvin P. Siedband, P.E., told workshop attendees.

The bad news is that "nothing is free," certainly not high-resolution images. But coupling physics with common sense safety practices can yield better images at lower patient (and operator) exposure, he said, pointing to adjustments made by mammography companies that have resulted in 30-40% decreases in patient exposure as an example of what should and can be done.

The "best way to decrease exposure," Dr. Siedband advised, "is to turn off the machine." Last-image hold should be a feature of every fluoroscopic system; and to increase one's distance from the "high-level scatter" that invariably accompanies high level control fluoro, "do just that--get further away. It works better than any shield," he said.

A certain amount of radiation is required to yield a signal-to-noise ratio sufficient to image objects of varying resolution and contrast; too little produces a noisy image lacking diagnostic quality and too much is a danger to patient and practitioner. All images, he said, should show some noise.

The following equation provides an estimate of the radiation exposure required for a fluoroscopic image (or for any radiograph) for each 0.2 sec the eye requires for continuous imaging:

$$\text{Exposure (Roentgen)/Image} = 2 \times 10^{-7} / (\text{RL}) (\text{QDE}) (\text{d})^2 (\text{C} - 0.05)^2$$

where:

**RL** is radiolucency (transmission of x-rays by the object)

**QDE** is quantum detection efficiency (the ratio of the number of photons that produce flashes of light to the number of photons incident on the detecting system)

**d** is the diameter in mm of the object of interest

**C** is the approximate contrast of the object

This equation is useful for small objects with moderate contrast, Dr. Siedband said, elaborating on several points of information contained in the formula: radiation increases rapidly if diameter is decreased and resolution increased; "low contrast anatomic objects need more radiation to be seen than high contrast test patterns"; and a low-QDE image intensifier needs more radiation than a high efficiency tube.

Basically, the radiation requirements for a given image are established by photon statistics.

## FLUOROSCOPIC SYSTEMS CONTROL, EVALUATION AND PERFORMANCE

JOEL E. GRAY, PH.D.

PROFESSOR OF DIAGNOSTIC RADIOLOGIC PHYSICS, MAYO MEDICAL SCHOOL,  
ROCHESTER, MINNESOTA.

There are three major ways to reduce fluoroscopic radiation dose, according to Joel Gray, Ph.D.: use pulsed progressive fluoroscopy (PPF), eliminate grids wherever possible, and eliminate the "high level control" mode. Beyond that, there are two ways to ensure optimal fluoroscopy systems: uncompromising demands and eternal vigilance.

Despite an age range of from 2 to 21 years among the ten cardiac cath. labs. at Mayo Clinic, fluoroscopic image quality and dose are excellent and similar throughout, a feat attributable to the team of responsible personnel: a medical physicist, video engineer, quality control technologist and, perhaps most relevant, an in-house service engineer. Average cardiac staff exposure is under 1.0 rem a year, with a 3.5 rem/year maximum, and good image quality is achieved with fluoro rates of 0.7-1.0 R/min. Regulatory dosage priorities notwithstanding, at Mayo "it's the image quality that comes first; if you do the image quality right, the dose comes along," he maintained.

First, he said, the staff will not accept "average" image quality. The vendors balk, but we insist on the 95th percentile of image quality and that all equipment performs to staff satisfaction. Numerical specifications for systems performance surpass the federal requirement: at Mayo, HVL is at least 3.0 mm Al at 80 kVp, well above the 2.3 mm federal level, which, Dr. Gray noted, decreases patient exposure by 30%. Rigorous specifications for video resolution (for 6" mode--2.3 lp/mm), contrast ratio (for 10 mm thick lead disk--16:1; for 10% area lead disk--25:1), brightness falloff (20%), and third field lag (under 12%) contribute further to image optimization. The medical physicist also stipulates Plumbicon camera tubes for minimum lag and maximum resolution, video monitor calibration with a 1.0 volt peak-to-peak signal, and remote control iris for video signal optimization for recording.

Dose optimization begins with grid removal for all conventional fluoroscopy, interventional neuroradiology, electrophysiology procedures, pacemakers, and pediatric cardiac procedures. Only during cine recording are grids needed, he said, adding that he'd like to have them removed for all cardiac procedures, but, again, the manufacturers "balk." This maneuver, however, halves the dose, he said, asking workshop participants to signify if they do conventional fluoro without grids in place. (No hand was raised.)

PPF, which allows 30 rather than 60 X-ray pulses a second, also halves the dose and is used for all cardiac fluoroscopy. But unless the radiologist or cardiologist specifically asks for PPF, manufacturers generally don't provide it. PPF is the only radiation protection measure, he emphasized, that actually yielded lower personal radiation badge readings. Between 1984 and 1987, caseload increased by 63% and the numbers of coronary angioplasties increased by 244%, but cardiologist radiation exposure decreased by 37% as a result of PPF. PPF should be required for interventional and special procedures (an additional \$50,000 isn't much compared to the overall \$1 million for a cath. lab., he commented).

Other features that manufacturers ought to supply include: increased HVL to at least 3 mm Al. at 80 kVp, grid automatically removed for fluoro and inserted for cine or image recording, elimination of the 5 R/min maximum normal exposure rate with high level control

capacity and elimination of high level control itself (these two would confer better user dose discretion and result in more lower dose selections above the 5 R/min level).

High level control might also be superfluous if manufacturers supplied manual control and automatic iris to prevent light-starved video, Dr. Gray said, continuing to expand his list of needed features: automatic gain control, automatic digital window and level for fluoro and digital display, cumulative fluoro time displays on monitors, no access to video monitor brightness and contrast controls, variable apertures in the imaging chain, removable grids for C-arms for electrophysiology studies, and automatic focal spot selection.

Fluoroscopy should be limited to 70 or 80 kVp and above--actually 80. He advised participants to be wary of manufacturer claims, citing one firm whose claims that its PPF feature reduced the dose by two times were tarnished by the fact that they'd also reduced the kVp and actually increased the dose by four times.

For system maintenance and quality control, Dr. Gray advised, substitute in-house maintenance for service contracts and perform preventive maintenance monthly, evaluate major equipment every 3 months, check cine projector and video display monitor (Windex away the blood, iodine, and fingerprints) monthly, institute a daily quality control routine, and include a resolution, density, and contrast phantom on every cine run or video recording as part of equipment quality assurance.

Of 64 interventional procedures reviewed in a 1991 dosimetry study, only 23 required high dose rate fluoroscopy, used only for a few seconds to determine if the balloon were properly inflated. For patients thicknesses up to 28 cm, rates were under 10 R/min.

Typical radiation exposure rates with PPF (and grids) are 1.5-2.0 R/min for 6-inch I.I. and 0.7-1.0 R/min for 9-inch I.I. fluoroscopy; 15 R/min for 6-inch I.I. cine, 2.0-2.5 R/min (low) and 4.0-4.5 R/min (high) for 6-inch I.I. video recording.

#### FLUORO EXPOSURE TIMES (MIN.)

<u>PROCEDURE</u>	<u>AVERAGE</u>	<u>STD. DEV.</u>	<u>RANGE</u>
CORONARY ANGIOGRAPHY	7.5	7.0	1-43
LEFT VENTRICULOGRAPHY & CORONARY ANGIOGRAPHY	9.7	5.4	2-39
PTCA	31.3	26.6	5-121
LASER PTCA	43.8	25.1	24-95
EP-Dx	9.7	5.7	0.5-20
EP-Rx	87.6	64.2	41-179

## EVALUATION OF SYSTEMS WITH HIGH LEVEL CONTROL MODES

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The various proposals for HLC fluoroscopy ceilings have little in common with HLC capacities "out there" in machines currently in use in the real world. "I was shocked," Christopher Cagnon said of the results of a survey involving six California medical institutions, eight machines, six models, and four manufacturers. Four C-arms were included.

The maximum HLC fluoroscopy rates of the eight tested machines ranged from 21 R/min. to 93 R/min., with a mean of 48.7 R/min. "No machine allowed for operator-controlled incremental increases, and no one really had any idea of how high the exposure could actually go," he recounted. The simple activation of HLC increased typical patient exposure 2.3 to 6.6 times immediately. (Various proposed regulatory limits range from 10 R/min to 23 R/min).

It is important to note that machines from the same manufacturer had exposure rates that varied by 42% and that two machines of the same model from another manufacturer varied by 16%. The four manufacturers complied with current FDA requirements for continuous manual activation of HLC in quite different ways, ranging from a two-position foot pedal, with which normal fluoro is activated by stepping half-way down and HLC is triggered by pressing all the way down, to a system requiring two people, one in the room operating a foot switch and the other in a control booth simultaneously turning a key and pushing in on a button.

The American Association of Physicists in Medicine has recommended limiting HLC to 10 R/min "unless a specific clinical need has been identified." Los Angeles County recommends a maximum exposure rate of 15 R/min and the FDA has proposed a 23 R/min (20 cGy/min) limit. "All of these limits," Cagnon said, "seem somewhat arbitrarily set." Moreover, available machinery bears "no coherence with recommended exposure limits" and there is "no industry standard." Manufacturers involved in the study suggested that their machines may have been "modified" to achieve high exposure rates, he said. Cagnon concluded with a series of questions, expressing his own opinion regarding some.

**Should government set HLC limits?**

**Should limits be set by physicians? Medical physicists? Manufacturers? All three?**

(Currently, Cagnon observed, exposure levels are typically set by the manufacturer or, in practice, by the installation or service engineer.)

**Should HLC activation methods be standardized?** (Yes, said Cagnon, but more important is the issue of operator awareness of exposure magnitude and the potential for confusing HLC activation with post-image processing--a consequence of the variety of lively terms coined by manufacturers: "fluoro boost," "high contrast," "image enhance," "low noise," and "image record.")

**Should normal mode fluoro be restricted to 5 R/min. in machines with HLC capacity?** (No, said Cagnon, noting that this limit probably causes HLC activation more than would otherwise be necessary simply to reduce unacceptable noise that might be taken care of at less than high level output. He welcomed FDA's apparent decision not to pursue such a limit.)

**Should the maximum exposure rate for any given machine be clearly documented?**

(Yes, said Cagnon. but whose obligation would this be? The manufacturer? The physicist? The service engineer?)

Rates should be monitored and the physician informed of them, perhaps best by a real-time display).

**What about tube filtration?** Increased beam filtration would be appropriate, especially for obese patients. Increasing HVL to 3-4 mm Al equivalent would enable a lower dose.)

## ASSESSMENT OF FLUOROSCOPIC SYSTEM PERFORMANCE

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Assessing fluoroscopy system performance has always been difficult, entailing as it does not a single exam but a series of images with varying field sizes, anatomical positionings, x-ray intensities and beam quality, and fluoroscopic scan times, as well as dynamic and static imaging components.

Nonetheless, the Food and Drug Administration, in collaboration with the Conference of Radiation Control Program Directors (CRCPD), targeted upper gastrointestinal fluoroscopy for the 1991 leg of the NEXT (Nationwide Evaluation of X-ray Trends) study.

"We've observed poor fluoroscopic performance, Orhan Suleiman, Ph.D., told the workshop. "It's obvious," he said, "that there are good imaging systems with low entrance exposure rates, and it is also obvious that there are some very marginal imaging systems in use," he said, asking attendees, "what's acceptable? And why is there such variation--is it technique or equipment?"

NEXT examined entrance exposure rates utilizing a phantom of a typical abdominal region (21.5 cm) with and without simulation of barium. Average exposure rates were 4.4 R/min which increased to 6.4 and 6.7 R/min, respectively, with the addition of copper to simulate barium or lead to obtain maximum output.

An average 12-13 spot films were done during the typical GI exam. Spatial resolution varied widely, with the number of mesh lines per inch ranging from fewer than 12 to 60.

## **SESSION 2: QUESTIONS AND DISCUSSION PERIOD**

Dr. Gray voiced his opinion that FDA doesn't have enough data to set another HLC limit and that any it proposes is as arbitrary as any other. He reemphasized the need to eliminate high level control, though not high dose, by eliminating the position on the foot switch that "takes the dose up 4 to 5 times. Instead, we'll go up to 10 and do something, and then to 12, and then to 13, and so on," he elaborated. He also clarified that his 80 kVp minimum does not apply to pediatrics.

Dr. Siedband remarked that though he agrees with Dr. Gray regarding removing grids to lower dose, he does not agree with the kVp limit, nor has he obtained the same good results with pulsed progressive fluoroscopy. "It is not quite as clear as Joel makes it," he commented.

Dr. Suleiman commented that there is "no relation between dose and image quality in practice."

### SESSION 3: CLINICAL PERSPECTIVES OF FLUOROSCOPY

#### GENERAL/GASTROINTESTINAL RADIOLOGY

**DAVID W. GELFAND, M.D.**

PROFESSOR OF RADIOLOGY, BOWMAN GRAY SCHOOL OF MEDICINE  
WINSTON-SALEM, NORTH CAROLINA.

When the fluoroscopy suite at Bowman Gray Medical Center is occupied, 99% of the time the procedure involves a gastrointestinal site. Between 6,000 and 7,000 diagnostic procedures are done yearly, ranging in complexity from the relatively routine esophogram to the more demanding endoscopic retrograde cholangiopancreatography (ERCP) and enteroclysis procedures.

Regardless of procedural intricacies, said GI fluoroscopist David W. Gelfand, there are exposure time ceilings beyond which benefit is doubtful. In the case of feeding tube placement, for instance, we have found the yield past 15 minutes to be very small, and have set an absolute time limit at 20 minutes. With reduction in radiation exposure a conscious objective, any number of technique- or machine-related measures may be taken. At his own facility, the switch to a remote control table alone yielded a five-fold decrease in personnel radiation badge readings. Other strategies include: intermittent fluoroscopy, coning down, compression to decrease thickness (and consequently decrease the radiation dose), automatic collimation, automatic exposure control, image intensification, pulsed fluoroscopy, last image hold, carbon fiber table tops, digital spot filming, and videotape instead of cine.

GI fluoroscopy enables introduction of contrast media, structural diagnosis by observation, patient positioning for films, tube and catheter maneuvers, abscess and fistula opacification, and observation of normal and abnormal function.

The following table lists GI fluoroscopic procedures, estimated average and maximum fluoro times, the number of films, and the number of exams performed in a year's time at Bowman Gray.

#### GASTROINTESTINAL FLUOROSCOPIC PROCEDURES

EXAM	FLUORO TIME	FILMS	
	AVERAGE (MAX) (Minutes)	PER EXAM	#/YEAR
Oropharyngeal function study	2 (5)	0	450
Esophogram	2 (5)	1-2	923
Upper GI series	5 (10)	6-10	1111
Small bowel series	2 (5)	3-6	604
Enteroclysis	20 (30)	6-12	88
Single contrast barium enema	3 (10)	8-12	542
Double contrast barium enema	5 (10)	10-12	312
ERCP	10 (20)	2-8	150
Feeding tube placement	10 (20)	1	233
Hysterosalpingogram	2 (5)	2	446

Overall, GI fluoroscopic volume has been decreasing over the last two decades, especially barium procedures, though the numbers of functional and interventional studies are growing.

## **INTERVENTIONAL RADIOLOGY**

**JOHN F. CARDELLA, M.D.**

ASSOCIATE PROFESSOR AND CHIEF, CARDIOVASCULAR/INTERVENTIONAL RADIOLOGY, PENNSYLVANIA STATE UNIVERSITY HOSPITAL, HERSHEY, PENNSYLVANIA. (REPRESENTING THE SOCIETY OF CARDIOVASCULAR / INTERVENTIONAL RADIOLOGY).

Dr. John F. Cardella underscored the "exquisite concern" for radiation exposure that he and his associate in interventional radiology share. The extended radiation exposure that accompanies interventional radiology procedures is such that as technologies evolve, the day will come (or may already be here) when the risks of acute radiation exposure to the patient should be included in the informed consent discussion prior to the procedure, and the risks of chronic radiation exposure should be included in the career decision of the practitioner.

Performing an average of 18 clinical cases per week, 44 weeks a year, Dr. Cardella accrues a mean film badge reading of 560 mrem/month (range 230-1450 mrem) and a mean ring badge reading of 4500 mrem/month (range 2380-7250 mrem). His associate's personal exposure is 865 mrem a month collar badge (range 680-1110 mrem) and 6000 mrem a month ring badge (range 2800-12000 mrem) from doing 22 cases per week, 44 weeks a year. "These readings," Dr. Cardella observed, "are in the face of good radiation protection practices and having radiology residents 'share' the radiation exposure." Good protection practices beyond the basic time, distance and shielding, he said, include the use of "pull down" shields, pulsed progressive fluoroscopy and last image hold. Fluoroscopists, he urged, should always wear badges to record their exposure, especially since exposure levels are rising with increasing fluoroscopy unit output and "on-time". Thyroid shielding, lead glasses and 0.5mm lead wraparound aprons are mandatory for anyone doing these procedures. He also advocated more comprehensive education for all fluoroscopists, state credentialing or licensing procedures, limits on fluoroscopic and recording exposure levels, and technical improvements by industry that don't increase radiation dosages.

Interventional radiology includes all noncoronary angiography, angioplasty, atherectomy, thrombolysis, foreign body retrieval, biliary and gastrointestinal procedures, TIPS, genitourinary drainages, including stent placement, biopsies, abscess drainage, and intravascular chemotherapy. That these interventions in many cases treat conditions that would otherwise require open surgery affects the potential radiation hazards incurred in producing the "exquisite fluoroscopic images" these interventions demand. Angioplasty, for instance, involves the use of guidewires as tiny as 0.010 inch thick; plastic drainage catheters deep within patients may be 2 mm in diameter; the copper wire used in metallic stent construction is generally 0.004 inch. The fluoroscopic image needed by the interventionalist must resolve small, low contrast structures; monitor device motion; visualize multiple angles and not become degraded upon magnification. Even with all these demands, an analysis of their own fluoroscopic practices in the preceding 60 days revealed that fluoro time per patient averaged just a little over 8 minutes (range 0.7 minutes for a PICC insertion to 63.7 minutes for a complex biliary drainage) and that 95% of their work could be accomplished in standard nonmagnification mode at a maximum table-top dose rate of 8.33 R/min. In only 5% of cases was completion dependent on HLC fluoroscopy. Their particular high level control system requires a second person for activation, is accompanied by continuous chimes and has two maximum output exposure rates of 34 and 50 R/min at table-top.

## **CARDIOVASCULAR: DIAGNOSTIC AND INTERVENTIONAL**

**MALCOLM R. BELL, M.D.**

SENIOR ASSOCIATE CONSULTANT IN CARDIOVASCULAR DISEASES AND INTERNAL MEDICINE AND ASSISTANT PROFESSOR OF MEDICINE, MAYO MEDICAL SCHOOL AND MAYO CLINIC, ROCHESTER, MINNESOTA.

Interventional cardiology demands superb fluoroscopic image quality, yet only certain aspects of one particular procedure--percutaneous transluminal coronary angioplasty (PTCA)--depend upon the high level control mode. Generally, the entrance exposure rate is 5-10 R/min for this procedure with an upper limit of about 20 R/min. Because some interventional procedures require very long fluoro times and may needlessly be performed using HLC at high radiation exposure rate; many cardiologists would be astounded at the radiation dose values described here today. PTCA demands the highest quality video x-ray imaging of any procedure performed in the laboratory. How else could one steer minuscule guidewires through small, diseased, tortuous vessels to place tiny balloons in narrowed arterial lumens in the context of a moving heart and arterial tree that requires multiple angles for visualization? More than 400,000 PTCA's were performed in this country in 1992 and the numbers are growing, especially in the more complex cases involving multiple vessels and chronic total obstructions, as well as in the immediate management of acute myocardial infarction. "During such procedures generally the last thing on a physician's mind is the potential radiation exposure hazard," Dr. Bell observed.

While diagnostic coronary angiography, the most common cath. lab. procedure, takes about 9 minutes and requires an average of 20 R entrance exposure (range 4-36 R), PTCA fluoroscopic time averages 47 minutes with an average entrance exposure of 69 R (range 8-130 R). The radiation exposure is even greater for cases of chronic occlusion, multiple vessel studies and newer laser procedures that take more time. High-volume cardiologists who perform more than 200-250 procedures a year must be concerned about their own potential radiation overexposure and that of their patients', since 30% of them may require repeat procedures within a few months.

At the Mayo Clinic, the sharp increase in radiation exposure to cardiologists from 1978 to 1984 was then dramatically decreased by the introduction of pulsed progressive fluoroscopy. Pediatric fluoroscopic radiation exposure arising from the diagnosis and treatment of congenital heart malformations is largely uncharted territory, thick with the potential risk of latent increased cancer induction. Lengthy or multiple exams with the use of biplane fluoroscopy and angulated views, all contribute to concerns for pediatric exposure. The average fluoro time for pediatric diagnostic procedures at the Mayo clinic is 21 minutes and for the growing numbers of interventional procedures 53 minutes, with a range of 40 minutes to 2 hours.

Radiofrequency catheter ablation (RFCA), a new and increasingly utilized alternative to open heart surgery or lifelong drug therapy to treat life-threatening arrhythmias, requires long fluoroscopy beam "on" times. Between 40 and 50 minutes appears to be the average fluoroscopic beam "on" time, but exposure times approaching two and three hours are not uncommonly reported for isolated cases. The mean patient age is around 40, with many patients in the adolescent range. Shielding, field collimation, and--since high-resolution fluoroscopy is not required--removal of the antiscatter grid if possible should all be employed in RFCA to reduce radiation exposure.

A physician who performs 250 cases a year will have a predicted exposure tally of 450 mrem at the femoral site (hand exposure) and 900 mrem at the collar level. CV lab. monitoring technicians and nurses will be exposed to 162 mrem and 54 mrem, respectively. On average, the patient will receive 447 mrem/min at the 9th vertebral body, 36 mrem/min at the thyroid, and 64 mrem/min at the posterior iliac crest.

"The amount of radiation to which patients are actually exposed may surprise some cardiologists," Dr. Bell cautioned, advocating the recording and display of cumulative fluoro time. Other strategies for decreasing exposure include avoiding magnification; reducing the frame rate for cine, increasing x-ray tube filtration; and eliminating high level control, which is often not needed, or setting an upper limit of exposure rate for HLC.

High level control, he emphasized, is necessary only to visualize balloon inflation or complications during PTCA--and only for seconds at a maximum of 15-20 R/min. It should be used in conjunction with strict, manually controlled collimation, and it should not be used simply for catheter placement. (Other terms for high level control include fluoro boost, high contrast fluoro, high resolution, and turbo fluoro, he noted, adding his voice to the chorus requesting standardized nomenclature.)

He recommended universal application of pulsed progressive fluoroscopy (PPF) and replacement of cine with digital imaging (expected to halve the exit dose) as means to reduce radiation exposure without sacrificing image quality. Going from 60 to 30 pulses per second will drop the radiation exposure from 74 R to 34 R in a PTCA study for subtotal occlusion and from 115 R to 53 R for chronic total occlusion, he said, commenting on a "dramatic drop" in pediatric exposures between 1988 and 1989 compared to 1982 and 1983 with the introduction of PPF.