

1 10A NCAC 14C .1603 is proposed for readoption with substantive changes as follows:

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3 **10A NCAC 14C .1603 PERFORMANCE STANDARDS**

4 ~~(a) An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable~~
5 ~~of meeting the following standards:~~

6 ~~(1) — each proposed item of cardiac catheterization equipment, including mobile equipment but excluding~~
7 ~~shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60~~
8 ~~percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A~~
9 ~~NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of~~
10 ~~the project;~~

11 ~~(2) — if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the~~
12 ~~applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least~~
13 ~~100 therapeutic cardiac catheterization procedures, during the third year of operation following~~
14 ~~completion of the project;~~

15 ~~(3) — if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic~~
16 ~~cardiac catheterization team shall be performing at an annual rate of at least 200~~
17 ~~diagnostic equivalent cardiac catheterization procedures by the end of the third year following~~
18 ~~completion of the project;~~

19 ~~(4) — at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients~~
20 ~~residing within the primary cardiac catheterization service area;~~

21 ~~(b) An applicant proposing to acquire mobile cardiac catheterization equipment shall:~~

22 ~~(1) — demonstrate that each existing item of cardiac catheterization equipment, excluding mobile~~
23 ~~equipment, located in the proposed primary cardiac catheterization service area of each host facility~~
24 ~~shall have been operated at a level of at least 80 percent of capacity during the 12 month period~~
25 ~~reflected in the most recent licensure form on file with the Division of Health Service Regulation;~~

26 ~~(2) — demonstrate that the utilization of each existing or approved item of cardiac catheterization~~
27 ~~equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization~~
28 ~~service area of each host facility shall not be expected to fall below 60 percent of capacity due to~~
29 ~~the acquisition of the proposed mobile cardiac catheterization equipment;~~

30 ~~(3) — demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac~~
31 ~~catheterization service area of each host facility shall have been performing at least an average of~~
32 ~~four diagnostic equivalent cardiac catheterization procedures per day per site in the proposed~~
33 ~~cardiac catheterization service area in the 12 month period preceding the submittal of the~~
34 ~~application;~~

35 ~~(4) — demonstrate that each item of existing or approved mobile equipment to be operating in the proposed~~
36 ~~primary cardiac catheterization service area of each host facility shall be performing at least an~~

1 ~~average of four diagnostic equivalent cardiac catheterization procedures per day per site in the~~
2 ~~proposed cardiac catheterization service area in the applicant's third year of operation; and~~

3 (5) ~~provide documentation of all assumptions and data used in the development of the projections~~
4 ~~required in this Rule.~~

5 (c) ~~An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac~~
6 ~~catheterization shall:~~

7 (1) ~~demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment,~~
8 ~~located in the proposed cardiac catheterization service area operated at an average of at least 80~~
9 ~~percent of capacity during the twelve month period reflected in the most recent licensure renewal~~
10 ~~application form on file with the Division of Health Service Regulation;~~

11 (2) ~~demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment,~~
12 ~~shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the~~
13 ~~fourth quarter of the third year following completion of the project; and~~

14 (3) ~~provide documentation of all assumptions and data used in the development of the projections~~
15 ~~required in this Rule.~~

16 (d) ~~An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable~~
17 ~~State Medical Facilities Plan shall:~~

18 (1) ~~demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform~~
19 ~~a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth~~
20 ~~quarter of the third year following completion of the project; and~~

21 (2) ~~provide documentation of all assumptions and data used in the development of the projections~~
22 ~~required in this Rule.~~

23 (e) ~~If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant~~
24 ~~shall demonstrate that it meets the following additional criteria:~~

25 (1) ~~the facility has the capability to perform diagnostic and therapeutic cardiac catheterization~~
26 ~~procedures and open heart surgery services on patients age 14 and under; and~~

27 (2) ~~the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization~~
28 ~~procedures on patients age 14 or under during the fourth quarter of the third year following initiation~~
29 ~~of the proposed cardiac catheterization procedures for patients age 14 and under.~~

30 (a) An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the
31 annual State Medical Facilities Plan in effect as of the first day of the review period shall:

32 (1) identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or
33 a related entity and located in the proposed fixed cardiac catheterization equipment service area;

34 (2) identify the approved fixed cardiac catheterization equipment owned or operated by the applicant
35 or a related entity and located in the proposed fixed cardiac catheterization equipment service area;

1 (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs
2 (a)(1) and (a)(2) of this Paragraph and the proposed fixed cardiac catheterization equipment during
3 each of the first three full fiscal years of operation following completion of the project;

4 (4) provide the assumptions and methodology used to project the utilization required by Subparagraph
5 (a)(3) of this Paragraph; and

6 (5) project that the cardiac catheterization equipment identified in Subparagraphs (a)(1) and (a)(2) of
7 this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more
8 diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization
9 equipment during the third full fiscal year of operation following completion of the project.

10 (b) An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination
11 in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

12 (1) provide projected utilization of the proposed shared fixed cardiac catheterization equipment during
13 each of the first three full fiscal years of operation following completion of the project;

14 (2) provide the assumptions and methodology used to project the utilization required by Subparagraph
15 (b)(1) of this Paragraph; and

16 (3) project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more
17 diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal
18 year of operation following completion of the project.

19 (c) An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in
20 the State Medical Facilities Plan in effect as of the first day of the review period shall:

21 (1) identify the existing mobile cardiac catheterization equipment owned or operated by the applicant
22 or a related entity that provides cardiac catheterization services at host sites located in the proposed
23 mobile cardiac catheterization equipment service area;

24 (2) identify the approved mobile cardiac catheterization equipment owned or operated by the applicant
25 or a related entity that will provide cardiac catheterization services at host sites located in the
26 proposed mobile cardiac catheterization equipment service area;

27 (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs
28 (c)(1) and (c)(2) of this Paragraph and the proposed mobile cardiac catheterization equipment during
29 each of the first three full fiscal years of operation following completion of the project;

30 (4) provide the assumptions and methodology used to project the utilization required by Subparagraph
31 (c)(3) of this Paragraph; and

32 (5) project that the cardiac catheterization equipment identified in Subparagraphs (c)(1) and (c)(2) of
33 this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more
34 diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization
35 equipment during the third full fiscal year of operation following completion of the project.

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37 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*

1 *Eff. January 1, 1987;*
2 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
3 *becomes effective, whichever is sooner;*
4 *Amended Eff. November 1, 1996; February 1, 1994;*
5 *Temporary Amendment Eff. January 1, 1999;*
6 *Temporary Eff. January 1, 1999 Expired on October 12, 1999;*
7 *Temporary Amendment Eff. January 1, 2000;*
8 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
9 *originally proposed to be effective August 2000;*
10 *Temporary Amendment Eff. January 1, 2001;*
11 *Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking*
12 *originally proposed to be effective April 1, 2001;*
13 *Temporary Amendment Eff. January 1, 2002;*
14 *Amended Eff. August 1, 2002;*
15 *Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective*
16 *August 1, 2002;*
17 *Amended Eff. April 1, 2003;*
18 *Temporary Amendment Eff. February 1, 2006;*
19 *Amended Eff. November 1, ~~2006.~~ 2006.*
20 *Readopted Eff. January 1, 2022.*