"Diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without surgery backup. These facilities have laboratories which must meet the higher requirement of procedures performed on 500 patients annually.

"Hospital–based" means the provision of a health care service that is physically located on the campus of, and is a permanent structure within, a licensed acute care hospital offering inpatient support services.

"Left–heart catheterization" refers to the measurement of left heart hemodynamics and definition of left heart anatomy/function by catheter delivered radiopaque contrast media.

"Low–risk patients" shall be as defined by the November 1, 1994 participation guidelines of the American College of Cardiology's Database Committee, and "low-risk patients" are those patients excluded from the definition of "high risk" who are able to be managed by the pilot facilities for diagnostic cardiac catheterization.

"Medically underserved" means segments of the population whose utilization of health care services is less than those numbers approximately proportionate to their presence in the population as adjusted to account for their need for such services. Medically underserved includes, but is not limited to, racial and ethnic minority populations, migrant workers, the handicapped, Medicaid recipients, and the medically indigent, defined as those individuals lacking third party insurance coverage whose income is less than or equal to 200 percent of the United States Department of Health and Human Services Income Poverty Guidelines, 42 U.S.C. § 9902(2).

"Open heart surgery" refers to a procedure using a heart-lung by-pass machine to perform the functions of circulation during surgery.

"Pediatric cardiac surgery centers" are those cardiac surgery centers specifically designated to provide the full range of invasive cardiac diagnostic, therapeutic and surgical services to patients less than 16 years of age.

"Percutaneous transluminal coronary angioplasty" (PTCA) means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PTCA also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

"Pilot catheterization program" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services within its permanent structure as defined in "hospital-based" above that is limited in the provision of its service to low risk adult patients. Patients with the following conditions listed below are to be considered high risk and shall be excluded from catheterization at pilot facilities and transferred in accordance with N.J.A.C. 8:33E–1.8:

1. Left main coronary syndrome;
2. Unstable myocardial infarction;
3. Acute myocardiac infarction within three days;
4. Unstable angina with persistent angina;
5. Congestive heart failure, defined as NYHA Class III or IV;
6. Cardiogenic shock or severe hemodynamic instability;
7. Aortic stenosis, as measured by Doppler mean gradient over 40 mm of Hg;
8. Ejection fraction below 30 percent; or
9. Concomitant severe medical or vascular problems.

8:33E–1.3 General criteria for invasive cardiac diagnostic facilities

(a) For the purposes of certificate of need application and licensure, invasive cardiac diagnostic facilities shall be categorized as follows:

1. Cardiac surgery center;
2. Cardiac catheterization facility (without cardiac surgery);
3. Low-risk diagnostic cardiac catheterization facility hereinafter referred to as pilot catheterization program; and
4. Pediatric cardiac surgery center.

(b) All cardiac catheterization procedures, regardless of the category, shall be performed in a hospital-based facility where inpatient services are available on site.

(c) Only facilities with invasive cardiac diagnostic and pediatric cardiac surgery programs shall be licensed to perform invasive cardiac diagnostic procedures on pediatric patients.

(d) Electrophysiology studies (EPS and/or percutaneous transluminal coronary angioplasty (PTCA) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing EPS and/or PTCA shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E–2.3(d).

Case Notes

Denial of certificate of need application for pediatric invasive cardiac diagnostic and surgery services was reversed when underutilization of

nearby provider was found to be due to reluctance of physicians to refer patients to that provider. St. Joseph's Hospital v. Health Care Administration Board, 96 N.J.A.R.2d (HLT) 103.

Denial of Certificate of Need for cardiac-catherization laboratory was not arbitrary or capricious. Pascack Valley Hospital v. New Jersey Department of Health. 93 N.J.A.R.2d (HLT) 21.

8:33E–1.4 Utilization criteria for invasive cardiac diagnostic facilities

(a) Utilization criteria for all invasive cardiac diagnostic facilities are based on the number of patients upon whom invasive cardiac diagnostic procedures (cardiac catheterization) are performed.

(b) Except as specifically set forth with respect to pilot catheterization program, at (c) below, all facilities licensed to provide invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per cardiac laboratory is 500 per year. New services must attain this minimum utilization level within three years of operation. Existing services must achieve minimum utilization levels by February 20, 1997. Those laboratories unable to achieve the minimum level as set forth in this paragraph will not be issued a license renewal to continue to provide this service.

2. Each physician must perform procedures on a minimum of 50 patients a year with a minimum of 100 patients over a two year period. (This minimum caseload may be accomplished at more than one laboratory).

3. Diagnostic cardiac catheterization facilities (without cardiac surgery) shall meet the minimum criteria and standards outlined in this subchapter by February 20, 1997, and each year thereafter, or will not be issued a license renewal to continue to provide this service.

(c) All facilities licensed to provide low risk invasive cardiac diagnostic services pursuant to pilot catheterization program described in this subchapter shall be required, as a condition of continued licensure, to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per year is 350. Those laboratories unable to achieve this minimum level by the end of the second year of operation as set forth at N.J.A.C. 8:33E–1.14, will not be issued license renewal to continue to provide this service.

2. Physicians practicing in hospitals participating in the pilot catheterization program shall meet minimum volume criteria in order for the hospital to retain a license after the initial two years of operation. For the Director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the pilot laboratory of which the physician is Director. For other physicians with privileges in the pilot laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory.)

8:33E–1.5 Facility personnel

(a) All facilities applying to provide or providing any invasive cardiac diagnostic services pursuant to this subchapter shall provide for and maintain the following minimum staff members:

1. One physician;

2. One registered nurse; and

3. One technician who must be qualified in at least one of the technician categories listed at (b)6 through 8 below.

(b) While the following functions shall be performed within each facility, more than one function may be executed by a single individual if that individual has been appropriately cross-trained to perform the required functions:

1. The laboratory director (physician in charge) shall be the chief diagnostician within the unit, and shall be certified by the Cardiovascular Sub–Specialty Board of the American Board of Internal Medicine or by the Sub–Specialty Board of Pediatric Cardiology of the American Board of Pediatrics. In addition to Board certification, the director shall have broad experience and training in invasive cardiac diagnostic procedures, including, but not limited to, a minimum of 12 months in a cardiac catheterization training program and the performance of 200 cardiac catheterization procedures with 100 of these procedures performed as the primary operator.

2. Associate physicians may be assigned to the laboratory and shall meet the identical training and certification requirements for laboratory director contained in (b)1 above. In addition, all catheterizing physicians shall adhere to the minimum physician volume standards established by each laboratory in accordance with N.J.A.C. 8:33E–1.4(b)2.

i. Exceptions to these minimum training and certification requirements for incumbent Directors and associate physicians requirements may be granted by the Commissioner upon application by an institution providing documentation as to the physician's qualifications, in accordance with the requirements of this chapter, N.J.A.C. 8:43G–7.15(b), 7.40, 7.28, and N.J.A.C. 13:35.

3. Physicians practicing in hospitals participating in the pilot catheterization program shall meet minimum volume criteria in order for the hospital to retain a license after the initial two years of operation. For the director of the laboratory, the standard is left-heart catheterizations on 150 patients per year, at least 100 of which must be performed at the pilot laboratory of which the physician is director. For other physicians with privileges in the pilot laboratory, the standard is left-heart catheterizations on 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory.)

4. The registered nurse shall assist with administration of medications and the preparation and observation of the patient. The nurse shall have intensive cardiac care unit (ICCU) experience, shall meet the licensing requirements specified at N.J.A.C. 8:43G–7.15(d), and shall have knowledge of cardiovascular medications, experience with catheterization and pediatric experience for pediatric cardiac surgery centers.

5. The cardiac catheterization technician shall handle blood samples and assist in the performance tests. The technician shall help in the maintenance of equipment and supplies and should be trained to aid in patient observation and acute cardiac care.

6. The cardiac catheterization technician shall be responsible for constant monitoring and recording of all physiologic data including the electrocardiogram.

7. The radiologic technician shall be skilled in conventional radiography and shall have special training and skills in angiographic techniques. This technician shall be competent in magnification radiography, subtraction photography, cine recording, television presentations and the use of video tape and be responsible for the care and maintenance of all radiologic equipment.

8. The electronic and radiological repair technician shall be available for consultations regarding the operation and maintenance of all radiographic and physiologic measuring and recoding instruments in the laboratory. This person shall be immediately available to carry out repairs in the event of equipment failures during the course of the procedure.

9. Hospitals providing invasive cardiac diagnostic services should, to the extent possible, have bilingual clinical personnel available who can overcome language barriers and know and understand cultural differences among patients.

(c) One physician trained and experienced in cardiac catheterization shall be present in the room during all catheterization and angiographic procedures. An appropriately trained and experienced registered nurse and technician shall also be present during all procedures.

8:33–1.6 Quality improvement

(a) All facilities applying to provide or providing any invasive cardiac diagnostic services pursuant to this subchapter shall provide for and shall maintain an appropriate mechanism for peer review which shall include, but not necessarily be limited to, the delineation of criteria for the evaluation of:

1. Overall case selection for study (for example, rate of normal studies, rate of surgical referral);

2. Laboratory and physician performance including physician performance guidelines (for example, patient volume, mortality and complication rates per physician); and

3. Quality of studies (for example, number of incomplete studies, diagnostic adequacy of films, number of restudies performed elsewhere);

(b) In all cases, there shall be documentation that criteria selection is based on sound medical practice and consistent with the literature.

(c) Each peer review team shall include at least one cardiovascular surgeon from the surgical center to which surgical candidates are commonly referred.

(d) All facilities applying to provide or providing a pilot cardiac catheterization program shall also provide written documentation that the proposed service shall adhere to the following quality of care outcome measures:

1. A low-risk patient mortality and morbidity rate as reviewed by the hospital's peer review mechanism and submitted to the Department of Health for review and approval;

2. A physician-specific and overall pilot laboratory percentage of normal studies that does not exceed 25 percent of total annual cardiac catheterization cases;

3. Review by the hospital's peer review mechanism of any pilot laboratory reporting more than a 50 percent increase in the number of normal studies during any reporting period and the submission to the Department within 60 days of such review of a plan for corrective action to restore normal studies to the level permitted herein.

4. The percentage of all patients undergoing diagnostic cardiac catheterization in the pilot catheterization program who have subsequently undergone a therapeutic interventional cardiac procedure (for example, coronary angioplasty, directional atherectomy, coronary bypass surgery) as a direct result of the findings of the diagnostic cardiac catheterization procedure performed at this pilot catheterization program will be monitored by the Department. In doing so, the Department will seek the assistance of the Cardiovascular Health Advisory Panel; and

5. Careful monitoring of the clinical appropriateness of the performance of right heart catheterization procedures during the pilot study.

8:33E–1.7 Community outreach, access and prevention

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter shall develop and maintain appropriate mechanisms to assure access to services and to promote cardiac health among the underserved population in its service area which shall include, but not necessarily be limited to, the following components:

1. All hospitals, including those participating in the pilot catheterization program, shall document their community prevention services for all populations, specifically targeting minorities, elderly and under–12 population groups, in accordance with license renewal standards at N.J.A.C. 8:33E–1.13 and 1.14. Examples of community prevention programs are those primary and secondary prevention initiatives which include: diet and drug therapy for hypercholesterolemia in patients at high risk or with established coronary artery disease; smoking cessation programs with objective outcome measures; exercise rehabilitation programs for patients with established coronary artery disease; and public education programs.

2. All hospitals, including those participating in the pilot catheterization program, shall provide a plan, as part of their application, that is designed to ensure that appropriate access to their respective programs by medically underserved and minorities (for example, African–Americans, Latino–Americans, Asian–Americans), and other population groups that have historically been under-represented in the provision of cardiac catheterization services (for example, Medicaid recipients, indigent/self–pay patients), will be achieved. The plan is subject to review and approval by the Department and will be based on the extent that cardiac catheterization services will be provided to these population groups in comparison to inpatient admission rates for acute myocardial infarction or other access criteria developed by the Department of Health by these same population groups in the proposed area.

3. All hospitals shall document in their application the proportion of Medicaid-eligible and medically underserved groups residing in the proposed service area. In addition, the applicant shall, in delivering the proposed service, provide care on a free or partial pay basis to Medicaid-eligible and medically underserved population groups at least in proportion to their representation in the proposed service area.

8:33E–1.8 Agreements for cardiac surgery services

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter which is not also licensed to provide cardiac surgery services on site shall develop and maintain written agreements with cardiac surgery centers which shall include, but not necessarily be limited to: provisions for insuring quality control, rapid referral for surgery, emergency backup procedures, and regular communication between the cardiologist performing catheterization and the surgeons to whom patients are referred. In addition, one of the referral agreements must be within one hour travel time from the diagnostic facility and at least one of the referral agreements shall be written with a New Jersey cardiac center.

(b) To insure that costs are not unnecessarily increased by duplication of procedures, written assurance shall be included within the referral agreement stating that, to the greatest extent possible, the receiving facility will accept the results of the diagnostic facility's examinations. Departures from this practice shall be limited to an established peer review mechanism at the receiving center.

8:33E–1.9 Data reporting

(a) Every facility licensed to provide invasive cardiac diagnostic services in accordance with this subchapter shall maintain and provide statistical patient level data as set forth in this subchapter on the operation of the program and report those data to the Department of Health on a quarterly basis and in a standardized format determined by the Department. These cumulative patient level data will be submitted to the Department of Health on a quarterly basis, within 30 days after the close of the quarter. Copies of the full text of the required quarterly reporting forms may be obtained upon written request to The New Jersey State Department of Health, Division of Health Care Systems Analysis, Research and Development Program, Room 600 CN 360, Trenton, New Jersey 08625.

1. In addition to the reporting requirements of paragraph (a) above, statistical data submitted by all facilities licensed to provide low risk invasive cardiac diagnostic services pursuant to the pilot catheterization program described in this subchapter must, prior to submission to the Department, be audited and verified by an independent auditing body approved by the Department. Each pilot catheterization program will be responsible for the entire cost of its own audits and shall provide the Department with any and all documentation substantiating the findings of the auditor for compliance with utilization and quality standards at N.J.A.C. 8:33E–1.4 and 1.6. This independent auditing requirement shall apply only to pilot catheterization programs.

8:33E–1.10 Certification of nondiscriminatory practices

Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter shall provide the Department with, and shall maintain current, a written certification of compliance with all Federal and State laws regarding nondiscrimination in the admission and/or treatment of patients as those laws may be amended from time to time.

8:33E–1.11 Requirements for submission of certificate of need applications to initiate invasive cardiac diagnostic services other than pilot catheterization programs

(a) Applications to initiate invasive cardiac diagnostic services will only be accepted by the Department in response to a call for such services which may be issued at the discretion of the Commissioner. All such applications will be subject to the full certificate of need review process set forth at N.J.A.C. 8:33–4.

(b) All applications to initiate invasive cardiac diagnostic services shall include full written documentation of the projected implementation and operational costs of the proposed program. This documentation shall include direct and indirect costs, that is, construction, equipment, supplies, personnel, maintenance, overhead costs, as well as projected costs of remodeling or renovation necessary to accommodate the program. Projections of anticipated revenues shall be supplied for at least the first three years.