Optimal Resources for the Examination and Endovascular Treatment of the Peripheral and Visceral Vascular Systems

AHA Intercouncil Report on Peripheral and Visceral Angiographic and Interventional Laboratories

John F. Cardella, MD, William J. Casarella, MD, James A. DeWeese, MD, Gerald M. Dorros, MD, Joel E. Gray, PhD, Barry T. Katzen, MD, John H. Laragh, MD, David C. Levin, MD, Victoria M. Marx, MD, Edward L. Nickoloff, ScD, Michael J. Pentecost, MD, Gary S. Roubin, MD, Eric C. Martin, MD (Task Force Chair)

HISTORICAL PERSPECTIVE

In 1969 the Intersociety Commission for Heart Disease Resources was established through a contract with the American Heart Association under Public Law 89-239. Its responsibility was to produce guidelines defining optimal medical resources and care for the prevention and treatment of cardiovascular disease, including guidelines for radiologic facilities (1). This resource guideline was revised in 1976 (2) and again in 1983 (3).

The Intersociety Commission was disbanded shortly thereafter, but a joint ad hoc task force of the American Heart Association and the American College of Cardiology continued this work with “Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories” (4), published in 1991. The task force concluded that “... while noncardiac diagnostic and therapeutic procedures are growing in number... guidelines for these services are beyond the scope of this document.”

These documents have charted the evolution of cardiac catheterization from a procedure performed in a few highly specialized laboratories for cardiovascular research to one performed in a number of interventional cardiac laboratories. The documents also have provided useful optimal resource guidelines. In the 1983 report similar standards for angiographic facilities were implied but never specifically stated, with the emphasis always on the heart. Nevertheless, the report mentioned angiographic facilities and considerable involvement by radiologists.

Just as cardiac catheterization has evolved, so too have peripheral and visceral angiography. Diagnostic angiography proliferated in the 1960s and the 1970s, and interventional radiology emerged in the 1980s. Nevertheless, optimal resource standards have never been promulgated except in an abbreviated form (5).

In 1989 the Council Affairs Committee of the AHA approved the formation of a committee on peripheral vascular disease under the auspices of the Council on Cardiovascular Radiology. In 1992 an ad hoc task force was created, with members from the Councils on Cardiovascular Radiology, Cardio-Thoracic and Vascular Surgery, Clinical Cardiology, and Kidney in Cardiovascular Disease, to develop guidelines for peripheral and visceral angiographic and interventional laboratories. Task force members are Eric C. Martin, MD, chair; William J. Casarella, MD (Council on Cardiovascular Radiology); Barry T. Katzen, MD (Council on Cardiovascular Radiology); Gerald M. Dorros, MD (Council on Clinical Cardiology); Gary S. Roubin, MD (Council on Clinical Cardiology); James A. DeWeese, MD (Council on Cardio-Thoracic and Vascular Surgery); and John H. Laragh, MD (Council on Kidney in Cardiovascular Disease). The task force is grateful for the contributions of the following consultants: John F. Cardella, MD; Joel E. Gray, PhD; Victoria M. Marx, MD; Edward L. Nickoloff, ScD; Michael J. Pentecost, MD; and David C. Levin, MD.

INTRODUCTION AND STATEMENT OF PURPOSE

In the past three decades the role of the angiographic laboratory has progressed from diagnosis of disease by a study of the arterial and venous systems to definitive treatment of certain patients by endovascular means. These facilities have also been used for nonvascular interventional radiology: the diagnosis and treatment of nonvascular disease. However, optimal resources for peripheral and visceral angiographic and interventional facilities have never been formally examined.
During the past decade invasive vascular imaging studies (angiography and venography) have achieved a new level of complexity and sophistication. With this high degree of specialization has come the need to design angiographic facilities capable of meeting the demands of current practice. This report describes the optimal angiographic facility in which peripheral and visceral vascular studies, both diagnostic and therapeutic, should be performed; this will also be the model for nonvascular procedures. The equipment and personnel requirements are unique and distinct from the requirements of a dedicated cardiac catheterization laboratory or neuroradiology facility.

In this report all aspects of a modern peripheral, visceral, and interventional facility are discussed. It is recognized that many existing facilities have developed slowly and do not meet these standards. These statements should therefore be viewed as recommendations only.

Every reasonable attempt has been made to seek opinions and guidance from the cardiovascular and interventional community and those with whom they most frequently interact. Although standards of practice documents touch on the equipment required for particular procedures, they represent minimum standards. This report describes guidelines for the optimal management of peripheral and visceral vascular disease and its interventional management and should serve as a model for future installations.

OPERATIONS

Utilization

Complex diagnostic and therapeutic procedures should only be performed in rooms designed for this purpose. Optimal performance requires a caseload sufficient to maintain the skill and efficiency of the staff. Diagnostic quality may be compromised and procedures may be unnecessarily prolonged if physicians are not adequately trained in these procedures, thereby increasing risk to the patient and subjecting patients and staff to excessive radiation. The task force endorses the principle that procedures should be performed by trained personnel who maintain their skills. These matters have been addressed by several credentialing documents, most notably “Training Standards for Physicians Performing Peripheral Angioplasty and Other Percutaneous Peripheral Interventions” (6), an AHA intercouncil medical/scientific statement prepared by radiologists, cardiologists, and cardiovascular surgeons. In addition, the report “Guidelines for Performance of Peripheral Percutaneous Transluminal Angioplasty” (7) was issued by the Society of Cardiac Angiography and Interventions to define standards for cardiologists performing peripheral angioplasty and was followed by “Recommendations for Peripheral Transluminal Angioplasty: Training and Facilities” (8), issued by the ACC. The Society of Cardiovascular and Interventional Radiology issued “Angioplasty Standard of Practice” (9) and “Standards for Interventional Radiology” (10). The latter report covers procedural standards for peripheral and visceral arteriography; peripheral, renal, and visceral angioplasty; and outpatient angiography. Both reports were endorsed by the American College of Radiology. The Society of Vascular Surgery (North American chapter) and the International Society for Cardiovascular Surgery issued a report entitled “Endovascular Surgery, Credentialing, and Training for Vascular Surgeons” (11).

In 1983 the InterSociety Commission for Heart Disease Resources wrote the compelling economic reason for the high utilization of facilities and suggested that the cost of laboratory radiology equipment be amortized over 5 to 7 years (3). Although there has been little change in the life expectancy of major x-ray equipment since that time, the task force does not believe it is valuable to calculate amortization costs here but believes that the principle remains valid.

Patient Management

Ideally, procedures should be performed in a hospital, in a dedicated peripheral vascular and visceral interventional laboratory. The range of procedures involved seldom allows for the optimum management of patients in a free-standing facility, although selected procedures may be performed on some outpatients. Standards of practice for angiography (10) and peripheral angioplasty (9,12) have already been published. The most recent document, “Guidelines for Peripheral Percutaneous Transluminal Angioplasty of the Abdominal Aorta and Lower Extremity Vessels” (12), is an intercouncil AHA medical/scientific statement. The optimal standards of care are summarized below.

Preprocedural care. A note should be written in the patient’s record summarizing indications for study, pertinent history, physical findings, and indications for the procedure. The patient’s medications, history of allergy, relevant medical and surgical history, and any vascular risk factors, including smoking, hypertension, and hyperlipidemia, should also be noted.

A physical examination should be performed, including a detailed vascular examination and a general examination of sufficient detail to exclude concurrent acute illnesses. For patients with chronic lower extremity atherosclerotic disease, noninvasive flow studies, including ankle-brachial systolic indexes and pulse volume recordings, should be performed and the results recorded.

Informed consent must be obtained from all patients and documented and must include indications, risks, and alternatives. Surgical consultation may be advisable for many interventional procedures, and it is preferable that decisions about therapy be made in consultation with all physicians involved. In emergencies, when informed consent cannot be obtained from the patient or a family member, individual hospital policies should be followed. These customarily require written statements by the patient’s physician, countersigned by a hospital officer, that the procedure is indicated.

Laboratory evaluation may be necessary, including measurement of hemoglobin, hematocrit, creatinine, electrolytes, coagulation parameters, and electrocardiogram, as well as blood lipids when applicable.

Procedural care. All patients should undergo cardiac monitoring continuously during the procedure, with intermittent blood pressure monitoring. A record of vital signs should be maintained.

All patients should have secure intravenous access for the administra-
tion of fluids and medications as needed.

If the patient is to receive conscious sedation, pulse oximetry or end-tidal carbon dioxide monitoring should be used. A registered nurse whose primary responsibility is to monitor the patient should be present. Records should be kept of medications given, including doses and times of administration, in conformance with hospital policy.

During intravascular studies continuous pressure measurement should be available.

A physician should be available during the period immediately after the procedure to ensure that there is adequate compression at the puncture site and that the patient is stable before transfer to the postprocedure care area. Initial stabilization is best provided in a recovery area adjacent to the angiography suite by nurses familiar with the procedures performed.

Postprocedural care. A physician's procedure note should be written in the patient's chart summarizing the major findings of the study and any immediate complications.

All patients should be confined to bed rest and observed after the procedure. Depending on the site and size of the vascular puncture and the risk factors, bed rest may be required for up to 24 hours. During the first 4 to 6 hours after the procedure, skilled nurses or other appropriate staff should periodically monitor the puncture site and the status of the pulses distal to the puncture site. The patient should be monitored for urinary output, cardiac symptoms, pain, and other indications of systemic complications; this period may be extended for the full 24 hours of bed rest.

The patient's initial ambulation must be supervised. Vascular perfusion, puncture site stability, and independent patient function and mobility must be ensured.

When either treatment or vascular access requires catheter manipulation in the thoracic aorta or brachiocephalic vessels, the neurologic status should be assessed periodically.

The operating physician or a designate should evaluate the patient after the procedure, and the findings should be summarized in a progress note. The physician or designate should be available for continuing care during hospitalization and after discharge.

Selection criteria for short-term observation. The duration of observation after the procedure must be decided on an individual basis. Diagnostic arteriography may be performed on some patients with only a short period of postprocedure observation (less than 8 hours) before they go home. Other patients require overnight care. Short-term observation may be considered when all of the following conditions can be met:

1. The patient should be capable of independent ambulation before the procedure and must have demonstrated stable independent ambulation after the procedure. Alternatively, a nonambulatory patient should have assistance after discharge from the hospital that is adequate to provide care as needed.
2. The patient must be able to follow instructions and detect changes in symptoms. Alternatively, patients with impaired mental status should have assistance adequate to provide care as needed after discharge from the hospital.
3. A responsible adult should be present during the first night after discharge from the hospital.
4. The patient should be free of concurrent serious medical illness that might contribute to a significantly increased risk of complications.
5. The patient must have recovered from the effects of sedation.
6. Travel time to the hospital or another acute care facility from the place where the patient is to spend the first night after the procedure should be reasonably brief.
7. The patient should have transportation to and from the hospital.

Contraindications to short-term observation. Several factors must be considered in determining the length of skilled nursing care needed after the procedure. Some of the relative contraindications to short-term observation are listed below. This list is not meant to be comprehensive, and any clinical circumstance that might predispose the patient to a significant complication should prompt overnight admission:

1. Poorly controlled hypertension in patients who have an increased risk of hematoma formation
2. A significant risk of contrast-induced renal injury that might be avoided by periprocedural intravenous hydration
3. Coagulopathy or electrolyte abnormalities that require correction
4. Insulin-dependent diabetes in patients who have significantly elevated or labile serum glucose levels
5. Complications occurring during or after angiography or angioplasty, e.g., a large hematoma, nausea and vomiting, neurologic deficits, or thromboembolic events
6. Hemodynamic instability or significant arrhythmias during or after the procedure

The decision about short-term or longer-term postprocedure observation must be made on an individual basis, and patient care may vary from these criteria for sound clinical reasons. In each case the decision must be made by the operating physician after a review of all pertinent data.

Monitoring equipment. The facility should be capable of electrocardiographic, heart rate, and blood pressure monitoring and pulse oximetry; the equipment should be available in each laboratory and in the recovery room. Responsibility for patient monitoring rests primarily with the registered nurse supervised by the operating physician.

Sterile Technique

Angiographic and interventional procedures should be performed in strictly aseptic conditions. Scrub suits should be worn by all personnel in the laboratory. Primary and secondary operators should wear sterile gowns and gloves as well as surgical caps and masks. Glasses should be worn to protect the eyes against splashes. In the preparation of side tables and during the passage of equipment and devices to the primary operators, aseptic tech-
nique should be followed by all per-
sonnel (13,14).
Sterile, impervious barriers should be available to cover any part of the equipment that may contaminate the field. Either sterilizable handles or disposable transparent covers for the controls should be available. The handling of needles, syringes, and other contaminated sharp devices should be in accordance with Occupational Safety and Health Administration regulations and hospital policies. Disposal containers for needles and other sharp instruments should be readily available in the laboratory. There should be an institutional policy about stab wounds from contaminated instruments. Universal precautions should be practiced with every patient, and all personnel should be protected from contact with body fluids (15–24). Appropriate receptacles for contaminated items should be readily available.

Emergency Management
Resuscitation equipment and personnel trained and experienced in its use must be immediately available for dealing with a variety of complications that can arise during angiographic and interventional procedures, including cardiac arrest, life-threatening hemorrhage, anaphylactic reactions, and sedation-related respiratory compromise (29–32). All personnel in the facility should be trained in emergency resuscitation. A peripheral vascular and interventional radiology suite should be equipped with a standard, approved hospital crash cart containing the full complement of resuscitative drugs, a defibrillator with monitoring capability, intubation equipment, and an Ambu bag for temporary ventilation. The hospital should have electrical pacing capability. There should be plans for the expedient transfer of patients to suitable facilities for emergency surgery when necessary. For this reason surgical consultations are desirable for all patients who may be at risk for emergency surgery.

Information and Film Handling
As films are processed they should be reviewed by the primary operator for both diagnostic content and technical acceptability. Films should be read on a daily basis. Films should also be available for consultation, which may require the filing of cases over the short term in the angiographic and interventional facility. Typewritten or audiorecorded reports of the procedures should be available within 24 hours of performance. It is preferable that films be placed on large-capacity film alternators.

Anesthesia
The vast majority of procedures can be performed with the patient under local anesthesia supplemented by intravenous analgesia and anxiolytics. Midazolam and fentanyl are commonly used. In long, painful interventional procedures, standby anesthesia may be valuable, while general anesthesia may also be used electively or, very occasionally, on an emergency basis (29–32). Accordingly, the room size must be adequate for the necessary equipment (see “Department Layout”).

Equipment and Inventory Control
The number of catheters, wires, and devices required for angiography and interventional procedures continues to increase rapidly. Not only is significant storage space required (see “Department Layout”), but an inventory control system is rapidly becoming necessary. Such a system must take into account expiration dates of catheters and guidewires. Some equipment will need to be resterilized, and facilities for cleaning and gas sterilization should be available.

STAFFING
Physician Staff
Peripheral vascular and interventional facility director. The director should be a physician with the experience and leadership qualities necessary to control the laboratory environment. The director should be board certified in his or her specialty and fully trained in cardiovascular and interventional procedures. Recently appointed directors should be fellowship trained and thoroughly experienced in performing the procedures specific to the laboratory. The director will supervise the procedures performed in the section and will be responsible for directing the laboratory. The director should be responsible for the quality assurance program. A continuing education program should be maintained, and CME attendance should be documented.

Attending staff. All physicians credentialed to operate in the laboratory (including the director) should have met the training standards recently developed by the involved specialties for physicians performing peripheral angioplasty and associated percutaneous peripheral interventions. In sum, these involve board eligibility or certification and require qualification by training in a fellowship program or documented experience (6–8,11). Staff physicians should spend enough time doing procedures to fulfill the obligations of the laboratory and should perform a sufficient number of procedures to maintain proficiency and competence (6–8,11).

Staffing should be appropriate for the caseload, with adequate emergency coverage. Many procedures may require the presence of two staff members. The staffing level should be sufficient for consultation with clinicians and completion of the caseload within the limits of reasonable radiation exposure. The facility should have a caseload sufficient to meet the credentialing requirements for staff and any trainees.

Fellows. Fellowship training is recommended for all practitioners participating in these procedures. Fellows should only be trained at facilities with caseloads sufficient to meet the requirement of the appropriate credentialing standards and standards of practice documents (6–8,10–12).

Residents. It should be the goal of the peripheral vascular and interventional section to provide residents with the opportunity to master general diagnostic angiography in the peripheral vascular and visceral areas. Residents must be closely supervised by the laboratory director or a designated staff member. Training facilities for residents should meet the appropriate credentialing standards (6–8,11).
Nursing Staff

It is recommended that facilities performing peripheral vascular, visceral, and interventional procedures should have a minimum, per room, of one full-time registered nurse with special training in critical-care nursing. Nurses should be fully conversant with intravenous techniques, patient monitoring, including electrocardiography and pulse oximetry (31), and intravenous sedation, analgesia, pressure measurements, and other pertinent laboratory procedures. The nursing staff should be responsible for maintaining records of patients' vital signs, medication logs, and drug inventory records.

Technical Staff

Technologists working in the peripheral vascular and interventional laboratory should be registered and certified radiologic technologists with additional training in angiographic and interventional procedures. The rapidly changing nature of the specialty requires that technologists receive additional continuing education by the facility director or physician staff. The technologist staff should be under the direct administrative supervision of a chief technologist who has sufficient experience to manage and train the staff. All technologists working in the laboratory should have a good working knowledge of the inventory and specialized equipment.

Service Support Personnel

Service support personnel should maintain and record in a service log the preventive maintenance schedule on all radiographic equipment in the angiographic and interventional laboratory. Service personnel should be under the direction of the medical physicist and the facility director.

Medical Physics Staff

Image quality, radiation safety, and all quality control data should be reviewed at least annually by a medical physicist with special expertise in diagnostic imaging. The medical physicist should be board certified in diagnostic medical physics by the American Board of Radiology, or diagnostic imaging physics by the American Board of Medical Physics, or possess equivalent qualifications.

Computer Scientist

Computers are playing ever-increasing roles in diagnostic imaging, and it is essential to ensure that computer-generated data are correct. Any modifications to software, or software written for a specific application, must be thoroughly evaluated in accordance with procedures similar to those required by the Food and Drug Administration for software verification and quality assurance to ensure proper performance. In addition, the computer scientist, in cooperation with the medical physicist, should test any software providing quantitative data from medical images to ensure the accuracy of the data.

ARCHITECTURE

Depending on the size of the institution, one or several peripheral vascular and interventional laboratories will be required. The facility should be self-contained, with the laboratories and support space constituting a definable entity.

Department Layout

Laboratory. An angiographic and interventional suite must have adequate space for radiographic equipment, ancillary and monitoring equipment, and any emergency care equipment as well as adequate space for patient access and care during the procedure. The optimum size is 700 ft², not including the control room. Oversized lead-lined doors are required at patient entrance and exit points, with a minimum door width of 48 in. The ideal ceiling height is 12 ft, with at least a 3-ft mechanical access space above the ceiling. This ceiling height permits adequate focal spot-to-patient distance and focal spot-to-film distance for long-leg cut film imaging. In newly constructed facilities the ceiling should be washable. The facility should be equipped with the following utility features:

1. Three-phase 220V and 440V AC power with a minimum of 100 amperes per phase
2. Hot and cold water in the room with a scrub sink in or very near the room
3. A “dirty” sink just outside the room
4. Suction and 100% oxygen-any inhalational anesthetic gases needed may be brought on the anesthesia cart, and a scavenging system for medical gases may be appropriate
5. A ceiling-mounted surgical light
6. Fully rheostated ceiling lights for infinite control of the room lighting during fluoroscopy (fluorescent lighting does not provide the range of lighting adjustments required in these rooms, and fluoroscopic activation of dimming is desirable)
7. Ample counter and cupboard space in the room for preparation of equipment and materials used during a procedure, and glass-fronted storage cabinets on the available free wall space
8. Sealed floor and walls; or the floor and walls should have a continuous, hard, washable surface (floor electrical troughs should be avoided whenever possible to allow for appropriate cleaning)
9. Adequate electrical receptacles around the room and angiographic table for ancillary equipment.

Because of the increase in scope of interventional procedures and the imminent availability of stented grafts, new facilities should conform to Association of Operating Room Nurses standards (33).

Control Room

Ideally, at least 120 ft² are provided for this area. The design should allow ready access to all instrumentation. The control room should have leaded glass to allow visual communication with the laboratory. Blinds should be considered to inhibit viewing when necessary. A two-way intercom system is essential.

Equipment Room

Transformers, power modules, and other related electrical equipment may be placed in the procedure room, the control room, or, preferably, in a sep-
Arterial, cooled room with adequate air flow around the electronics cabinets and computer flooring. If placed in the control room or the laboratory itself, the equipment should be enclosed in a space with adequate cooling and ventilation. There should be adequate access for maintenance. If equipment is placed in the control room, the bay should be appropriately larger.

The equipment should be positioned so that high voltage cables do not exceed 50 ft in length. Ready access to the equipment should be provided, and the room should be fully air conditioned. The recommended size for the equipment room is 80 to 100 ft².

Recovery Room

A recovery room should be in close proximity to the laboratory. The area should be divided into individual patient bays with at least one more bay than the number of laboratories. At least 60 ft² should be allocated for each bay. Monitoring equipment that can be readily used in each bay should be available (see "Monitoring Equipment").

Storage Room

Adequate storage space for catheters, wires, and other equipment is essential. Each peripheral vascular and interventional laboratory should have ample in-room storage space for frequently used catheters, wires, interventional devices, and ancillary support equipment. The out-of-room storage space should be at least 250 ft² per procedure room. The storage space should be close to each laboratory.

Ancillary Space

The procedure, control, equipment, storage, and recovery rooms do not constitute a total functioning laboratory unit. Additional support space is required. The following facilities should be available in the immediate vicinity:

- Waiting and holding areas
- Dark room
- Reception area
- Changing rooms for outpatients and staff
- Viewing and reporting area

Additional facilities may be shared with other services at more remote locations:

- Conference room
- Library and study room
- Room for teaching aids and files
- Additional office space
- Staff lounge
- Janitorial space
- Equipment storage

These requirements are similar to those in the ACC/AHA guidelines for cardiac catheterization and cardiac catheterization laboratories (4).

Air Conditioning

A professional engineer with expertise in heating, ventilation, and air conditioning should review all plans for the facility. Heat generated by each piece of equipment in the suite should be considered, as should the maximum number of staff working in the room. Potential additional equipment for the suite and increased heat loading that will result from the addition of equipment should be anticipated. There should be adequate capacity for humidification and dehumidification of the facility.

Three factors are important in determining air-conditioning requirements. Cooling of 3 to 4 BTU per hour should be provided for every cubic foot of interior space. In addition, 400 to 1500 BTU per hour should be added for each person continuously present in the room. For equipment that generates heat, the number of BTUs per hour is determined by multiplying the kilowatt-hours of the equipment by 3420. The total load is the sum from these three calculations. In general, the air-conditioning units should have a capacity 30% to 50% greater than needed. Air-conditioning units are often specified in tons of cooling capacity; one ton equals 12 000 BTUs per hour. A laboratory would typically require 40 000 to 70 000 BTUs of cooling per hour.

A comfortable environment, in terms of both temperature and humidity, should be maintained. The humidity must be maintained between 45% and 55% to prevent static discharge problems on the films and to ensure that the film transport systems function properly.

EQUIPMENT

X-ray Stand

The stand should be a C- or U-type, able to rotate around the patient in both the axial and sagittal planes. The stand should be motor driven, and the angle in each plane should be displayed. Manual override is essential. The mounting should be counterbalanced with the ability to vary the source-to-image receptor distance. Locks should be provided. The C-arm should be a size sufficient for easy access to the patient and should allow performance of procedures from the jugular vein or the axilla as well as the customary femoral and peripheral access sites. The stand should swing away from the patient for access in an emergency. The C-arm should be mounted with a 14-in (36-cm) or larger image intensifier interfaced with a video camera. At present a film changer should be mounted on the stand; in the future this will almost certainly be replaced by digital filming. A 100-mm or 105-mm camera coupled to the image intensifier significantly decreases both the radiation per film and, typically, the study time but increasingly is being replaced by modern digital units.

Table

The table may be ceiling- or floor-mounted. The table (or C-arm) should "step" unless an additional long-leg changer is to be used. The table should rapidly swing out from under the stand for easy access to the patient. The table should have a carbon fiber top with a weight limit of at least 140 kg.

Radiation Source

Generator. The generator should be either a three-phase, 12-pulse generator or a high-frequency inverter generator with a power rating of 80 to 100
kW. A compact, modern generator with self-diagnostics is desirable. Pulsed progressive fluoroscopy at 30 pulses per second with the image displayed at 60 fields per second reduces the radiation exposure by 30% to 50% and is therefore desirable.

X-ray tube. A dual (0.6-mm and 1-mm or 1.2-mm) or a trifocused (0.3-mm, 0.6-mm, and 1-mm or 1.2-mm) x-ray tube with focal spot sizes as indicated is recommended. The x-ray tube heat capacity should be at least 800 000 to 1 million heat units. The recommended x-ray tube housing heat capacity is at least 1.7 million heat units. The kilowatt rating of the x-ray tube should match the generator chosen and should be 80 to 100 kW for the large focal spot size. There should be an x-ray tube heat monitoring system as a constant reminder of the heat capacity limitations. To avoid anode cutoff, the anode angle should be at least 12° to 13° to accommodate the serial film changer and large-field-of-view image intensifier. A high-speed rotor with a diameter of at least 6 in (15 cm) should be provided, as should a heat exchanger that cools at the rate of at least 100 000 heat units per minute.

Image Intensifier

The image intensifier should be of the large-field-of-view (14 to 16 in) (36 to 41 cm) variety with three or four modes of magnification. The input phosphor should be cesium-iodide with a titanium window to reduce radiation dose. The conversion gain should be greater than 250 candelas per meter squared per milliroentgen per second measured at 80 KVP (kilo-volt peak). The spatial resolution should be at least 2.5 line pairs/mm in the 14-in (36-cm) field of view, 3.3 line pairs/mm in the 9-in (23-cm) field of view, and 4.6 line pairs/mm in the 6-in (15-cm) field of view. Vignetting and nonlinear distortion should be minimal. The image intensifier should be able to visualize a 1/16-in (1.6-mm) hole in a 1-mm aluminum plate contained within a 38-mm-thick aluminum penetrator. The contrast ratio of the intensifier should be at least 20:1. The veiling glare should be greater than 85%. The system should have automatic brightness control.

Television Chain

Ideally, both the television camera and the monitor should display 1000 raster lines per frame. Flicker-free, high-refresh rate systems are reaching production. The spatial resolution should be equal to or greater than 1.2 line pairs/mm in the 14-in (36-cm) mode, 1.8 line pairs/mm in the 9-in (23-cm) mode, and 2.6 line pairs/mm in the 6-in (15-cm) mode. Television monitors should measure 17 in (43 cm) or more on the diagonal and should have an antiglare coating. The signal-to-noise ratio for the television camera should be more than 1000:1. The system should have a frequency band pass of at least 20 MHz. Lag should be limited. The system should have circular blanking, white compression, dy-
namic range compression, and uniformity corrections.

Digital Subtraction and Acquisition

Digital imaging capabilities should be included in all peripheral vascular and interventional suites.

The system should have a 1024x1024 image matrix and a monitor capable of displaying this matrix. The system should also be able to display compressed images on a 512x512 matrix. It should be operable in both the fluoroscopic and pulsed radiographic modes with scanned progressive readout and should have a freeze-frame mode. The system should be able to acquire and display at least five frames per second in the 1024x1024 mode. Data storage and display should be available in both linear and logarithmic format with a minimum of 10 bits/pixel storage from the analog to digital converter. The console should have both an image display and a text monitor, and a second image display monitor should be located inside the procedure room. The analysis console should have an alphanumeric keyboard, function buttons, a region-of-interest cursor, window level and width controls, and image management functions. A second control console should be available in the procedure room. A handheld control device is ideal. A multifORMAT laser camera should be used to obtain hard copies of the images.

The unit should contain at least 500 megabytes of CPU. The storage device should be capable of storing at least 4000 compressed images and have a retrieval time of less than 1 second per image. A 2-gigabyte digital optical disc drive may be useful for long-term storage.

The unit should have automatic selection of exposure techniques. An automatic iris device to moderate light output from the image intensifier should be part of the digital system. Entrance exposure into the image intensifier should be less than 1 mR/frame for high-quality digitally subtracted images.

The unit should have the following capabilities:

Frame averaging to form masks
Post-image acquisition enhancement (smoothing and edge enhancement)

Histogram creations
Pixel shifting for reregistration
Annotation
Cine display
Flow measurements and profiles
Windowing
Contrast and brightness adjustments
Region-of-interest and distance measurements
Roadmapping
Stenosis quantification
Vessel size determination
Image management functions

The unit should also be capable of resolving a 0.4-mm vessel with 1% iodine contrast. The high-contrast spatial resolution should be comparable to the television system spatial resolution and should be at least 2.5 line pairs/mm in the 6-in (15-cm) field of view. The dynamic range of the system must be at least 1000:1, and the radiographic mottle should be acceptable to the operating physicians. Time jitter and lag in the system should be minimal to permit dynamic studies to be accurately evaluated.

The digital monitor is a good location for the display of additional information such as intraluminal ultrasound. In the future, simultaneous viewing of multiple images from different modalities will become commonplace. This will be developed first at the workstation, but it will also be desirable in the procedure room.

BEAM MODIFICATION DEVICES

Grids. Standard grids prevent some of the scattered x-rays from entering the image intensifier, so the patient entrance exposure must be increased by a factor of about two to compensate for the loss of these photons. The additional radiation also results in about twice the additional scatter radiation exposure to the operator. For this reason it has been suggested that grids be removed for patients in whom the scatter radiation does not significantly degrade image quality and in whom the highest quality fluoroscopy is not required (34). Carbon fiber grids, by nature of their construction, maintain the improved image quality associated with standard grids with only a 60% dose increase. Procedures requiring both high resolution and contrast can benefit from the use of a grid; the carbon fiber grid is a reasonable compromise. It is desirable that it be easily removed. A 6:1 to 10:1 grid ratio is recommended for the image intensifier. The focal length of the grid should match the source-to-image receptor distance of the unit. A similar grid would be suitable for the serial film changer.

Filters. Federal regulations specify a minimum half value layer of 2.3 mm of aluminum at 80KVP. However, the radiation dose can be reduced by adding additional filtration to the x-ray tube without significantly degrading image quality. Metals with atomic numbers less than 42 are as acceptable as aluminum. Usually 2 mm of aluminum or other equivalent material can be added to the minimum filtration provided by the manufacturer. By increasing the half value layer to 3 mm of aluminum, the entrance exposure rate can be reduced by approximately 30% without degrading image quality or increasing the x-ray tube heat loading substantially.

Collimators. The collimators should be adjusted so that the edges are just visible inside the fluoroscopic image. Because digital imaging is becoming more and more important and ultimately will replace conventional filming, additional iris or rectangular collimation is necessary. Rotating collimators should be provided to replace external devices used to administer boluses.

Automatic gain and iris control. Both features contribute to reduced patient exposure and are desirable. Automatic gain control of the video camera allows greater penetration for less exposure, and automatic opening of the iris allows additional light into the camera. Both, however, result in noisier images.

Contrast Injector

Power injectors should be capable of very slow injection rates as well as injection rates up to 50 mL/s. They should be flow rate-controlled but should have a mechanical stop and a pressure limit control. The syringe should be electrically isolated, the injector should have a ground cable attached to the patient support ground, and there should be an audible warning sound with current flows of more than 20 μA. The syringe should be
Physiologic Monitoring

A mechanism for monitoring the patient's blood pressure and cardiac rhythm is necessary for the safe performance of angiography. Intravascular pressures are most commonly recorded from fluid-filled catheters connected to strain gauge transducers. Transducers should have a linear response from -10 to 400 mm Hg. Two pressure channels and two ECG channels should be available, and a strip chart readout is desirable, as are a junction box and underfloor cabling. Currently, the waveforms are displayed on a separate oscilloscopic monitor. Ideally, they should be displayed full size on the fluoroscopic monitor when it is not in use and should be compressed to the bottom of the monitor when fluoroscopy is on.

Intravascular Imaging

Intravascular ultrasound. Intravascular ultrasound has been demonstrated to provide accurate diagnostic information about atherosclerotic occlusive disease (35). By providing real-time, two-dimensional, cross-sectional images of the vessel wall, it allows better determination of the extent of disease and the true extent of luminal compromise (36). Intravascular ultrasound provides detailed differentiation of the vessel wall layers, a unique characteristic (37). It also may allow more accurate determination of the end point in complex interventions such as percutaneous atherectomy and intravascular stent deployment (38). Images may be further enhanced by three-dimensional reconstruction. Accurate measurements of luminal diameter and cross-sectional area may be made with intravascular ultrasound, and there is promise of further development of tissue characterization.

Although the technology has improved rapidly, the limitations of intravascular ultrasound include the prolonged catheter time and the additional expense of catheters and capital equipment. The technology is a useful adjunct to angiographic equipment and, though not essential, it is probably desirable for the optimal environment.

Angioscopy. Some investigators feel that the use of percutaneous angioscopy can be beneficial. The miniaturization of fiber-optic devices has produced catheters as small as 4Fr. The advantages of angioscopy include visualization of the luminal surface, differentiation of thrombus from plaque, and the ability to directly guide endovascular devices.

Visualization is dependent on the displacement of blood, which is generally accomplished by a continuous, high-volume fluid infusion. This can result in the use of a high volume of fluid, which limits the visualization time. Because optimal visualization occurs in an occluded environment, angioscopy has only limited applications for percutaneous procedures.

CONTINUOUS QUALITY IMPROVEMENT

Personnel

The Joint Commission on the Accreditation of Health Care Organizations mandates that every health care institution have an ongoing quality improvement program to monitor itself and ensure that a high level of quality care is provided. The accreditation manual states that a departmental quality assurance program must "...objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and clinical performance and resolve identified problems" (39). The essential steps of monitoring and evaluating a continuous quality improvement program are summarized below.

A qualified person should assume responsibility for the monitoring and evaluation of quality in the department. Although the overall responsibility must rest with the physician, he or she may delegate duties to appropriate technologists, nurses, or administrative staff, who in turn must fully incorporate the interventional program into the remainder of the hospital's quality improvement efforts.

The person responsible for quality assurance must identify important aspects of care related to the procedures performed that have measurable outcomes: eg, the success rate of crossing and performing a primarily successful angioplasty. These data should be collected not only for the whole department but for each physician. It may also be appropriate to report long-term follow-up (40). Suitable reporting standards have been described for peripheral vascular disease (41).

The department should also identify complications pertinent to a particular procedure (eg, hematoma formation after catheterization as well as other relevant morbidities) and, again, report these not only for the whole department but for each operator.

These data should be collected from the facility and compared with national norms. In many instances these have been established by standards-of-practice documents so that standards may be set for the performance of each physician and the department as a whole (12). Another relevant document provides guidelines for establishing a quality assurance program in vascular and interventional radiology (35). It expands considerably on the comments above. Most standards-of-practice documents allow sufficient latitude to permit local adjustment to reflect regional practice differences. With this information, the practitioners and personnel in the facility may compare their performance to outside norms so that care can be improved and this improvement documented (39,42).

Database software to aid in gathering information for the assessment of quality is becoming increasingly available, and some medical organizations have developed peer programs tailored to the needs of interventional departments. Such databases should be considered a supplement to the presence of appropriately trained personnel with a commitment of medical staff leadership to support the assessment and assurance of quality care.

Equipment

Quality control charts should be maintained on the x-ray equipment and photographic processors because this method of data recording allows for early detection of drifts in operating levels. The responsible staff radiologist and technologist should review these data at least quarterly with the people collecting and interpreting data. In addition, all quality control
data should be reviewed by the medical physicist at least semiannually.

The responsible technologist should be familiar with the National Council on Radiation Protection and Measurements (NCRP) document entitled Quality Assurance for Diagnostic Imaging Equipment (45) and with the types of quality control tests that should be performed, the frequency of those tests, and a general idea of quantitative data that should be considered “reasonable.”

Photographic processors. Daily sensitometric testing of the processor should be performed to ensure proper and consistent film processing conditions, and a quality control chart should be maintained to detect subtle changes and drift in the film processing conditions. Weekly cleaning and regular preventive maintenance should be performed.

X-ray equipment. Daily testing of the fluoroscopic imaging system is necessary. Fluoroscopic image evaluation should include assessment of spatial resolution, image sharpness, and the visibility of low-contrast objects. This information, including the exposure factors, should be recorded to enable comparison with past and future data.

Physics test equipment. Instruments should be available to the physicist(s) to perform routine quality control measurements, radiation protection evaluations, and regulatory compliance assessment on the generator, x-ray tube, and image quality. Equipment for measurement of the ionizing radiation output should also be available.

PATIENT SAFETY

Electrical

Patients are connected to, and may come in contact with, numerous pieces of electrical equipment that have the potential to produce a low-impedance electrical pathway that may cause cardiac arrhythmias. Such problems can be prevented by proper design of the electrical system.

The facility should have a safe electrical primary wiring system; proper electrical isolation of all equipment attached to the patient; an equipotential, hardwired, grounding system for all equipment; and an effective, periodic (at least quarterly) inspection program for the electrical system. Measurements of electrical current leakage between all pieces of equipment that are attached to the patient and that may come in contact with the patient should be made during these quarterly inspections. The responsible physicist must keep abreast of evolving guidelines to ensure that the facility meets these standards. Electrical safety checks should be reviewed at least annually by a qualified medical physicist.

Mechanical

Mechanical safety checks must cover all aspects of every piece of equipment in the vascular and interventional facility, and defective equipment should be replaced immediately. Safety checks should be reviewed at least annually by a qualified medical physicist.

Radiation Safety

Because no exposure to ionizing radiation can be considered absolutely safe, the National Council on Radiation Protection and Measurements has established guidelines for occupational radiation exposure that are encompassed by the phrase “as low as reasonably achievable” (44). Furthermore, the council has established guidelines for maximum permissible occupational exposure levels (45). There are no maximum dose limits for patients undergoing diagnostic studies using ionizing radiation, because the immediate medical benefit is assumed to outweigh the potential radiation risk (45). The interests of optimum radiation safety, however, are best served when the vascular and interventional laboratory operates under the “as low as reasonably achievable” philosophy with respect to both patient and personnel exposure (46).

The cornerstone of minimizing radiation dose are minimizing exposure time, maximizing distance from the x-ray source, and using appropriate shielding. For angiographic and interventional radiologic procedures, however, in which fluoroscopy is used extensively, distance cannot be altered much: the patient must be close to the x-ray tube and the primary operating physician must be close to the patient. Therefore, in practice, optimization of radiation safety in the peripheral and interventional laboratory means minimizing fluoroscopy time and maximizing shielding.

Minimizing Radiation Dose to the Patient

The key to minimizing patient radiation dose is to limit the amount of radiation, particularly fluoroscopy (47), needed to accomplish the interventional procedure. Anything that contributes to decreased exposure time, decreased exposure rate, and decreased exposure area will contribute to decreased radiation dose to the patient.

Specific equipment features. NCRP recommendations for the design of structural shielding (48) and x-ray equipment (49) should be followed. A spacer should be affixed to the output side of the x-ray tube to prevent the table (and patient) from resting directly on the x-ray source. The grid should be detachable and should be removed for procedures that do not require high spatial resolution. Pulsed progressive fluoroscopy, which can decrease patient radiation dose by 30% to 50% compared with standard continuous fluoroscopy, should be available. Last image hold of the fluoroscopic image, as well as rotating lead collimators with manual hand controls within easy access of the operator, should be standard.

Federal regulations regarding maximum fluoroscopic radiation exposure rates must be followed. If high-level control fluoroscopy is available, activation should require specific, separate initiation by the physician; activation of high-level control fluoroscopy by a single two-stage foot pedal is not advisable (50). Activation of this fluoroscopic mode must be accompanied by a continuous audible signal, and the output of the x-ray tube in high level control fluoroscopy mode should be closely monitored and measured and should not exceed 20R/min.

A cumulative monitor of fluoroscopy time should be present and located in a position easily seen by the primary operator. The fluoroscopy time monitor should continuously emit an auditory signal at 5-minute intervals of elapsed fluoroscopy time until reset.
Equipment maintenance. All equipment items in the imaging chain should be maintained in optimal working order. This serves first to ensure the highest possible fluoroscopic image quality which can, in turn, contribute to lowered patient dose by resulting in decreased fluoroscopy time and decreased need for filming. In addition, equipment maintenance can ensure that optimum imaging is being accomplished with the lowest possible radiation output.

Endoluminal equipment. Radiopacity should be one consideration in choosing catheters, guidewires, and other devices for use in interventional procedures. Use of endoluminal tools that are not easily seen on the fluoroscopic image can contribute to prolonged fluoroscopy time.

Operator-controlled factors. All angiographic and interventional physicians must have documented training in radiation physics, radiation biology, and radiation safety. All angiographic and interventional physician trainees should practice only under the supervision of a fully qualified physician. In addition, all physicians should be familiar with the specific features of each piece of x-ray equipment they use to minimize patient and operator dose.

Record keeping. The fluoroscopy time and KVP for each case should be recorded.

Minimizing Radiation Dose to Personnel

Fluoroscopy is the major source of occupational radiation exposure (46). The primary operating physician is most at risk of receiving the maximum occupational dose. Minimizing patient radiation dose will help lower operator dose (51).

When positioned under the table, the x-ray tube will minimize backscatter radiation to the operator’s head and neck (52). Fluoroscopic equipment with an overtable x-ray tube is not appropriate for peripheral vascular and interventional laboratories. Long-leg changers have a tube above the table, but these are cut film units only.

Because the staff must be close to the x-ray tube and patient during fluoroscopy, the following shielding devices must be available:

Lead aprons. Lead aprons providing at least 0.5 mm lead equivalent thickness are necessary for all staff present in the laboratory during procedures. It is recommended that full-time physicians, technologists, and nurses wear custom-fitted aprons to ensure optimum coverage and maximum comfort. A wraparound style is recommended (51). Extra aprons should be available for visitors to the interventional suite, particularly anesthesia personnel, nursing staff, residents, and students.

Maternity aprons providing 1.0 mm lead equivalent thickness to the abdomen front and sides must be available to pregnant workers, especially to full-time physicians who can receive under-lead doses approaching 5 mSv/y (the NCRP-recommended maximum for gestational exposure (45)) with 0.5 mm lead equivalent coverage (53). Like standard aprons, maternity aprons should be custom-fitted for full-time workers. The 1.0 mm lead equivalent thickness provides only a little more protection than 0.5 mm, but this is likely to be perceived as important.

Supplemental shielding devices. Supplemental lead shielding to the head and neck is advisable for the primary operating physician who may have yearly external over-lead (ie, collar badge readings) radiation doses well above the maximum permissible dose of 50 mSv in a single year or 10 mSv/y averaged over a lifetime (53). Reported doses to technologists and nursing staff are much lower, and supplemental shielding devices are not absolutely necessary for these workers (54–56). Doses to anesthesia personnel can be higher (55). Because personal perception of risk varies so much (57), it may be necessary to provide the items listed below to all members of the laboratory upon request, but they are not a substitute for education about radiation protection.

Thyroid collars. If the customized apron does not shield the thyroid gland, the primary operator should wear a thyroid collar. (See “Leaded Face Shields” and “Ceiling-Suspended Leaded Glass Shields” for alternatives.)

Leaded glasses. The lens of the eye is the critical organ not covered by the lead apron (45). Maximum yearly recommended dose to the lens is 150 mSv (15 rem) (45), a dose approached by busy interventional physicians (53). Therefore, full-time angiographic and interventional physicians should wear leaded glasses with side shields. These can be incorporated into goggles designed for body-fluid shielding. Like the lead aprons, the glasses should be custom-fitted. (See “Leaded Face Shields” and “Ceiling-Suspended Leaded Glass Shields” for alternatives.)

Leaded face shields. An alternative to glasses and thyroid collars are head-mounted or shoulder-mounted leaded face shields. These provide both radiation and body-fluid protection.

Leaded gloves. Because the NCRP-recommended maximum permissible dose to the extremities is 500 mSv/y (45), lead glove protection is optional. These gloves are thicker than standard surgical gloves and should not be worn if they interfere with the technical demands of the physician’s task. They only reduce skin dose by about 10% to 20%. The best way to minimize operator hand dose is to use tools designed to keep the hands as far from the primary x-ray beam as possible.

Ceiling-suspended leaded glass shields. Each room should be equipped with a ceiling-suspended leaded acrylic shield (providing at least 0.5 mm lead equivalent protection) that can be placed in front of the operator’s face. This can be used in addition to, or instead of, other head and neck shielding. The boom should be mounted on a ceiling track, available for use on both sides of the table as well as at the head. The angiographic and interventional laboratory director should be consulted about the design and placement of the shield at the time the room is being designed. These items are frequently underserved because they do not serve the needs of the operating physicians with respect to flexibility of placement and angulation (53).

Other leaded shields. Leaded acrylic shields (providing at least 0.5 mm lead equivalent protection) that can be moved around the floor on wheels should be available (58,59). Appropriate storage racks for lead aprons, thyroid collars, glasses, and face shields should be available in or in close proximity to the laboratory. A regular schedule should be followed to check lead shielding devices for
cracks. Defective shielding items should be repaired or replaced promptly.

Personnel dosimetry. Radiation safety is best managed when the radiation safety officer understands angiographic and interventional procedures and is considered an integral part of the team.

State regulations on personnel dosimetry, including location of dosimeter badges, must be followed. All personnel who work full-time or regularly in the laboratory (eg, anesthesia staff) must wear at least one assigned film badge or thermoluminescent dosimeter. The badges should be read monthly and the results reported to the workers. Doses that exceed monthly or quarterly maximums should be investigated by the radiation safety officer.

Ring badges should be available on request and are recommended for physicians who exceed monthly or quarterly radiation exposure limits as measured by the collar dosimeter. If a ring badge is worn, it should be on the hand usually closest to the primary x-ray beam.

The pregnant worker deserves special consideration with regard to occupational radiation safety. (See above for recommendations for lead apron use.) It is the responsibility of the worker to notify the laboratory director and the radiation safety officer of her pregnancy. It is possible to ensure that the fetal radiation dose remains well below the NCRP maximum permissible doses of 5 mSv for the entire gestational period and 0.05 mSv/mo (52). According to Title VII of the 1964 Civil Rights Act, a pregnant worker cannot be forced to discontinue her actual duties (60). However, the laboratory director and the radiation safety officer must remain sensitive to the fact that personal perception of risk varies, and good-faith attempts should be made to modify the pregnant worker’s duties in accordance with her risk perception if she requests a change in her job description during pregnancy. An under-apron waist dosimeter should be provided to the pregnant worker to document skin dose and provide information about her actual exposure levels.

Because angiographic and interventional procedures account for some of the highest occupational exposure levels (61), personnel dosimetry practices in the interventional laboratory may exceed state regulations. Each worker should wear two badges—one at the collar outside the lead apron to register the approximate head/neck dose and one under the apron at waist level to register approximate gonadal dose. The readings of the two badges can be used to estimate (62,63) total body effective dose equivalent as recommended by the International Commission on Radiation Protection (64). Effective dose equivalent calculations provide a way to relate the risk from partial body exposure to equivalent whole-body dose. Therefore, effective dose equivalent calculations may provide a more accurate estimation of radiation risk to partially shielded workers than does the dose to a point dosimeter. In the future, estimated effective dose equivalent rather than point dosimetry (ie, collar badge readings) may be used for monitoring by state regulatory agencies.

Recommendations for occupational exposure to low linear energy transfer radiation are evolving as a result of a report in which it was concluded that the ill effects of low linear energy transfer radiation are two to four times more significant than was previously believed (65). The ICRP has lowered its recommended maximum yearly total body effective dose equivalent from 50 mSv/y to 20 mSv/y for people whose occupations expose them to radiation (64). NCRP recommendations on permissible occupational exposure (44) are used as guidelines by state regulatory agencies in the United States, but not all states have produced legislation in response to this new information. Nevertheless, meticulous attention to radiation safety issues is becoming increasingly important in the practice of angiographic and interventional medicine, and the requirements for optimum resources may change as regulations change.

References

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Tobacco Cessation Guidelines

In 1964, the U.S. Surgeon General issued the first reports on the dangers of cigarette smoking, providing clear and convincing evidence that smoking is dangerous, and warning the public officially of these dangers. New studies continually add to this body of evidence.

Tobacco cessation should be an important part of patient management for all interventional radiologists (IR). The care and management of patients that IRs treat are often complicated by ongoing cigarette consumption. One of the most valuable services that physicians can provide to their patients is to help them stop smoking.

Institution in how to counsel patients, the biochemistry of nicotine addiction, drug therapies for patients who need to quit smoking, and methods physicians can use to help facilitate the process should be an integral part of IR practice. Understanding the biochemistry of tobacco addiction is important information needed to counsel patients about smoking cessation and available drug therapies that can help them stop smoking.