

1 10A NCAC 14C .2703 is readopted with changes as published in 36:02 NCR 94-108 as follows:

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3 **10A NCAC 14C .2703 PERFORMANCE STANDARDS**

4 ~~(a) An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:~~

5 ~~(1) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a~~
6 ~~controlling interest in and operates in the mobile MRI region in which the proposed equipment will~~
7 ~~be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most~~
8 ~~recent 12 month period for which the applicant has data [Note: This is not the average number of~~
9 ~~weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the~~
10 ~~exception that in the event an existing mobile MRI scanner has been in operation less than 12 months~~
11 ~~at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner~~
12 ~~performed an average of at least 277 weighted MRI procedures per month for the period in which it~~
13 ~~has been in operation;~~

14 ~~(2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least~~
15 ~~3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI~~
16 ~~scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which~~
17 ~~the proposed equipment will be located [Note: This is not the average number of weighted MRI~~
18 ~~procedures performed on all of the applicant's mobile MRI scanners.]; and~~

19 ~~(3) document the assumptions and provide data supporting the methodology used for each projection~~
20 ~~required in this Rule.~~

21 ~~(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI~~
22 ~~scanners described in Paragraphs (c) and (d) of this Rule, shall:~~

23 ~~(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a~~
24 ~~controlling interest in and locates in the proposed MRI service area performed an average of 3,328~~
25 ~~weighted MRI procedures in the most recent 12 month period for which the applicant has data;~~

26 ~~(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a~~
27 ~~controlling interest in and operates in the proposed MRI service area except temporary MRI~~
28 ~~scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which~~
29 ~~the applicant has data [Note: This is not the average number of weighted MRI procedures performed~~
30 ~~on all of the applicant's mobile MRI scanners.];~~

31 ~~(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI~~
32 ~~scanners which the applicant or a related entity owns a controlling interest in and locates in the~~
33 ~~proposed MRI service area are reasonably expected to perform the following number of weighted~~
34 ~~MRI procedures, whichever is applicable, in the third year of operation following completion of the~~
35 ~~proposed project:~~

36 ~~(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed~~
37 ~~MRI scanners are located,~~

- 1 (B) ~~3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed~~
 2 MRI scanner is located;
- 3 (C) ~~4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed~~
 4 MRI scanners are located;
- 5 (D) ~~4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed~~
 6 MRI scanners are located, or
- 7 (E) ~~4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or~~
 8 more fixed MRI scanners are located;
- 9 (4) ~~if the proposed MRI scanner will be located at a different site from any of the existing or approved~~
 10 MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of
 11 the proposed fixed MRI scanner is reasonably expected to perform the following number of
 12 weighted MRI procedures, whichever is applicable, in the third year of operation following
 13 completion of the proposed project:
- 14 (A) ~~1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed~~
 15 MRI scanners are located;
- 16 (B) ~~3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed~~
 17 MRI scanner is located;
- 18 (C) ~~4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed~~
 19 MRI scanners are located;
- 20 (D) ~~4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed~~
 21 MRI scanners are located, or
- 22 (E) ~~4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or~~
 23 more fixed MRI scanners are located;
- 24 (5) ~~demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner~~
 25 which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI
 26 service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of
 27 operation following completion of the proposed project [Note: This is not the average number of
 28 weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and
- 29 (6) ~~document the assumptions and provide data supporting the methodology used for each projection~~
 30 required in this Rule.
- 31 (e) ~~An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which~~
 32 the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the
 33 need determination shall:
- 34 (1) ~~demonstrate annual utilization of the proposed MRI scanner in the third year of operation is~~
 35 reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure
 36 per hour times 40 hours per week times 52 weeks per year; and

1 ~~(2) — document the assumptions and provide data supporting the methodology used for each projection~~
 2 ~~required in this Rule.~~

3 ~~(d) An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State~~
 4 ~~Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:~~

5 ~~(1) — demonstrate annual utilization of the proposed MRI scanner in the third year of operation is~~
 6 ~~reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to~~
 7 ~~10A NCAC 14C .2702(f)(7); and~~

8 ~~(2) — document the assumptions and provide data supporting the methodology used for each projection~~
 9 ~~required in this Rule.~~

10 ~~(e) An applicant proposing to acquire a fixed multi position MRI scanner for which the need determination in the~~
 11 ~~State Medical Facilities Plan was based on an approved petition for a demonstration project shall:~~

12 ~~(1) — demonstrate annual utilization of the proposed multi position MRI scanner in the third year of~~
 13 ~~operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant~~
 14 ~~in response to 10A NCAC 14C .2702(g)(7); and~~

15 ~~(2) — document the assumptions and provide data supporting the methodology used for each projection~~
 16 ~~required in this Rule.~~

17 (a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State
 18 Medical Facilities Plan in effect as of the first day of the review period shall:

19 (1) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and
 20 located in the proposed fixed MRI scanner service area;

21 (2) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and
 22 located in the proposed fixed MRI scanner service area;

23 (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity
 24 that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service
 25 area during the 12 months before the application deadline for the review period;

26 (4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
 27 that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service
 28 area;

29 (5) provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4)
 30 of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years
 31 of operation following completion of the project;

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

34 (7) project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph
 35 and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation
 36 following completion of the [project:] project as follows:

1 (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more
 2 fixed MRI scanners in the fixed MRI scanner service area;

3 (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI
 4 scanners in the fixed MRI scanner service area;

5 (C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI
 6 scanners in the fixed MRI scanner service area;

7 (D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI
 8 scanner in the fixed MRI scanner service area; or

9 (E) 1,201 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI
 10 scanners in the fixed MRI scanner service area; and

11 (8) project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall
 12 perform 3,328 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal
 13 year of operation following completion of the project.

14 (b) An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State
 15 Medical Facilities Plan in effect as of the first day of the review period shall:

16 (1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity
 17 that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service
 18 area during the 12 months before the application deadline for the review period;

19 (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity
 20 that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner
 21 service area;

22 (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that
 23 are located in the proposed mobile MRI scanner service area;

24 (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that
 25 will be located in the proposed mobile MRI scanner service area;

26 (5) identify the existing and proposed host sites for each mobile MRI scanner identified in
 27 Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;

28 (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4)
 29 of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years
 30 of operation following completion of the project;

31 (7) provide the assumptions and methodology used to project the utilization required by Subparagraph
 32 (b)(6) of this Paragraph;

33 (8) project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph
 34 and the proposed mobile MRI scanner shall perform 3,328 or more adjusted MRI procedures per
 35 MRI scanner during the third full fiscal year of operation following completion of the project; and

1 (9) project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph
 2 shall perform during the third full fiscal year of operation following completion of the [project]
 3 project as follows:

4 (A) 3,364 or more adjusted MRI procedures per fixed MRI scanner if there are four or more
 5 fixed MRI scanners in the fixed MRI scanner service area;

6 (B) 3,123 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI
 7 scanners in the fixed MRI scanner service area;

8 (C) 2,883 or more adjusted MRI procedures per fixed MRI scanner if there are two fixed MRI
 9 scanners in the fixed MRI scanner service area;

10 (D) 2,643 or more adjusted MRI procedures per fixed MRI scanner if there is one fixed MRI
 11 scanner in the fixed MRI scanner service area; or

12 (E) 1,201 or more adjusted MRI procedures per MRI scanner if there are no fixed MRI scanners
 13 in the fixed MRI scanner service area.

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 15 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
 16 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
 17 *becomes effective, whichever is sooner;*
 18 *Eff. February 1, 1994;*
 19 *Temporary Amendment Eff. January 1, 1999;*
 20 *Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;*
 21 *Temporary Amendment Eff. January 1, 2000;*
 22 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
 23 *originally proposed to be effective August 2000;*
 24 *Temporary Amendment Eff. January 1, 2001;*
 25 *Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking*
 26 *originally proposed to be effective April 1, 2001;*
 27 *Temporary Amendment Eff. January 1, 2002;*
 28 *Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective,*
 29 *August 1, 2002;*
 30 *Temporary Amendment Eff. January 1, 2003;*
 31 *Amended Eff. August 1, 2004; April 1, 2003;*
 32 *Temporary Amendment Eff. January 1, 2005;*
 33 *Amended Eff. November 1, 2005;*
 34 *Temporary Amendment Eff. February 1, 2006;*
 35 *Amended Eff. November 1, 2006;*
 36 *Temporary Amendment Eff. February 1, 2008;*
 37 *Amended Eff. November 1, ~~2008~~. 2008;*

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