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ACC POSITION STATEMENT

Use of Radiographic Devices by Cardiologists

American College of Cardiology Cardiac Catheterization Committee

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Fluoroscopic imaging plays a fundamental role in the diagnosis and treatment of cardiovascular disease. Cardiologists perform ~1.1 million diagnostic catheterizations, 400,000 interventions, 95,000 permanent pacemaker lead implantations, 40,000 electrophysiologic studies (including ablations) and an indeterminate number of bedside procedures using X-ray guidance. Although other imaging modalities, such as echocardiography and magnetic resonance, may have reduced the need for some diagnostic radiographic studies, it is likely that the use of fluoroscopy will continue to increase as the number and variety of interventional procedures grow. Inherent in the application of these diagnostic and therapeutic procedures is exposure to radiation, which is associated with a finite risk of stochastic (malignancy) and nonstochastic (direct tissue damage) injury to patient and staff. These hazards are a function of absorbed dose and have generally been considered small when compared with other procedural risks to the patient (1) as well as those of not performing the procedure. Because of the increased fluoroscopy time required to perform interventional procedures, radiation exposure to the patient may be more than three times that associated with diagnostic angiography (2). Cumulative operator and staff exposure, primarily resulting from scattered radiation, may be considerable, especially if large numbers of complex interventional procedures requiring prolonged fluoroscopy are performed (3). The advent of new interventional technologies does not in itself mandate increased radiation exposure (4); however, the aggressive approach to more complex anatomy and the use of tiered modalities to optimize or salvage procedures is associated with greater fluoroscopy time. Although properly functioning equipment in a well designed facility helps to limit the risk to patients and staff, there remains an opportunity for significant exposure to ionizing radiation with potentially serious consequences.

It is essential that any operator of an X-ray-generating device have the basic knowledge of

radiation physics and safety to use the equipment appropriately. Although both states and the federal government have regulatory control over X-ray equipment, there has been relatively little required of a physician-operator other than that he or she be a licensed practitioner. Credentialing of users of fluoroscopy is not, in general, required by the state (with the exception of California) or individual facility. The availability of X-ray systems capable of producing levels of radiation exceeding suggested standards for image enhancement (high level control fluoroscopy) has refocused attention on the risk of fluoroscopy. These devices may produce maximal exposure rates of up to 93 R/min (5), which are far in excess of the Food and Drug Administration (FDA)-mandated 10 R/min upper limit for routine fluoroscopy. Although the increased image quality obtained with high level control fluoroscopy can be of benefit in performing interventional procedures, this modality may be overused, resulting in excessive radiation exposure to patients and staff. The lack of standardization and acceptable limitation of high level control fluoroscopy is of considerable concern to the FDA, which has already received reports of radiation-induced morbidity associated with large radiation exposures during fluoroscopic procedures (6). Although the primary recipient of radiation is the patient, the interventionalist, because of his or her proximity to the source of scattered radiation, receives significantly more radiation than the other staff members in attendance (7). Currently, cardiologists account for the vast majority of physician occupational overexposures to radiation, and this number is thought to be grossly underreported (8). A recent report by the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR) proposes a further reduction in annual and lifetime exposure limits (9). Although the justification for new guidelines may be debated, they are likely to have a significant effect on invasive cardiologists (10).

The potential adverse effects of radiation exposure may not be well appreciated by physicians because they are not immediate. Even cutaneous manifestations may take weeks to appear. Radiation itself is neither seen nor felt, and the "dosage" delivered is dependent on a number of factors, of which fluoroscope time is only one. The risk/benefit ratio of successfully completing a procedure, regardless of radiation exposure, is often considered justifiably small. Although technologic innovations have and will continue to reduce patient and operator radiation doses (11), it is important to emphasize the degree to which modification of practice habits by knowledgeable physicians can reduce exposure while maintaining the image quality necessary to ensure successful completion of the study (12). It should be the goal of all users of fluoroscopic equipment to adhere to the ALARA principle: use of a dose level As Low As Reasonably Achievable for obtaining satisfactory imaging (13). Proper instruction in the principles of radiation physics and safety should be part of every cardiologist's education. Unfortunately, this aspect of fellowship training often receives a low priority even among physicians intending to base their careers in the catheterization laboratory. Furthermore, knowledge gained in this area is not assessed by the specialty board certification examination. In view of the risks inherent to the patient and practitioner when X-ray imaging is used, it is important that all cardiologists have the opportunity to upgrade their knowledge in this field. It is the perception of the American College of Cardiology that there is a need for a mechanism by which cardiologists may obtain this information.

The College proposes to develop a curriculum based on that suggested by the American College of Radiology/Food and Drug Administration Workshop on Fluoroscopy (8). The major topics to be covered in this curriculum include:

- X-Ray Production
- Generator/Controls
- Equipment (fluoroscopy, fluorographic and digital imaging)
- Quality Control/Measurement
- Film/Processing
- Image Quality
- Dosimetry Concepts
- Biological Effects/Risk

- Radiation Protection
- Optimal Fluoroscopic Techniques
- Regulatory Aspects

The curriculum will be made available to fellowship programs and will be delivered in a series of courses across the country by the College. It is not the primary intention of the College to "certify" physicians as such; however, it is important that knowledge in this area be assessed and acknowledged. Although primarily directed at those physicians most concerned with fluoroscopic procedures (e.g., angiographers, interventionists, electrophysiologists), it is hoped that all cardiologists who utilize this equipment will partake of this educational effort.

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