

## ACC/AHA AD HOC TASK FORCE REPORT

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### ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories

#### American College of Cardiology/American Heart Association Ad Hoc Task Force On Cardiac Catheterization

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##### Introduction

During the past four decades an evolution in cardiac catheterization has taken place. The role of the cardiac catheterization laboratory has progressed from study of cardiac function and anatomy for purposes of diagnosis to evaluation of candidates for surgery and finally to providing catheter-based, nonsurgical interventional treatment. This progress has stimulated an increase in demand for cardiac catheterization services. However, as a result of the need to decrease health care costs, there have also been major changes in the types of patients admitted to hospitals. Accordingly, an increasing proportion of catheterizations are being conducted in settings other than traditional hospital-based catheterization laboratories. As newer cardiac diagnostic and treatment modalities are developed, it is highly likely that the role of cardiac catheterization will continue to evolve. From this evolution a number of concerns have been raised about the ability of catheterization services to meet constantly changing patient care needs while maintaining patient safety and restricting possible overutilization.

##### Objectives/Statement of Purpose

The purpose of this report is to critically examine all types of cardiac catheterization laboratory services and their specific role in providing optimal care for patients with known or suspected cardiac disease. The task force was asked to examine all laboratory activities, including their recent proliferation and modifications. Issues such as ambulatory cardiac catheterization, mobile laboratories, and ethics were specifically targeted. To address this charge, for more than 2 years the task force conducted numerous deliberations, reviewed current literature, conducted two surveys of both members and nonmembers of the American College of Cardiology and the American Heart Association, and collected testimony and correspondence from members of the cardiology community in the United States. Based on this examination, recommendations and guidelines for catheterization laboratories were developed. These guidelines should not be considered rigid; rather, they are to be modified by clinical judgment, individual patient needs, and advances in technology.

##### Traditional Cardiac Catheterization Settings Inception, Development, and Expansion

Between 1940 and the early 1950s, a few highly specialized laboratories for cardiovascular research and limited diagnosis were located in large medical centers and were used primarily to assess cardiac function and identify anatomic abnormalities in patients with congenital or valvular

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heart diseases (1-3). The patients studied were mostly in New York Heart Association (NYHA) functional classes III and IV (see Appendix A) for heart failure. Between the mid-1950s and late 1960s, more catheterization laboratories were established, also at major medical centers. This expansion was largely fueled by the development and application of new techniques such as percutaneous and transeptal approaches and selective coronary angiography, as well as cardiopulmonary bypass and surgical procedures for treatment of patients with congenital or valvular heart diseases. Some patients were studied for diagnosis of coronary artery disease. Cardiac catheterization was used increasingly for diagnostic purposes at many centers. Because most of the patients studied were potential candidates for surgery, most were symptomatic, with heart failure or angina pectoris or both.

### *The "Coronary Era"*

From approximately 1970 to the early 1980s, the numbers of cardiac catheterization laboratories and procedures performed continued to grow and then plateaued. This growth was stimulated by a highly successful technique for coronary artery bypass surgery, as well as by the improved safety of cardiac surgery in general. New catheter materials and better radiological equipment reduced the time required as well as the risks of catheterization while improving the quality of the study. The number of patients studied for diagnosis and selected for coronary bypass and other types of cardiac surgery increased substantially. This growth was accommodated by an increase in traditional cardiac catheterization laboratories. Most laboratories were located in larger centers, but some were established at satellite centers without cardiac surgery support and were dependent on a strong relationship with a nearby cardiac surgical program. Because candidates for surgery were usually selected from these studies, most patients were in NYHA classes III and IV. Some patients with less severe symptoms (Canadian Cardiovascular Society [CCS] classes I and II [see Appendix B]) were also studied to determine the presence and extent of coronary artery disease. The relative number of patients studied for diagnosis of congenital heart and valvular heart disease diminished as echocardiography and other noninvasive diagnostic modalities improved. But a relatively constant number of patients were sufficiently symptomatic to warrant preoperative evaluation for valvular and congenital heart diseases and continued to be seen at these expanded laboratories.

### *The "Therapeutic Era"*

From about 1982 to the present, there has been an unprecedented proliferation of cardiac catheterization services (2), which have now been expanded to a wider group of patients and diseases. One reason is the almost totally unrestricted environment for development and growth that many regions of the country have given cardiac catheteriza-

tion services (4). The increase in patients and laboratories has also been stimulated by the development of nonsurgical, catheterization laboratory-based therapeutic procedures for palliation of both stable and unstable ischemic heart disease as well as selected valvular and congenital heart diseases, arrhythmias, and other problems. Widespread use of cardiac surgical procedures, cardiac assist devices, cardiac transplantation, and electrophysiological studies, all of which require cardiac catheterization, has also led to a more aggressive management approach for patients with heart failure, cardiogenic shock, and arrhythmias. Many noncardiac diagnostic and therapeutic vascular procedures are now being performed in cardiac catheterization laboratory settings, but this area is still evolving, and guidelines for these services are beyond the scope of this document.

### *Cost-Benefit Considerations*

Over the years, traditional catheterization laboratories have gained a highly regarded reputation for excellence in physiologically oriented and anatomically precise diagnosis. These laboratories provided major research advances as well as catheter-based therapies (2). Their safety record was excellent even for very sick patients (5), who received care with a very favorable cost-benefit ratio. In fact, these factors led to the conclusion in at least one report (6) that catheterization laboratory evaluation of the middle-aged man with chest pain was the most efficient initial step in management of such patients.

### **Nontraditional Cardiac Catheterization Settings**

As the need for cardiac catheterization services increased and hospital admissions were limited by third-party agencies, a number of nontraditional settings for cardiac catheterization emerged, including catheterization of less sick ambulatory patients in traditional catheterization laboratories and the development of a number of other settings (7-17). The nontraditional settings are best characterized by freestanding cardiac catheterization laboratories, which first evolved in relatively rural settings and now also exist in large urban areas, sometimes near major medical centers with traditional cardiac catheterization laboratories. With adaptation and modification of equipment, self-contained mobile (18) and modular laboratories have been developed. In these nontraditional laboratories the major stated goals are to reduce costs and bring cardiac catheterization services closer to patients. Most of these laboratories focus on the low-risk ambulatory patient.

### **Questions and Concerns**

The evolution of cardiac catheterization and proliferation of different cardiac catheterization settings, along with the variation in the type of patients studied (e.g., from very symptomatic to asymptomatic), have raised numerous ques-

tions, for example about the type of laboratory best suited for specific patients and its location. Other concerns are cost-benefit ratios and absence of hospital-based or other regulatory controls. All of these questions relate directly or indirectly to the quality of patient care.

## Quality of Patient Care

### *Patient Safety*

Issues of patient safety can be divided into the following areas: 1) general laboratory organization and safety (protection from infection [e.g., hepatitis, acquired immune deficiency syndrome], excessive radiation); 2) credibility of the operator and other staff; 3) quality control of equipment and emergency back-up for the operator and other staff (the quality of the study must be optimal for precise diagnosis and appropriate referral for surgery or catheterization laboratory intervention, as well as for diagnosis to exclude important cardiac disease. Major concerns have been raised about some of the newer catheterization settings—mobile laboratories, for example—because it is often difficult to plan for emergency back-up. Most radiography equipment was adapted for use in these new settings rather than specifically designed for this setting, and quality control procedures vary widely); 4) risk stratification before catheterization to ensure that candidates are screened appropriately to reliably identify those who may undergo certain studies in a nontraditional setting at low risk; 5) risk-benefit ratios (many patients in the newer settings are less symptomatic and may have a better prognosis than those who are severely symptomatic, so risk-benefit ratios may be less favorable. Because risks were assessed largely in the more symptomatic patient populations studied in traditional settings, it may not be appropriate to compare them with studies in less traditional settings); 6) assured, timely access to emergent or urgent cardiac surgery, vascular surgery, cardiac anesthesia, cardiovascular radiology, and so on; and 7) the assumption of responsibility in the event of an emergency by the nontraditional laboratory operator, the hospital providing holding area support, or the hospital providing surgical back-up.

### *Lack of Definitions and Indications*

There is confusion about the terms used to describe the newer settings as well as a lack of uniform definitions for these settings and for many of the procedures used in these settings. Although the ambulatory, less symptomatic patient is, in general, studied in the newer settings, indications for cardiac catheterization in this type of patient have not been clearly defined. This leads to confusion among primary care physicians, other cardiovascular referral sources, and patients about who should be candidates for study in nontraditional settings. Likewise, third-party reimbursement programs and government agencies have difficulty defining which procedures should be reimbursed in which patients

and in what type of environment. State and local planning agencies are handicapped by limited and confusing information. There are no guidelines for possible additional legal liability to the physician who refers patients to these newer settings for cardiac catheterization.

### *Lack of General Guidelines for Catheterization Laboratory Service Development*

The number of patients and the kinds of resources required to justify development of cardiac catheterization laboratories, particularly newer nontraditional laboratories, have not been defined. This lack of guidelines may lead to unnecessary growth of services. For example, the optimal location for these services has not been evaluated, and duplication of services within certain geographic locations could lead to cost-cutting measures by existing laboratories to remain competitive, which could have important implications for quality and safety. There is no current (i.e., periodically updated), central source of information about any type of catheterization laboratory, numbers and types of procedures performed, the locations served, and so on.

### *Lack of Documentation for Cost-Containment Justification*

There is also concern about the lack of published, objective data to support the claim of a substantial difference in cost between cardiac catheterizations in traditional laboratories and less traditional settings (8,19). Although in theory it seems that ambulatory catheterization in any setting represents a potential savings over costs incurred by hospitalization, there are limited data relative to the actual magnitude of the difference (19). Some questions remain: What are the total cost implications for a given region if there is further proliferation of catheterization services in that region? What is the response of physicians to the newer ambulatory care settings for catheterization when these centers provide doctors with financial incentives to increase revenues? (20).

### *Ethical Concerns*

The evolution and expansion of cardiac catheterization services in a rapidly changing professional and industrial environment have coincided with a crescendo of interest in both medical and business ethics (21-23). This increased interest has placed numerous ethical dilemmas before physicians and hospitals who face a large number of economic pressures. Patients, the public, and government are seeking greater assurances that physicians hold the best interests of the patients above their own (23). Siegler et al. (24) summarized the situation when they stated that the "central moral dilemma facing concerned patients and conscientious physicians today is to balance the rights of patients and responsibilities of physicians with the rights of physicians and the responsibilities of patients at a time when societal values and

expectations are changing." This position was endorsed at a recent Bethesda conference on ethics in cardiovascular medicine (23).

### *Self-Ownership of Laboratories*

The proliferation of cardiac catheterization services, often removed from the hospital environment, has led to concerns about conflicts of interest in ownership and operation. Some of these ventures are limited partnerships, with the catheterizing physician as the general partner and the referring physicians as limited partners. This is an important concern because in some for-profit ambulatory care centers, physicians increased the number of laboratory tests and x-rays performed per patient visit when financial incentives were provided (20). Ownership by physicians who operate, or refer patients to, laboratories could lead to serious problems. These concerns are similar to those raised about radiologists working in x-ray facilities and surgeons operating in surgical centers in which they have a financial interest. Conflicts of interest exist when a physician, as owner or investor, may benefit financially over and above the fee for service when procedures are done (23,25-29).

### *Self-Referral of Patients to Laboratories*

Cardiologists who also operate catheterization laboratories are in a unique position; they can refer patients seen in clinical settings to their own catheterization laboratory practices (23,25,28,30). It is not unusual for the cardiologist who makes the initial clinical assessment, which includes diagnostic studies such as the electrocardiogram (ECG), echocardiogram, and stress test, to also recommend further diagnostic testing, such as catheterization. This same cardiologist might then perform the catheterization and make further recommendations for, or even perform, therapeutic catheterization procedures such as percutaneous transluminal coronary angioplasty (PTCA). Although the cardiologist may receive a fee for each of these procedures, this does not necessarily represent a conflict of interest, for which there is little public tolerance (23,25,28,30), if the procedures were done for justifiable medical reasons.

As catheterization services are established in rural areas, there is a possibility of close association with, and even ownership by, large group practices or health maintenance organizations. There is also potential for self-referral of patients within a large group partnership.

### *Self-Reporting of Outcome*

Concerns have been raised about the accurate reporting of catheterization results and complications in the newer cardiac catheterization settings. The potential for conflicts of interest is compounded if data are collected and reported by the referring cardiologist who is also the catheterizing cardiologist and who also has a business interest in the laboratory. Should uncontrolled proliferation of laboratories con-

tinue, intense local competition could occur, resulting in the potential for suppression of clinical data on adverse events. Increasing local pressures could also produce a need to maintain an unreasonably low cost and low adverse event rate to solicit third party-payer contracts, eventually resulting in reduced quality of care.

### *Advertising*

Because many of these new catheterization services are small business ventures, advertising is not unexpected. A general concern is that advertising may tarnish the image of the entire cardiology community and increase costs when directed at increasing patient interest in a particular physician-owned laboratory. Questions about the use of investigational cardiac catheterization devices as a marketing ploy have also surfaced when these devices are used in a setting without a past record of interest in clinical investigation. The role of industry as initiators in the "seeding" of non-investigationally oriented clinical practice catheterization laboratories is another concern, particularly when the seeding is done solely to gain a marketing edge on other "investigational" catheterization devices.

### **Definitions**

To facilitate meaningful communications and recommendations about these concerns, it seems appropriate to first define different catheterization settings before preparing recommendations and guidelines for physical facilities, personnel, and patients.

### *General Information*

For the purposes of this review and subsequent dialogue, it is helpful to classify cardiac catheterization laboratory settings as traditional and nontraditional. Because there is no official guide, a central information source would be helpful and is strongly recommended to maintain data on the types, numbers, locations, regions served, and services performed by each catheterization facility. On a national level, organized cardiology should consider developing this service and updating it yearly. On a local level, state planning agencies, medical societies, or American College of Cardiology chapters should consider taking an active role to provide updated information on cardiac catheterization services.

### *Traditional Laboratory Settings*

There are several types of traditional cardiac catheterization laboratory facilities, the term 'traditional' meaning that these laboratory facilities are organized and operated physically and administratively in a hospital. One type of laboratory is operated in a hospital with in-house cardiovascular surgical support. These laboratories may offer full service or focus on a specialized service. Examples of specialized laboratories are therapeutic (interventional), electrophysiological, and pediatric catheterization laboratories. Another

type of laboratory is operated in a hospital in which there is no in-house cardiac surgery support. This type of laboratory offers limited service.

**Full-service laboratory with in-house cardiovascular surgery.** In this type of facility, both diagnostic (e.g., angiographic and physiological) and therapeutic procedures are performed on the heart and great vessels for a wide variety of cardiovascular diseases. Depending on volume and case-load, some hospitals may contain more than one such laboratory. A laboratory of this type should be fully equipped and staffed, as outlined in Appendixes C and D, so that excellence in diagnosis and therapy is attained at minimum risk to the patient. It should operate at near-optimum capacity to justify the expense of operation, maintain the skills and teamwork of the operators and staff, and provide maximum patient and operator safety. The need for documentation of results is discussed in Appendix C.

**Specialized service laboratory with in-house cardiovascular surgery.** The services of this type of facility are focused on a specific area of interest. Laboratories of this type usually exist in hospitals that also have full-service catheterization laboratories. The specialized laboratories must be organized and operate in the same optimum fashion described for full-service laboratories, but they also require specialized equipment and resources. The needs for staffing and documentation of results and complications for specialized laboratories, as well as suggested laboratory arrangements, are outlined in Appendixes C and D.

Some examples of specialized laboratories are worthy of further discussion. Diagnostic laboratories may offer only diagnostic procedures and should be supervised by an operator experienced in diagnostic catheterization. Other hospitals may have separate therapeutic (interventional) laboratories for the performance of coronary angioplasty, peripheral angioplasty, and balloon valvuloplasty, although these procedures do not necessarily require a dedicated specialized laboratory. Therapeutic laboratories should be supervised by a physician experienced in diagnostic catheterization who has additional training and expertise in the specialized therapeutic procedure performed. Physicians performing these therapeutic procedures, whether in a full-service or specialized facility, must show evidence of proper training and skill before they are credentialed. A low complication rate must also be documented as an ongoing review process. Laboratory personnel can often have the same skills as those employed in a full-service laboratory, but they require special training in patient observation and management and in the use of special equipment (e.g., balloon catheters, lasers, and atherectomy devices). Therapeutic laboratories may have specialized recording equipment requirements. It is important to reemphasize that cardiac surgical support for these laboratories must be in-house and immediately available. Although a recent report (31) from Northern Ireland implies that adequate management of acute coronary artery disease after PTCA can be achieved in hospitals without in-house surgery, this task force rejects this notion for

laboratories in the United States. More than one third of acute occlusions (11 of 32) occurring after PTCA were "handled medically" after unsuccessful attempts at redilatation in the Irish report. At least three patients died (related to acute coronary occlusions). This high frequency of acute occlusion, handled without emergency surgery, after unsuccessful attempts at redilatation is not currently acceptable practice in the United States and was probably influenced by the lack of in-house cardiac surgery. In addition, the average delay for those sent to surgery was 273 minutes, which is also not acceptable in the United States. Emergency cardiac surgery can be started in most hospitals within 30-45 minutes for critical cases with acute occlusion after PTCA.

**Clinical electrophysiology laboratory.** An electrophysiology laboratory must be supervised by a trained and experienced clinical electrophysiologist. Physicians operating in the laboratory must be thoroughly trained in the interpretation and treatment of arrhythmias and conduction disorders. Provisions for pacing, defibrillation, and resuscitation must be immediately available. Specialized equipment needs should allow for complete electrophysiological study of patients with any type of cardiac electrical disturbance. The technical staff of other types of laboratories should not be used in electrophysiology laboratories without in-depth special training.

**Pediatric diagnostic and/or therapeutic catheterization laboratory.** This specialized laboratory should be supervised by a pediatric cardiologist and must be supported by pediatric cardiac surgery and pediatric anesthesia. The number of studies required for optimum use of such a laboratory is lower than for a nonpediatric laboratory but should be adequate for the maintenance of operating excellence (see Appendix C). Biplane cineangiographic equipment must be available in this type of laboratory to obtain quality studies while keeping contrast agent volume at safe levels. Proper temperature regulation equipment is required for the neonate.

**Laboratories without in-house cardiovascular surgery.** Although it may be possible for a cardiac catheterization laboratory to function well in an institution without a cardiac surgical program, these laboratories will offer limited services. To function, formal arrangements between this type of laboratory and a hospital with cardiovascular surgery must be made. These arrangements must be recorded and periodically updated to facilitate patient care and rapid information transfer when necessary. Regulatory agencies and third-party reimbursement agencies should require that these arrangements be documented and reviewed on a regular basis. Laboratories without surgery available on site will also see less variety in the condition of patients undergoing evaluation because they must exercise particular caution to not accept unstable, acutely ill, or other high-risk patients for study. Patients at high risk for catheterization-associated complications should be referred to centers where on-site surgery is available for stabilization and diagnostic catheterization procedures. Diagnostic procedures that may be as-

sociated with a relatively high complication rate, such as transseptal puncture or transthoracic left ventricular puncture, should not be performed in a hospital without cardiac surgical support. Myocardial biopsy also should not be done without surgical support. Infants and children are another high-risk group and should be catheterized only in an institution that has an established pediatric cardiovascular surgical program. Therapeutic procedures such as PTCA and balloon valvuloplasty must not be attempted without in-house cardiac surgical support. All procedures that require extracorporeal circulation in the laboratory must have formal consultation with a cardiothoracic surgeon whenever the use of this type of support is contemplated. In some emergency situations, however, formal consultation may not be possible.

### *Nontraditional Laboratory Settings*

**The freestanding cardiac catheterization laboratory.** A freestanding cardiac catheterization laboratory is a laboratory that provides catheterization services but is not physically attached to a hospital, and may or may not be under hospital administration. It may be located adjacent to a hospital, near a hospital, or even miles from a hospital. "Adjacent" is taken to mean so close that patients could be transported by gurney from the freestanding laboratory to the hospital providing cardiac surgical support.

**The mobile cardiac catheterization laboratory.** By definition, a mobile laboratory for cardiac catheterization is an entire laboratory, consisting of a single unit or multiple units joined together, that is transportable by land, sea, or air. This type of laboratory may stay in one location on a temporary basis. Sometimes, by the addition of side panels or the combination of several movable units into a single unit, the laboratory is referred to as a "modular" laboratory. The essential element in the definition of these facilities is that the laboratory is, or can be made, transportable to another location. In practical terms, the mobile cardiac catheterization laboratory provides catheterization laboratory services in one location and then may be quickly relocated, usually by being hauled behind a truck, and rapidly set up to provide services at another location (18).

Several types of mobile catheterization laboratories exist:

**The mobile catheterization laboratory with hospital and emergency cardiovascular surgical support.** This kind of laboratory is transportable, temporary, and adjacent to a hospital with a functioning cardiac catheterization program and cardiac surgical capability. Again, "adjacent" is taken to mean so close that patients can be transported by gurney from the temporary laboratory to the hospital. It is anticipated that this kind of laboratory service will provide catheterization services during installation of a new laboratory or loss of a laboratory due to equipment failure or fire for example. In such cases the laboratory would be used only temporarily and, although transportable, would remain on a single site at all times. Hospital personnel who staff the

regular hospital-based laboratory would operate the mobile laboratory and would use all quality assurance and administrative procedures followed by the hospital.

A variation of this type of laboratory may be one providing catheterization services only intermittently on a recurring basis. Again, patients could be moved from the temporary catheterization laboratory to the hospital by gurney; however, this laboratory may or may not be under the quality assurance and administrative control of the hospital. If it is, the hospital must provide written guarantees of quality assurance.

**The mobile catheterization laboratory with the support of a hospital that does not have an active cardiovascular surgical program.** Physically, this is the type of laboratory described above, except that the hospital near which it operates does not have cardiac surgical support. If emergencies arise during catheterization, patients must be transported by ambulance (land or helicopter) to a hospital with surgical support. In this setting, the hospital providing the surgical support must formalize the support agreement in writing and oversee quality assurance.

**The completely mobile and temporary cardiac catheterization laboratory without hospital hook-up, surgical back-up, or administration.** This type of mobile catheterization laboratory is entirely freestanding, without immediately available hospital or surgical support. Patients must be moved by air or land ambulance if emergency hospital care is needed. Likewise, patients must be moved by ambulance to the hospital at which cardiac surgical support is provided. The task force does not believe that adequate arrangements for these emergency services could be demonstrated in our current technological environment.

### *Recommendations for Laboratory Development, Design, and Operation*

Many cardiac catheterization laboratories are without surgical back-up. Despite this fact, there is little documentation of patient safety, laboratory quality, and need. The cautious attitude to be taken toward such facilities and their development is particularly necessary for the development of nontraditional (e.g., freestanding or mobile) laboratories. Patient safety and other quality indications must be documented in the future through well designed clinical trials and careful prospective collection of data. Only through data from such studies documenting need, safety, and cost reduction can commitment of resources be justified.

A recommendation for the development of new facilities or expansion of existing cardiac catheterization services must be based on patient need. Documentation of this need must be determined from objective estimates of the number of patients residing within a geographic area with known or suspected cardiac diseases that meet generally accepted indications for catheterization laboratory study. Because the task force could find no uniformly acceptable criteria to define the need for a new laboratory, a very cautious

approach to the development of new laboratory services is recommended. Most patients already live less than 30-60 minutes away (by land or air ambulance) from an existing laboratory. When a need can be documented, a traditional laboratory with cardiac surgery support is recommended. Without supporting data from appropriate clinical trials, the development of new laboratories without cardiovascular surgical back-up cannot be recommended at this time.

In general, recommendations for administration, personnel, staffing, use of the laboratory evaluation of performance, and conduct of the examination are the same for traditional and nontraditional laboratories. For the nontraditional laboratory, specific areas that require emphasis are the need for a formal agreement by a hospital to provide emergency surgical support and quality assurance. In addition, it is imperative that if the patient is hospitalized, the catheterization records and cine films be stored in that hospital if the procedure is performed in one of the newer, nontraditional catheterization facilities. If the patient is ambulatory, records and films should remain with the patient at the holding area, which may be physically removed from the laboratory. After the patient leaves the holding area, these documents must be stored where they can be promptly retrieved if an emergency, such as a late complication or rapid disease progression, arises. (See Appendixes C and D for recommendations for laboratory development, design, and operation.)

### *Types of Procedures*

A number of procedures may be done in any laboratory setting. The different types of cardiac catheterization procedures that may be performed should be standardized in nomenclature and description. A uniform description for each of these procedures is provided in Appendix E.

### *Types of Patients Undergoing Catheterization*

Patients undergoing cardiac catheterization may be classified as ambulatory patients or inpatients. The ambulatory patient does not stay in the hospital overnight. This definition excludes patients who spend either the night before or after the procedure in the hospital, even though they may spend less than 24 hours in the hospital. However, this definition does include patients who spend a night before or after the procedure in a hotel, the holding area of the laboratory, or other nonhospital facility. The patient who spends 23 hours in the facility is clearly not considered an ambulatory patient. Ambulatory patients should be at low risk for complications from cardiac catheterization or rapid disease acceleration. All other patients likely to undergo cardiac catheterization procedures are considered inpatients for the purposes of this document. In general, inpatients are those at somewhat higher risk for complications associated with catheterization or for rapid disease acceleration.

## **Recommendations for Catheterization of Patients in Different Settings**

In any catheterization setting, patient safety must be of paramount importance and must supersede all other considerations. Two recent ACC/AHA task force reports have outlined guidelines for appropriate selection of patients for coronary angiography (32) and PTCA (33) in the traditional inpatient laboratory setting. Clearly, not all patients eligible for coronary angiography, and *no* patients undergoing PTCA, should be considered candidates for ambulatory catheterization; and although many clinically stable patients with coronary artery, valvular, congenital, or myocardial disease may be evaluated appropriately in the ambulatory setting, placing any patient at an increased risk for the sake of patient convenience or monetary savings cannot be condoned.

Published objective data on rigorous analysis of the risks of ambulatory catheterization are limited. Most reports are based on catheterization laboratory evaluation of ambulatory patients in a hospital environment. These reports suggest that ambulatory catheterization performed in selected adult (7-10) and pediatric patient populations may be done safely (11). These studies, however, exclude many patients on the assumption that certain subsets of patients who are at higher risk are inappropriate candidates for ambulatory cardiac catheterization. In the only controlled study reported to date comparing inpatient and ambulatory procedures, an estimated 80% of candidates for cardiac catheterization were excluded for ambulatory catheterization because the risk was not thought to be acceptable (12). Despite this rigorous screening, urgent hospitalization was still required in 12% of those evaluated in the ambulatory catheterization setting. These data strongly suggest that the decision to perform ambulatory cardiac catheterization must be made cautiously. Furthermore, reports from uncontrolled trials in which the majority of patients were not excluded as candidates suggest that different populations of patients may have been studied. It must be recognized that no absolute guidelines can be derived from existing data that will permit reliable exclusion of all patients potentially at risk for complications. Furthermore, a small but significant proportion of serious catheterization-related complications occur suddenly and unexpectedly during or after a procedure (5,34). Thus, before ambulatory catheterization, plans must be formalized for urgent hospitalization and special care after catheterization should the need arise. For ambulatory catheterization in a limited-service laboratory without in-house cardiac surgery, it is mandatory that these arrangements be formalized before the first patient is studied. These agreements must be available for review and periodically updated. Before catheterization, the patient must be informed about possible urgent hospitalization arrangements. A realistic discussion of the potential risks associated with possible delays, particularly those related to the nontradi-

tional aspects and the setting of the ambulatory procedure, should be presented before obtaining informed consent.

### Classification of Candidates for Cardiac Catheterization in Various Laboratory Settings

The guidelines recommended here are based on task force discussions about the clinical ability of physicians to eliminate from candidacy for ambulatory procedures most of the patients at high risk. If skilled clinical risk stratification is not available or if the patient requires hospitalization for any cause, ambulatory catheterization should not be performed. These guidelines are structured to conform with other ACC/AHA guidelines, that is, Class I describes conditions in which there is general agreement that ambulatory catheterization can be safely performed, Class III describes conditions in which there is general agreement that ambulatory catheterization in any setting is clearly inappropriate, and Class II describes conditions in which there are differences of opinion. Because the task force found data adequate to justify exclusion of some patients from treatment in certain catheterization laboratory settings, Class III indications are presented first. This presentation seems to more definitively exclude certain patients for treatment in special laboratory settings. These guidelines also apply to catheterization in any setting without in-hospital cardiac surgical support. Candidates are considered generally and also in specific disease states to conform with the ACC/AHA task force guidelines for coronary angiography (32).

### The Patient at Risk for Complications From Cardiac Catheterization

A variety of sources provide useful information about patients at greatest risk for an adverse event related to cardiac catheterization (5,34-36). Mortality statistics for catheterization in general are outlined in Table 1. These data are useful to help identify those who are at greatest risk for adverse outcomes of ambulatory catheterization. Features of other patients at potentially increased risk for adverse outcomes of ambulatory catheterization are summarized in Table 2. Because some complications that occur during catheterization may require immediate access to a hospital and often to cardiac surgery, patients at highest risk for adverse events must not undergo catheterization without such support. Clinically, those at greatest risk include the very young and very old (more than 75 years), those with important (NYHA functional class III or IV) congestive heart failure symptoms, those with acute or unstable ischemic syndromes (e.g., unstable angina or acute myocardial infarction), and those with noninvasive tests showing severe ischemia (32). Patients with suspected or known extensive coronary artery disease (e.g., left main or three-vessel) and those with reduced left ventricular systolic function (e.g., ejection fraction less than or equal to 35%) are potentially at greater risk. Suspected severe or moderately severe aortic stenosis or mitral regurgitation further increases the risk,

**Table 1.** Mortality Data for Cardiac Catheterization

Patient Characteristics*	Mortality Rate (%)
Overall mortality from cardiac catheterization	0.14
Age-related mortality	
Less than 1 year	1.75
More than 60 years	0.25
Coronary artery disease	
One-vessel disease	0.03
Three-vessel disease	0.16
Left main disease	0.86
Congestive heart failure	
NYHA functional class I or II	0.02
NYHA functional class III	0.12
NYHA functional class IV	0.67
Valvular heart disease	
All valvular disease patients	0.28
Mitral valve disease	0.34
Aortic valve disease	0.19

\*Other reported high-risk characteristics are unstable angina, acute myocardial infarction, renal insufficiency, ventricular arrhythmias, cyanotic congenital heart disease and congenital heart disease (including arterial desaturation and pulmonary hypertension). However, detailed data from large-scale studies on these characteristics are unavailable.

particularly in patients with poor left ventricular function or clinical heart failure.

Because vascular complications may not become apparent until several hours after the procedure and may require urgent surgical repair, patients at high risk for vascular complications are also not candidates for ambulatory procedures or procedures done in settings without in-house vascular surgical support. This category includes patients with severe peripheral vascular disease, severe systolic hypertension, a bleeding diathesis, need for continuous anticoagulation therapy, or severe obesity. Renal insufficiency, very

**Table 2.** Clinical Characteristics of Patients Who Require Supervision After Catheterization and Would Not Be Candidates for Ambulatory Cardiac Catheterization

High risk for vascular complications
Morbid obesity
Severe peripheral vascular disease
Mechanical prosthetic valve
General debility or cachexia
Low ejection fraction (less than or equal to 35%)
Anticoagulation or bleeding diathesis
Uncontrolled systemic hypertension
Patient's home a significant distance from catheterization laboratory
Diabetes mellitus that is difficult to control
Chronic corticosteroid use
History of radiographic contrast material allergy
Severe chronic obstructive lung disease
Less than 21 years of age or complex congenital heart disease, regardless of age
Recent stroke (within 1 month)
Severe ischemia during stress testing
Pulmonary hypertension
Arterial desaturation

frequent ventricular ectopy, a history of contrast allergy, severe chronic obstructive lung disease, unstable diabetes mellitus, corticosteroid dependency, or generalized debility may predispose patients to complications. In patients with or without congenital heart disease, the presence of pulmonary hypertension or arterial desaturation also increases the risk of the procedure. Patients with any of these conditions can benefit from hospitalization in that a possible complication may be prevented or its impact lessened from prompt recognition and correction.

### **General Criteria for Exclusion From Ambulatory Catheterization**

Based on the above description of high-risk patients, some general exclusion criteria have been developed and should apply regardless of the specific disease state being investigated.

#### **Class III**

1. Geographic remoteness (more than 1 hour drive) from the laboratory with inadequate or unreliable follow-up likely over the next 24 hours
2. An interventional therapeutic procedure (e.g., PTCA or valvuloplasty)
3. Infancy
4. Noncandidacy for cardiac catheterization because of other circumstances (e.g., fever, active infection, severe anemia or electrolyte imbalance, bleeding diathesis, uncontrolled systemic hypertension or digitalis toxicity)
5. Transient cerebral ischemic episodes or recent stroke (less than 1 month before)
6. Suspected severe pulmonary hypertension
7. Severe peripheral vascular disease
8. Severe insulin-dependent diabetes
9. Noninvasive testing data suggesting that detected ischemia may be associated with a high risk for adverse outcome (see Appendix F)

#### **Class II**

1. History of contrast material allergy
2. More than 75 years old
3. Severe obesity
4. Generalized debility or dementia
5. Frequent ventricular arrhythmias
6. Renal insufficiency (serum creatinine more than 2 mg/dl)

### **Discussion of General Criteria for Exclusion**

Patients who are not candidates for elective catheterization under any conditions are obviously not candidates for ambulatory catheterization. These include patients with fever, active infection, severe anemia or electrolyte imbalance, bleeding diathesis, uncontrolled hypertension, or digitalis toxicity. Beyond these broad exclusion criteria, however, one must consider that ambulatory patients will be in an unmonitored, nonmedical environment immediately after leaving the ambulatory care holding area. They are thus

at risk for potential problems that might, in a monitored hospital setting, be readily resolved before resulting in serious complications or their consequences. Some examples might be unrecognized hypotension in a patient with severe coronary artery disease or unrecognized hypertension in a patient with heart failure. Factors associated with increased mortality from catheterization appear in Table 1. Clinical features of patients who may be at increased risk in an unsupervised environment soon after the procedure are described in Table 2.

Numerous reports have documented that congestive heart failure increases catheterization-related morbidity (5,34-36). Similarly, unstable ischemic syndromes, such as unstable rest angina or acute myocardial infarction and the extremes of age, contribute to a high-risk profile (Class III). Renal insufficiency (creatinine more than 2.0 mg/dl) often worsens after contrast media administration, probably because of either renal vasoconstriction or direct renal tubular toxicity (37). It remains unclear whether newer, low-osmolar contrast agents reduce the risk of contrast-related renal insufficiency (38) and whether factors other than serum creatinine identify those at high risk (39,40). Contrast allergic responses vary from mild (e.g., urticaria) to severe (e.g., anaphylaxis), and all occur more frequently in atopic individuals and in those with a history of contrast reactions (41). Low osmolar contrast agents cause less histamine release (42) and are associated with a lower incidence of hemodynamic, electrocardiographic, and allergic reactions (43,44). Most of the other higher risk (Class III) characteristics relate to concerns about the patient's exposure to an unmonitored nonmedical environment soon after a stressful invasive procedure. These characteristics include poorly controlled diabetes, recent stroke, ventricular arrhythmias, severe pulmonary hypertension, and high risk for vascular complications (e.g., marked obesity and severe peripheral vascular disease).

### **Criteria for Exclusion From Ambulatory Cardiac Catheterization in Hospital-Based Laboratories With Access to Immediate In-House Cardiovascular Surgery**

As a general rule, only patients with stable symptoms should be candidates for ambulatory cardiac catheterization. Patients with unstable symptoms or any other clinical features suggesting a higher risk for cardiac or vascular complications (Class III) should be studied as inpatients. The only setting in which patients at moderate risk for complications may be safely studied in an ambulatory setting is the hospital-based laboratory with in-house cardiac surgical back-up. Only those at lowest risk (Class I) should be candidates for ambulatory procedures in settings without immediate in-house cardiac surgical support. In this regard, hospital-based ambulatory cardiac catheterization without surgical support offers the advantage over freestanding and mobile facilities of postprocedure monitoring in a medical

environment, which may prevent or lessen the consequences of some complications and provide ready access to noncardiac surgical (e.g., vascular) support. Criteria for exclusion in a hospital-based laboratory with immediate cardiac surgical support are summarized in Table 3 and are modified for the setting without such support in Table 4. Each disease category is divided into generally accepted and controversial guidelines for exclusion as explained above.

### *Discussion of Specific Criteria for Exclusion*

**Known or suspected coronary artery disease.** Patients with suspected coronary artery disease who are at highest risk for complications are those with unstable symptoms and those with more extensive disease. Many patients in the latter group can frequently be prospectively identified by assessment of clinical factors that may predispose the patient to the presence of coronary disease (45) and by the use of exercise electrocardiogram (ECG), exercise or pharmacological stress thallium, or radionuclide angiography studies suggesting severe ischemia, high risk for adverse outcome, and possible left main or severe multivessel disease (32,46).

Many studies have shown that the presence of congestive heart failure increases the risk of cardiac catheterization, and these patients (Class III) are best studied as inpatients in case the procedure worsens heart failure. Patients with ischemic cardiomyopathy and stable symptoms, left ventricular aneurysm, and reduced left ventricular ejection fraction with mitral regurgitation may also be at increased risk from the procedure and are best studied in a setting in which prolonged monitoring is available.

**Known or suspected valvular disease and heart failure.** The presence of severe valvular disease and heart failure (NYHA functional class III or IV) or poor left ventricular function (i.e., ejection fraction less than or equal to 35%) is a particularly high risk for catheterization. Those with pulmonary congestion may become desaturated while supine, and congestion may worsen because of the effects of both the supine position and the volume load resulting from radiographic contrast administration. These patients may benefit from the use of nonionic contrast media (46). Patients with active endocarditis may be at particularly high risk and should not undergo ambulatory procedures. Patients receiving anticoagulation and those with wide pulse pressures due to aortic insufficiency are at a higher risk for bleeding from access sites and should be studied as inpatients. No patient requiring left ventricular puncture for diagnosis should be studied in the ambulatory setting. There is difference of opinion whether those needing transseptal puncture should be excluded; these patients are therefore included in Class II. There may be circumstances, in very experienced hands with stable patients, in which transseptal procedures could be done in ambulatory patients. Transseptal puncture, however, should be performed only with cardiac surgery support because of the risk of

tamponade requiring prompt surgical repair. The risk of thrombotic events associated with a reduction of warfarin dose in prosthetic mechanical valve patients may be low enough to allow an ambulatory catheterization procedure to be safely performed, but there is difference of opinion when anticoagulation cannot be interrupted. Anticoagulation should not be interrupted in patients with previous thromboembolic episodes, heart failure with atrial fibrillation, or valves at high risk for thrombosis. Patients with suspected severe pulmonary hypertension are at increased risk for death. The presence of severe left ventricular dysfunction (i.e., ejection fraction less than or equal to 35%) also contributes to an increased risk for catheterization, regardless of symptoms. And finally, whether the presence of a valve lesion associated with mild symptoms and moderate left ventricular dysfunction (i.e., ejection fraction less than or equal to 45% but greater than 35%) provides an unacceptable risk for ambulatory catheterization is controversial.

**Known or suspected congenital disease.** Cardiac catheterization procedures in pediatric patients or patients with complex congenital heart disease (regardless of age) should be performed only in a traditional catheterization laboratory setting with immediate access to pediatric cardiovascular surgeons and operating facilities. The decision to perform pediatric catheterizations on an ambulatory basis rests largely with the judgment of the pediatric cardiologist. Many of the factors contributing to increased risk in patients with valvular disease and heart failure that are discussed above (reduced ejection fraction, symptomatic heart failure, etc.) also contribute to increased risk in patients with congenital heart disease. Besides diagnosis and age, factors that affect the decision include the reliability of the parents or guardians who take the patient home and the location of the postcatheterization overnight stay (either at home or at an affordable facility within easy and rapid access to the hospital). The patient should be fully awake, afebrile, able to take fluids for 2-4 hours without nausea or vomiting, and have stable vital signs with stable cardiac rhythm and dry catheterization sites with warm and well perfused extremities distal to the catheterization sites.

Postcatheterization overnight hospitalization is usually necessary if the pediatric patient requires intravenous fluids or medication after catheterization, if any evidence of decompensation is noted, or if complications occurred during catheterization, including dysrhythmias or block, sustained hypotension, prolonged fever, excessive blood loss, arterial or venous damage, or even questionable neurological changes. Hospitalization is required if the patient had a therapeutic catheterization procedure, such as angioplasty, valvuloplasty, or umbrella occlusion of a patent ductus arteriosus, atrial septal defect, or ventricular septal defect. If the patient has complex or unstable congenital heart disease, and especially if the patient is cyanotic, he or she is usually

**Table 3. Additional Criteria for Exclusion From Ambulatory Cardiac Catheterization in Hospital-Based Laboratories With Access to Immediate In-house Cardiovascular Surgery\***

*Known or suspected coronary artery disease*

**Class III**

1. Unstable or progressive classic angina including angina at rest (CCS functional class IV)
2. Acute myocardial infarction (within the past 7 days)
3. NYHA functional class III or IV for congestive heart failure
4. Pulmonary edema thought due to transient myocardial ischemia

**Class II**

1. Noninvasive testing suggests high risk for adverse outcome, possibly due to left main or severe multivessel disease
2. NYHA functional class I or II for congestive heart failure with left ventricular ejection fraction less than or equal to 35%
3. Known left ventricular aneurysm
4. Left ventricular ejection fraction less than 45% associated with significant mitral regurgitation

**Class I**

Most other conditions not listed under exclusions

*Known or suspected valvular heart disease*

**Class III**

1. NYHA functional class III or IV for congestive heart failure
2. Suspected severe right ventricular failure or severe pulmonary hypertension
3. Suspected severe or moderately severe aortic stenosis
4. Suspected active endocarditis
5. Need for continuous anticoagulation
6. Suspected severe aortic insufficiency with pulse pressure greater than or equal to 80 mm Hg
7. Need for left ventricular puncture for appropriate diagnosis
8. Patients with Marfan's syndrome and a dilated aortic root

**Class II**

1. Need for transseptal catheterization for appropriate diagnosis
2. Evaluation of prosthetic mechanical valve function
3. Ejection fraction less than or equal to 35%
4. NYHA functional class I or II associated with valvular disease thought to be hemodynamically severe

**Class I**

Most other conditions not listed under exclusions

*Known or suspected congenital heart disease*

**Class III**

1. NYHA functional class III or IV for congestive heart failure
2. Suspected severe right ventricular failure or severe pulmonary hypertension
3. Suspected severe or moderately severe aortic stenosis
4. Suspected active endocarditis
5. Need for continuous anticoagulation
6. Suspected severe aortic insufficiency with pulse pressure greater than or equal to 80 mm Hg

**Class II**

1. Need for transseptal catheterization for appropriate diagnosis
2. Evaluation of prosthetic mechanical valve function
3. Ejection fraction less than or equal to 35% associated with any valvular lesion
4. Arterial desaturation

**Class I**

Most other conditions not listed under exclusions

*Known or suspected myocardial disease*

**Class III**

1. NYHA functional class III or IV for congestive heart failure
2. Suspected severe right ventricular failure or severe pulmonary hypertension
3. Need for continuous anticoagulation

**Class II**

1. NYHA functional class I or II for congestive heart failure with ejection fraction less than or equal to 35%
2. Suspected obstructive hypertrophic cardiomyopathy

**Class I**

Most other conditions not listed under exclusions.

\*See Table 2 for general criteria for exclusion from ambulatory cardiac catheterization.

**Table 4. Additional Criteria for Exclusion From Ambulatory Cardiac Catheterization in the Hospital Setting Without In-House Cardiovascular Surgery\****Known or suspected coronary artery disease***Class III**

1. Unstable or progressive angina including angina at rest (CCS functional class IV)
2. Acute myocardial infarction (less than 7 days)
3. NYHA functional class III or IV for congestive heart failure
4. Noninvasive testing suggests high risk for adverse outcome, possibly due to left main or severe multivessel disease

**Class II**

1. NYHA functional class I or II for congestive heart failure with left ventricular ejection fraction less than or equal to 35%
2. Known left ventricular aneurysm
3. Ejection fraction less than 45% associated with significant mitral regurgitation

**Class I**

Most other conditions not listed under exclusions

*Known or suspected valvular heart disease***Class III**

1. NYHA functional class III or IV for congestive heart failure
2. Suspected severe right ventricular failure or severe pulmonary hypertension
3. Suspected severe or moderately severe aortic stenosis
4. Suspected active endocarditis
5. Need for continuous anticoagulation
6. Suspected severe aortic insufficiency with pulse pressure greater than or equal to 80 mm Hg
7. Need for either transseptal or left ventricular puncture for appropriate diagnosis
8. Ejection fraction less than 35%

**Class II**

1. NYHA functional class I or II for congestive heart failure with ejection fraction less than or equal to 45%
2. Evaluation of prosthetic mechanical valve function

**Class I**

Most other conditions not listed under exclusions

*Known or suspected congenital heart disease***Class III**

1. All pediatric patients
2. Arterial desaturation
3. NYHA functional class III or IV for congestive heart failure
4. Suspected severe right ventricular failure or severe pulmonary hypertension (systolic pressure greater than 90 mm Hg)
5. Suspected severe or moderately severe aortic stenosis
6. Suspected active endocarditis
7. Need for continuous anticoagulation
8. Suspected severe aortic insufficiency with pulse pressure greater than or equal to 80 mm Hg
9. Ejection fraction: less than or equal to 35%

**Class II**

1. NYHA functional class I or II for congestive heart failure with ejection fraction less than or equal to 45%
2. Evaluation of prosthetic mechanical valve function

**Class I**

Most other conditions not listed under exclusions

*Known or suspected myocardial disease***Class III**

1. NYHA functional class III or IV for congestive heart failure
2. Severe right ventricular failure or severe pulmonary hypertension
3. Need for continuous anticoagulation
4. Myocardial biopsy, except in postcardiac transplant patients

**Class II**

1. NYHA functional class I or II for congestive heart failure with ejection fraction less than or equal to 35%
2. Suspected obstructive hypertrophic cardiomyopathy

**Class I**

Most other conditions not listed above

\*See Table 2 for general criteria for exclusion from ambulatory cardiac catheterization.

kept overnight. Infants should stay overnight after cardiac catheterization.

Hospitalization the night before and the night after the catheterization is usually required for infants, patients undergoing therapeutic catheterization, unstable patients, hypoxemic patients, and patients with dysrhythmias requiring monitoring. It is also necessary when geographic constraints, such as living too far (in terms of distance or time) from the hospital, or social constraints, such as parental unreliability, do not allow an ambulatory procedure.

### *Special Considerations*

Angiography of peripheral, carotid, or pulmonary arteries and the aorta is often performed by cardiologists in cardiac catheterization laboratories. Most clinically stable patients without acute symptoms of cardiovascular disease may be safely evaluated in the ambulatory environment. As a general rule, no cardiac therapeutic procedures in an ambulatory catheterization setting or a catheterization setting outside of a hospital with cardiac surgery support can be justified.

### **Quality Assurance**

In general, the risk associated with cardiac catheterization of relatively stable patients is very low. The sample size required to detect significant differences in event rates is in the range of 300,000 patients (10). Thus, monitoring of individual cases and operators, as well as pooling of data from well designed cohort type or registry studies, is important.

### *Mechanism for Documenting and Reporting Results*

Meeting of quality standards may be ensured in nontraditional catheterization settings if these units are subject to inspection and approval by a body such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). These laboratories should have the same inspection and approval processes as those required for hospital-based facilities. Local state health regulatory agencies could also play a role in ensuring that standards of quality are met.

When cardiac catheterization is performed on ambulatory patients by hospital personnel in a hospital-equipped laboratory, there is no reason for the quality and efficacy of that procedure to differ from those of procedures performed on inpatients (14). Ambulatory procedures performed in the hospital are usually under the quality control of the in-hospital review committee and the JCAHO. At present, it is not clear to what, if any, quality assurance group freestanding catheterization laboratories are to report. This task force generally recommends that a hospital providing cardiovascular surgical support for a freestanding or mobile catheterization laboratory also be responsible for credentialing and quality assurance in that laboratory. Furthermore, the hos-

pital providing the surgical support should be responsible for including the laboratory in its JCAHO accreditation process to ensure that appropriate records and complications are reported and peer-reviewed.

A most important issue is whether more catheterization laboratories may actually dilute utilization and skill levels beyond acceptable standards. Reports in the early 1980s suggested that many catheterization laboratories were underutilized (14). Optimal utilization appears to be one of the major features of a built-in safeguard for patient care.

### *Referral Mechanisms for Patient Safety*

Adequate screening is one of the most important quality assurance measures for the safety of patients undergoing any form of ambulatory cardiac catheterization. Screening permits a thorough understanding of the patient's current medical history as well as significant past history and physical examination. In addition, pertinent laboratory data should be available. The patient must be seen by the invasive cardiologist or the designate on the day before or the day of the procedure as well as after the procedure. It is recommended that a follow-up telephone call be made on the next day to check on the patient's condition if the patient was an ambulatory patient.

Preexisting written agreements and arrangements between centers with nontraditional cardiac catheterization laboratories and centers with total cardiovascular surgical capability and immediate consulting capability must be formalized. There must be a written agreement for acceptance and transfer of these patients for emergency surgery or evaluation and any other necessary care. Practice patterns and referrals of patients to institutions and cardiovascular surgeons qualified and willing to accept these patients must be established and continually reviewed. It must be acknowledged that a catheterization laboratory without in-house cardiovascular surgery may have arranged for several hospitals to provide surgical and additional cardiology support, and precise language must be used to identify which facility is responsible for what, and when. Immediate and urgent access to hospital facilities might prevent a fatal event in patients at some nontraditional cardiac catheterization laboratories. Benefits from immediate access to a cardiac surgical team would be less apparent than benefits from hospitalization, because an even smaller number of those benefiting from hospitalization would benefit from immediate cardiac surgery. Data defining rates of benefit from immediate access to surgical teams are not available (14).

A<sup>1</sup> issue is whether a system of transportation can be ensured for the patient who requires emergency hospitalization during or shortly after catheterization in a nontraditional facility. The transport services must include advanced life support capabilities and must be part of any intrahospital transfer agreement, because some procedures may take place in a rural environment in which advanced life support is not available. Referring physicians, cardiologists, and

regulatory agencies should address the question of whether transfer can be guaranteed at no significantly greater risk than if the procedure had been performed in a hospital with surgical support. If the answer is either unclear or in the negative, the procedure must be done with in-hospital cardiac surgical support.

### **Recommendations for Avoiding Potential Ethical Issues**

#### *Conflicts of Interest*

The following paragraphs contain recommendations for recognizing and avoiding potential ethical issues. To our knowledge, these areas have not been addressed before with regard to the cardiac catheterization laboratory. Surveys and comments to the task force indicate a need to call attention to possible future problems. The following comments should not be construed as suggesting that these practices are widespread.

#### *Self-Referral of Patients to Laboratories*

The practice of referring a patient to the physician's own laboratory for diagnostic or therapeutic cardiac catheterization services or both may not always be in the best interest of the patient (21-30,48,49). To avoid losing the patient's trust, the cardiologist must ensure that the medical appropriateness of the cardiac catheterization take precedence over any other consideration, including personal or group business arrangements (28,30). The cardiologist who has doubts about the necessity of the procedure or who feels the need for assistance in making that decision has an ethical responsibility to ask another cardiologist for a consultation. Second opinions from other qualified cardiologists without fiscal connection to the primary cardiologist and the catheterization laboratory should be recommended when questions arise about the appropriateness of any procedure.

#### *Physician Ownership and Industry Relations*

To avoid potential conflicts of interest, the cardiologist should not have a direct or indirect financial interest in the cardiac catheterization facilities to which he or she refers patients (26,27,50). Cardiologists must avoid any business or industry arrangements that might, because of personal financial gain, influence their decisions about the care of patients. Should a potential conflict arise, the ethical principle that must guide behavior is that the welfare of the patient comes first. Physicians should learn the types of financial investments that are prohibited by law. Disclosure may help the physician to deal with potential conflicts of interest. While physicians are expected to earn a living from the practice of medicine, society expects that physicians will subordinate their own economic interests to the interests of the patient (23). The appropriateness of medical care must in all instances be paramount. Under no circumstance should fiscal considerations dictated by financial arrangements in-

fluence patient care. Referral of a patient for services to a catheterization facility from which the patient's cardiologist collects earnings or shares in profits based on volume performance is a conflict of interest. Remuneration from manufacturers for the use of their devices, catheters, or drugs is also a conflict of interest and may be illegal when the patient is also charged for the use of the catheters or devices. More information about disclosure and implications for physicians may be found elsewhere (50).

#### *Other Ethical Issues*

**Sharing of fees, fee splitting, and fee fixing.** Cardiologists' fees should be billed only for catheterization services provided directly to a patient. It is unethical to receive or offer a shared fee with another physician for cardiac catheterization. Likewise, it is unethical for a cardiologist to receive an admission fee, referral fee, or other "kickback" or commission for admitting or referring a patient to a hospital or a catheterization facility, and no compensation of any kind should be based on the number of catheterization procedures or cases referred by the physician to the laboratory. Such practice is a form of fee splitting and is also unethical. This ethical principle applies not only to fees, commissions, and compensations received from other physicians and hospitals but also to those received from manufacturers of catheters, medications, instruments, devices, or supplies that may be used in the catheterization setting. (This, of course, does not apply to research grants from an industrial concern.) Collusion with any health care provider for personal gain is unethical, and when such arrangements involve Medicare funds and are construed as inducement for referral, they are illegal (26). Collusion with other cardiologists in an attempt to fix fees for catheterization services may also violate antitrust laws.

**Teaching.** The word "doctor" comes from the Latin "docere," meaning "to teach." The physician has a responsibility to share knowledge with his or her patients and professional colleagues. Direct and clear communication from the cardiologist to the patient (and, when appropriate, to the patient's family) about the findings or results of diagnostic and therapeutic catheterization services is essential. It is also the responsibility of the physician to teach and supervise those in training. In the field of invasive cardiology, the attending cardiologist is responsible for the patient's welfare and must ensure appropriate supervision of patient care before, during, and after the procedure. It is unethical to delegate this responsibility to anyone not appropriately experienced in caring for cardiac catheterization patients.

With the patient's consent, it is not unethical for the cardiologist to delegate the performance of certain aspects of a procedure to assistants, assuming this is done under direct participatory supervision (i.e., the cardiologist must be present for the procedure). Fellows or other physicians-in-training can, if qualified, perform certain invasive procedures on patients if they are closely supervised at all times

by the attending cardiologist. Patients should be informed beforehand that fellows or other physicians may be participating in some aspects of these procedures. The patient is entitled to the services of the particular cardiologist with whom he or she has contracted.

**Operator assistant's fees.** Occasionally a procedure in the cardiac catheterization laboratory requires the participation of two cardiologists. This is particularly true for some therapeutic procedures like mitral valvuloplasty. Each cardiologist directly engaged in the procedure is entitled to compensation commensurate with the value of his or her services. No cardiologist should be paid for a service that he or she does not personally perform. It is unethical for a cardiologist to charge an operator assistant's fee when he or she has not directly participated in the catheterization.

**Unnecessary services.** Cardiologists should neither provide nor seek compensation for catheterization services known to be unnecessary. Without specific indications, "routine" right heart catheterization, pacemaker placement during elective coronary angiography, and simple coronary angioplasty and peripheral angiography are unnecessary. A charge to interpret ("overread") either data or angiograms by someone who has not performed the procedure is an unnecessary duplication of services and fees. Diagnostic angiography, when performed at the same time as a coronary angioplasty, should not be billed as a separate service. The bill should show a combined fee, reflecting the fact that the combined procedure reduces physician time as well as the need for repeat arterial puncture, preliminary angiograms, and so on. The cardiologist must be ethical and responsible in all billing procedures.

**Informed consent.** Informed consent is necessary for all cardiovascular catheterization procedures (50). The patient should make his or her own determination about the necessity for treatment. The cardiologist should present the medical facts accurately to the patient (or the family or person responsible for the patient's care) in a manner the patient can understand. It is the physician's obligation to help the patient choose from among the various diagnostic and therapeutic alternatives the option that is in the patient's best interest. Expressed consent should be obtained for procedures. It is not appropriate to first approach a patient during a diagnostic catheterization about the immediate necessity for a therapeutic procedure (i.e., for ad hoc angioplasty). This possibility should have been discussed with the patient beforehand and documented in writing in the patient's record. However, it is recognized that on infrequent occasions urgent situations may arise in the laboratory when it is not possible to have prepared the patient for all possible emergency interventions.

**Reporting of outcome.** As a recognized part of good patient care, all catheterization laboratories are responsible for collection of data relating to adverse outcome. The method used to report these results must be open to peer review. The reporting team should include persons not involved in the business and financial interests of the labo-

ratory and persons not medically involved in the procedures. Data should be obtained from all patients 24 hours after the procedure. Every quality assurance program should have a mechanism for obtaining data on late complications (e.g., approximately 1 week after catheterization).

**Advertising.** Advertising may be considered a form of communication between the physician (or institution) and the general public. The purpose of professional advertising of cardiac catheterization services should be to inform the general public about the availability of services rather than to promote business. Ethical advertising might be in the form of a pamphlet with information about the type of catheterization practice, specialty board certification, location of practice or facility, description of catheterization services, and fee schedule. Because a cardiac catheterization laboratory generally receives patients only by professional referral and not directly from the public, it is anticipated that this type of advertising will be directed only to other physicians. Ethical informational advertising to the general public will be limited to telephone or similar directories. Cardiologists are referred to the American Medical Association statement on advertising and communications with media relations for further guidance (49).

The issue of use of investigational new devices for marketing purposes only requires the attention of cardiologists, industry, and the New Device section of the Food and Drug Administration. Laboratories and operators that use these new devices to advertise their services or to gain a competitive edge in a community without regard for scientific evaluation of the devices should be warned that this practice is unethical. If the practice continues, it should be brought to the attention of the Ethics Committee of the American College of Cardiology as well as local medical associations and the Food and Drug Administration. The practice is readily recognized when a person involves the local media in the process.

## Summary and Conclusions

It is evident that the practice of cardiac catheterization has undergone, and continues to undergo, marked change. Most prominent are the recent very rapid proliferation of catheterization laboratories in general and the development of newer types of catheterization laboratory. No uniform definitions exist for these newer laboratories, so meaningful communication is difficult. The new settings are of particular concern because their location, mobility, organization, and ownership raise questions about the quality of patient care. Most difficult to address are the questions about patient safety and physician conflict of interest. There are no objective data in peer-reviewed literature to support the reported safety and cost savings of these newer settings. Through deliberations, surveys, interviews, and correspondence with the cardiology community embraced by the ACC and the AHA, the task force generally found that in free-standing catheterization laboratories, access to emergency

hospitalization may be delayed, and appropriate oversight may be lacking. Additionally, opportunities for self-referral may be fostered and the perception of commercialism and entrepreneurial excess in practice created. All of these problems must be avoided. The growth and development of some freestanding facilities, particularly the mobile laboratories, do not seem to have been driven by an increased need in remote communities or for temporary support but rather almost exclusively by a desire to capture market share. Accordingly, a series of definitions, guidelines, and recommendations for the laboratories as well as for patient selection has been developed. The consensus was that a very restrictive and cautious attitude to the newer settings is appropriate at this time.

The justification for development or expansion of cardiac catheterization services must be patient need. Documentation of this need must be based on objective estimates of the number of patients with known or suspected cardiac disease who meet generally accepted indications for laboratory study. Concerns about the lack of data from prospective clinical trials of patient safety in such a group necessitate a very cautious attitude toward any new catheterization services, in particular those without in-house cardiac surgical support. In view of the lack of appropriately controlled safety and need data for hospital-based, mobile, or freestanding laboratories operating without on-site (accessible by gurney) cardiac surgery facilities, the task force reaffirms the position that further development of these services cannot be endorsed at this time. In addition, there is reason for major concern that such proliferation in catheterization services may contribute to increasing costs and troubling ethical questions.

## APPENDIX A

### *New York Heart Association Functional Classification of Heart Failure*

*Note:* The classification of patients according to cardiac functional capacity is only a part of the information needed to plan the management of the patient's activities. A recommendation or prescription for physical activity should be based on information derived from many sources. The functional classification is an estimate of what activities the patient's heart will allow and should not be influenced by the character of the structural lesions or an opinion about treatment or prognosis.

#### **Class I**

Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.

#### **Class II**

Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest.ordi-

nary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

#### **Class III**

Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.

#### **Class IV**

Patients with cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms of cardiac insufficiency or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

## APPENDIX B

### *Grading of Angina of Effort by the Canadian Cardiovascular Society*

I. "Ordinary physical activity [such as walking or climbing stairs] does not cause . . . angina" (angina occurs with strenuous or rapid or prolonged exertion at work or recreation)

II. "Slight limitation of ordinary activity" (angina occurs with walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold or wind, under emotional stress, or only during the few hours after awakening, walking more than two blocks on the level, or climbing more than one flight of ordinary stairs at a normal pace and in normal conditions)

III. "Marked limitation of ordinary physical activity" (angina occurs with walking one to two blocks on the level or climbing one flight of stairs in normal conditions and at normal pace)

IV. "Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest"

## APPENDIX C

### *Recommendations for Laboratory Operation*

**Interdisciplinary Interaction, Support Services, and Facilities.** For optimal results and safety of cardiac catheterization, interdisciplinary interaction among adult cardiology, pediatric cardiology, cardiovascular radiology, and cardiovascular surgery is essential (51,52). All must be immediately available for assistance. Although surgical back-up is not required for all cases, it should be immediately available for high-risk patients. Certain procedures, including percutaneous transluminal coronary angioplasty (PTCA), valvuloplasty, myocardial biopsy, transseptal catheterization, and direct left ventricular puncture, should only be performed in a laboratory with in-house surgical support. Infants and children or patients with known or suspected complex congenital heart disease should not undergo cardiac catheterization in an institution without established pediatric cardiology and cardiovascular surgical programs.

In-house support personnel should include cardiovascular anesthesiologists, perfusion teams, inhalation therapists, and critical care staff, as well as biomedical, electronic, and radiation safety specialists. In addition to the physical laboratory and radiological and recording equipment, resuscitation equipment, including endotracheal tubes and a defibrillator, and intra-aortic balloon pump facility, a stat chemistry laboratory, and rapid repair service for radiological and hemodynamic monitoring equipment should be available. A back-up laboratory is highly desirable.

**Administration.** The mission of the laboratory must be clearly defined. In institutions in which training and research are also performed, it is important to delineate the goals and priorities for diagnosis, training, and/or research. The administration and organization of the laboratory should then be based on these specified purposes. The laboratory should be an administrative unit with a physician director qualified to assume professional, organizational, and managerial responsibilities (53). In some hospitals, the administration may be a cooperative effort shared by the cardiology and radiology departments, but this does not obviate the need for one laboratory director. Although the relationship among the catheterization laboratory, clinical departments, and administration may vary from hospital to hospital, the laboratory should have an identifiable budget based on realistic cost accounting. The budget should include a salary for the director. The expectations and importance of this administrative duty should be clearly identified. To ensure adequate peer review and quality assurance, the physician director should be supported by a laboratory committee composed of representatives of all services using the laboratory and some that do not, as well as hospital administration. Operation of the laboratory must be a cooperative undertaking among many disciplines so patients' needs will be met and safety protected.

## Personnel

### Laboratory Director

The laboratory director should be a physician with the experience and leadership qualities necessary to properly control the laboratory environment (54). The director is charged with the responsibility for policy development, quality control, and fiscal administration. Depending on the type of laboratory and type of patients studied, the director may be a cardiologist, cardiovascular radiologist, or pediatric cardiologist, and may have special interests such as interventional cardiology or electrophysiology. The director should be board certified and thoroughly trained in cardiac radiographic imaging and radiation protection. The director must be proficient in performing procedures specific to the laboratory and a skilled administrator tolerant and supportive of the needs of the departments served. The director's qualifications should include at least 5 years of catheterization experience and recognized skill in the laboratory (54). The director of an adult diagnostic laboratory should have

performed at least 200 catheterizations per year during the 5 years of experience.

The duties and responsibilities of the director are multiple and wide-ranging, and demand significant management skills. The director shall set criteria for granting privileges to physicians and then review and make recommendations about applications for those privileges. It is highly recommended that privileges be granted for only 1 year at a time in this rapidly changing specialty. The director must periodically review physician performance, make recommendations for renewal of laboratory privileges, review performance of nonprofessional staff, and provide training necessary to the personnel. The director shall establish and monitor quality control including morbidity and mortality. Other responsibilities include control of patient scheduling, procurement and maintenance of equipment and supplies, preparation and monitoring of the budget, organization of regular conferences of laboratory personnel, and production of regular reports of laboratory activity. The director shall maintain communication and cooperation among the laboratory, the clinicians, and the hospital administration to ensure that the patient is best served. The director must designate a substitute who will act in the director's absence.

### Physicians

Physicians credentialed to operate in the laboratory must have proper training (55-58). This training may be in cardiology, pediatric cardiology, or cardiovascular radiology. Clinical training in one of these fields should fulfill requirements for that specialty board. In-laboratory training should encompass a total period of at least 1 year, although 2 years in a recognized training program is preferable. The physician must also be trained in emergency care and radiation physics and be certified as competent by the program director of his or her training institution. A laboratory physician should be a fully accredited member of the hospital staff and, ideally, be specially certified or at least board qualified with the intention of taking boards at the earliest available date. A physician who provides only laboratory service without being a full member of the hospital staff should not be granted laboratory privileges. He or she must participate in the laboratory's quality assurance program, including peer review.

Maintenance of proficiency should include an anticipated adult caseload of approximately 150 cases per year (55) or pediatric caseload of 50-100 (58,59). This should be attainable within 2 years of working in the laboratory. Too many physicians in any laboratory may dilute the caseload to the point where some will not adequately maintain their skills. In some cases the laboratory director may decide that some physicians' skills are such that they do not need an annual caseload of 150 to maintain their proficiency, but this privilege must be closely monitored.

Occasionally, a physician who was trained in catheterization does not perform it for a period of time and then decides

to return to the laboratory. To be credentialed, this person must first be certified as adequately trained and competent by the director of his or her training program. If the time away from the cardiac catheterization has been 1-3 years, the physician should undergo a period of preceptorship, working under the direct observation of the laboratory director until the director can certify the competence of that individual. This work should include at least 25 cases with a variety of diagnoses. In longer absences from the laboratory, credentials should not be granted until the physician fulfills at least 3 months of formal laboratory training at an institution with fellowship training program and is certified by the program director.

Performance of special procedures—for example, PTCA, percutaneous transluminal angioplasty, valvuloplasty, electrophysiology, or pediatric cardiac catheterization—requires separate credentialing (60). Training requirements for these procedures have been well detailed in the literature (56). In addition, the physician performing these procedures should be certified as proficient by the director of the training program. To maintain proficiency in various special procedures, the physician should maintain an adequate caseload and have results peer reviewed.

### *Nursing Personnel*

The type and number of nursing personnel depend on the laboratory caseload and mix, and may include nurse practitioners, registered nurses, licensed vocational nurses, or, at times, nursing assistants. A nurse practitioner or physician's assistant with competence in the cardiovascular field may assume some responsibilities of a physician, including initial patient work-up, education and mental preparation of the patient, assistance in obtaining informed consent, postprocedural supervision, explanation of angiographic findings, and providing an outline of follow-up care. The nurse practitioner may participate directly in the laboratory procedure itself, as designated by the physician responsible. A nurse practitioner may at times supervise laboratory nursing and technical personnel.

In most laboratories the nursing supervisor will be a registered nurse. This nurse must be familiar with the overall function of the laboratory, help set the tone of the patient surroundings, and influence the efficiency and safety of procedures. The registered nurse may also directly participate in observation and nursing care of the patient during the catheterization and be ready to respond to any emergency. The nursing supervisor should be in charge of the preprocedure and postprocedure holding areas, particularly when there is prolonged detention of the patient after an outpatient procedure.

The background of a catheterization laboratory nurse should include critical care experience, knowledge of cardiovascular medications, ability to start intravenous solutions, and experience in operating room techniques. Experience with vascular catheter instrumentation, and especially

with identification, cleaning, sterilization, and storage, is necessary. Knowledge of vascular catheter materials, shaping techniques, and proper size correlations for catheters, guidewires, and adaptors is important, as is experience in manipulation of manifolds, performance of test contrast injections, and changing of guidewires and catheters. There must be a thorough understanding of the flushing of catheters and prevention of clot or air emboli.

A licensed vocational nurse with the proper background and experience may have duties similar to those of the registered nurse. However, a licensed practical nurse should not supervise laboratory nursing. In some laboratories an appropriately trained nursing assistant may be responsible for some duties. This person may be a cardiopulmonary technician who is familiar with procedures in associated disciplines and is thereby able to function in the dual capacity of cardiopulmonary technician and nursing assistant.

### *Nonnursing Personnel*

Several types of technical knowledge are required in the cardiac catheterization laboratory, although any one person may have all the different types of technical expertise. At least one technologist, who may or may not be a certified radiological technologist, should be skilled in radiographic and angiographic imaging principles and techniques. This technologist should be experienced in the proper use of x-ray generators, cine pulse systems, image intensification, automatic film-processing equipment, pressure injection systems, video systems, and cine cameras, and, in cooperation with electronic and radiological service engineers, should be responsible for routine care and maintenance of radiological equipment. A basic knowledge of simple troubleshooting is advantageous. This technologist, in cooperation with a radiation physicist, should monitor radiation safety techniques for both the patient and laboratory personnel. Immediate availability of a radiological engineer in the event of equipment failure is highly desirable.

Laboratory technologists should be skilled in managing blood samples, performing blood gas measurements and calculations, and assisting with indicator dilution studies. They should be qualified in monitoring and recording electrocardiographic and hemodynamic data and have enough skill and experience in interpreting these data to immediately report significant changes to the physician who is responsible for the patient. During any one procedure, the monitoring technician must have no responsibilities other than monitoring and observing patient status. Training should include skills in patient observation and preparation for assistance in acute cardiac care, including resuscitation and related therapeutic efforts.

At least one technologist should be skilled as a darkroom technician, because the quality of images recorded on film is heavily dependent on darkroom technique. This person must be trained in photographic processing and operation of automatic film processors and should be familiar with the

characteristics of the film and chemicals used for cardiovascular procedures. Skills should be acquired in techniques of day-to-day calibration and maintenance of automatic processors and the use of densitometric/densometric equipment and data. These skills are necessary for the technologist to perform a daily program of quality control to ensure the high quality of the diagnostic images.

### Staffing Patterns

A catheterizing attending physician should be present in the laboratory during each procedure and must be responsible for the outcome. To maintain effective and safe laboratory operation, each basic support function should be performed by adequately trained personnel who constantly maintain their skills and credentials. There should be adequate cross training among laboratory staff so that personnel can rotate responsibilities and provide 24-hour coverage of essential team functions. Complex studies, especially those of neonates and acutely unstable patients, require personnel with special training to deal with the particular requirements of these procedures. Frequently, the presence of a second physician is important for optimal care in such cases.

### Cardiopulmonary Resuscitation

All members of the catheterization team—physicians, nurses, and technologists—should maintain a current course completion card in cardiopulmonary resuscitation. Certification in advanced cardiac life support is desirable.

### Utilization Levels

#### Laboratory

For optimum laboratory performance and cost-effectiveness, an adequate caseload is required for the staff to maintain their skills and efficiency. The laboratory should be used only for cardiac catheterization procedures, use as a general or multipurpose radiology room is no longer acceptable. If catheterizations are not performed on a daily basis, then the laboratory should not continue to exist as a cardiac catheterization laboratory. Laboratories for adult studies should maintain a minimum caseload of 300 per year (51). A minimum of 150 cases per year (60) is required for pediatric laboratories. These studies are longer in duration and more complex and frequently require two physicians per study. It is particularly important that infants and all patients with complex congenital heart disease be catheterized only in centers with active pediatric cardiac surgical programs.

#### Physician-Operator

To maintain adequate performance levels and to minimize risks, each physician must perform procedures relatively frequently. Inexperienced or infrequent operators may compromise the quality of the diagnostic or therapeutic outcome, which in turn may lead to prolongation and repetition of

studies or result in excessive radiation to both the patient and laboratory personnel. An experienced physician will rarely need to repeat a study because of inadequate data or poor processing of data obtained. It is generally accepted that an individual physician should have a minimum of 150 cases per year (51). A physician who operates in more than one laboratory should perform at least 150 studies per year in toto, with no fewer than 50 in any one laboratory unless the operating principles are identical in all laboratories utilized (55). Physicians with extensive experience (more than 1,000 independently performed cases) can probably obtain high-quality data at low patient risk with fewer studies per year. A somewhat lower number of studies must be performed each year by physicians who perform pediatric catheterization. However, because of the complexity of these cases, a physician should perform at least 50–100 studies per year (51). To maintain skill in PTCA, a physician should perform at least 50 such procedures annually (59,61). An electrophysiologist should perform no fewer than 100 electrophysiological studies per year (62). Although adequate caseloads for balloon valvuloplasty have not been established, it seems reasonable that a laboratory and participating physician should perform at least 25 studies a year to maintain skill and safety.

A maximum total caseload for any single physician is approximately 1,000 cases per year. When a physician performs more than this number individually, it is likely that quality and patient care interactions will be sacrificed for the sake of efficiency. In addition, a physician performing more than 1,000 studies yearly is exposed to a large amount of radiation and its concomitant risk to health.

These caseload recommendations are offered as guidelines. Their principal objective is to encourage development of laboratories in settings capable of generating the critical density of clinical experience required to maintain performance at the highest level of diagnostic skill with maximum patient and operator safety.

### Evaluation of Laboratory Performance

Laboratory safety and efficiency can be estimated in part by procedural complication rates. The laboratory director has a responsibility to set and maintain high standards of performance and operation. It is imperative that laboratories keep thorough records of performance and complication rates, both for the laboratory as a whole and for each physician working in the laboratory, and that these records be reviewed periodically. To limit complications, it is imperative that stringent credentials for both training and experience be met before initial laboratory privileges are granted. Review of performance must be undertaken on a regular basis. It is understood that catheterization laboratory examination of patients with suspected cardiovascular disease cannot be undertaken without a certain minimal risk of morbidity and mortality, which must be balanced against the consequences of not obtaining necessary information. It is

also understood that some patients without significant heart disease will be studied to exclude suspected heart disease. Using current indications for catheterization, this percentage should not exceed 10-20% of the total patients studied by any physician or by the laboratory as a whole (51).

The frequency of major complications (e.g., myocardial infarction, thromboembolic accidents, and death) is related to several elements. The experience and knowledge of the performing physician are critical, as are the experience and teamwork of laboratory personnel. Equally important is the underlying condition of the patient. In laboratories in which patients with severe coronary disease are studied, particularly patients with severe left ventricular dysfunction, the frequency is expected to be somewhat higher. Neonates and elderly patients also are at higher risk. Severe arterial hypoxemia and pulmonary hypertension are special risks for pediatric as well as adult patients. Medical problems such as renal insufficiency, bleeding diatheses, and systemic illness add to the risk. Experienced physicians consider these factors when deciding whether to perform a procedure and how to perform it.

Complication rates are best evaluated by a prospective registry maintained by each laboratory, which should include clinical, hemodynamic, and angiographic characteristics of each patient and other information that may permit assessment of the extent and severity of illness. Every complication, minor or major, should be entered into the registry. It is important that someone other than the physician performing the procedure can enter data into this complication registry. A more detailed record of major complications is made so that the director and others can efficiently review the overall performance of the laboratory, as well as the performance of each physician. The registry must be regularly reviewed and reported to ensure fastidious record keeping and maintenance of high standards for the laboratory.

Deaths related to catheterization are infrequent in elective, stable adult patients and should occur in no more than 0.1-0.2% of cases (5,63,64). Higher mortality rates can be expected in studies of neonates or adults with acute myocardial infarction or in cardiogenic shock. When evaluating laboratory performance, patient records must be reviewed and a judgment made whether death resulted from a patient's primary disease, the procedure, or both. If such deaths are frequent in a laboratory, patient selection for catheterization should be reviewed and reevaluated. It is now common for elderly patients to undergo diagnostic and interventional procedures, and the risks associated with these procedures are relatively high in these patients. The higher risk of major complications and death must be carefully considered before these patients undergo cardiac catheterization and/or angiography.

Although right heart catheterization is commonly considered a relatively low-risk procedure, it carries considerable risk when performed at the bedside by an inexperienced and perhaps overly confident operator and when performed in

the laboratory in patients with significant pulmonary hypertension, profound cyanosis, or polycythemia, especially when the patient also has congenital heart disease. In either setting, right heart catheterization must be conducted by physicians with expertise in the management of critically ill patients and experience in general catheterization and angiographic procedures.

The rate of major complications must be maintained at the same low level in all laboratories regardless of location or laboratory characteristics. Institutions having laboratory fellowship training programs should not, when the mix and characteristics of their cases are considered, have a higher incidence of major complications or death than other laboratories. This can be achieved if a skilled physician works closely with each trainee during each procedure. The preceptor is ultimately responsible for the safety and quality of the study.

Although the complication rate is the most important index of laboratory performance, another important measure is the number of studies that must be repeated because of inadequate data or image quality. As a rule, no more than approximately 1% of studies should require repetition simply to obtain more or better quality data. However, at times, particularly in cases of complex congenital heart disease, it may be safer for the patient to undergo two studies rather than a single prolonged study or to exceed in a single study the recommended total contrast dose. For many patients who require angioplasty, it is best to do the initial arteriogram and then the angioplasty at separate settings. This allows for greater interpretation of angiographic information before performing the procedure. Likewise, some multiple vessel dilation procedures are most safely performed when staged on two separate occasions.

In laboratories in which research protocols are combined with diagnostic catheterization procedures, research studies must not increase the risk of major complications. The following guidelines may be useful: 1) an investigational procedure, when possible, should be carried out after the essential diagnostic information has been obtained, but should be postponed if the patient's condition is not stable, if the diagnostic procedure has been prolonged, or if the patient is exhausted; 2) the investigational procedure should not markedly prolong the overall duration of the study, if an arterial catheter is in place for an extended time; 3) investigational studies performed on critically ill or hemodynamically unstable patients should be expeditiously managed, and procedures conducted, only by the most experienced physicians; 4) consideration should be given to performing investigational procedures apart from diagnostic procedures, offering the benefit of defining which procedures are diagnostic and which are investigative, and taking advantage of the fact that two brief catheterizations may be safer and better tolerated by the patient than a single prolonged procedure; and 5) all research procedures done in the catheterization laboratory must be reviewed and approved by a committee established according to institutional review board guidelines.

## Conduct of the Examination

A cardiac catheterization procedure must never be viewed as a routine or casually ordered technical service. The procedure should be considered a consultation between the referring physician and the diagnostic team, involving sophisticated study techniques and highly specialized personnel. This will result in maximum safety and diagnostic benefit for the patient. The timing of the study is most important. If possible, it should be performed when problems such as arrhythmias, congestive heart failure, or azotemia are stable or improving. Otherwise, misleading physiological data may be obtained, and the risks of the procedure may increase. In some cases this is not possible, and studies must be performed on patients who are acutely ill and whose conditions are unstable. The physician performing the laboratory examination must take the time to critically review the patient's history, physical exam, and pertinent laboratory data before performing the study. Ideally this should be done the day before the procedure, although with the compression of hospital stays and with ambulatory catheterization, this is not always possible.

The importance of properly preparing the patient for the study cannot be overemphasized. It is most important for the physician who will be involved in the study to obtain informed consent from the patient or the patient's parents or guardian. The patient and, whenever possible, a responsible member of the family should be fully briefed on the procedure, preferably by the physician performing the study. This discussion should include the reasons for the study, its potential benefits and complications, and a description of the actual examination.

Although many laboratories emulate surgical operating rooms in their strictness of sterile techniques, there is no evidence that for the usual diagnostic percutaneous study there is any need for the operator to wear a cap or perform a surgical scrub before donning gloves to protect the patient from infection. It seems reasonable that for more complex and lengthy procedures (e.g., cutdown PTCA or valvuloplasty), a more rigorous sterile technique should be followed. For implantation procedures, such as implantation of permanent pacemakers, full surgical sterile technique is required. Protection of the patient, staff, and operating physician from blood-transmitted diseases, such as hepatitis or acquired immune deficiency syndrome, must be constantly kept in mind. Special clothing must be provided to workers to protect them from direct exposure to blood or other potentially infectious materials. This clothing should include personal protective equipment such as gloves, gowns, laboratory coats, and other coverings as needed. Furthermore, the hospital should ensure employee use of, and provide for the cleaning and laundering of, such personal protective equipment, in accordance with the United States Department of Labor, Occupational Safety and Health Administration (OSHA) guidelines (65). In addition, hepatitis B

virus vaccination should be offered at no cost to laboratory employees (65).

Laboratories and physicians often vary in the use of heparin and the dose administered. There is no question that if an operator works efficiently, flushes the catheter frequently, and avoids frequent or lengthy use of a guidewire, catheterization can almost always be completed without thrombotic complications. Bleeding complications are generally easier to handle than thrombotic ones; for this reason, most laboratories use heparin for temporary anticoagulation during the study (34). More complex studies, especially those of an interventional type, should always be done with full heparinization. Because nonionic contrast agents inhibit blood clotting and platelet aggregation less than ionic agents, heparin should be routinely administered when nonionics are used for angiography.

It has become obvious that the proper selection of contrast agent is mandatory. Newer, low-osmolal agents have been shown to have less detrimental hemodynamic and electrophysiological effects on the cardiovascular system, but their high cost blocks their use for all patients in some laboratories. Although patient discomfort is reduced in all patients, those with stable clinical syndromes, good left ventricular function, and normal renal function have such low morbidity rates that it is difficult to document other advantages. However, in patients who are clinically unstable, have significant hemodynamic impairment, or have significant renal insufficiency, these agents are recommended over the ionic contrast agents (40,47).

Postprocedural orders should be written, and special orders should be clearly noted. Standard orders should include checking and recording blood pressure, pulse rate, distal pulses, and status of bandage sites every 15-30 minutes for 2 hours, then every hour for several hours. It should be noted that evidence of impairment of circulation or any other complication should be brought to the immediate attention of the responsible physician. A member of the catheterization team should examine the patient later in the day and subsequently, as indicated.

There should be an adequate postprocedural holding area, especially for patients who are studied as outpatients. This should include proper nursing care and monitoring equipment, as well as provisions for emergency treatment of any complication that might develop. There must be a plan for admitting to the hospital any outpatient who develops a major complication. The patient should receive specific verbal instructions concerning activities allowable after leaving the laboratory. Written instructions on the specific procedures to be followed, should a complication arise after the patient leaves the holding area, should be given to every patient.

## APPENDIX D

### *Suggested Laboratory Requirements*

The safety and efficacy of cardiac catheterization depends to a great degree on the available equipment and its physical

arrangement. While already emphasized in a 1983 study group report (51), this area deserves revision in view of the changes in equipment and practice of invasive cardiology. The growing use of thrombolysis and revascularization (surgical and catheterization laboratory-based) and the increasing complexity of therapy necessitate higher-quality fluoroscopy and angiography than needed in the past. In addition, regulatory concerns, such as mandated ambulatory catheterization and the desirability of quantitative assessment of angiographic results, impose new logistical requirements. A catheterization facility may be configured in a variety of ways with equipment from many manufacturers. The continuing evolution of hardware and software makes recommendations for optimal resources precarious. Considerable changes are likely as imaging and digital technology continue to advance. These recommendations represent the current state of the art and update the previous study group report (51).

### Physical Arrangements and Space Requirements

The catheterization laboratory may consist of the procedure, control, equipment, and utility rooms. These areas are critical for the performance of catheterization, but additional facilities are required for an ideal functioning laboratory. In the traditional hospital-based situation, some or all of these areas may be shared with other services. Such may not be the case for freestanding and mobile laboratories, depending on their location; nonetheless, ready access to these areas must be ensured.

Suggested dimensions are given in square feet in terms of minimum and recommended areas. Larger areas are desirable when possible to allow more space for ancillary equipment (e.g., intra-aortic balloon console, respirator, echocardiographic and electrocardiographic recorders, crash cart, laser equipment). Larger rooms also provide orderly storage of supplies. Dimensions vary in accordance with the type of radiographic equipment (for example, biplane digital computer equipment may require additional space) and the manufacturer. Minimum space recommendations are not absolute, and the equipment may be placed in smaller confines, but this is not recommended. Some radiographic equipment might be configured for a restricted space, as may be necessary in mobile laboratories. With the understanding that specific recommendations should be obtained from the equipment vendor and, in general, the more space the better, the following guidelines are suggested (see Table D-1).

#### Procedure Room

The recommended size of the procedure room is approximately 500 ft<sup>2</sup>, although an optimum size may be more than 600 ft<sup>2</sup>. A minimum size is approximately 400 ft<sup>2</sup>. Recommendations for room height vary with specific equipment, but 9 ft 10 in to 10 ft is generally acceptable. In some situations, electronic equipment, usually located in an equipment room, is instead housed in a procedure or control

**Table D-1.** Suggested Size of Rooms in the Cardiac Catheterization Laboratory

Use	Suggested area (ft <sup>2</sup> )
Soiled utility room	70
Staff dressing room	70
Darkroom and film processing	60
Patient preparation room	120
Recovery/observation room	120
Holding room	120
Reception/secretarial/transcription/viewing/reporting room	70
Scrub facility	30
Film/record storage	60
Toilet facility	30
Patient dressing room	12
Janitorial space	20
Equipment storage	90
Pharmacy area	30
Blood gas area	20
Staff lounge	70
Conference room	120
Library	70
Office space (per office)	70

room. Although this arrangement saves space, it also requires that the minimum size requirements given above for the procedure room be increased so that approximately 500 ft<sup>2</sup> is available for working space. The procedure room should be constructed to contain radiation and ensure electrical safety (see "Radiographic Equipment" and "Electrical and Radiation Safety").

#### Control Room

The control room should be of a size and configuration to allow ready and unencumbered access to x-ray controls, image recording devices (video tape, disks, and digital controls), and physiological monitors and recorders. The recommended floor space for the control room is approximately 150 ft<sup>2</sup>, with a minimum of about 96 ft<sup>2</sup>. Room height need only be 8 ft.

#### Equipment Room

Electrical components of the x-ray equipment must be stored in a well ventilated space. Traditionally, these components were kept in an equipment room, but much of this apparatus may be stored in enclosed panels in the procedure room. The recommended floor space for an equipment room is about 120 ft<sup>2</sup>, with a minimum of about 90 ft<sup>2</sup>. The advent of digital technology requires computer and data storage space. It is necessary to ensure proper temperature control for these components. Computer flooring is recommended to provide space for and easy access to cabling.

#### Clean Utility Room

An area of at least 90 ft<sup>2</sup> is necessary for preparation and storage of clean and sterile supplies. Specific angiographic

tables may be set up in this area, and items such as disposable packs, catheters, guidewires, syringes, and intravenous fluids stored.

Additional spaces should be available for proper functioning of the catheterization laboratory (Table D-1). While suggestions for space are given, these may vary in accordance with the type of facility (teaching vs. nonteaching), its location (in-hospital, mobile attached to hospital, freestanding), and number and type of patients anticipated. For instance, patient preparation, holding, recovery, and observation areas may need to be expanded if most of the studies performed are ambulatory procedures.

### Equipment Requirements

It would be ideal if any given laboratory were dedicated to only one task (e.g., coronary angiography and left ventriculography, coronary angioplasty, pediatric catheterization) so it could be specifically equipped. This would be economically advantageous and would avoid the compromises necessary to accommodate all users. In practice, however, this may not be feasible, and careful consideration should be given to the use of the room before equipment is ordered. A wide variety of durable and disposable components are necessary. They may be classified by the function they perform: 1) physiological data acquisition; 2) imaging and image processing; and 3) support.

#### Physiological Data Acquisition

A mechanism for monitoring blood pressure and the ECG is necessary for safe performance of cardiac catheterization. In certain patients, cardiac output measurements and oximetry are done. Monitoring and recording physiological events requires a system capable of detecting the event, converting it into electrical energy, faithfully amplifying that energy, and displaying and recording the information. The system components must exhibit stability, sensitivity, linearity, and adequate frequency response. The system should be able to reproduce up to the tenth harmonic of a waveform without amplitude or phase distortion. Pressure readings are most commonly obtained from fluid-filled catheters connected to strain-gauge pressure transducers inputted to a polygraph capable of amplifying and displaying the waveforms on an oscilloscopic monitor, from which they are recorded. Pressure channels should be calibrated with a mercury manometer before every case, and care must be taken to standardize the zero pressure reference level with each case. Although there are advantages to catheter tip transducers, fluid-filled catheter systems are most often used and are adequate for clinical purposes. Transducers should have low volume displacement and be linear from -10 to 400 mm Hg. Monitors must be available to make pressure signals visible to the operating physician as well as to the recording technician. The remote monitor should be positioned next to the video monitor to give the physician ready visual access to physiological data while manipulating cath-

eters. The physiological recorder should have a minimum of five input channels; most laboratories will use six- or eight-channel devices, and 12-channel recorders may be necessary in some situations (e.g., electrophysiology studies). A minimum of three pressure channels should be available for the simultaneous recording of two pressures while an additional channel is used as a spare. At least two ECG channels are needed, and the ability to freeze a baseline tracing is desirable, especially when interventional procedures are being performed. One should be able to select any of the 12 standard electrocardiogram (ECG) leads for monitoring and recording. This requires the use of chest electrodes, which, unless totally radiolucent, obscure imaging. In most situations, monitoring two standard limb leads (e.g., leads I and II) is adequate. A strip chart paper recorder, allowing superimposition of pressure tracings, is necessary. The physiological recorder and operating technician must be located outside the procedure room for radiation protection. Communication between recording technician and physician may be facilitated by an intercom. The use of a junction box and underfloor cabling is highly recommended. Many physiological recorders offer digital display and computer capability to process data. It is important, however, that the pressure waveforms be recorded and reviewed by the physician to ensure that the computer properly selected and interpreted the appropriate data.

An additional standard ECG machine should be available in each laboratory to facilitate interpretation of arrhythmias and allow comparison with previous tracings should a clinical event occur. Standard recordings are helpful during provocative testing for ischemia (e.g., pacing or ergonovine administration). Facilities for blood gas determination should be available, preferably in the laboratory. At the minimum, a reflectance oximeter is needed to measure oxygen saturation.

Cardiac output determinations are necessary in the evaluation of stenotic valvular lesions and give useful information in many other conditions. Cardiac output may be measured by a number of different techniques, thermodilution being the simplest and most commonly performed. The ability to perform and analyze dye dilution curves may also be necessary for the diagnosis of shunts.

#### Radiographic Equipment

High-quality x-ray imaging is mandatory for evaluation of cardiovascular anatomy and for the safe and efficacious placement of catheters and interventional devices. The goal of equipping a laboratory is to obtain the highest-quality images with the least radiation exposure to patient and staff. These suggested guidelines may not be completely met by all existing laboratories. The minimal acceptable criterion is diagnostic-quality images obtained safely and consistently using radiation dosages within acceptable standards. Both diagnostic and therapeutic catheterization procedures require television fluoroscopy. The primary recording medium

is 35 mm cineangiography. Larger format spot-film and serial-film radiography are now infrequently used in adult cardiac catheterizations, but serial-film radiography has an important role in the evaluation of certain congenital heart disorders and of diseases of the aorta and pulmonary and peripheral vasculature. The cost and complexity of adding a larger film format to cineangiography are usually not justified. Digital angiographic systems provide an alternative to static filming.

When equipping a catheterization laboratory, the major concerns are whether the laboratory is to be used for pediatric or adult cases and whether interventional, as well as diagnostic, procedures are to be performed. While excellent cineangiographic images are expected from both diagnostic and therapeutic procedures, a greater amount of highly detailed fluoroscopy is required for the latter. Interventional laboratories may benefit by having equipment to enhance the fluoroscopic image and lessen radiation exposure. This might include pulsed fluoroscopy with progressive scanning high-resolution 1023-line video systems, digital filters, and, in some cases, digital subtraction angiography. Another question is whether to have biplane capability. An advantage of biplane capability in the adult patient is its use for ventriculography, aortography, and, rarely, coronary angiography to obtain orthogonal views without the risk of a second contrast injection. For interventional procedures, biplane fluoroscopy conserves time when wires and balloons are being positioned. Pediatric studies require biplane angiography. The primary limitation of biplane systems is their cost. A secondary limitation is their large space requirement.

The x-ray equipment should be configured of components designed to function together and not mixed and matched. After installation, all equipment should undergo testing to ensure that specifications are met. Specific performance criteria, such as 1) input dose levels of all imaging modes behind the grid, 2) cine spatial resolution, 3) focal spot size, 4) cine pulse width, 5) automatic brightness control system stabilization during cine, 6) video spatial resolution, and 7) video low-contrast sensitivity, should be stated in the purchase agreement and demonstrated on site. Finally, equipment should be designed specifically for installation in the setting in which it is going to be used. It is not appropriate to attempt to adapt equipment designed for installation in a fixed hospital laboratory to a mobile unit. A complete discussion of the physical principles of x-ray imaging is beyond the scope of this document; however, comments as to current recommendations for components of a catheterization laboratory x-ray system follow.

**Generators.** A three-phase, 12-pulse generator with an output of 80–100 kW or a constant potential generator with an output of at least 100 kW at 100 kV is recommended, although a less expensive low-output (60 kW) system may be satisfactory if a stable high-potential waveform and constant tube current output during pulsing are maintained. Potential is applied to the x-ray tube by either primary or secondary switching. Primary switching is achieved when the current to

the tube is turned on or off by closing or opening the primary transformer winding. Secondary switching occurs when the tube is switched on and off at the high voltage side of the transformer or at the x-ray tube itself. Secondary switching, or grid control switching, is advantageous in that it does not produce preexposure or postexposure soft radiation caused by charge stored in the capacitance of the high-voltage cables. It produces a square wave voltage output and is ideal for pulsed fluoroscopy and low-dose cineangiography, such as are needed in pediatrics. Modern cardiac catheterization laboratories use only secondary switching. The maximum tube current available with this type of generator is limited in practice to about 800 mA.

A method for coordinating the time of x-ray exposure with the cinecamera function is necessary. The cine pulse system regulates the amount of x-ray photon flow from the x-ray tube by controlling the duration of each exposure. Ideally, the exposure setting is short enough to stop motion but long enough to allow adequate x-ray quanta to impact the input phosphor of the image intensifier. Too short an exposure will either degrade the image by limiting the radiation or decrease the image contrast by driving up the voltage. Exposures of about 3–8 msec for adults and 2–4 msec for children are recommended if the voltage range can be maintained at 70–90 kV for adults and 60–80 kV for children. A cine pulse system should have a working output of at least 50–60 kW.

**Automatic exposure control.** Maintenance of the brightness level of the image intensifier is accomplished by varying any of three exposure factors: voltage, current, and exposure duration. Kilovoltage automatic control provides a wide dynamic range, and small changes in voltage will affect film blackening to a greater degree than large changes in either current or pulse duration. With this type of system, current may be constant or may be automatically reduced with increases in voltage to maintain radiation dose or constant power to the x-ray tube. Combined cine pulse systems may vary all three of the primary exposure factors.

**X-ray tubes.** The conversion of electrical energy into x-radiation is inefficient and is accompanied by considerable heat production, which must be dissipated to prevent damage to the x-ray tube. The minimum recommended heat storage capacities of the anode and tube housing are 1 million HU and 1.75 million HU, respectively. Mechanisms for monitoring heat build-up that indicate excess heat by an initiating signal are available. The monitoring device may automatically suspend function when the heat of the target approaches a maximal level. Liquid cooling of the x-ray tube is preferred but may not be convenient for tubes mounted in a C-, U-, or Z-arm configuration. Forced air cooling is the minimal requirement for such equipment.

X-ray tubes are distinguished by a number of characteristics, including anode material, rotor speed and support, target diameter, focal spot, and target angle. Anodes should be capable of high-speed rotation (10,000 rpm) to dissipate heat. The target should be 100 to 125 mm in diameter. An

anode angle between 8° and 10° is recommended because it allows for an increased output compared with tubes having larger angles. Although field coverage is less, it is adequate for cardiac cineangiography. A disadvantage of smaller target angles is that more absorption of x-rays may occur within the anode mass, producing what is called the anode heel effect. This reduces the radiation intensity on the anode side of the field and reduces field coverage. The heel effect is not significant for cineangiography; however, it can be important when angles between 6° and 9° are used in conjunction with an appropriate image intensifier field size, assuming the usual source-to-image distance of 70-100 cm and correct tube alignment.

The focal spot size is of considerable importance because it greatly influences image resolution. Current National Electrical Manufacturers Association recommendations for the measurement of focal spot size and acceptable tolerances are being revised. Because cardiac imaging now requires x-ray tubes mounted for multiaxis positioning, the capability of varying between two focal spots is desired. A larger focal spot of 1.0-1.2 mm (50-80 kW) is preferred for the long source-to-image distances required with isocentric positioning, as well as for handling the increased radiation required for steep angulation imaging. A smaller focal spot of 0.6-0.7 mm (35-50 kW) will increase image resolution and is used when imaging in the usual viewing angles at short (75-90 cm) source-to-image distances or in pediatrics.

**Collimation.** Proper collimation will minimize off-focus radiation and reduce scatter, which in turn improves image quality and reduces radiation to the patient and operator. A collimator that extends into the recess of the tube housing minimizes the distance between it and the anode and is better able to reduce scatter. In addition, a lead diaphragm should restrict the tube port opening to the maximum field size that will be used. Collimation is more convenient when circular collimators are used, but if rectangular collimators are used, their edges should be visible in the fluoroscopic field. Dual-shape collimators incorporating both circular and elliptical shutters may be used to modify the field for cardiac contour collimation. Partially absorbent contoured filters are also available to control the bright spots produced by the lung tissue bordering the heart.

**Image intensifiers.** Because of the necessity of imaging large fields (e.g., for ventriculography, aortography) as well as small fields (coronary arteries), multimode (double or triple) cesium iodide image intensifiers are recommended. Formats available vary with the manufacturer but are typically 9 in/6 in (4.5 in (9/6/4.5), 9/6, 10/4, and 9/5. When smaller modes are used, resolution is increased and vignetting decreased. Gain also drops considerably when going from a larger to a smaller mode. Resolution is greatest at the center of the field and decreases at the periphery. Measurements of resolution through the optical system are made with a 0.05-0.2 mm lead line test object situated on the intensifier face without phantom at 50 kV. Minimal resolution of a 6- to 7-in mode should be four line pairs/mm, and that in the 9-in

mode should be in excess of three line pairs/mm. Resolution in the 4.5-in mode may exceed five line pairs/mm. The measured contrast ratio of the image intensifier should not be less than 12:1, as measured with a standard lead disk. Quantum detection efficiency should be in excess of 60%. Dual mode intensifiers should have a conversion factor of 150-200 for the large field and 75-100 for the small field. A tube should be selected for maximum resolution and adequate gain as opposed to maximum gain.

**Grids.** Radiographic grids are required to improve contrast by decreasing scatter radiation. A 6:1-10:1 (depending upon lead content) focused 40 lines/cm fiber-spaced grid is recommended for cinefilming. Focused grids should be used within the focal range indicated by the manufacturer and selected in accordance with the working conditions of the specific x-ray equipment. Using a grid to improve contrast results in some increase in radiation exposure to the patient. Use of grids having fiber spacers and covers will require less radiation exposure than grids having aluminum spacers and covers.

### Optics

High-quality matched optics are necessary for transfer of the image from the output phosphor of the intensifier to the video camera tube or the cinecamera. The entire optical system should be system-engineered to maximize image information transfer. The collimator lens collects light from the output screen of the intensifier and focuses it into a beam of parallel rays. The collimator lens and the camera lenses should be designed for tandem operation. All lens element surfaces should be coated and periodically cleaned to ensure high contrast and high transmission efficiency. The contrast ratio of the optical system should exceed 20:1 when subjected to a 10% area opacity test. The modulation transfer function of the optical system should exceed that of the image tube. Focal length should be chosen to optimize film area utilization for the application. Focal length of the collimator lens divided by the diameter of the intensifier output phosphor equals the focal length of the camera lens divided by the desired image diameter on film (all measurements in millimeters). In general, it is best to use f-stop openings at least one stop smaller than maximum, preferably in the range of f:4.0 to f:6.3. Lens openings smaller than f:8 do not improve the image quality and may require additional radiation or the use of fast x-ray film. With too small an f-stop, the image may be degraded by diffraction.

### Cinecamera

Cineangiographic imaging is best filmed with a synchronous 35-mm camera. The camera's shutter is controlled by the frequency of the power supply (60 cycles/sec) and synchronized to the 30 frames/sec video. Thus, cinefilm rates are multiples or divisions of 30. Filming rates of 60 frames/sec can be used when viewing cardiac motion, although adequate imaging can be obtained at 30 frames/sec

with a reduction in total radiation exposure. Precise frame registration, film pull-down, and maintenance of a flat film plane are essential. When filming in the biplane mode, the cinecameras should operate out of phase to avoid exposure overlap, reduce scatter, and improve the image. Image tube electronic blanking also helps prevent scatter from biplane operation.

"Framing" refers to the method by which the circular image produced by the image intensifier is recorded on the rectangular frame of the cinefilm. Maximal horizontal overframing uses 88% of the available film area and encompasses 84% of the image presented to it. This method is recommended for cardiac imaging. More severe overframing may be useful when higher magnification is desired; however, this will result in a greater loss of the output phosphor viewing area. The amount of overframing is controlled by the focal length of the cinecamera lens.

### Video System

Television fluoroscopy is essential during the catheterization procedure, and the highest-quality images are essential for interventional procedures. An integral part of the video chain, recording and playing back the video image, may be accomplished using analog video tape or a digital acquisition and storage system. Video tape recorders are most commonly used at present. These must be of high quality, allow automatic recording with fluoro and/or cine activation, have a cueing capability, and provide forward and reverse slow motion and freeze-frame playback.

The television system should have excellent image clarity and signal regulation. Minimal lag will improve viewing of moving objects, which may be especially helpful for interventional procedures. Low-lag pick-up tubes, however, cause unwelcome flicker when recording in the cine mode at 30 frames/sec. This may be reduced by using 60 frames/sec cine or by using scan conversion. The system's automatic brightness control should respond rapidly. Contrast may be improved by circular blanking. A provision for external synchronization is desirable for digital application.

A high-quality, 525-line 5-10-MHz (-3db) bandwidth television camera system and monitor, with a signal-to-noise ratio of no less than 45 db, is suggested. High-resolution systems using line scan rates of 1023 or 1049 are available, although it is not yet established whether these systems offer a significant advantage over the 525-line systems. The 1023- and 1049-line systems require a wider bandwidth and therefore are subject to more noise. One property of high-line-rate systems is the lessening of artifact caused by raster line. This may be of some advantage in the performance of interventional procedures. These systems also provide increased vertical resolution in still-field playback from analog (video tape recorders). Measured resolution of a line pair test wedge of 0.1 mm lead equivalent placed in the entrance plane of the image intensifier should not be less than 1.8 line pairs/mm for a 6-7-in field size, and 1.4 line pairs/mm for a

9-10-in field size, when the limiting resolution of the image intensifier is not less than 4 line pairs/mm under conditions corresponding to 40  $\mu$ R/sec at 50 kV without additional filtration, significant magnification, and on-site focal spot and distance geometry.

### Patient and Equipment Support

Compound and steeply angulated radiographic views necessitate that the x-ray equipment have multiaxial positioning capability. Newer equipment may be microprocessor controlled so that a variety of positions may be preprogrammed and easily selected from a menu. The ability to obtain very steep sagittal plane angulation (in excess of 45°) is desirable. An image intensifier with a diameter of more than 9 in is not recommended for cardiac catheterization laboratories because its size interferes with the ability to obtain steep sagittal angulation. Patient and equipment support devices should be configured so that the procedure may be comfortably performed from either the brachial or femoral route and from either side. Access to the head and neck of the patient should be unencumbered in case the need arises for ventilatory support or jugular venous catheterization. The patient support should be able to accommodate patients weighing at least 300 lb and to withstand forces engendered with the delivery of cardiopulmonary resuscitation. The overall design of this equipment should allow easy positioning for all single and biplane views. For biplane systems, overhead support of the lateral imaging system may facilitate patient access and has been recommended.

Exposure of the operator to radiation is somewhat greater with C-arm devices, and equipment to limit this exposure should be available and used. This equipment is usually an x-ray-dense glass shield positioned between the x-ray tube and the operator.

Carbon-fiber table tops are recommended. Patient supports should be as radiolucent as possible (no more than the x-ray equivalent of 0.7 mm aluminum). Most tops are now free-floating and have manual lateral and longitudinal movement with lock release and motor-driven capability to raise or lower the top. Rotating patient supports may be useful in some situations, and if used should provide for rapid positioning, as well as the ability to obtain true lateral views.

### Contrast Injectors

Power injectors are necessary to deliver relatively large volumes of contrast through intravascular catheters in order to obtain adequate opacification of large vessels and cardiac chambers. Some operators use the power injector for coronary angiography and for the timed injection of therapeutic agents such as streptokinase.

Injectors for cardiac angiography should be flow rate controlled and capable of delivering up to 50 ml/sec. The ability to deliver very low flow rates may be desirable for the delivery of therapeutic agents. There should be a capability for the automatic detection and termination of an over-rate

injection. Injection volume control allows for the selection of small test injections. A mechanical stop is required, as is pressure limit control. The injector should have a trigger control as well as a remote control. These should function to automatically terminate the injection when released. The syringe should be electrically isolated, and the injector should have a ground cable, independent of the electrical ground, to be attached to the patient support ground. There should be an audible signal indicating current flow of more than 20  $\mu$ A. Syringes may be disposable or reusable and should be transparent to allow detection of air or particulate matter. A syringe heater to maintain contrast material at about 37°C is desirable. These heaters are not designed to heat contrast to 37°C from room temperature, but rather to maintain this temperature. Injectors may have mobile stands or may allow mounting of the power ram on the patient support. Special circuitry may allow the injector to be interfaced with the film changer, cinecamera, x-ray generator, or ECG for certain applications.

### *Cineangiographic Film and Processing*

The type of film used is but one element in the determination of the ultimate quality of the image derived. The contrast observed is dependent on the entire system, which includes radiographic factors, image intensifier contrast, the optical system, and processing and viewing conditions, as well as on the inherent contrast of the film. A wide-latitude, low-contrast, low-base fog film processed to an average gradient of 1.2-1.6 is recommended. Fast films tend to have a more grainy image and increased quantum mottle. The selection of a specific film is best based on the contrast produced by the entire system and should be tested on appropriate phantoms with different f-stop settings. The film should then be viewed under the same conditions as clinical studies.

The ability to review the processed cineangiogram as soon as possible after its recording may be important in decision-making because of the higher-quality image afforded by the film compared with video tape. This means that processing capability should be immediately at hand. Responsibility for monitoring the quality of films rests with the catheterization laboratory director, and he or she should be familiar with processing technique as well as methods of quality control. Excellent film processing is essential and should be the responsibility of a highly skilled individual. A number of film processors are commercially available. Some, but not all, require an attendant to couple the leader to the film when the end of the film has been reached. There are a number of other variables affecting film quality, including but not limited to film path length, film speed range, reel capacity, and variable developer time. For any processor, consistently good results are obtained only if there is careful control of all the mechanical and chemical factors involved.

Cinefilm processing involves developing, stopping, fixing, washing, and drying the film. Variables involved in processing include:

1. Temperature control: developer temperature should be automatically maintained within 0.3°C (0.5°F)
2. Development time: the actual film transport speed should be within 5% of that required for acceptable processing and continuously variable
3. Agitation: proper agitation is essential to prevent mottle and irregular streaking and to ensure uniform processing
4. Replenishment: proper replenishment of developer and fixer is necessary and may be accomplished by replacing exhausted components or by flood replenishment
5. Filtration: particulate matter larger than 25  $\mu$ m should be filtered
6. Film drying: proper film drying is necessary to prevent tackiness or brittleness and curl

Quality control of film processing is essential. This may be accomplished with a sensitometer by exposing film strips to precisely controlled steps of increasing light intensity. A densitometer then measures the relative densities produced on the processed film strip. This should be done on a daily basis and whenever maintenance is performed on the processor. Values can then be graphed to monitor daily variations in film speed, contrast, base, and fog of the system.

### *Cinefilm Viewing*

Maximum information is obtained from a cinefilm when it is viewed in motion because the eye integrates five or more successive images into a composite picture. Cinefilm projectors must transport the film and project the image. Two basic types of projectors, those with intermittent film advance and those with a rotating prism, are available. Each has advantages and disadvantages. Desirable qualities of the projector include:

1. High-intensity light source with variable brightness control
2. High-quality and high-resolution optics capable of faithful reproduction of the cine image across the entire field
3. Focus control mechanism
4. Heat control system to prevent film damage when viewing of a single frame is prolonged
5. Easy access to the optics to facilitate cleaning
6. Mechanism for image rotation and reversal
7. Easy access to light source for replacement and adjustment
8. Large field capacity
9. Adaptability for still or television camera
10. Flickerless film transport and motionless film stop
11. Ability to accept any standard film, spool, or reel and accommodation for film length of up to 400 ft
12. Transport of film at variable speeds (forward and reverse up to 60 frames/sec) and single frame advancement without film damage
13. Fast forward and reverse
14. Low noise level

15. Reliable, easily maintained, and convenient
16. Remote control operation for teaching

### Support Equipment

An adequate supply and variety of catheters, guidewires, sheaths, and other equipment should be immediately available. The laboratory should be equipped to perform procedures from either the femoral or brachial approach.

A crash cart containing the necessary medications and equipment for ventilatory support should be located in or immediately adjacent to the procedure room. This cart should be periodically checked and replenished. A defibrillator/cardioverter should be present in the procedure room and should be available for immediate discharge. Its function should be routinely checked. A temporary pacemaker is necessary. The device should have adjustable energy output, pacing rate, and sensitivity levels. The ability to attain high pacing rates for the termination of certain arrhythmias is desirable. An intra-aortic balloon pump may be desirable for the diagnostic laboratory and is essential for the interventional laboratory. A pump designed for ambulance transport should be considered for laboratories physically separate from cardiac surgical support. Devices that can provide peripheral cardiopulmonary support in the catheterization laboratory using percutaneous cannulae are now available. Use of this equipment requires special expertise, including that of a perfusionist.

### Digital Imaging

While traditional film-based cineangiography continues to be the standard method for coronary imaging, advances in digital technology have led many to believe that it will eventually be replaced by a computer-based system. Digital techniques have been shown to be useful in the acquisition, processing, analysis, and storage of imaging data. When first introduced, the prospect of using subtraction techniques to obtain high-quality imaging at lower radiation doses, with less contrast and with nonselective injection, was entertained. These goals have not yet been realized in coronary imaging, because problems such as cardiac and respiratory motion, parallax, and vascular overlay limit the use of digital subtraction. The major advantages of digital imaging of the coronary arteries at present are: 1) the rapidity with which high-quality images may be reviewed after acquisition; 2) the increased contrast resolution obtainable via image processing; and 3) the ability to quantitate coronary luminal dimensions and more precisely characterize stenoses using edge detection or videodensitometric techniques. Digital techniques have also been used to obtain physiological data; for example, the measurement of myocardial contrast appearance time under basal and hyperemic conditions provides information as to coronary flow and its restriction. If and when digital imaging completely replaces conventional film recording, there may be an additional logistic and economic advantage.

Digital subtraction techniques have been used for right and left ventriculography and for the imaging of noncardiac vascular structures, providing the advantage of nonselective injection or lessened contrast administration. This methodology is frequently used in vascular interventional procedures as a substitute for serial filming. However, the small field size of the image intensifier limits its use for diagnostic peripheral arteriography.

In current practice, it is not essential that every catheterization laboratory have digital imaging capability. In some laboratories, digital systems purchased as part of a "state-of-the-art" package have seen little or no use. Because a digital system is expensive, careful consideration should be given to the need for it before acquisition. While such systems may be retrofitted for use in most existing catheterization laboratories, it must be realized that the quality of digital imaging is dependent on the existing x-ray system (the x-ray generator, tube, image intensifier, and television system). An independent evaluation of the existing x-ray system should be performed before the purchase of an add-on digital system to ensure that optimal imaging may be obtained. All things being equal, there is an advantage in obtaining digital units at the time of purchase of the x-ray equipment and from the same manufacturer. Matched equipment would probably optimize results of the imaging chain and, in the event of a performance failure, would facilitate troubleshooting and repair.

The basic architecture of a typical digital system involves a television camera that feeds the image obtained from the image intensifier to a preamplifier from which it is sampled and quantized by an analog-to-digital converter. The latter converts the image to a digital matrix consisting typically of 512 lines, each having 512 picture elements (pixels). The sampled analog signal is quantized at each pixel location by 256-1024 levels of coded gray scale (8-10-bit resolution). The digital information is then sent to semiconductor memory, which interfaces with the controlling computer, mass storage, and image processor. From the latter an eight-bit digital-to-analog converter allows display of 256 gray scale levels on a monitor.

The spatial resolution of the digital image is limited by the digital matrix and is less than that of cinefilm. Although higher resolution would be obtained with a 1024 × 1024 matrix, the amount of information that must be processed and stored and the speed with which it must be accomplished preclude an imaging rate of 30 frames/sec. The use of high-speed digital disks limits the number of images that can be stored, requiring that data be erased or downloaded to another storage system. Recent developments, including the simultaneous storage of digital information on tape cassette, facilitate data transfer.

Hard copies of digital images may be obtained in a number of ways. Individual images may be recorded by a thermal printer, a multiformat video camera, or a laser film recorder. The best images are obtained by the laser film recorder, but it is the most expensive device. In the absence

of simultaneous cinefilm recording, video tapes may be produced from the digital data.

### *Quantitative Angiography*

The traditional method of assessing coronary stenoses by visual estimation of percent diameter stenosis is associated with a high degree of inter- and intraobserver variability. Geometric and nongeometric techniques of quantitating lesion significance have been validated and have become increasingly important in clinical research. There remains some controversy as to the preferable technique, especially for the analyses of eccentric lesions and postintervention images where extravascular contrast may exist. The actual lesion cross-sectional area has greater physiological importance than does percent diameter stenosis.

It is possible that some form of quantitation of lesion severity will be required in the future to justify interventional procedures. Although, as noted above, digital angiography lends itself to quantitation, similar measurements may be made from the processed cinefilm. This may be performed with calipers or may be computer-assisted.

## **Safety Requirements**

### *Radiological and Surgical Support*

Occasionally it is helpful to have the expertise of skilled radiologists and surgeons available during the catheterization process. The presence of a radiologist may be beneficial in the performance of combined angiographic procedures. At times, pathology is discovered during the catheterization that requires angiographic techniques unfamiliar to the cardiologist.

Vascular and cardiovascular surgical assistance may be required for complications encountered during the procedure. Most commonly, complications requiring surgical expertise arise in the peripheral vasculature and are related to catheter insertion or manipulation. Sometimes, however, dissection or thrombosis of a coronary artery may occur, and rarely, a cardiac chamber or great vessel may be perforated, requiring emergency cardiac surgery. Consultation with a surgeon before catheterization may also be helpful in establishing precisely the information desired from the procedure before a decision about surgical intervention is undertaken.

### *Electrical and Radiation Safety*

By their very nature, x-ray imaging and the collection of physiological data in the catheterization laboratory offer hazards to patients and personnel involved with the procedure. These hazards include the risk of electrical shock and the exposure to ionizing radiation. While shock is a danger wherever electrical equipment is used, the number and variety of electrical devices to which the patient is directly or indirectly exposed and the potential low-impedance route to the heart offered by intravascular catheterization present

additional risk. The hazards of radiation exposure are more insidious and complex. Benefits to patients and staff derived from improvements in equipment and shielding have been countered by the increased fluoroscopy time and repeated angiographic procedures associated with the performance of interventional procedures. In addition, because the effects of radiation are not immediately seen or felt, there may be a tendency by staff and patients to ignore or minimize the risk of exposure. Guidelines for electrical safety and radiation protection in the cardiac catheterization laboratory continue to evolve (51,66,67). It is the responsibility of the director of the laboratory to ensure that the facility meets these standards, perhaps by use of the services of an imaging equipment service engineer, electrical engineer, radiological engineer, and radiation physicist. It is assumed that all catheterization laboratory facilities, be they hospital-based, freestanding, or mobile, meet national (or state, if more stringent) guidelines. The task force does not propose to establish minimal guidelines but rather to emphasize electrical and radiation safety considerations.

### *Electrical Safety*

The four principles of electrical safety in the catheterization laboratory are 1) the presence of a safe electrical primary wiring system; 2) the electrical isolation of all equipment attached to the patient; 3) the use of an equipotential hardwired grounding system for all equipment; and 4) periodic inspection of the electrical system and measurement of interequipment current leakage.

At installation, all electrical wiring and fittings must conform to good electrical practice as specified in the National Electrical Code prepared by the National Fire Protection Association (NFPA 70) and the standards for the safe use of electricity in health care facilities (NFPA 99, 1987 ed.). During installation, wiring and grounding systems should be inspected and certified by a qualified engineer familiar with the specific grounding needs of a catheterization laboratory and the equipment being installed. Electrical safety inspections should be performed thereafter at 3-6 month intervals and every time new equipment is introduced into the electrical environment. Relatively inexpensive equipment is available for the testing of current leakage, which may be performed by the laboratory director or a designee.

As suggested above, the nature of cardiac catheterization and of the equipment used to accomplish it poses such a high level of risk for electrical shock that additional protection, in the form of an equipotential, hardwired, omnipresent, low-impedance grounding system for both fixed and moveable equipment, is required to ensure that the maximum current flow between any two exposed conductive surfaces will be less than 20  $\mu$ A during normal laboratory function.

Because of the variety of type and manufacture of catheterization laboratory equipment, each having its own grounding system, there exists the possibility of the formation of ground loops and significant current flow between

these systems and the electrical supply ground, even when isolation transformers are used. This hazard is avoided by having all equipment grounded to an equipotential buss bar. Direct grounding to the buss bar is preferred, but limited branching is acceptable. In some cases, two buss bars are used, one located at the patient support and the other in the equipment and control area. When this is done, the buss bars must be connected by 600 or larger copper cable. Special attention to grounding should be paid to equipment that is supported by bearings because of the poor conduction of greasy bearings. Mobile equipment that cannot be hardwired to the equipotential ground system should have an audible ground disconnect warning. The standard three-prong plug-in connector does not provide adequate grounding for moveable equipment in the catheterization laboratory. Such equipment should have an additional common electrical ground terminal on the patient support.

The electrical power system's neutral wire should be grounded only at the service entrance or step-down transformer.

### *Radiation Protection*

Because no level of exposure to ionizing radiation is considered safe, the cardinal principle of diagnostic imaging is to limit x-ray exposure to the patient and the staff to the minimal level compatible with high-quality care. To ensure this, every step, from laboratory construction to the purchase, installation, and use of equipment, should take radiation protection into consideration. Physicians, technologists, and nurses working in the laboratory should be familiar with the principles of radiation protection and diligently adhere to them. Ancillary personnel not essential to the performance of the procedure or immediate patient care should not be in the procedure room during imaging. Recording and monitoring technologists should not be located in the procedure room. On occasion, the assistance of individuals other than the laboratory staff (e.g., anesthesiologists, surgeons, or perfusionists) may be required in the procedure room. It should not be assumed that they are knowledgeable in radiation protection, and care should be taken to ensure that they are protected. It is the operator's responsibility to prevent unnecessary x-ray exposure.

**Facility design and equipment.** Recommendations for the design and evaluation of structural shielding have been published by the National Council on Radiation Protection and Measurements (NCRP Report No. 49, 1976). While diagnostic x-ray equipment manufactured after August 1, 1974, must meet minimum federal performance standards, it is important that such equipment be installed and used properly and that periodic evaluation of radiation protection be made. Guidance as to the proper design, performance, and use of x-ray imaging devices in general, and cardiac radiological equipment specifically, is found in NCRP Report No. 102 (1989). It should be emphasized that optimiza-

tion of all elements of the imaging chain will reduce unnecessary radiation exposure.

**Radiation exposure.** Individuals in the cardiac catheterization laboratory may be exposed to primary beam or scatter radiation. Only the patient should be exposed to the primary beam and that exposure should be limited to the region of clinical interest. Fluoroscopy and cineangiography should be limited to that clinically necessary. Fluoroscopy should not be performed while the operator's attention is directed away from the television monitor. Consideration should be given to filming at 30 frames/sec whenever possible. Fluoroscopic timers are required and serve to alert the physician as to the duration of total x-ray exposure. An audible signal should sound after every 5 minutes of exposure, although this signal should not be associated with an immediate automatic termination of the x-ray beam before being reset. The operator should be made aware of the cumulative amount of exposure time during the procedure. In training programs there should be a limit to the amount of fluoroscopic time granted to a trainee to complete a specific task, based on a number of considerations such as the progress being made and the complexity of the procedure.

Scatter is the major source of radiation exposure to catheterization laboratory personnel. The highest amounts of scatter are produced by units having the x-ray tube over the procedure table and the image intensifier below the table. This type of configuration should not be used. Equipment consisting of a fixed, under-table x-ray tube and above-table intensifier produce the least scatter radiation, especially when the patient support (most often a cradle) is mounted flush with edges of the table.

Multiaxial imaging equipment (C-, U-, and Z-arm) present problems in terms of radiation protection. Inasmuch as these units are now the most commonly installed and offer advantages in imaging that may be especially useful for interventional procedures, greater consideration should be given by industry to providing protection from scatter radiation. At a minimum, a freely movable lead glass or acrylic shield suspended from the ceiling should be used. Its sterility may be maintained by using disposable plastic covers. Leaded drapes are also available that may be attached to the patient support.

Each procedure room should have a detailed determination of exposure levels performed by a qualified radiation physicist. Measurements should be made with the x-ray equipment in each of the commonly used configurations. This information should be used to guide personnel to the lowest-exposure location compatible with the performance of the procedure.

**Protection of laboratory personnel.** The primary mode of protection for laboratory personnel is the protective apron, which should be of at least 0.5 mm lead equivalent. The apron should be the wraparound type, extend to the knees, and have a shallow neck cutout to protect the sternum. The use of a belt will help support some of the weight and may protect from back strain. Two-piece (vest and skirt) aprons are becoming popular, but care should be taken that they

extend low enough and that there is adequate overlap of vest and skirt when the body is extended. Care should be taken in the handling of aprons to prevent damage to the protective element. Aprons should be coded and periodic radiographic inspection (every 3 months and whenever damage is suspected) should be made of each with the results recorded in a central log. Protective eyewear of 0.5 mm lead equivalent with wraparound shields and thyroid shields will also reduce radiation exposure and should be considered essential in the absence of alternative shielding of these areas.

**Radiation monitoring.** An essential element of an effective radiation safety program is the monitoring of exposure to radiation of laboratory personnel. A film badge or thermoluminescent badge should be worn by all members of the laboratory staff. The thermoluminescent badge is more accurate and more expensive. Although these monitors cannot prevent x-ray exposure, they provide a quantitation of exposure such that the individual may alter his or her behavior (e.g., presence at fewer procedures, more effective use of shielding) in such a way that exposure does not reach suggested maximum permissible dose limits (NCRP Report No. 48).

### *Catheterization Laboratory Quality Control*

Every laboratory should have a periodic surveillance and preventive maintenance program. Preventive maintenance should be carried out in accordance with manufacturer's specifications and may be performed by in-house personnel, by the manufacturer, or contracted out to a third party. It is helpful to have the services of in-house bioscience engineers available for immediate assistance should a problem arise; many malfunctions occurring in the catheterization laboratory are caused by relatively minor faults that can easily be diagnosed and repaired. There is a tendency in the busy laboratory to assign a low priority to preventive maintenance and quality assurance inspections. A published schedule and commitment to its adherence are essential components of a well-functioning laboratory. The availability of a second laboratory lessens the burden of closing a laboratory for maintenance and also provides a mechanism for completing a study in a patient in the event of malfunction during a procedure.

Guidelines for a quality assurance program for imaging equipment are detailed in NCRP Report No. 99. Daily checks of system image quality using resolution bars and phantoms are suggested. Frequent checks of film processing, as noted above, are essential.

## APPENDIX E

### *Types of Procedures*

1. **Aortic root angiography:** A recording of images of the aortic root using radiographic contrast material
2. **Atrial septostomy:** Also called the Rashkind procedure, in which a catheter-mounted inflated balloon is used to enlarge or create an intra-atrial shunt
3. **Catheter atherectomy:** The use of a catheter-based

device to selectively remove an atheroma from the wall of an artery (*directional, rotational, other*)

4. **Catheter-based electrophysiological studies:** The evaluation of the cardiac conduction system and regions of impulse formation, using strategically placed catheters within the cardiac chambers or blood vessels

5. **Catheter-delivered occlusion device:** Umbrella occlusion of patent ductus arteriosus, atrial septal defect, ventricular septal defect, or detachable balloon occlusion of a shunt

6. **Catheter endomyocardial biopsy:** The removal of a portion of endomyocardium using a catheter biptome

7. **Fluoroscopy:** Imaging of the cardiovascular and other structures using real-time x-ray methods

8. **Hemodynamic assessment:** The recording of pressure data from selected cardiac chambers or vasculature; includes the determination of cardiac output by any of a number of means when appropriate

9. **Hemodynamic stress testing:** The evaluation of the hemodynamic alterations associated with exercise or other stressful interventions

10. **Intra-aortic balloon counterpulsation:** The insertion of an intra-aortic balloon pump device for the purpose of mechanically augmenting cardiac output, unloading the left ventricle, and improving coronary perfusion

11. **Intracoronary administration of thrombolytic drugs:** The selective injection of a thrombolytic agent into a coronary artery or graft in an effort to reduce luminal obstruction due to an intravascular thrombus

12. **Left heart catheterization:** The insertion of a catheter into the central arterial system for the purpose of recording ascending aortic and/or left ventricular pressures and/or performing angiography and/or obtaining blood samples

13. **Left ventricular angiography:** The recording of images made of the left ventricle using radiographic contrast material

14. **Left ventricular puncture:** The percutaneous insertion of a needle or catheter directly into the left ventricle through the chest wall for the purpose of recording pressure and/or performing angiography

15. **On-site surgical support:** A cardiac operating facility accessible by gurney

16. **Percutaneous cardiopulmonary support:** The insertion of venous and arterial catheters connected to an external pump oxygenator to provide augmentation of cardiac output and arterial oxygenation

17. **Percutaneous catheter balloon valvuloplasty:** The inflation of one or more balloon-tipped catheters in the orifice of a cardiac valve to reduce valvular stenosis

18. **Percutaneous transluminal coronary angioplasty:** The inflation of a balloon-tipped catheter at the site of a coronary artery stenosis to attempt to enlarge the diameter of the lumen

19. **Percutaneous transluminal peripheral vessel angioplasty:** The inflation of a balloon-tipped catheter at the site of a stenosis in a peripheral artery to attempt to enlarge the diameter of the lumen

20. *Pericardiocentesis*: The removal of pericardial fluid by inserting a needle or catheter directly into the pericardial space

21. *Permanent cardiac pacing*: The use of an electrode catheter and implantable generator to initiate cardiac contractions by direct delivery of an electrical stimulus

22. *Pharmacological study*: The evaluation of the hemodynamic or angiographic response to an acutely administered pharmacological agent

23. *Pulmonary angiography*: A recording of images of the pulmonary arteries made using radiographic contrast material

24. *Retrieval of foreign bodies*: The insertion of a transvascular catheter device for the purpose of removing an intravascular foreign body

25. *Right heart catheterization*: The insertion of a catheter into the venous system for the purpose of recording right heart and/or pulmonary pressures and/or performing angiography and/or obtaining blood samples

26. *Saphenous vein or internal mammary coronary bypass graft angiography*: A recording of images of saphenous vein grafts or internal mammary grafts made using selective injection of radiographic contrast material

27. *Selective coronary angiography*: A recording of images of a coronary artery with selective injection of radiographic contrast material

28. *Temporary pacing*: The use of an electrode catheter and external generator to temporarily initiate cardiac contractions by direct delivery of an electrical stimulus

29. *Transcatheter ablation of arrhythmia foci or conduction pathways*: The delivery of an electrical discharge to a specific portion of the conduction system or heart using intracardiac catheter techniques

30. *Transseptal catheterization*: The placing of a catheter within the left atrium by crossing the interatrial septum, using direct needle puncture when necessary

## APPENDIX F

### Evidence From Noninvasive Testing Suggesting High Risk\* for Cardiac Events

#### Exercise electrocardiogram (ECG)

Abnormal horizontal or downsloping

ST segment depression†

Onset at heart rate <120/min (off  $\beta$ -blockers) or  $\leq 6.5$

METS‡

Magnitude  $\geq 2.0$  mm

Postexercise duration  $\geq 6$  minutes

Present in multiple leads, reflecting multiple regions

Abnormal systolic blood pressure response during progressive exercise§

\*High-risk patients generally are those with reduced life expectancy because of left main or multivessel coronary artery disease, often with impaired left ventricular function (see References 33 and 46).

†Except for patients with ST segment depression at rest, intraventricular conduction defects excluding right bundle branch block, or electrolyte abnormalities or those taking certain drugs such as digitalis glycosides the latter

With sustained decrease of  $>10$  mm Hg or flat blood pressure response ( $\leq 130$  mm Hg), associated with electrocardiography evidence of ischemia

Other potentially important determinants

Exercise-induced ST segment elevation in leads other than aVR

Exercise-induced ventricular tachycardia

#### Thallium scintigraphy

Abnormal thallium distribution in more than one vascular region at rest or with exercise that redistributes at another time

Abnormal distribution associated with increased lung uptake produced by exercise in the absence of severely depressed left ventricular function at rest

Enlargement of the cardiac pool of thallium with exercise

#### Radionuclide ventriculography

A fall in left ventricular ejection fraction of  $\geq 0.10$  during exercise

A rest or exercise left ventricular ejection fraction of  $<0.50$ , when suspected to be due to coronary artery disease

## APPENDIX G

### Task Force Interviewees

The following individuals were interviewed by the Task Force:

Jean Bernard, New Orleans, Louisiana  
Paul Bremer, Stuart, Florida  
Charles M. Elliott, MD, Charlotte, North Carolina  
Joseph P. Galichia, MD, Wichita, Kansas  
John J. Hallmark, Stuart, Florida  
Roy F. Pearson, Nashville, Tennessee  
Robert C. Ripley, MD, Nashville, Tennessee  
Charles Steiner, MD, Marrero, Louisiana  
William R. Storer, MD, Indianapolis, Indiana  
Walt F. Weaver, MD, Lincoln, Nebraska  
David E. Wertheimer, MD, Port Saint Lucie, Florida

## APPENDIX H

### Survey Results

The 1990 survey provided data and information on the issue of whether or not the ACC/AHA should publish new guidelines for cardiac catheterization. Most respondents (63.4%) wanted the 1985 ACC/AHA guidelines revised. More members in academia favored this action (73.7%) than did nonacademicians (61%), but both groups supported this initiative.

More than half endorsed the inclusion of the following

group frequently develop ST segment depression suggestive of ischemia during exercise testing). Recommendations in this section based on ECG criteria during exercise may not apply if these conditions are present.

†This unit of energy expenditure at rest is equivalent to an oxygen uptake of approximately 3.5 ml O<sub>2</sub>/kg body weight/min.

§A decline in systolic blood pressure may occur in some patients without heart disease during sustained maximal exercise, or if certain medications are in use at the time of the exercise test.

subjects in the new guidelines: 1) more stringent selection criteria for ambulatory catheterization patients (72.2%); 2) more stringent criteria for proliferation of any new catheterization laboratories (68.2%); and 3) more stringent criteria and guidelines for hospitals for ethical issues involving cardiac catheterization (52.6%). However, only 47.4% wanted more stringent criteria and guidelines for physicians performing cardiac catheterization, this percentage being higher among members who did no cardiac catheterization procedures in 1989.

Most respondents supported the need for better guidelines for establishing new catheterization laboratories and for the type of catheterization laboratories to be developed, as well as for the patients most suited to treatment in various catheterization laboratory settings. Most found current laboratory definitions inadequate (except those for traditional hospital-based laboratories). Most believed that referrals by physicians to laboratories in which they have financial interests are a problem and that catheterization laboratory advertising is unacceptable, although a sizable minority disagreed. The overwhelming majority believed that percutaneous transluminal coronary angioplasty and other interventional procedures should not be performed in an ambulatory setting. Many would not refer patients to a freestanding catheterization laboratory for even a diagnostic cardiac catheterization, although substantial levels of disagreement and indecision were noted.

Respondents were primarily non-pediatric cardiologists who practice invasive cardiovascular medicine in a traditional inpatient setting. Most did not report nontraditional ambulatory catheterization laboratories, such as freestanding or mobile catheterization laboratories, operating in their practice area. Very few referred patients to freestanding catheterization laboratories or performed cardiac catheterization procedures in such laboratories in 1989. Most members did not report risky procedures such as percutaneous transluminal coronary angioplasty on outpatients in their geographical area. Also, most respondents did not characterize the ambulatory cardiac catheterization patients in their area as "high-risk" and most would not refer such patients for this procedure, although hypothetical exceptions were noted by 40.2% of respondents. These specific exceptions may be worth consideration by the task force as it evaluates patient suitability.

Two new questions in the 1990 survey yielded surprising results. First, only 3.5% of respondents reported any cardiac catheterization complications attributable to the facility where the procedure was performed, raising some questions as to the extent to which poor outcomes result from characteristics of the facility as opposed to other factors, for example, the patient or the procedure. Second, 32% of respondents indicated that they might refer patients to a freestanding laboratory for a diagnostic catheterization, raising doubts about whether there is a consensus on not referring patients to such facilities for cardiac catheterization procedures.

A separate 1989 pretest of the survey suggested that nonmembers held attitudes similar to those of members, so the results of this survey may apply to the specialty of cardiovascular medicine as a whole and not solely to ACC members. Preliminary inspection of the results of the 1990 survey found them to be consistent with those of the 1989 pretest. Moreover, the accuracy of the estimates for those who responded is reasonable. With a sample of 450 from a total membership of some 18,000, most of the survey percentages reported have an error rate of  $\pm 4.7\%$ , according to Kish (68). The reader is cautioned to consider each percentage as falling in a range of values, not at one precise value.

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