

1 10A NCAC 14C .1903 is proposed for readoption with substantive changes as follows:

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3 **10A NCAC 14C .1903 PERFORMANCE STANDARDS**

4 ~~(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will~~
5 ~~be met:~~

6 ~~(1) an applicant's existing linear accelerators located in the proposed radiation therapy service area~~
7 ~~performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine~~
8 ~~in the twelve months prior to the date the application was submitted;~~

9 ~~(2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV~~
10 ~~treatments during the third year of operation of the new equipment; and~~

11 ~~(3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are~~
12 ~~projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine~~
13 ~~during the third year of operation of the new equipment.~~

14 ~~(b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides~~
15 ~~documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.~~

16 ~~(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the~~
17 ~~following information:~~

18 ~~(1) the number of patients who are projected to receive treatment from the proposed radiation therapy~~
19 ~~equipment, classified by type of equipment, diagnosis, treatment procedure, and county of~~
20 ~~residence; and~~

21 ~~(2) the maximum number and type of procedures that the proposed equipment is capable of performing.~~

22 ~~(d) The applicant shall document all assumptions and provide data supporting the methodology used to determine~~
23 ~~projected utilization as required in this Rule.~~

24 An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities
25 Plan in effect as of the first day of the review period shall:

26 (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in
27 the proposed LINAC service area;

28 (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in
29 the proposed LINAC service area;

30 (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the
31 proposed LINAC during each of the first three full fiscal years of operation following completion
32 of the project;

33 (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of
34 this Rule;

35 (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall
36 perform during the third full fiscal year of operation following completion of the project:

37 (A) 6,750 or more ESTVs per LINAC; or

1 (B) serve 250 or more patients per LINAC.

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

4 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*

5 *becomes effective, whichever is sooner;*

6 *Eff. January 4, 1994;*

7 *Amended Eff. November 1, 1996*

8 *Temporary Amendment Eff. January 1, 1999;*

9 *Temporary Amendment effective January 1, 1999 expired October 12, 1999;*

10 *Temporary Amended Eff. January 1, 2000;*

11 *Temporary Amendment Eff. February 1, 2006;*

12 *Amended Eff. November 1, 2006.*

13 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*

14 *originally proposed to be effective August 2000;*

15 *Amended Eff. April 1, 2001;*

16 *Temporary Amendment Eff. March 15, 2002; January 1, 2002; Amended Eff. April 1, 2003;*

17 *Temporary Amendment Eff. February 1, 2008;*

18 *Amended Eff. November 1, 2008;*

19 *Temporary Amendment Eff. February 1, 2009;*

20 *Amended Eff. November 1, ~~2009~~. 2009;*

21 *Readopted Eff. January 1, 2022.*