

1 10A NCAC 14C .1701 is proposed for readoption with substantive changes as follows:

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3 **SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND**  
4 **HEART-LUNG BYPASS MACHINES**

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6 **10A NCAC 14C .1701 DEFINITIONS**

7 ~~The following definitions apply to all rules in this Section:~~

- 8 (1) ~~"Approved heart lung bypass machine" means a heart lung bypass machine that was not operational~~  
9 ~~prior to the beginning of the review period.~~
- 10 (2) ~~"Capacity" of a heart lung bypass machine means 400 adult equivalent open heart surgical~~  
11 ~~procedures per year. One open heart surgical procedure on persons age 14 and under is valued at~~  
12 ~~two adult open heart surgical procedures. For purposes of determining capacity, one open heart~~  
13 ~~surgical procedure is defined to be one visit or trip by a patient to an operating room for an open~~  
14 ~~heart operation.~~
- 15 (3) ~~"Cardiac Surgical Intensive Care Unit" means an intensive care unit as defined in 10A NCAC 14C~~  
16 ~~.1201(2) and that is for exclusive use by post surgical open heart patients.~~
- 17 (4) ~~"Existing heart lung bypass machine" means a heart lung bypass machine in operation prior to the~~  
18 ~~beginning of the review period.~~
- 19 (5) ~~"Heart lung bypass machine" has the same meaning as defined in G.S. 131E-176(10a).~~
- 20 (6) ~~"Open heart surgery services" has the same meaning as defined in G.S. 131E-176(18b).~~
- 21 (7) ~~"Open heart surgical procedures" means specialized surgical procedures that:~~  
22 ~~(a) utilize a heart lung bypass machine (the "pump"); and~~  
23 ~~(b) are designed to correct congenital or acquired cardiac and coronary disease by opening the~~  
24 ~~chest for surgery on the heart muscle, valves, arteries, or other parts of the heart.~~

25 The following definitions shall apply to all rules in this Section:

- 26 (1) "Approved heart-lung bypass machine" means a heart-lung bypass machine that was issued a  
27 certificate of need but is not being used as of the application deadline for the review period.
- 28 (2) "Existing heart-lung bypass machine" means a heart-lung bypass machine that is being used as of  
29 the application deadline for the review period.
- 30 (3) "Health service facility" shall have the same meaning as defined in G.S. 131E-176(9b).
- 31 (4) "Heart-lung bypass machine" shall have the same meaning as defined in G.S. 131E-176(10a).
- 32 (5) "Open-heart surgical procedure" means one visit by a patient to an operating room for open heart  
33 surgery services.
- 34 (6) "Open-heart surgery services" shall have the same meaning as defined in G.S. 131E-176(18b).
- 35 (7) "Proposed heart-lung bypass machine" means the heart-lung bypass machine proposed in the  
36 application under review.

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1 *History Note: Authority G.S. 131E-177(1); ~~131E-183~~; 131E-183(b);*  
2 *Eff. January 1, 1987;*  
3 *Amended Eff. November 1, 1989;*  
4 *Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule*  
5 *becomes effective, whichever is sooner;*  
6 *Amended Eff. November 1, 1996; January 4, 1994;*  
7 *Temporary Amendment Eff. January 1, 1999;*  
8 *Temporary Eff. January 1, 1999 Expired on October 12, 1999;*  
9 *Temporary Amendment Eff. January 1, 2000 and shall expire on the date on which the permanent*  
10 *amendment to this Rule, approved by the Rules Review Commission on November 17, 1999, becomes*  
11 *effective;*  
12 *Amended Eff. July 1, 2000;*  
13 *Temporary Amendment Eff. March 1, 2010;*  
14 *Amended Eff. January 1, 2013; November 1, ~~2010~~; 2010;*  
15 *Readopted Eff. January 1, 2022.*