

10A NCAC 14C .1903 is readopted with changes as published in 36:02 NCR 94-108 as follows:

10A NCAC 14C .1903 PERFORMANCE STANDARDS

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

- ~~(1) an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;~~
- ~~(2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and~~
- ~~(3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.~~

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

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

- ~~(1) the number of patients who are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and~~
- ~~(2) the maximum number and type of procedures that the proposed equipment is capable of performing.~~

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

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

- (1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- (2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;
- (3) provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;
- (5) project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the [project] project either:

- 1 (A) 6,750 or more ESTVs per LINAC; or
 2 (B) serve 250 or more patients per LINAC.

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 4 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
 5 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
 6 *becomes effective, whichever is sooner;*
 7 *Eff. January 4, 1994;*
 8 *Amended Eff. November 1, 1996*
 9 *Temporary Amendment Eff. January 1, 1999;*
 10 *Temporary Amendment effective January 1, 1999 expired October 12, 1999;*
 11 *Temporary Amended Eff. January 1, 2000;*
 12 *Temporary Amendment Eff. February 1, 2006;*
 13 *Amended Eff. November 1, 2006.*
 14 *Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking*
 15 *originally proposed to be effective August 2000;*
 16 *Amended Eff. April 1, 2001;*
 17 *Temporary Amendment Eff. March 15, 2002; January 1, 2002; Amended Eff. April 1, 2003;*
 18 *Temporary Amendment Eff. February 1, 2008;*
 19 *Amended Eff. November 1, 2008;*
 20 *Temporary Amendment Eff. February 1, 2009;*
 21 *Amended Eff. November 1, ~~2009~~ 2009;*
 22 *Readopted Eff. January 1, 2022.*

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

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

- ~~(1) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;~~
- ~~(2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and~~
- ~~(3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.~~

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

- ~~(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;~~
- ~~(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];~~
- ~~(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:~~
 - ~~(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation 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

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

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

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

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

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

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

*History Note: Authority G.S. 131E-177(1); 131E-183(b);
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. February 1, 1994;
Temporary Amendment Eff. January 1, 1999;
Temporary Amendment Eff. January 1, 1999 Expired on October 12, 1999;
Temporary Amendment Eff. January 1, 2000;
Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;
Temporary Amendment Eff. January 1, 2001;
Temporary Amendment effective January 1, 2001 amends and replaces a permanent rulemaking originally proposed to be effective April 1, 2001;
Temporary Amendment Eff. January 1, 2002;
Temporary Amendment Eff. January 1, 2002 amends and replaces the permanent rule effective, August 1, 2002;
Temporary Amendment Eff. January 1, 2003;
Amended Eff. August 1, 2004; April 1, 2003;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2006;
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Temporary Amendment Eff. February 1, 2008;
Amended Eff. November 1, ~~2008~~. 2008;*

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10A NCAC 14C .3701 is readopted with changes as published in 36:02 NCR 94-108 as follows:

SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

10A NCAC 14C .3701 DEFINITIONS

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

- ~~(1) "Approved positron emission tomography (PET) scanner" means a PET scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need.~~
- ~~(2) "Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.~~
- ~~(3) "Dedicated PET Scanner" means PET Scanners as defined in the applicable State Medical Facilities Plan.~~
- ~~(4) "Existing PET scanner" means a PET scanner in operation prior to the beginning of the review period.~~
- ~~(5) "Mobile PET Scanner" means a PET scanner and transporting equipment that is moved, at least weekly, to provide services at two or more host facilities.~~
- ~~(6) "PET procedure" means a single discrete study of one patient involving one or more PET scans.~~
- ~~(7) "PET scan" means an image scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure.~~
- ~~(8) "PET scanner service area" means the PET Scanner Service Area as defined in the applicable State Medical Facilities Plan.~~
- ~~(9) "Positron emission tomographic scanner" (PET) is defined in G.S. 131E-176(19a).~~
- ~~(10) "Radioisotope" means a radiochemical which directly traces biological processes when introduced into the body.~~

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

- (1) "Approved PET scanner" means a positron emission tomography (PET) scanner that was issued a certificate of need but is not being used to provide services as of the application deadline for the review period.
- (2) "Existing PET scanner" means a PET scanner that is being used to provide services as of the application deadline for the review period.
- (3) "Fixed PET scanner" means a PET scanner that is not mobile.
- (4) "Fixed PET scanner service area" shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- (5) "Host site" means the location where the mobile PET scanner provides services.

(6) “Mobile PET scanner” means a PET scanner that is moved weekly to provide services at two or more host sites.

(7) “Mobile PET scanner service area” shall have the same meaning as defined in the annual State Medical Facilities Plan in effect as of the first day of the review period.

(8) [~~“PET”~~ “Positron emission tomography scanner” shall have the same meaning as defined in G.S. 131E-176(19a).

(9) “Proposed PET scanner” means the PET scanner proposed in the application under review.

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

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Eff. January 4, 1994;

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Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;

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