10A NCAC 14C .1901 is proposed for readoption with substantive changes as follows:

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT LINEAR ACCELERATORS

10A NCAC 14C .1901 DEFINITIONS

These definitions shall apply to all rules in this Section:

(1) "Approved linear accelerator" means a linear accelerator which was not operational prior to the beginning of the review period.

(2) "Complex Radiation treatment" is equal to 1.0 ESTV and means: treatment on three or more sites on the body; use of techniques such as tangential fields with wedges, rotational or arc techniques; or use of custom blocking.

(3) "Equivalent Simple Treatment Visit [ESTV]" means one basic unit of radiation therapy which normally requires up to fifteen (15) minutes for the uncomplicated set up and treatment of a patient on a megavoltage teletherapy unit including the time necessary for portal filming.

(4) "Existing linear accelerator" means a linear accelerator in operation prior to the beginning of the review period.

(5) "Intermediate Radiation treatment" means treatment on two separate sites on the body, three or more fields to a single treatment site or use of multiple blocking and is equal to 1.0 ESTV.

(6) "Linear accelerator" shall have the same meaning as defined in G.S. 131E-176(14g).

(7) "Linear accelerator service area" means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.

(8) "Megavoltage unit" means MRT equipment which provides a form of teletherapy that involves the delivery of energy greater than, or equivalent to, one million volts by the emission of x-rays, gamma rays, electrons, or other radiation.

(9) "Megavoltage radiation therapy (MRT)" means the use of ionizing radiation in excess of one million electron volts in the treatment of cancer.

(10) "MRT equipment" means a machine or energy source used to provide megavoltage radiation therapy including linear accelerators and other particle accelerators.

(11) "Radiation therapy equipment" means medical equipment which is used to provide radiation therapy services.

(12) "Radiation therapy services" means those services which involve the delivery of controlled and monitored doses of radiation to a defined volume of tumor bearing tissue within a patient. Radiation may be delivered to the tumor region by the use of radioactive implants or by beams of ionizing radiation or it may be delivered to the tumor region systemically.

(13) "Radiation therapy service area" means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.
"Simple Radiation treatment" means treatment on a single site on the body, single treatment field or parallel opposed fields with no more than simple blocks and is equal to 1 ESTV.

"Simulator" shall have the same meaning as defined in G.S. 131E-176(24b).

"Special technique" means radiation therapy treatments that may require increased time for each patient visit including:

(a) total body irradiation (photons or electrons) which equals 2.5 ESTVs;
(b) hemi-body irradiation which equals 2.0 ESTVs;
(c) intraoperative radiation therapy which equals 10.0 ESTVs;
(d) neutron and proton radiation therapy which equals 2.0 ESTVs;
(e) intensity modulated radiation treatment (IMRT) which equals 1.0 ESTV;
(f) limb salvage irradiation at lengthened SSD which equals 1.0 ESTV;
(g) additional field check radiographs which equals .50 ESTV;
(h) stereotactic radiosurgery treatment management with linear accelerator or gamma knife which equals 3.0 ESTVs; and
(i) pediatric patient under anesthesia which equals 1.5 ESTVs.

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

(1) “Approved LINAC” means a linear accelerator (LINAC) 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) “Equivalent Simple Treatment Visit (ESTV)” 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.
(3) “Existing LINAC” means a LINAC that is being used to provide services as of the application deadline for the review period.
(4) “LINAC 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) “Linear accelerator (LINAC)” shall have the same meaning as defined in G.S. 131E-176(14g).
(6) “Proposed LINAC” means the LINAC proposed in the application under review.

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. January 4, 1994;
Amended Eff. November 1, 1996;
Temporary Amendment January 1, 1999;
Temporary Amendment Eff. January 1, 1999 expired 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;
Amended Eff. April 1, 2001;
Temporary Amendment Eff. January 1, 2002;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2006;
Amended Eff. November 1, 2006, 2006;