"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 the left heart anatomy/function by catheter-delivered radiopaque contrast media.

"Low risk cardiac catheterization facility" 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 myocardial 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.

"Low-risk patients" shall be 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 low risk 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).

"Normal coronary study" means a clinical finding subsequent to the performance of a cardiac catheterization procedure indicating less than 50 percent stenosis in all of the following arteries: left main, proximal left anterior descending (LAD), right coronary artery (RCA) or left circumflex (LCX). A finding of any stenosis of greater than or equal to 50 percent is considered an abnormal cardiac catheterization study. A finding of valvular disease is to be considered as an abnormal finding in a study. A case in which there is a finding of cardiomyopathy or congenital cardiac disorder shall be excluded from the normal coronary study calculation.

"Open heart surgery" refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalous conditions (for example, coronary artery bypass surgery, heart valve replacement), often 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 coronary intervention (PCI)" 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, PCI also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

"Primary angioplasty" means the mechanical reopening of an occluded vessel using a balloon-tipped catheter in patients with acute myocardial infarction (AMI) who have not received antecedent thrombolytic therapy.

"Stent procedure" means the use of a wire mesh tube (a stent) to prop open an artery that has recently been cleared using coronary angioplasty. The stent is collapsed to a small diameter, placed over an angioplasty balloon catheter and moved into the area of the blockage. Once the balloon is inflated, the stent expands, locks in place and forms a permanent scaffold to hold the artery open. Stents may be used as an alternative to—or in combination with—angioplasty.

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In "Full service adult diagnostic cardiac catheterization facility", inserted "cardiac" preceding "surgery backup" in the first sentence and substituted "400" for "500" preceding "patients" in the second sentence; rewrote "Normal coronary study"; in "Open heart surgery", substituted "anomalous" for "anomalic".
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
In definition "Cardiac surgery center", substituted "PCI" for "PTCA"; changed definition "Percutaneous transluminal coronary angioplasty (PTCA) or balloon angioplasty" to "Percutaneous coronary intervention (PCI)"; and in definition "Percutaneous coronary intervention (PCI)", substituted "PCI" for "PTCA", ", laser)" for "laser", and "procedures" for "procedures)", at the end.

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

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

1. Cardiac surgery center;

2. Full service cardiac catheterization facility (without cardiac surgery);

3. Low-risk diagnostic cardiac catheterization facility (without cardiac surgery); 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) Complex electrophysiology studies (EPS) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site. Facilities providing complex EPS shall also be required to meet all applicable standards and criteria at N.J.A.C. 8:33E-2.3(e). Elective PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent during acute myocardial infarction) PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
In (a)2, substituted "Full service cardiac" for "Cardiac" and rewrote (a)3; in (d), substituted "Complex electrophysiology" for "Electrophysiology" and inserted "complex" preceding "EPS".
Amended by R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Rewrote (d).
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In (a)3, inserted "(without cardiac surgery)"; in (d), substituted "N.J.A.C. 8:33E-2.3(e)" for "N.J.A.C. 8:33E-2.3(d)" and inserted "during acute myocardial infarction" following "emergent".
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
In (d), substituted "PCI" for "PTCA" two times.

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-catheterization 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 low risk cardiac catheterization facility, at (c) below, all facilities licensed to provide full service 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 full service cardiac laboratory is 400 per year. New full service providers (those previously operating as low risk cardiac catheterization laboratories) must provide documentation of full compliance with the minimum utilization level during their second year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Existing full service invasive cardiac diagnostic providers (with or without cardiac surgery on site) must achieve minimum utilization levels each year. Compliance with minimum annual facility volume requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those new and existing full service laboratories unable to achieve the minimum level as set forth in this paragraph will be subject to the provisions of N.J.A.C. 8:33E-1.13.

2. Each physician must perform left heart catheterizations on a minimum of 50 patients per year. (This minimum caseload may be accomplished at more than one laboratory in or out of State). 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 full service laboratory of which the physician is Director (the remaining 50 case requirement may be accomplished at more than one laboratory in or out of State).

i. Exceptions for cardiologists to the minimum director and physician volume requirements may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform cardiac catheterization, physician not a member of the staff for an entire year, or new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances shall require the submission by the hospital of a written waiver request in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G-2.8.

moved into the area of the blockage. Once the balloon is inflated, the stent expands, locks in place and forms a permanent scaffold to hold the artery open. Stents may be used as an alternative to—or in combination with—angioplasty.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
Rewrote "Cardiac surgery center" definition; and inserted new "Hospital system", "Inner city cardiac satellite demonstration project", "Inner city hospital", "Invasive therapeutic cardiac services" and "Satellite hospital" definitions.
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In "Full service adult diagnostic cardiac catheterization facility", inserted "cardiac" preceding "backup" in the first sentence and substituted "400" for "500" preceding "patients" in the second sentence; rewrote "Normal coronary study"; in "Open heart surgery", substituted "anomalous" for 'anomalic".
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
Substituted "PCI" for "PTCA" throughout; in definition "Complex electrophysiology study", removed capitalization of "electrophysiology study"; in definition "Invasive therapeutic cardiac services", deleted "transluminal" preceding "coronary" and substituted "intervention" for "angioplasty"; and in definition "Percutaneous transluminal coronary angioplasty or balloon angioplasty", substituted "Percutaneous coronary intervention (PCI)" for " 'Percutaneous transluminal coronary angioplasty or balloon angioplasty' (PTCA)".

8:33E-2.3 Utilization of cardiac surgical centers

(a) The following shall apply to adult cardiovascular surgical units:

1. An applicant for a certificate of need to initiate adult cardiac surgery services shall provide written documentation of the ability to achieve an annual volume of 350 open heart surgical cases by the end of the third year of operation and annually thereafter.

2. All existing regional adult cardiac surgical centers shall continue to perform at least 350 open heart surgical procedures per year to ensure the competency of the surgical services team and to provide for efficient and economical operation. Compliance with this annual facility volume requirement will be calculated on the basis of the last four quarters of data submitted to and reviewed by the Department prior to the facility's licensure anniversary date. Facilities that perform fewer than 350 open heart surgical procedures per year shall alternatively achieve a risk-adjusted mortality rate (mortality at discharge) for isolated coronary artery bypass graft (CABG) surgery for the most recent four quarters that is lower than the Statewide observed mortality rate (mortality at discharge) for isolated CABG surgery (the alternative method).

i. Data for calculating a facility's risk-adjusted isolated CABG mortality rate shall be derived from the Department's open heart data base.

ii. The Statewide observed isolated CABG mortality rate shall be the Statewide rate for the most recent calendar year reported in the Department's most recent published report on cardiac surgery performance.

iii. Calculation of a facility's risk-adjusted mortality rate shall be based on the risk-adjustment model used to create the Department's most recent published report on cardiac surgery performance. However, there shall be no use of a confidence interval in determining how a facility's risk-adjusted mortality rate compares to the Statewide observed mortality rate.

iv. The facility risk-adjusted and Statewide observed mortality rates shall be expressed as a percentage calculated to two decimal places.

v. A facility that demonstrates compliance through the alternative method shall be licensed unconditionally for the licensure period. However, a sample of patient medical records designated by the Department shall be examined in a timely fashion by a Department-approved auditor at the facility's expense to confirm the accuracy of the information relevant to the risk-adjustment calculation submitted by the facility to the Department's open heart data base. Audit results shall be submitted directly by the auditor to the Department. If audit adjustments result in a revised facility risk-adjusted mortality rate that is higher than the Statewide observed mortality rate, then the facility shall be licensed conditionally and the provisions of N.J.A.C. 8:33E-2.13(a) shall apply.

3. Each cardiac surgical center shall establish a minimum caseload per physician in order to ensure a consistent level of proficiency within the surgical program. A minimum of 100 cases per year shall be performed by each cardiac surgeon performing as the primary surgeon on any case. This volume shall be achieved at each licensed site in New Jersey at which the physician practices as primary surgeon on any case. Compliance with annual physician volume standards will be calculated on a calendar year basis. Physicians that perform fewer than 100 open heart surgical procedures per year shall alternatively achieve a risk-adjusted mortality rate (mortality at discharge) for isolated coronary artery bypass graft (CABG) surgery that is lower than the Statewide observed mortality rate (mortality at discharge) for isolated CABG surgery (the alternative method).

i. Data for calculating a physician's risk-adjusted isolated CABG mortality rate shall be derived from the isolated CABG cases in the Department's open heart database for the most recent four years that the physician has performed open heart cases. For physicians performing surgery in New Jersey for less than four years, the review shall include all isolated CABG cases performed in a New Jersey cardiac surgery center.

ii. The Statewide observed isolated CABG mortality rate shall be the Statewide rate for the most recent

calendar year reported in the Department's most recent published report on cardiac surgery performance.

iii. Calculation of a physician's risk-adjusted mortality rate shall be based on the risk-adjustment model used to create the Department's most recent published report on cardiac surgery performance. However, there shall be no use of a confidence interval in determining how a physician's risk-adjusted mortality rate compares to the Statewide observed mortality rate.

iv. The physician risk-adjusted and Statewide observed mortality rates shall be expressed as a percentage calculated to two decimal places.

v. A physician who demonstrates compliance through the alternative method shall be considered in compliance with the minimum annual physician volume standard and the physician's annual volume will not be considered in the hospital's relicensure evaluation for that year. However, the Department reserves the right to confirm the accuracy of the information relevant to the risk-adjustment calculation submitted by the facility to the Department's open heart database. If the Department's audit adjustments result in a revised physician risk-adjusted mortality rate that is higher than the Statewide observed mortality rate, then the facility shall be licensed conditionally and the provisions of N.J.A.C. 8:33E-2.13(a) shall apply.

(b) The following shall apply to pediatric cardiac diagnostic and surgical services:

1. An applicant for a certificate of need as a regional pediatric cardiac surgical center shall provide written documentation that the proposed center will perform at least 150 pediatric open and closed heart surgery procedures per year, at least 75 of which must be open heart procedures, for each operating room utilized for pediatric open heart surgery by the end of the third year of operation and each year thereafter.

2. A regional pediatric cardiac surgical center shall continue to perform at least 150 pediatric open and closed heart surgery procedures per year per operating room to insure the competency of the pediatric surgical services team and to provide for an efficient and economical operation. Existing pediatric cardiac surgical centers shall achieve this utilization standard within one year of the effective date of this subchapter and shall maintain the standard on an annual basis thereafter.

3. The minimum acceptable number of pediatric cardiac catheterization patients per invasive pediatric cardiac diagnostic laboratory is 150 per year. New pediatric surgical centers shall achieve this minimum level of utilization in their invasive pediatric cardiac diagnostic laboratory within three years from the initiation of the service. As cited at N.J.A.C. 8:33E-1.3(c), pediatric patients requiring invasive cardiac diagnostic procedures shall undergo these procedures only in centers with invasive pediatric cardiac diagnostic and pediatric cardiac surgery programs.

4. Each invasive pediatric cardiac laboratory shall establish a minimum number of procedures for each physician with laboratory privileges in order to maintain a consistent level of proficiency within the laboratory. A minimum of 50 pediatric cases a year with a minimum of 100 pediatric cases over a two year period shall be maintained to preserve a consistent level of proficiency.

(c) The following shall apply to adult full service cardiac diagnostic services located within the cardiac surgery center:

1. In accordance with N.J.A.C. 8:33E-2.1(c) and except as specifically set forth at N.J.A.C. 8:33E-2.3(d) through (e), 2.4(d) through (f), 2.10 and 2.14 the provision of adult full service cardiac diagnostic services by cardiac surgery centers shall be subject to all applicable utilization criteria at N.J.A.C. 8:33E-1.

2. The laboratory must be prepared to perform pre- and post-operative examinations on a scheduled basis, and emergency examinations at all times.

3. As a planning guideline, the accepted ratio of examinations to cardiac operations shall be at least two examinations to one operation.

(d) The following shall apply to adult cardiac surgery centers providing or seeking to provide PCI services:

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide PCI services in its invasive cardiac diagnostic laboratory must provide written documentation that the center will perform a minimum of 200 PCI procedures per year by the third year of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels for either the program or individual physicians during the third year of operation or thereafter will be required to submit to the process that has been established at (d)2 below.

2. A regional adult cardiac surgery center shall continue to perform a minimum of 200 PCI procedures annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing PCI shall comply with this utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for PCI will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter for either the program or individual physicians will be required to submit to the following:

i. An external review from an independent external organization approved by the Department to assess the overall performance of the facility and its staff;

ii. A detailed plan of correction shall be submitted to the Department within 30 days of notification of its

failure to maintain compliance with annual minimum facility volume standard in (d)1 or 2 above, whichever is applicable, and physician volume standard in (d)4 below. Where applicable, plans of correction shall be submitted indicating the licensure renewal criteria that have not been achieved, the corrective actions that are to be put in place or the systemic changes that shall be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers to licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction shall not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall result in a revocation of the facility's license unless an appeal is filed with the Commissioner within 60 days after receiving the Department's notice of revocation. The Department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it shall be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat;

(2) The frequency of the occurrence;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.

3. Elective PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site. Primary (that is, emergent during acute myocardial infarction) PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33E-2.16.

4. Each PCI facility shall establish a minimum number of PCI procedures for each physician with PCI laboratory privileges. Each physician performing PCI procedures as the primary operator shall perform a minimum of 75 PCI cases a year. (This minimum caseload may be accomplished at more than one laboratory in or out of State.) The physician's minimum annual patient volume is to be achieved at the end of a three year phase-in period, requiring 50 PCI cases as primary operator during the first (CY 2004) and second year (CY 2005), and 75 PCI cases by the end of the third year (CY 2006) and annually thereafter.

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform PCI; physician not a member of the staff for an entire year; or new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission by the hospital of a written waiver request in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G-2.8.

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

iii. The Department will not consider in its annual licensing evaluation the annual volume of physicians with hospital privileges to perform PCI with the exception of annual laboratory director volumes set forth at N.J.A.C. 8:33E-1.4(b)2.

(e) The following shall apply to adult cardiac surgery centers providing or seeking to provide complex electrophysiology studies (EPS):

1. An applicant for a certificate of need as a regional adult cardiac surgery center that also seeks to provide complex electrophysiology studies or an existing, cardiac surgery center seeking to initiate complex electrophysiology services must provide written documentation that the center will perform a minimum of 100 electrophysiology studies per year, with at least 50 of these studies representing initial studies of patients. These new complex electrophysiology services must achieve this minimum utilization level within three years of operation. A regional adult cardiac surgery center with the inability to achieve minimum utilization levels for either the program or individual physicians during the third year of operation or thereafter will be required to submit to the identical process that has been established at (e)2 below.

2. A regional cardiac surgery center shall continue to perform a minimum of 100 complex electrophysiology studies annually in order to assure acceptable institutional quality. Existing cardiac surgery centers providing complex electrophysiology studies shall comply with this

utilization standard on an annual basis. Compliance with minimum annual facility volume requirements for complex EPS will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those existing or new cardiac surgery centers unable to achieve the minimum level as set forth in this subchapter for either the program or individual physicians will be required to submit to the following:

i. An external review from an independent external organization approved by the Department to assess the overall performance of the facility and its staff;

ii. A detail plan of correction shall be submitted to the Department within 30 days of notification of its failure to maintain compliance with annual minimum facility volume standard in (e)1 or 2 above, whichever is applicable, and physician volume standard in (e)4 below. Where applicable, plans of correction shall be submitted indicating the licensure renewal criteria that have not been achieved, the corrective actions that are to be put in place or the systemic changes that shall be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers to licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction shall not be considered final until it has been approved by the Department;

iii. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables shall result in a revocation of the facility's license unless an appeal is filed with the Commissioner within 60 days after receiving the Department's notice of revocation. The Department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it shall be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law. In exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat;

(2) The frequency of the occurrence;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.

3. Complex electrophysiology studies shall be performed in a hospital-based facility where cardiac surgery services are immediately available on site.

4. Each complex electrophysiology service shall establish a minimum number of complex electrophysiology studies for each physician with electrophysiology laboratory privileges. A minimum of 50 complex electrophysiology cases a year, with at least 25 as initial studies, shall be maintained to preserve a consistent level of proficiency.

i. Exceptions for cardiologists to the minimum physician volume requirement may be granted by the Commissioner upon application by a hospital for specific facility circumstances. Such circumstances as the temporary inability to perform complex EPS; physician not a member of the staff for an entire year; new program in operation less than one year require only timely written notification to the Department. Any other extraordinary circumstances will require the submission of a written waiver request by the hospital in accordance with the hospital licensing waiver provisions as set forth at N.J.A.C. 8:43G-2.8.

ii. Compliance with the physician's minimum annual patient volume for cardiologists with laboratory privileges shall be based on the most recent calendar year's performance data available prior to the hospital's licensure anniversary date.

Amended by R.1998 d.280, effective June 1, 1998.
See: 30 N.J.R. 1008(a), 30 N.J.R. 1996(a).
In (a), rewrote 1, substituted "350" for "250" following "at least" in 2, deleted former 3 and 4, and rewrote and recodified former 5 as 3; and in (e)1, substituted "operation" for "service implementation" at the end.
Amended by R.2001 d.210, effective June 18, 2001.
See: 33 N.J.R. 616(b), 33 N.J.R. 2105(a).
Rewrote section.
Amended by R.2001 d.482, effective December 17, 2001.
See: 33 N.J.R. 3256(a), 33 N.J.R. 4342(a).
Rewrote (d)3.
Amended by R.2004 d.37, effective January 20, 2004.
See: 35 N.J.R. 3773(a), 36 N.J.R. 416(a).
In (a), rewrote 2; in (b), amended the N.J.A.C. reference in 3; rewrote (d) and (e).
Amended by R.2006 d.263, effective July 17, 2006.
See: 38 N.J.R. 53(a), 38 N.J.R. 3025(a).
Substituted "PCI" for "PTCA" throughout; in (a)3, added final sentence; added (a)3i through (a)3v; in introductory paragraph of (d), deleted "percutaneous transluminal coronary angioplasty"; in (d)4i, inserted "or"; and added (d)4iii.

8:33E-2.4 Cardiac surgery center personnel

(a) The following shall apply to cardiovascular surgical units:

1. Cardiac surgery is most successful when performed by a smoothly functioning team. The basic team of the