NORTH CAROLINA

REGISTER



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NORTH CAROLINA ADMINISTRATIVE CODE CLASSIFICATION SYSTEM

The North Carolina Administrative Code (NCAC) has four major classifications of rules. Three of these, titles, chapters, and sections are mandatory. The major classification of the NCAC is the title. Each major department in the North Carolina executive branch of government has been assigned a title number. Titles are further broken down into chapters which shall be numerical in order. Subchapters are optional classifications to be used by agencies when appropriate.

	NCAC TITLES		TITLE 21 LICENSING BOARDS	TITLE 24 INDEPENDENT AGENCIES
1	ADMINISTRATION	1	Acupuncture	1 Housing Finance
2	AGRICULTURE & CONSUMER SERVICES	2	Architecture	2 Agricultural Finance Authority
3	AUDITOR	3	Athletic Trainer Examiners	3 Safety & Health Review
4	COMMERCE	4	Auctioneers	Board
5	CORRECTION	6	Barber Examiners	4 Reserved
6	COUNCIL OF STATE	8	Certified Public Accountant Examiners	5 State Health Plan Purchasing
7	CULTURAL RESOURCES	10	Chiropractic Examiners	Alliance Board
8	ELECTIONS	11	Employee Assistance Professionals	
9	GOVERNOR	12	General Contractors	
10A	HEALTH AND HUMAN SERVICES	14	Cosmetic Art Examiners	
11	INSURANCE	16	Dental Examiners	
12	JUSTICE	17	Dietetics/Nutrition	
13	LABOR	18	Electrical Contractors	
14A	CRIME CONTROL & PUBLIC SAFETY	19 20	Electrolysis Foresters	
15A	ENVIRONMENT &NATURAL RESOURCES	20	Geologists	
16	PUBLIC EDUCATION	21	Hearing Aid Dealers and Fitters	
17	REVENUE	25	Interpreter/Transliterator	
18	SECRETARY OF STATE	26	Landscape Architects	
10 19A	TRANSPORTATION	28	Landscape Contractors	
20	TREASURER	29	Locksmith Licensing	
20	OCCUPATIONAL LICENSING BOARDS	30	Massage & Bodywork Therapy	
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22	(REPEALED)	32	Medical Examiners	
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		52	Contractors Podiatry Examiners	
		52 53	Professional Counselors	
		55 54	Psychology	
		56	Professional Engineers & Land Surveyors	
		57	Real Estate Appraisal	
		58	Real Estate Commission	
		60	Refrigeration Examiners	
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		62	Sanitarian Examiners	
		63	Social Work Certification	
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			Audiologists	
		65	Therapeutic Recreation Certification	
		66	Veterinary Medical	
		68	Substance Abuse Professionals	
		69	Soil Scientists	

Note: Title 21 contains the chapters of the various occupational licensing boards and Title 24 contains the chapters of independent agencies.

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Publication Schedule for January 2006 – December 2006

FILING DEADLINES			NOTICE OF TEXT		PERMANENT RULE			TEMPORARY RULES
Volume & issue number	Issue date	Last day for filing	Earliest date for public hearing	End of required comment period	Deadline to submit to RRC for review at next meeting	Earliest Eff. Date of Permanent Rule	Delayed Eff. Date of Permanent Rule (first legislative day of the next regular session)	270 th day from publication in the Register
20:13	01/03/06	12/08/05	01/18/06	03/06/06	03/20/06	05/01/06	05/09/06	09/30/06
20:14	01/17/06	12/21/05	02/01/06	03/20/06	04/20/06	06/01/06	01/07	10/14/06
20:15	02/01/06	01/10/06	02/16/06	04/03/06	04/20/06	06/01/06	01/07	10/29/06
20:16	02/15/06	01/25/06	03/02/06	04/17/06	04/20/06	06/01/06	01/07	11/12/06
20:17	03/01/06	02/08/06	03/16/06	05/01/06	05/22/06	07/01/06	01/07	11/26/06
20:18	03/15/06	02/22/06	03/30/06	05/15/06	05/22/06	07/01/06	01/07	12/10/06
20:19	04/03/06	03/13/06	04/18/06	06/02/06	06/20/06	08/01/06	01/07	12/29/06
20:20	04/17/06	03/24/06	05/02/06	06/16/06	06/20/06	08/01/06	01/07	01/12/07
20:21	05/01/06	04/07/06	05/16/06	06/30/06	07/20/06	09/01/06	01/07	01/26/07
20:22	05/15/06	04/24/06	05/30/06	07/14/06	07/20/06	09/01/06	01/07	02/09/07
20:23	06/01/06	05/10/06	06/16/06	07/31/06	08/21/06	10/01/06	01/07	02/26/07
20:24	06/15/06	05/24/06	06/30/06	08/14/06	08/21/06	10/01/06	01/07	03/12/07
21:01	07/03/06	06/12/06	07/18/06	09/01/06	09/20/06	11/01/06	01/07	03/30/07
21:02	07/17/06	06/23/06	08/01/06	09/15/06	09/20/06	11/01/06	01/07	04/13/07
21:03	08/01/06	07/11/06	08/16/06	10/02/06	10/20/06	12/01/06	01/07	04/28/07
21:04	08/15/06	07/25/06	08/30/06	10/16/06	10/20/06	12/01/06	01/07	05/12/07
21:05	09/01/06	08/11/06	09/16/06	10/31/06	11/20/06	01/01/07	01/07	05/29/07
21:06	09/15/06	08/24/06	09/30/06	11/14/06	11/20/06	01/01/07	01/07	06/12/07
21:07	10/02/06	09/11/06	10/17/06	12/01/06	12/20/06	02/01/07	05/08	06/29/07
21:08	10/16/06	09/25/06	10/31/06	12/15/06	12/20/06	02/01/07	05/08	07/13/07
21:09	11/01/06	10/11/06	11/16/06	01/01/07	01/22/07	03/01/07	05/08	07/29/07
21:10	11/15/06	10/24/06	11/30/06	01/15/07	01/22/07	03/01/07	05/08	08/12/07
21:11	12/01/06	11/07/06	12/16/06	01/30/07	02/20/07	04/01/07	05/08	08/28/07
21:12	12/15/06	11/22/06	12/30/06	02/13/07	02/20/07	04/01/07	05/08	09/11/07

EXPLANATION OF THE PUBLICATION SCHEDULE

This Publication Schedule is prepared by the Office of Administrative Hearings as a public service and the computation of time periods are not to be deemed binding or controlling. Time is computed according to 26 NCAC 2C .0302 and the Rules of Civil Procedure, Rule 6.

GENERAL

The North Carolina Register shall be published twice a month and contains the following information submitted for publication by a state agency:

- (1) temporary rules;
- (2) notices of rule-making proceedings;
- (3) text of proposed rules;
- (4) text of permanent rules approved by the Rules Review Commission;
- (5) notices of receipt of a petition for municipal incorporation, as required by G.S. 120-165;
- (6) Executive Orders of the Governor;
- (7) final decision letters from the U.S. Attorney General concerning changes in laws affecting voting in a jurisdiction subject of Section 5 of the Voting Rights Act of 1965, as required by G.S. 120-30.9H;
- (8) orders of the Tax Review Board issued under G.S. 105-241.2; and
- (9) other information the Codifier of Rules determines to be helpful to the public.

COMPUTING TIME: In computing time in the schedule, the day of publication of the North Carolina Register is not included. The last day of the period so computed is included, unless it is a Saturday, Sunday, or State holiday, in which event the period runs until the preceding day which is not a Saturday, Sunday, or State holiday.

FILING DEADLINES

ISSUE DATE: The Register is published on the first and fifteen of each month if the first or fifteenth of the month is not a Saturday, Sunday, or State holiday for employees mandated by the State Personnel Commission. If the first or fifteenth of any month is a Saturday, Sunday, or a holiday for State employees, the North Carolina Register issue for that day will be published on the day of that month after the first or fifteenth that is not a Saturday, Sunday, or holiday for State employees.

LAST DAY FOR FILING: The last day for filing for any issue is 15 days before the issue date excluding Saturdays, Sundays, and holidays for State employees.

NOTICE OF TEXT

EARLIEST DATE FOR PUBLIC HEARING: The hearing date shall be at least 15 days after the date a notice of the hearing is published.

END OF **REQUIRED COMMENT PERIOD** An agency shall accept comments on the text of a proposed rule for at least 60 days after the text is published or until the date of any public hearings held on the proposed rule, whichever is longer.

DEADLINE TO SUBMIT TO THE RULES REVIEW COMMISSION: The Commission shall review a rule submitted to it on or before the twentieth of a month by the last day of the next month.

FIRST LEGISLATIVE DAY OF THE NEXT REGULAR SESSION OF THE GENERAL ASSEMBLY: This date is the first legislative day of the next regular session of the General Assembly following approval of the rule by the Rules Review Commission. See G.S. 150B-21.3, Effective date of rules. Note from the Codifier: This Section contains public notices that are required to be published in the Register or have been approved by the Codifier of Rules for publication.

NOTICE OF RULE MAKING PROCEEDINGS AND PUBLIC HEARING

NORTH CAROLINA BUILDING CODE COUNCIL

Notice of Rule-making Proceedings is hereby given by NC Building Code Council in accordance with G.S. 150B-21.5(d).

Citation to Existing Rule Affected by this Rule-Making: NC Plumbing Code

Authority for Rule-making: G.S. 143-136; 143-138

Reason for Proposed Action: To incorporate changes in the NC Building Codes as a result of rulemaking petitions filed with the NC Building Code Council and to incorporate changes proposed by the Council.

Public Hearing: March 13, 2006, 1:00PM, Shell Island, 2700 North Lumina Avenue, Wrightsville Beach, NC 28480

Comment Procedures: Written comments may be sent to Barry Gupton, Secretary, NC Building Code Council, c/o NC Department of Insurance, 322 Chapanoke Road, Suite 200, Raleigh, NC 27603. Comment period expires on April 17, 2006.

Statement of Subject Matter:

1. Request by Steven Mayer, Harrell, Hopper and Associates to revise the 2006 NC Plumbing Code, Section 412.6 as follows:

412.6 Trap primers. The water sealer of floor drain traps shall be maintained <u>in conformance with 1002.4 Trap seals</u> by an automatic trap primer, drainage from a clear water fixture or other method acceptable to the authority having jurisdiction. **Exception:** Hose bibbs located in rooms with nonabsorbent floors may be used in lieu of an automatic trap primer.

Brad Lail made a motion to grant this petition and to send it to the Plumbing Code Committee. Dan Murray seconded the motion. The motion carried on 9/13/05. The Plumbing Code Committee recommended approval on 12/13/05.

Note from the Codifier: The notices published in this Section of the NC Register include the text of proposed rules. The agency must accept comments on the proposed rule(s) for at least 60 days from the publication date, or until the public hearing, or a later date if specified in the notice by the agency. If the agency adopts a rule that differs substantially from a prior published notice, the agency must publish the text of the proposed different rule and accept comment on the proposed different rule for 60 davs.

Statutory reference: G.S. 150B-21.2.

TITLE 2 – DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Agriculture intends amend the rule cited as 02 NCAC 20B .0104.

Proposed Effective Date: June 1, 2006

Instructions on How to Demand a Public Hearing: (must be requested in writing within 15 days of notice): Any person may request a public hearing on the proposed rule by submitting a request in writing no later than March 2, 2006, to David S. McLeod, Secretary, NC Board of Agriculture, 1001 Mail Service Center, Raleigh, NC 27699-1001.

Reason for Proposed Action: This Rule establishes admission ticket prices for the North Carolina State Fair. The proposed amendment would increase the price for an adult admission ticket by \$1, from \$6 to \$7. This was last increased in 1993. The increase is necessary to provide additional funds for operation, maintenance, and improvement of the State Fairgrounds.

Procedure by which a person can object to the agency on a **proposed rule:** Any person may object to the proposed rule by submitting a written statement of objection(s) to David S. McLeod, Secretary, NC Board of Agriculture, 1001 Mail Service Center, Raleigh, NC 27699-1001.

Comments may be submitted to: David S. McLeod, 1001 Mail Service Center, Raleigh, NC 27699-1001, phone (919)733-7125 x249, fax (919)716-0105, email david.mcleod@ncmail.net

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

	State
	Local
]	Substantive (≥\$3,000,000)
1	None

CHAPTER 20 – THE NORTH CAROLINA STATE FAIR

SUBCHAPTER 20B - REGULATIONS OF THE STATE FAIR

SECTION .0100 - GENERAL PROVISIONS

02 NCAC 20B .0104 **ADMISSION RULES**

(a) All persons entering the North Carolina State Fair grounds must pay the established admission fee, except persons holding worker's permits. One-time-only admissions may be issued to those persons who are employed by the fair Fair or are asked to appear on the grounds by the fair Fair management for a specific purpose, relative to the operation of the fair.

(b) The gates of the North Carolina State Fair shall be open to visitors from 9:00 a.m. until midnight each day of the fair. Exhibit buildings shall be open from 9:00 a.m. to 9:45 p.m. daily.

(c) The State Fair Manager may operate a pass-out system at one or more of the outside gates. Persons exiting through these gates may, upon request, have their hand or vehicle stamped for readmittance through the same gate without additional charge. Readmittance must occur before 10:00 p.m. on the same day as pass-out or the hand stamp shall not be honored.

(d) Outside gate admission prices are as follows:

- (1) adult/child, 13 years of age and over $\frac{6.00}{100}$
- (2) child, 6 through 12 years of age \$2.00
- (3) senior citizen, 65 and over Free
- (4) child, under 6 years of age Free

(e) Outside gate admission prices for advance ticket sales are as follows:

- (1) adult/child, 13 years of age and over \$5.00
- (2) child, 6 through 12 years of age \$1.00
- (3) senior citizen, 65 and over Free
- (4) child, under 6 years of age Free
- (5) adult group sales purchasing \$4.75
- a minimum of 40 tickets

Authority G.S. 106-503.

TITLE 11 – DEPARTMENT OF INSURANCE

Notice is hereby given in accordance with G.S. 150B-21.2 that the Department of Insurance intends to adopt rules cited as 11 NCAC 05A .0512- .0513, amend the rules cited as 11 NCAC 05A .0101, .0103, .0301- .0302, .0501, .0503- .0508 and repeal the rule cited as 11 NCAC 05A .0510.

Proposed Effective Date: June 1, 2006

Public Hearing:

Date: March 3, 2006 Time: 10:00 a.m. Location: 322 Chapanoke Road, Conference Room, Raleigh, NC 27603

Reason for Proposed Action: *To make technical corrections and update certification standards for fire departments.*

Procedure by which a person can object to the agency on a proposed rule: The Department of Insurance, Office of State Fire Marshal, will accept written objections to these rules until the expiration of the comment period on April 17, 2006.

Comments may be submitted to: *Ellen K. Sprenkel, 1201 Mail Service Center, Raleigh, NC 27699-1201, phone (919)733-4529, fax (919)733-6495, email esprenke@ncdoi.net*

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

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State Local Substantive (≥\$3,000,000) None

CHAPTER 5 - OFFICE OF STATE FIRE MARSHAL

SUBCHAPTER 05A - FIRE AND RESCUE

SECTION .0100 - GENERAL PROVISIONS

11 NCAC 05A .0101 DEFINITIONS

As used in this Chapter, the following terms shall be construed as follows:

- "Fire and Rescue Division" or "the division" shall mean the Fire and Rescue Services Division of the North Carolina Department of Insurance. "ISO" shall mean the Insurance Services Office, Inc.
- (2) "Rating Bureau" or "ISO" shall mean the ISO Commercial Risk Services, Inc. "Office of State Fire Marshal" or "OSFM" shall mean the Office of State Fire Marshal of the North Carolina Department of Insurance.
- (3) "Rate Bureau" shall mean the North Carolina Rate Bureau.

Authority G.S. 58-2-25; 58-2-40.

11 NCAC 05A .0103 MAILING ADDRESS

All requests for information, assistance, training, or required reports shall be directed to: North Carolina Department of Insurance, Fire and Rescue Services Division, 430 North Salisbury Street, P.O. Box 26387, Raleigh, North Carolina 27611. Office of State Fire Marshal, 1202 Mail Service Center, Raleigh, NC 27699-1202.

Authority G.S. 58-2-25; 58-2-40.

SECTION .0300 - FIREMEN'S RELIEF FUND

11 NCAC 05A .0301 ELIGIBLE MEMBERS

Before January 1, each year, the North Carolina State Firemen's Association shall provide the Fire and Rescue Services Division North Carolina Department of Insurance, Fire and Rescue Services Division, with a current list of all member fire departments in good standing, the balance in each local fund, the amount of bond covering each local fund, and verification that a financial statement was submitted. The State may provide a blanket bond for local government treasurers.

Authority G.S. 58-2-40(1); 58-84-30; 58-84-40.

11 NCAC 05A .0302 CERTIFICATION OF ELIGIBILITY

The certification form required by G.S. 58-84-46 shall be entitled "Report of Fire Conditions" and shall, in addition to the information required by G.S. 58-84-46, include the following:

- (1) The name of the city, fire district, or sanitary district;
- (2) Current number of personnel, type and amount of equipment and type of water supply used for fire suppression;
- (3)(2) Names of the "Board of Trustees of the Local Firemen's Relief Fund"; and
- (4)(3) Identity of the Treasurer of the Local Firemen's Relief Fund; and Fund.

(5) Membership status in the North Carolina State Firemen's Association;

Authority G.S. 58-2-40(1); 58-84-46.

SECTION .0500 - INITIAL CERTIFICATION AND RESPONSE RATINGS FOR FIRE DEPARTMENTS

11 NCAC 05A .0501 PURPOSE

The purpose of this Section is to set forth the minimum requirements that a fire department must meet in order to qualify for eligibility for death benefits under G.S. 143-166.1 and the North Carolina Firemen's Pension Fund under G.S. 58-86-25; G.S. 58-86-25; and for initial recognition in insurance premiums for a responding fire department. department; and for response rating to designate insurance premiums. Upon meeting these initial requirements for certification, a fire district will be given a rating of "9S". A fire district may get a rating from "1-8" upon improving their response capabilities with "1" being the best rating.

Authority G.S. 58-2-40; 58-86-25.

11 NCAC 05A .0503ESTABLISHMENT OF FIREDEPARTMENT

All fire departments wishing to become qualified shall meet the following criteria: <u>To become a certified fire department, a fire department shall apply and meet the following criteria:</u>

- (1) The fire department shall be incorporated under Chapter 55A of the General Statutes or be operated by a city, county, or sanitary district as a division of that governmental unit.
- (2) If the fire department is incorporated, it shall operate under a contract with either a city, county, or sanitary district or any combination thereof.
- (3) Boundaries defining the area of responsibility shall be established by a County Board of Commissioners for areas outside municipalities pursuant to G.S. 153A-233.
- (4) The fire department shall provide the Department of Insurance OSFM with a hand drawn map and written description or a GIS computer generated map of its initial or revised fire district.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0504 PERSONNEL

Upon initial eertification, certification as a Class "9S" fire department, the fire department shall have a minimum of 20 personnel, with at least two designated as traffic control and at least 18 designated as firefighters. At the time of re-inspection, a fire department shall maintain 20 personnel or show, through documentation, that an average of 12 persons personnel have responded on each of the last 20 structure fires. At least one engine with four personnel must respond to each reported structure fire alarm. A roster of personnel containing names, social security numbers, names and attendance of business

meetings and training meetings shall be kept. For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications kept by the Office of State Fire Marshal.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0505 TRAINING AND MEETING REQUIREMENTS

All members and fire departments shall comply with the training requirements of G.S. 58-86-25. G.S. 58-86-25 as a minimum. For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications kept by the Office of State Fire Marshal.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0506ALARM ANDCOMMUNICATIONS

Reliable communications facilities shall be provided for reporting emergencies, dispatching of fire apparatus, and notification of firefighters. The system shall provide one telephone listing for fire emergencies that reaches a location that can receive calls and can respond 24 hours a day. That location shall have the capability of activating sirens and/or pagers in order to dispatch the fire department. For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications kept by the Office of State Fire Marshal.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0507 RECORDS AND DOCUMENTS

In addition to personnel records, records shall be kept on dates, times and locations of emergencies, inventory of equipment, and maintenance of apparatus. The following documents shall be submitted to the Department of Insurance: roster, charter, contract(s) with city and county, service test report, weight tickets, current map and description, an inventory of protective clothing (if necessary), and verification from the county approving the fire district boundaries. For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications kept by the Office of State Fire Marshal.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0508 APPARATUS

To qualify for initial certification and receive a minimum rating of Class "9S", the fire department shall have the following apparatus and equipment:

(a)(1) Pumper.

(1)(a) The fire department shall have an approved pumper (automotive fire apparatus equipped with a fire pump

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and tank). To be approved, the fire department pumper must be certified by Underwriters Laboratories, Inc., and constructed in accordance with the National Fire Protection Association pamphlet 1901 for Automotive Standard Fire Apparatus which standard is incorporated by reference into this rule, but not including subsequent amendments or editions. The apparatus shall not be loaded beyond limits certified by the "Gross Vehicle Weight" label attached to the vehicle; nor shall the vehicle be modified in a manner that would invalidate this certification.

- (2)(b) The pump shall have a rated capacity of not less than 500 750 gallons per minute at 150 pounds per square inch net pump pressure.
- (3)(c) The pumper shall be equipped with at least a 500 gallon tank.
- (4)(d) A complete and accurate service test must have been performed on the "first responding" pumper during the 12-month period before the inspection. If the pumper has been purchased as new within the 12month period before the <u>"9S"</u> inspection, the U.L Certificate meets this requirement.
- (b)(2) Tanker.
 - (1)(a) The fire department shall have a motorized tank truck of at least 1000 gallons capacity or at least enough to equal 1500 gallons total for pumper and tanker. It is recommended that the capacity not exceed 1500 gallons.
 - (2)(b) The tanker shall be equipped with the necessary hose for filling the tank and hose for transferring water to the pumper.
 - (3)(c) The tankers, tanker, when fully loaded, shall not exceed the Gross Vehicle Weight limits as certified on the label attached to the vehicle; nor shall the vehicle be modified in a manner that would invalidate this certification. All tankers shall be baffled according to Section 4-2, NFPA 1903, and Standard for Mobile Water Supply Apparatus, which standard is incorporated by reference into this rule, but not including subsequent amendments or editions.
- (c)(3) Equipment. The following pumper equipment shall be carried on responding fire department vehicles:

- (1) Pumper:
 - (A)(a) The pumper shall be equipped with 2
 150' 1-1/2" hose lines with fog nozzles attached;
 - (B)(b) One booster reel and one preconnected hose or three preconnected hose lines;
 - (C)(c) Suction hose size necessary to flow the capacity of pumper - 2 - 10' sections;
 - (D)(d) Four OSHA approved self-contained breathing apparatus in good proper working condition;
 - (E)(e) OSHA approved protective clothing for all firefighters including helmet, helmets, hoods, coat, coats, pants, boots, and gloves; and reflective clothing and recommended helmet for traffic control personnel;
 - (F)(f) One 12' or 14' roof ladder;
 - (G)(g) One 24' or 35' extension ladder;
 - (H)(h) One axe;
 - (<u>I)(i)</u> One claw tool (Halligan Tool can replace claw tool and crowbar);
 - (J)(j) One crowbar (Halligan Tool can replace crowbar and claw tool);
 - (K)(k) One pike pole; pole, minimum 8';
 - (L)(1) Two portable hand lights ("4V" wet or "6V" dry);
 - (M)(m) 100 feet of rope; rope, minimum 1/2";
 - (N)(n) Two shovels;
 - (O)(o) Two <u>20 lb.</u> Class B-C portable extinguishers;
 - $(\underline{P})(\underline{p})$ One First Aid kit; and
 - (Q)(q) One bolt cutter. <u>cutter, 14" or</u> <u>longer..</u>
- (2) Tanker. The tanker shall be equipped with necessary suction hose for filling tank and hose for transferring water to pumper.

For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications kept by the Office of State Fire Marshal.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0510 INSPECTION

Personnel from the Fire and Rescue Services Division of the North Carolina Department of Insurance shall perform a field inspection to determine whether the initial certification requirements have been met. Any persons or fire departments needing more information on obtaining certification under this Section should contact:

Fire and Rescue Services Division N. C. Department of Insurance 111 Seaboard Avenue Raleigh, North Carolina 27603 (919)733-2142 Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0511 SIX MILE INSURANCE DISTRICT

To extend its insurance district to six miles, each fire department shall apply and meet the following criteria:

- (1) The fire department shall provide the OSFM with a hand drawn map and written description or a GIS computer generated map of its fire district.
- (2) The map and written description shall be presented to the County Commissioners for their approval, as set forth in G.S. 153A-233.
- (3) The department applying to extend its insurance district to six miles shall enter into a written automatic aid contract with the adjoining districts specifying that "an apparatus capable of transporting" a minimum of 1000 gallons of water will be dispatched simultaneously with the department whose district the incident is occurring within.
- (4) The County shall establish automatic aid protocols. These protocols shall be maintained at the county communication center and shall be used on all alarms involving reported structure fires.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0512 POLICY

(a) Non-Response Policy. The North Carolina Fire Suppression Rating Schedule (NCFSRS) shall be used for the purpose of determining Fire Insurance District Ratings Classifications. The fire department shall have sufficient membership to assure the response of at least four members and one engine to all fire and fire alarms in structures. The chief may be one of the four responding members. The minimum acceptable response to a structure fire/alarm will be one engine and four firefighters. Response of a fire department, as primary first alarm department, to a structural fire/alarm within its established fire insurance district with less than the minimum required engine or manpower will be considered by OSFM to be a Non-Response. Any department determined to have two or more "Non-Response" records will be placed on probation for a period of 12 months. The fire department shall submit to the OSFM inspector all fire/alarm response records for the next 12 consecutive calendar months that show there have been no additional "nonresponses" within that 12 month period. If the fire department fails to comply with this requirement, the insurance district for the fire department will be designated a "Class 10" rating.

(b) Retrogression Policy. Following evaluation of information and data collected during an NCRRS survey site visit, where the results indicate the fire department has retrogressed in class rating, the following must occur:

(1) North Carolina OSFM Senior Deputy Commissioner must notify the city/fire department officials, informing them of the retrogression. Information to be included within the written notification to the fire department officials shall include:

- (A) Hydrant flow tests/hauled water evaluations;
 - (B) Current classification detail; and

(C) Improvement statements.

- (2) The city/fire department official must respond to the Senior Deputy Commissioner in writing, within 30 days of receipt of the retrogression notification letter.
- (3) The current ratings classification will become effective, per established schedule, unless written notification is received within the 30 days time frame.
- (4) If required written notification is received by the Senior Deputy Commissioner, a letter shall be forwarded to the city/fire department officials acknowledging the fire department's desire to retain the previous ratings classification. In this letter the fire department will be instructed to contact the inspector assigned to this survey, and to develop a plan of action to correct the deficiencies ("Plan of Action") for use in the attempt to retain the previous ratings classification.
- (5) The fire department shall have no more than 90 days from the date of its receipt of the acknowledgment letter sent pursuant to paragraph (b)(4) of this rule to develop and submit its "Plan of Action" to OSFM for review and approval.
- (6) The city/fire department officials will be notified, in writing, once the proposed "Plan of Action" receives OSFM approval.
- (7) The fire department shall be allowed a maximum of 12 months to attain the defined goals of the approved "Plan of Action".

(c) Borrowing/Sharing of Equipment to Satisfy North Carolina RRS Survey Requirements.

The North Carolina Fire Suppression Rating Schedule (NCFSRS) will be used for the purpose of determining Fire Insurance District Ratings Classifications. The sharing or borrowing of equipment between fire departments or between stations within a fire department, the falsifying of documents, or engaging in any other act of misrepresentation, for the purpose of falsely satisfying the apparatus/equipment grading score of a North Carolina RRS survey, is strictly prohibited.

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

11 NCAC 05A .0513 INSPECTION

Personnel from the Office of State Fire Marshal of the North Carolina Department of Insurance shall perform a field inspection of the fire department to determine whether the initial certification requirements have been met and to establish its insurance rating. For ratings below a Class "9S", the fire department shall be evaluated using the current Insurance Services Office Fire Suppression Rating Schedule with North Carolina modifications maintained by the Office of State Fire

PROPOSED RULES

Marshal. Any persons or fire departments needing more information on obtaining certification or rating under this Section should contact:

> Office of State Fire Marshal North Carolina Department of Insurance 322 Chapanoke Road, Suite 200 Raleigh, NC 27603 (919) 661-5880

Authority G.S. 58-2-40; 58-86-25; 143-166.1.

TITLE 21 – OCCUPATIONAL LICENSING BOARDS

CHAPTER 14 – BOARD OF COSMETIC ART EXAMINERS

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Cosmetic Art Examiners intends to amend the rules cited as 21 NCAC 14I.0105, .0108.

Proposed Effective Date: June 1, 2006

Public Hearing: Date: March 2, 2006 Time: 9:00 a.m. Location: 1201 Front Street, Suite 110, Raleigh, NC 27609

Reason for Proposed Action: Addition to and clarification of current rule.

Procedure by which a person can object to the agency on a proposed rule: *Contact Stefanie Shore, phone (919)715-3171*

Comments may be submitted to: *Stefanie Shore, 1201 Front Street, Suite 110, Raleigh, NC 27609, phone (919)715-3171, fax (919)733-4127, email sshore@nccosmeticarts.com*

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

_____ State

Local

Substantive (≥\$3,000,000**)**

None None

SUBCHAPTER 14I - OPERATIONS OF SCHOOLS OF COSMETIC ART

SECTION .0100 – RECORD KEEPING

21 NCAC 14I .0105 TRANSFER OF CREDIT

(a) In order that hours may be transferred from one cosmetic art school to another, a student must pass an entrance examination given by the school to which the student is transferring.

(b) A cosmetology student must complete at least 500 hours in the cosmetic art school certifying his or her application for the state board examination.

(c) Upon written petition by the student, the Board shall make an exception to the requirements set forth in Paragraph (b) of this Rule if the student shows that circumstances beyond the student's control prohibited him or her from completing 500 hours at the school that certifies his or her application.

(d) A student who transfers from a cosmetology curriculum to a manicuring or an esthetics curriculum shall not receive credit for hours received in the cosmetology curriculum.

(e) A student who transfers from a manicurist or an esthetic curriculum to a cosmetology curriculum shall not receive credit for hours received in the manicurist or an esthetic curriculum.

(f) If a student is transferring from another state, the student shall submit certification of hours and performances to the cosmetic art school in which they are enrolled.

(g) Licensed manicurists and estheticians may apply up to 50 percent of required hours earned toward another cosmetic art discipline.

Authority G.S. 88B-4.

21 NCAC 14I .0108 SEAL

Each cosmetic art school must have an identifying seal, to be used on all applications, reports, drop-out notices, and other official papers. <u>Electronically sent enrollments and drop-out</u> notices are exempted from this requirement.

Authority G.S. 88-23; 88-30.

CHAPTER 46 – BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rule cited as 21 NCAC 46.3301.

Proposed Effective Date: June 1, 2006

Instructions on How to Demand a Public Hearing: (must be requested in writing within 15 days of notice): Persons may demand a public hearing by submitting a request for public hearing to David R. Work or Jay Campbell, NC Board of

NORTH CAROLINA REGISTER

Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Reason for Proposed Action: To clarify that the registration of a pharmacy technician expired more than 60 days must be reinstated pursuant to Rule .1612.

Procedure by which a person can object to the agency on a proposed rule: Persons may submit objections regarding the proposed rule changes to David R. Work or Jay Campbell, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Comments may be submitted to: David R. Work or Jay Campbell, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, 27517.

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

 □
 State

 □
 Local

 □
 Substantive (>\$3,000,000)

 ⊠
 None

SECTION .3300 – REGISTRATION OF A PHARMACY TECHNICIAN

21 NCAC 46 .3301 REGISTRATION

(a) Following initial registration with the Board, registration of a pharmacy technician shall be renewed annually and shall expire on December 31. It shall be unlawful to work as a pharmacy technician more than 60 days after expiration of the registration without renewing the registration. A registration expired more than 60 days may shall be renewed pursuant to 21 NCAC 46 .1612. upon written request and upon payment of the registration fee and a data processing fee of eleven dollars (\$11.00).

(b) The current registration of a pharmacy technician shall be readily available for inspection by agents of the Board.

(c) The training program described in G.S. 90-85.15A(b) is not required for students enrolled in a community college pharmacy technician program.

(d) Volunteer pharmacy technicians providing services at a facility which has a pharmacy permit designated as a free clinic shall complete the training program described in G.S. 90-85.15A(b) but need not register with the Board.

(e) A pharmacist may not supervise more than two pharmacy technicians unless the additional pharmacy technicians have passed a national pharmacy technician certification examination administered by a provider whose examination assesses the ability of the technicians to function in accordance with G.S. 90-85.3(q2) and approved by the Board according to these standards.

Authority G.S. 90-85.6; 90-85.15A; 150B-19(5)(e).

CHAPTER 50 – BOARD OF EXAMINERS OF PLUMBING, HEATING & FIRE SPRINKLER CONTRACTORS

Notice is hereby given in accordance with G.S. 150B-21.2 that the State Board of Examiners of Plumbing, Heating and Fire Sprinkler Contractors intends to adopt the rule cited as 21 NCAC 50 .0516 and amend the rules cited as 21 NCAC 50 .0301, .0506, and .1401.

Proposed Effective Date: June 1, 2006

Public Hearing: Date: April 11, 2006 Time: 8:30 a.m. Location: Offices of the State Board of Examiners of Plumbing, Heating and Fire Sprinkler Contractors, 1109 Dresser Court, Raleigh, NC 27609

Reason for Proposed Action: The Board, in response to a Petition for Rulemaking, wishes to hear public comment and debate on the desirability, feasibility, enforceability and public benefit of creating a limited license for persons desiring to engage in the business of contracting water heater installation as part of a plumbing system.

Procedure by which a person can object to the agency on a proposed rule: Any person desiring to comment upon or object to a proposed rule may do so either by appearing at the public hearing or in writing as set out below prior to the end of the comment period.

Comments may be submitted to: Sandra O'Brien, 1109 Dresser Court, Raleigh, NC 27609, phone (919)875-3612

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting

review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

	State
	Local
	Subst
\bowtie	None

Local Substantive (>\$3,000,000) None

SECTION .0300 - EXAMINATIONS

21 NCAC 50 .0301 **OUALIFICATIONS DETERMINED BY EXAMINATION**

(a) In order to determine the qualifications of an applicant, the Board shall provide an examination in writing or by computer in the following categories:

Plumbing Contracting, Class I Plumbing Contracting, Class II Heating, Group No. 1 - Contracting, Class I Heating, Group No. 1 - Contracting, Class II Heating, Group No. 2 - Contracting, Class I Heating, Group No. 3 - Contracting, Class I Heating, Group No. 3 - Contracting, Class II Fuel Piping

Limited residential water heater contractor

(b) Each applicant shall be required to read, interpret and provide answers to both the business and the technical parts of the examinations required by G.S. 87-21(b).

(c) Applicants for licensure as a fire sprinkler contractor, unlimited classification, must submit evidence of current certification by the National Institute for Certification and Engineering Technology (NICET) for Fire Protection Engineering Technician, Level III, subfield of Automatic Sprinkler System Layout as the prerequisite for licensure. Current certification by NICET is in lieu of separate examination conducted by the Board.

(d) After July 1, 2004, applicants for initial licensure in the Limited Fire Sprinkler Inspection Technician classification must submit evidence of Level II Certification in "Inspection and Testing of Water-based Protection Systems" by NICET in lieu of examination. License without examination shall be issued beginning July 1, 2003, and ending July 1, 2004, to applicants who meet the experience requirement in Rule .0306. Where certification based on NICET Level II certification was not required at the time of initial licensure, such certification must be obtained by December 31, 2005. After December 31, 2005, current NICET Level II certification is required as a condition of license renewal.

(e) After July 1, 2005, applicants for the Limited Fire Sprinkler Inspection Contractor classification must submit evidence of Level III certification in "Inspection and Testing of Water-based Fire Protection Systems" by NICET in lieu of examination.

License without examination shall be issued based on applications filed between July 1, 2003, and July 1, 2005, to applicants who meet the experience requirement in Rule .0306. Persons who obtain license by NICET certification must maintain such certification thereafter as a condition of license renewal.

(f) Applicants for license in the Limited Fire Sprinkler Maintenance classification are qualified based on maintenance experience, education and job classification set forth in Rule. 0306.

Authority G.S. 87-18; 87-21(a); 87-21(b).

SECTION .0500 - MINOR REPAIRS AND ALTERATIONS

21 NCAC 50 .0506 PLUMBING LICENSE **REQUIREMENTS AND MINOR REPAIRS AND** ALTERATIONS

(a) The connection of a factory installed and inspected mobile home drainage system to an existing approved premises sewer system, which premises sewer system extends from the septic tank or municipal sewer system, constitutes a minor repair or replacement. The connection of a factory installed mobile home water system to an existing potable water supply on the premises constitutes a minor repair or replacement.

(b) The initial installation or the subsequent replacement of a hot water heater in any structure requires a license as a in plumbing contracting contractor or as a Limited Water Heater Contractor.

The installation of a water purification system which (c) interrupts the potable water supply does not constitute a minor repair or replacement within the meaning of G.S. 87-21(c).

Any connection, repair, or alteration which requires (d) interruption of the potable water supply and if poorly performed creates risk of contamination of the potable water supply is not a minor repair, replacement or alteration.

Any connection, repair or alteration which if poorly (e) performed creates risk of fire or exposure to carbon monoxide, open sewage or other gases is not a minor repair, replacement or alteration.

(f) The failure to enumerate above any specific type of repair, replacement or alteration shall not be construed in itself to render said repair, replacement or alteration as minor within the meaning of G.S. 87-21(c).

Authority G.S. 87-18; 87-21(a)(1); 87-21(a)(5); 87-21(c).

21 NCAC 50 .0516 LIMITED RESIDENTIAL WATER HEATER CONTRACTOR LICENSE

, 2006, license in the limited water heater Beginning contractor classification is issued to persons who are not licensed as a plumbing contractor but who wish to engage in the business of contracting to perform or performing the installation in residential one and two family dwellings of hot water heaters with a storage capacity of less than 120 gallons and delivering water at a temperature less than 180 degrees together with lines for potable water to and from the appliance, each line not exceeding four feet in length and connected through the use of a threaded coupling.

Authority G.S. 87-21.

SECTION .1400 - CONTINUING EDUCATION

21 NCAC 50 .1401 CONTINUING EDUCATION REQUIREMENTS

(a) Beginning with renewals of license for years beginning on or after January 1, 2003, each holder of a Plumbing, Heating or Fuel Piping license, must have completed six hours of approved continuing education for each calendar year as a condition of license renewal.

(b) As part of and not in addition to the requirements set out in Paragraph (a) of this Rule, at least once every three calendar years, each applicant for license renewal, other than fire sprinkler licensees, must complete:

- (1) four hours instruction devoted entirely to N.C. building codes including recent changes or amendments to those codes;
- (2) a minimum of two hours instruction in system design;
- (3) a minimum of two hours instruction in system installation; and
- (4) two hours instruction in business courses such as business ethics, taxation, payroll, cash management, bid and contract preparation, customer relations or similar subjects.

(c) Courses must be in areas related to plumbing, heating and air conditioning contracting such as the technical and practical aspects of the analysis of plans and specifications, estimating costs, fundamentals of installation and design, equipment, duct and pipe sizing, code requirements, fire hazards and other subjects as those may relate to engaging in business as a plumbing, heating or fuel piping contractor or to plumbing or heating systems. No more than two hours annually may be dedicated to business ethics, taxation, payroll, cash management, bid and contract preparation, customer relations or similar subjects.

(d) Persons holding multiple qualifications from the Board must complete at least six hours annually, but are not required to take hours each year in each qualification. Licensees with multiple qualifications shall take instruction so as to remain current in all areas of contracting work in which actively engaged.

(e) Licenses may not be renewed without documentation of course attendance, course name, course number, content and teacher. Falsification or misstatement of continuing education information shall be grounds for failure to renew licenses and disciplinary action, including revocation or suspension of licenses.

(f) Continuing Education shall not be required of holders of Fire Sprinkler Contractor's licenses, licensed pursuant to the minimum requirements of certification for Level III, subfield of Automatic Sprinkler System Layout, National Institute for Certification of Engineering Technologies (NICET), or for persons holding NICET certification in Inspection and Testing of water-based Fire Protection Systems provided such persons submit evidence of continued compliance with the continuing education requirements of NICET. (g) Beginning with renewals of license on or after January 1, 2003, each holder of a Fire Sprinkler Contractors or Fire Sprinkler Inspection Contractor or Technician license not required to be current on the continuing education requirements of NICET must complete six hours of approved continuing education in areas related to fire sprinkler contracting during the preceding calendar year as a condition of license renewal. Licensees in the Limited Fire Sprinkler maintenance classification are required to the systems they maintain.

(h) Each holder of a limited water heater contractor license must complete four hours of approved continuing education during the preceding calendar year as a condition of license renewal.

Authority G.S. 87-21(b)(3); 87-22.

CHAPTER 65 – THERAPEUTIC RECREATION CERTIFICATION BOARD

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Recreational Therapy Licensure intends to adopt the rule cited as 21 NCAC 65 .0301.

Proposed Effective Date: June 1, 2006

Public Hearing:

Date: March 2, 2006 Time: 7:00pm Location: Dorothea Dix Hospital, Brown Bldg., 801 Biggs Drive, Raleigh, NC 27603

Reason for Proposed Action: *To establish permanent Rule for Educational Requirements under the newly adopted NC Recreational Therapy Licensure Act G.S. 90C.*

Procedure by which a person can object to the agency on a proposed rule: All written comments will be accepted by Becky Garrett, NC BRTL Executive Director at PO Box 67, Saxapahaw, NC 27340 until April 17, 2006.

Comments may be submitted to: *Becky Garrett, LRT/CTRS, PO Box 67, Saxapahaw, NC 27340, phone (336)212-1133*

Comment period ends: April 17, 2006

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or

facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact:

	State
	Local
	Substantive (>\$3,000,000)
\boxtimes	None

SECTION .0300 - REQUIREMENTS FOR LICENSURE

21 NCAC 65 .0301 MINIMUM LEVEL OF EDUCATION AND COMPETENCY FOR LICENSED RECREATIONAL THERAPIST

(a) For the purposes of G.S. 90C-27(a) an academic major is defined as a baccalaureate degree or higher in therapeutic recreation or recreational therapy or recreation and leisure studies, or recreation, or health and physical education, or health and human performance with a specialization, also known as an option, emphasis or concentration, in therapeutic recreation or recreational therapy from an college or university accredited by one if the accreditation bodies recognized by the United States Department of Education. The academic major must be verified by an official transcript. An academic major is defined by the following components:

(1)Coursework for a degree or specialization in therapeutic recreation or recreational therapy must reflect a minimum of three courses (nine semester hours) and as of July 1. 2006 December 31, 2007 four courses (12 semester hours) and as of July 1, 2010 five courses (15 semester hours) as established by this Rule in which the title, course description and course outline reflects therapeutic recreation or recreational therapy content according to the current National Council for Therapeutic Recreation Certification (NCTRC)© Job Study subsequent Analysis and any amendments and changes; For candidates for licensure who have passed the NCTRC examination and were certified by the NCTRC prior to December 31, 2002, a therapeutic recreation or recreational therapy content course taught is considered equivalent competency to taking a therapeutic recreation or recreational therapy content course. For candidates for licensure who have passed the NCTRC examination and were certified by the NCTRC prior to December 31, 2002, but have not taken or taught three therapeutic recreation or recreational therapy content courses will be licensed to practice as a recreational therapist with the requirement that they complete the number of recreational therapy or therapeutic recreation content courses they lack within a one year period from the date of licensure. During the time the required recreational therapy or therapeutic recreation courses are taken the recreational therapist must receive clinical supervision by a licensed recreational therapist to assure safe and effective practice. Once successful completion of the TR/RT courses is documented to NC BRTL clinical supervision is no longer required.

(2)Supportive coursework must include three semester hours of anatomy and physiology, three semester hours of abnormal psychology, three semester hours of human growth and development across lifespan, and nine semester hours in the area of health and human services. Health and human services course work may include content in the areas of education, ethics, and other supportive coursework relative to the practice of recreational therapy; Candidates who want to apply for licensure, but who lack required support content courses may be employed as a recreational therapy aide assisting in the provision of recreational therapy services while the required support content courses are completed. During this time, recreational therapy aides must act under the direction and on-site supervision of a LRT or LRTA and may perform related duties and functions of recreational therapy service provision that are commensurate with assessed competencies. Recreational Therapy Aides are not permitted to perform duties associated with independent practice as a recreational therapist or recreational therapy assistant, as defined by the ATRA Standards for the Practice of Therapeutic Recreation and Self-Assessment Guide.

(b) Field placement under the supervision of a North Carolina Licensed Recreational Therapist shall be a minimum of 480 hours. If the internship is done in a state other than North Carolina, supervision must be by a National Council for Therapeutic Recreation Certification Council (NCTRC) "Certified Therapeutic Recreation Specialist" who by January 15, 2008 meets the current North Carolina Board of Recreational Therapy Licensure (NCBRTL) requirements for licensure or by a North Carolina Therapeutic Recreation Certification Board Therapeutic Recreation Specialist. The field placement must be meet the criteria set forth by the National Council for Therapeutic Recreation Standards.

(1) Candidates for licensure who have completed all recreational therapy/therapeutic recreation content courses and all support content requirements and an internship out-of-state under an clinical supervisor who meets all requirements of G.S. 90C except the requirement to have the internship supervised by a clinical supervisor who is a Licensed Recreational Therapist (LRT), will be issued a license with the requirement that they complete a clinical experience requirement of 480 full time hours supervised by an LRT. During the supervised clinical experience the candidates may work as an LRT or LRTA with clinical supervision. The supervised clinical experience requirement must be completed within the first five months of the licensing period. Once the supervised clinical experience requirement documents the individual's competency for practice, the licensed recreational therapist may practice independently without clinical supervision by a LRT.

(c) Passing score of National Council for Therapeutic Recreation Certification (NCTRC) Examination is required.

Authority G.S. 90*C*-27(*a*).

Note from the Codifier: The rules published in this Section of the NC Register are temporary rules reviewed and approved by the Rules Review Commission (RRC) and have been delivered to the Codifier of Rules for entry into the North Carolina Administrative Code. A temporary rule expires on the 270^{th} day from publication in the Register unless the agency submits the permanent rule to the Rules Review Commission by the 270^{th} day.

This section of the Register may also include, from time to time, a listing of temporary rules that have expired. See G.S. 150B-21.1 and 26 NCAC 02C .0500 for adoption and filing requirements.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Rule-making Agency: Division of Facility Services

Rule Citation: 10A NCAC 14C .0203, .1501-.1505, .1601-.1603, .1605, .1901, .2101, .2103, .2203, .2502-.2503, .2505; .2602, .2701-.2705, .2801, .2806, .3501-.3502, .3504-.3505, .3702-.3704, .3901-.3906, .4001-.4005.

Effective Date: February 1, 2006

Date Approved by the Rules Review Commission: *January* 19, 2006

Reason for Action:

10A NCAC 14C .0203 – Several subject matters are addressed in the State Medical Facilities Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006.

10A NCAC 14C .1501-.1505 – Several subject matters are addressed in the State Medical Facilities Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to criteria and standards for Hospices.

10A NCAC 14C .1601-.1603; .1605 – Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for cardiac catheterization equipment and cardiac angioplasty equipment.

10A NCAC 14C .1901 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006.

This rule addresses changes to the criteria and standards for Radiation therapy equipment.

10A NCAC 14C .2101; .2103 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for surgical services and operating rooms.

10A NCAC 14C .2203 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. This rule addresses changes to the criteria and standards for End-Stage Renal Disease Services. **10A NCAC 14C .2502-.2503; .2505 -** Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Substance Abuse/Chemical Dependency Treatment beds.

10A NCAC 14C .2602 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. This rule addresses changes to the criteria and standards for Psychiatric beds.

10A NCAC 14C .2701-.2705 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Magnetic Resonance Imaging Scanner.

10A NCAC 14C .2801; .2806 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Rehabilitation Services.

10A NCAC 14C .3501-.3502, .3504-.3505 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Oncology Treatment centers.

10A NCAC 14C .3702-.3704 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Positron Emission Tomography Scanner.

10A NCAC 14C .3901-.3906 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Gastrointestinal Endoscopy procedure rooms in licensed health service facilities. 10A NCAC 14C .4001-.4005 - Several subject matters are addressed in the State Medical Faculties Plan (SMFP). Each year, changes to existing Certificate of Need rules are required to ensure consistency with the SMFP. The effective date of the 2006 SMFP is January 1, 2006. These rules address changes to the criteria and standards for Hospice Inpatient facilities and Hospice Residential Care facilities.

CHAPTER 14 – DIRECTOR, DIVISION OF FACILITY SERVICES

SUBCHAPTER 14C – CERTIFICATE OF NEED REGULATIONS

SECTION .0200 – APPLICATION AND REVIEW PROCESS

10A NCAC 14C .0203 FILING APPLICATIONS

(a) An application shall not be reviewed by the agency until it is filed in accordance with this Rule.

(b) An original and a copy of the application shall be <u>file-stamped</u> as received by the agency no later than 5:30 p.m. on the 15th day of the month preceding the scheduled review period. In instances when the 15th of the month falls on a weekend or holiday, the filing deadline is 5:30 p.m. on the next business day. An application shall not be included in a scheduled review if it is not received by the agency by this deadline. Each applicant shall transmit, with the application, a fee to be determined according to the following formula:

- (1) With each application proposing the addition of a sixth bed to an existing or approved five bed intermediate care facility for the mentally retarded, the proponent shall transmit a fee in the amount of two thousand dollars (\$2,000).
- (2) With each application, other than those referenced in Subparagraph (b)(1) of this Rule, proposing no capital expenditure or a capital expenditure of up to, but not including, one million dollars (\$1,000,000), the proponent shall transmit a fee in the amount of three thousand five hundred dollars (\$3,500).
- (3) With each application, other than those referenced in Subparagraph (b)(1) of this Rule, proposing a capital expenditure of one million dollars (\$1,000,000) or greater, the proponent shall transmit a fee in the amount of three thousand five hundred dollars (\$3,500), plus an additional fee equal to .003 of the amount of the proposed capital expenditure in excess of one million dollars (\$1,000,000). The additional fee shall be rounded to the nearest whole dollar. In no case shall the total fee exceed seventeen thousand five hundred dollars (\$17,500).

(c) After an application is filed, the agency shall determine whether it is complete for review. An application shall not be considered complete if:

(1) the requisite fee has not been received by the agency; or

(2) a signed original and copy of the application have not been submitted to the agency on the appropriate application form.

(d) If the agency determines the application is not complete for review, it shall mail notice of such determination to the applicant within five business days after the application is filed and shall specify what is necessary to complete the application. If the agency determines the application is complete, it shall mail notice of such determination to the applicant prior to the beginning of the applicable review period.

(e) Information requested by the agency to complete the application must be received by the agency no later than 5:30 p.m. on the last working day before the first day of the scheduled review period. The review of an application shall commence in the next applicable review period that commences after the application has been determined to be complete.

History Note: Authority G.S. 131E-177; 131E-182; Eff. October 1, 1981:

Temporary Amendment Eff. July 15, 1983, for a Period of 118 Days, to Expire on November 10, 1983;

Amended Eff. November 1, 1990: January 1, 1990;

Temporary Amendment Eff. August 11, 1993, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. December 1, 1994; January 4, 1994;

Temporary Amendment Eff. August 12, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Temporary Amendment Eff. January 1, 2000; Amended Eff. April 1, 2001; Temporary Amendment Eff. February 16, 2004; Amended Eff. August 1, 2004; Temporary Amendment Eff. February 1, 2006.

SECTION .1500 - CRITERIA AND STANDARDS FOR HOSPICES

10A NCAC 14C .1501 DEFINITIONS

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

- (1) "Bereavement counseling" means counseling provided to a hospice patient's family or significant others to assist them in dealing with issues of grief and loss.
- (2) "Caregiver" means the person whom the patient designates to provide the patient with emotional support, physical care, or both.
- "Care plan" means a plan as defined in 10A NCAC 13K .0102 of the Hospice Licensing Rules.
- (4) "Continuous care" means care as defined in 42 CFR 418.204, the Hospice Medicare Regulations.
- (5) "Home like" means furnishings of a hospice inpatient facility or a hospice residential care facility as defined in 10A NCAC 13K .1110 or .1204 of the Hospice Licensing Rules.
- (6)(5) "Homemaker services" means services provided to assist the patient with personal

care, maintenance of a safe and healthy environment and implementation of the patient's care plan.

- (7)(6) "Hospice" means any coordinated program of home care as defined in G.S. 131E-176(13a).
- (8)(7) "Hospice inpatient facility" means a facility as defined in G.S. 131E-176(13b).
- (9) "Hospice residential care facility" means a facility as defined in G.S. 131E-176(13c).
- (10) "Hospice service area" means for residential care facilities, the county in which the hospice residential care facility will be located and the contiguous counties for which the hospice residential care facility will provide services.
- (11)(8) "Hospice services" means services as defined in G.S. 131E-201(5b).
- (12)(9) "Hospice staff" means personnel as defined in 10A NCAC 13K .0102 of the Hospice Licensing Rules.
- (13)(10) "Interdisciplinary team" means personnel as defined in G.S. 131E-201(6).
- (14)(11) "Palliative care" means treatment as defined in G.S. 131E-201(8).
- (15)(12)"Respite care" means care provided as defined in 42 CFR 418.98.
- History Note: Authority G.S. 131E-177(1); Eff. July 1, 1994; Temporary Amendment Eff. January 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1502 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a hospice shall complete the application form for Hospice Services. An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall complete the application form for Hospice Inpatient and Hospice Residential Care Services.

(b) An applicant proposing to develop a hospice, hospice inpatient facility beds, or hospice residential care facility beds shall provide the following information:

- (1) the annual unduplicated number of hospice patients projected to be served in each of the first two years following completion of the project and the methodology and assumptions used to make the projections;
- (2) the projected number of <u>duplicated</u> hospice patients to be served by quarter for the first 24 months following completion of the project and the methodology and assumptions used to make the projections;
- (3) the projected number of patient care days, by level of care (i.e., routine home care, respite care, and inpatient care), by quarter, to be provided in each of the first two years of operation following completion of the project and the methodology and assumptions used to make the projections shall be clearly stated;

- (4) the projected number of hours of continuous care to be provided in each of the first two years of operation following completion of the project and the methodology and assumptions used to make these projections;
- (5) the projected average annual cost per hour of continuous care for each of the first two operating years following completion of the project and the methodology and assumptions used to make the projections;
- (6) the projected average annual cost per patient care day, by level of care (i.e., routine home care, respite care, and inpatient care), for each of the first two operating years following completion of the project and the methodology and assumptions used to project the average annual cost; and
- (7) documentation of attempts made to establish working relationships with sources of referrals to the hospice services and copies of proposed agreements for the provision of inpatient care.

(c) An applicant proposing to develop a hospice shall commit that it shall comply with all certification requirements for participation in the Medicare program within one year after issuance of the certificate of need.

(d) An applicant proposing to develop hospice inpatient or hospice residential care facility beds shall also provide the following information:

- (1) a description of the means by which hospice services shall be provided in the patient's own home;
- (2) copies of the proposed contractual agreements, with a licensed hospice or a licensed home care agency with a hospice designation on its license, for the provision of hospice services in the patient's own home;
- (3) a copy of the admission policies, including the criteria that shall be used to select persons for admission and to assure that terminally ill patients are served in their own homes as long as possible; and
- (4) documentation that a home like setting shall be provided in the facility.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. July 1, 1994;

Amended Eff. November 1, 1996;

Temporary Amendment Eff. January 1, 2003;

Amended Eff. August 1, 2004.

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1503 PERFORMANCE STANDARDS

(a) An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall demonstrate that:

> (1) the average occupancy rate of the licensed hospice beds in the facility is projected to be at least 50% for the last six months of the first

operating year following completion of the project;

- (2) the average occupancy rate for the licensed hospice beds in the facility is projected to be at least 65% for the second operating year following completion of the project; and
- (3) if the application is submitted to address the need for a hospice residential care facility, each existing facility which is located in the hospice service area and which has licensed hospice beds of the type proposed by the applicant attained an occupancy rate of at least 65% for the 12 month period reported on that facility's most recent Licensure Renewal Application Form.

(b) An applicant proposing to add beds to an existing hospice inpatient facility or hospice residential care facility shall document that the average occupancy of the licensed hospice inpatient and hospice residential care facility beds in its existing facility was at least 65% for the nine months immediately preceding the submittal of the proposal.

(c) An applicant proposing to develop a hospice shall demonstrate that no less than 80% of the total combined number of days of hospice care furnished to Medicaid and Medicare patients will be provided in the patients' residences in accordance with 42 CFR 418.302(f)(2).

History Note: Authority G.S. 131E-177(1); Eff. July 1, 1994; Temporary Amendment Eff. January 1, 1999; Temporary 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; Amended Eff. April 1, 2001; Temporary Amendment Eff. January 1, 2003;

Amended Eff. August 1, 2004;

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1504 SUPPORT SERVICES

(a) An applicant proposing to develop a hospice, hospice inpatient facility beds, or hospice residential care facility beds shall demonstrate that the following core services will be provided directly by the applicant to the patient and the patient's family or significant others:

- (1) nursing services;
- (2) social work services;
- (3) counseling services including dietary, spiritual, and family counseling;
- (4) bereavement counseling services;
- (5) volunteer services;
- (6) physician services; and
- (7) medical supplies.

(b) An applicant shall demonstrate that the nursing services listed in Paragraph (a) of this Rule will be available 24 hours a day, seven days a week.

(c) An applicant proposing to develop a hospice, hospice inpatient facility beds, or hospice residential care facility beds

shall provide documentation that the following services, when ordered by the attending physician and specified in the care plan, shall either be provided directly by the hospice or provided through a contract arranged by the hospice:

- (1) hospice inpatient care provided in a licensed hospice inpatient facility bed, licensed acute care bed or licensed nursing facility bed,
- (2) physical therapy,
- (3) occupational therapy,
- (4) speech therapy,
- (5) home health aide services,
- (6) medical equipment,
- (7) respite care,
- (8) homemaker services, and
- (9) continuous care.

(d) An applicant proposing to develop a hospice inpatient facility or a hospice residential care facility shall provide documentation that pharmaceutical services will be provided directly by the facility or by contract.

(e)(d) For each of the services listed in Paragraphs Paragraph (c) and (d) of this Rule which are proposed to be provided by contract, the applicant shall provide a copy of a letter from the proposed provider which expresses their interest in working with the proposed facility.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. July 1, 1994; Amended Eff. November 1, 1996; <u>Temporary Amendment Eff. February 1, 2006.</u>

10A NCAC 14C .1505 STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop a hospice, hospice inpatient facility beds, or hospice residential care facility beds shall document that staffing for hospice services will be provided in a manner consistent with G.S. 131E, Article 10.

- (b) The applicant shall demonstrate that:
 - the staffing pattern will be consistent with licensure requirements as specified in 10A NCAC 13K, Hospice Licensing Rules;
 - training for all hospice staff and volunteers will meet the requirements as specified in 10A NCAC 13K .0400, Hospice Licensing Rules;
 - a volunteer program will be established and operated in accordance with 10A NCAC 13K
 .0400 and .0500 and 42 CFR 418.70;
 - (4) an interdisciplinary team will be established which includes, at a minimum, a physician, a licensed nurse, a social worker, a clergy member, and a trained hospice volunteer, as specified in G.S. 131E-201;
 - (5) a qualified health care professional will coordinate the hospice interdisciplinary team to assure implementation of an integrated care plan and the continuous assessment of the needs of the patient and the patient's family or significant others;
 - (6) a written care plan will be developed by the attending physician, the medical director or

physician designee, and the interdisciplinary team before care is provided to a patient and the patient's family or significant others;

- (7) meetings of the interdisciplinary care team and other appropriate personnel will be held on a frequent and regular basis, at least once every two weeks, for the purpose of care plan review and staff support; and
- (8) each interdisciplinary team member will be provided orientation, training, and continuing education programs appropriate to their responsibilities and to the maintenance of skills necessary for the physical care of the patient and the psychosocial and spiritual care of the patient and the patient's family or significant others.

History Note: Authority G.S. 131E-177(1); Eff. July 1, 1994; Temporary Amendment Eff. February 1, 2006.

SECTION .1600 – CRITERIA AND STANDARDS FOR CARDIAC CATHETERIZATION EQUIPMENT AND CARDIAC ANGIOPLASTY EQUIPMENT

10A NCAC 14C .1601 DEFINITIONS

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

- (1) "Approved" means the equipment was not in operation prior to the beginning of the review period and had been issued a certificate of need.
- "Capacity" (2)of item cardiac an of catheterization equipment cardiac or means angioplasty--equipment 1500 diagnostic-equivalent procedures per year. One therapeutic cardiac catheterization procedure is valued at 1 75 diagnostic-equivalent procedures. One cardiac catheterization procedure performed on a patient age 14 or under is valued at two diagnostic-equivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure.
- (3) "Cardiac angioplasty equipment" shall have the same meaning as defined in G.S. 131E 176(2e).
- (4)(3) "Cardiac catheterization equipment" shall have the same meaning as defined in G.S. 131E-176(2f).
- (5)(4) "Cardiac catheterization procedure", for the purpose of determining utilization in a certificate of need review, means a single episode of diagnostic or therapeutic catheterization which occurs during one visit to a cardiac catheterization room, whereby a flexible tube is inserted into the patient's body and advanced into the heart chambers to perform a hemodynamic or angiographic examination or therapeutic intervention of the

left or right heart chamber, or coronary arteries. A cardiac catheterization procedure does not include a simple right heart catheterization for monitoring purposes as might be done in an electrophysiology laboratory, pulmonary angiography procedure, cardiac pacing through a right electrode catheter, temporary pacemaker insertion, or procedures performed in dedicated angiography or electrophysiology rooms.

- (6)(5) "Cardiac catheterization room" means a room or a mobile unit in which there is cardiac catheterization or cardiac angioplasty equipment for the performance of cardiac catheterization procedures. Dedicated angiography rooms and electrophysiology rooms are not cardiac catheterization rooms.
- (7)(6) "Cardiac catheterization service area" means a geographical area defined by the applicant, which has boundaries that are not farther than 90 road miles from the facility, if the facility has a comprehensive cardiac services program; and not farther than 45 road miles from the facility if the facility performs only diagnostic cardiac catheterization procedures; except that the cardiac catheterization service area of an academic medical center teaching hospital designated in 10A NCAC 14B shall not be limited to 90 road miles.
- (8)(7) "Cardiac catheterization services" means the provision of diagnostic cardiac catheterization procedures or therapeutic cardiac catheterization procedures performed utilizing cardiac catheterization equipment or cardiac angioplasty equipment in a cardiac catheterization room.
- (9)(8) "Comprehensive cardiac services program" means a cardiac services program which provides the full range of clinical services associated with the treatment of cardiovascular disease including community outreach, of cardiovascular emergency treatment illnesses, non-invasive diagnostic imaging modalities, diagnostic and therapeutic cardiac catheterization procedures, open heart surgery cardiac rehabilitation services. and Community outreach and cardiac rehabilitation services shall be provided by the applicant or through arrangements with other agencies and facilities located in the same city. All other components of a comprehensive cardiac services program shall be provided within a single facility.
- (10)(9) "Diagnostic cardiac catheterization procedure", for the purpose of determining utilization in a certificate of need review, means a cardiac catheterization procedure performed for the purpose of detecting and identifying defects or diseases in the coronary

arteries or veins of the heart, or abnormalities in the heart structure, but not the pulmonary artery.

- (11)(10) "Electrophysiology procedure" means a diagnostic or therapeutic procedure performed to study the electrical conduction activity of the heart and characterization of atrial ventricular arrhythmias.
- (12)(11) "Existing" means the equipment was in operation prior to the beginning of the review period.
- (13)(12) "High-risk patient" means a person with reduced life expectancy because of left main or multi-vessel coronary artery disease, often with impaired left ventricular function and with other characteristics as referenced in the American College of Cardiology/American Heart Association Guidelines for Cardiae Catheterization and Cardiae Catheterization Laboratories (1991) American College of Cardiology/ Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (June 2001) report.
- (14)(13) "Mobile equipment" means cardiac angioplasty equipment or cardiac catheterization equipment and transporting equipment which is moved to provide services at two or more host facilities.
- (15)(14) "Percutaneous transluminal coronary angioplasty (PTCA)" is one type of therapeutic cardiac catheterization procedure used to treat coronary artery disease in which a balloon-tipped catheter is placed in the diseased artery and then inflated to compress the plaque blocking the artery.
- (16)(15) "Primary cardiac catheterization service area" means a geographical area defined by the applicant, which has boundaries that are not farther than 45 road miles from the facility, if the facility has a comprehensive cardiac services program; and not farther than 23 road miles from the facility if the facility performs only diagnostic cardiac catheterization procedures; except that the primary cardiac catheterization service area of an academic medical center teaching hospital designated in 10A NCAC 14B shall not be limited to 45 road miles.
- (17)(16) "Therapeutic cardiac catheterization procedure", for the purpose of determining utilization in a certificate of need review, means a cardiac catheterization procedure performed for the purpose of treating or resolving anatomical or physiological conditions which have been determined to exist in the heart or coronary arteries or veins of the heart, but not the pulmonary artery.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 1, 1987;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. November 1, 1996; February 1, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary 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 1, 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;

Amended Eff. August 1, 2002;

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1602INFORMATION REQUIRED OFAPPLICANT

(a) An applicant that proposes to acquire cardiac catheterization or cardiac angioplasty equipment shall use the acute care facility/medical equipment application form.

(b) The applicant shall provide the following additional information based on the population residing within the applicant's proposed cardiac catheterization service area:

(1) the projected annual number of cardiac catheterization procedures, by CPT or ICD-9-CM codes, classified by adult diagnostic, adult therapeutic and pediatric cardiac catheterization procedure, to be performed in the facility during each of the first three years of operation following completion of the proposed project, including the methodology and assumptions used for these projections;

(2) documentation of the applicant's experience in treating cardiovascular patients at the facility during the past 12 months, including:

- (A) the number of patients receiving stress tests;
- (B) the number of patients receiving intravenous thrombolytic therapies;
- (C) the number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction;
- (D) the number of patients referred to other facilities for cardiac catheterization procedures or open heart surgery procedures, by type of procedure; and
- (E) the number of diagnostic and therapeutic cardiac catheterization procedures performed during the twelve month period reflected in the

most recent licensure form on file with the Division of Facility Services;

- (3) the number of cardiac catheterization patients, classified by adult diagnostic, adult therapeutic and pediatric, from the proposed cardiac catheterization service area that the applicant proposes to serve by patient's county of residence in each of the first three years of operation, including the methodology and assumptions used for these projections;
- (4) documentation of the applicant's projected sources of patient referrals that are located in the proposed cardiac catheterization service area, including letters from the referral sources that demonstrate their intent to refer patients to the applicant for cardiac catheterization procedures;
- (5) evidence of the applicant's capability to communicate with emergency transportation agencies and with an established comprehensive cardiac services program;
- (6) the number and composition of cardiac catheterization teams available to the applicant;
- documentation of the applicant's in-service training or continuing education programs for cardiac catheterization team members;
- (8) a written agreement with a comprehensive cardiac services program that specifies the arrangements for referral and transfer of patients seen by the applicant and that includes a process to alleviate the need for duplication in cardiac catheterization procedures;
- a written description of patient selection criteria including referral arrangements for high-risk patients;
- (10) a copy of the contractual arrangements for the acquisition of the proposed cardiac catheterization equipment or cardiac angioplasty equipment including itemization of the cost of the equipment; and
- (11)documentation that the cardiac catheterization equipment and cardiac angioplasty equipment and the procedures for operation of the equipment are designed and developed based College Americanthe ____f on Cardiology/American Heart Association Guidelines for Cardiac Catheterization Laboratories (1991) American College of Cardiology/ Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (June 2001) report.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. January 1, 1987;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Amended Eff. November 1, 1996; February 1, 1994; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) An applicant shall demonstrate that the project is capable of meeting the following standards:

- each proposed item of cardiac catheterization equipment or cardiac angioplasty equipment, including mobile equipment but excluding shared fixed cardiac catheterization or angioplasty equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;
- (2) if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;
- (3) if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;
- (4) at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;

(b) An applicant proposing to acquire mobile cardiac catheterization or mobile cardiac angioplasty equipment shall:

- (1) demonstrate that each existing item of cardiac catheterization equipment and cardiac angioplasty equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Facility Services;
- (2) demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment and cardiae angioplasty equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed cardiac catheterization, cardiac

angioplasty, or mobile <u>cardiac catheterization</u> equipment;

- (3) demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;
- (4) demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation; and
- (5) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

(c) An applicant proposing to acquire cardiac catheterization or cardiac angioplasty equipment excluding shared fixed and mobile cardiac catheterization or cardiac angioplasty equipment shall:

- (1) demonstrate that its existing items of cardiac catheterization and cardiac angioplasty equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80% of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Facility Services;
- (2) demonstrate that its existing items of cardiac catheterization equipment or cardiac angioplasty equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and
- (3) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

(d) An applicant proposing to acquire shared fixed cardiac catheterization or cardiac angioplasty equipment as defined in the applicable State Medical Facilities Plan shall:

- (1) demonstrate that each proposed item of shared fixed cardiac catheterization or cardiac angioplasty equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and
- (2) provide documentation of all assumptions and data used in the development of the projections required in this Rule.

(e) If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:

- (1) the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and
- (2) the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 1, 1987;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. November 1, 1996; February 1, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary 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;

Amended Eff. August 1, 2002;

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

August 1, 2002;

Amended Eff. April 1, 2003;

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .1605 STAFFING AND STAFF TRAINING

(a) The applicant shall provide documentation to demonstrate that the following staffing requirements shall be met:

- (1) one physician licensed to practice medicine in North Carolina who has been designated to serve as director of the cardiac catheterization service and who has all of the following special credentials:
 - (A) board-certified in internal medicine, pediatrics or radiology;
 - (B) subspecialty training in cardiology, pediatric cardiology, or cardiovascular radiology; and
 - (C) current clinical experience in performing physiologic procedures, angiographic procedures, or both;
- (2) at least one specialized team to perform cardiac catheterizations, composed of at least

the following professional and technical personnel:

- (A) one physician licensed to practice medicine in North Carolina with evidence of training and current experience specifically in cardiovascular disease and radiation sciences;
- (B) one nurse with training and current experience specifically in critical care of cardiac patients, cardiovascular medication, and catheterization equipment; and
- (C) at least three two technicians with training specifically in cardiac care who are capable of performing the duties of a radiologic technologist, cardiopulmonary technician, monitoring and recording technician, and darkroom technician.

(b) The applicant shall provide documentation to demonstrate that the following staff training shall be provided for members of cardiac catheterization teams:

- (1) certification in cardiopulmonary resuscitation and advanced cardiac life support; and
- (2) an organized program of staff education and training which is integral to the cardiac services program and ensures improvements in technique and the proper training of new personnel.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. January 1, 1987; Amended Eff. February 1, 1994; Temporary Amendment Eff. February 1, 2006.

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

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 special 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" means MRT equipment which is used to deliver a beam of electrons or photons in the treatment of cancer patients. 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.
- (14) "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.
- (15) "Simulator" means a machine that reproduces the geometric relationships of the MRT equipment to the patient. shall have the same meaning as defined in G.S. 131E-176(24b).
- (16) "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 2.0 1.0 ESTVs; 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.

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.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2101 DEFINITIONS

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

- (1) "Ambulatory surgical facility" means a facility as defined in G.S. 131E-176(1b).
- (2) "Operating room" means an inpatient operating room, an outpatient or ambulatory surgical operating room, <u>or</u> a shared operating room, or an endoscopy procedure room in a licensed health service facility. room.
- (3) "Ambulatory surgical program" means a program as defined in G.S. 131E-176(1c).
- (4) "Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals which were reported in

the License Application for Ambulatory Surgical Facilities and Programs and in Part III of Hospital Licensure Renewal Application Form submitted to the Licensure Section of the Division of Facility Services and which were licensed and certified prior to the beginning of the review period.

- (5) "Approved operating rooms" means those operating rooms that were approved for a certificate of need by the Certificate of Need Section prior to the date on which the applicant's proposed project was submitted to the Agency but that have not been licensed. and certified. licensed.
- (6) "Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).
- (7) "Outpatient or ambulatory surgical operating room" means an operating room used solely for the performance of surgical procedures which require local, regional or general anesthesia and a period of post-operative observation of less than 24 hours.
- (8) "Service area" means the Operating Room Service Area as defined in the applicable State Medical Facilities Plan.
- (9) "Shared operating room" means an operating room that is used for the performance of both ambulatory and inpatient surgical procedures.
- (10) "Specialty area" means an area of medical practice in which there is an approved medical specialty certificate issued by a member board of the American Board of Medical Specialties and includes, but is not limited to the following: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, urology, orthopedics, and oral surgery.
- (11) "Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24c).
- (12) "Surgical case" means an individual who receives one or more surgical procedures in an operating room during a single operative encounter.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. November 1, 1990;

Amended Eff. March 1, 1993;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. January 4, 1994;

Temporary Amendment Eff. January 1, 1999;

Temporary 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;

Amended Eff. April 1, 2001;

Temporary Amendment Eff. January 1, 2002; July 1, 2001; Amended Eff. August 1, 2002; Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the existing, approved and proposed operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, to increase the number of operating rooms (excluding dedicated Csection operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall not be approved unless the applicant documents that the average number of surgical cases per operating room to be performed in each facility owned by the applicant in the proposed service area, is reasonably projected to be at least 2.4 surgical cases per day for each inpatient operating room, room (excluding dedicated open-heart and dedicated C-Section operating rooms), 4.8 surgical cases per day for each outpatient or ambulatory surgical operating room, 7.2 cases per day for each endoscopy procedure room, and 3.2 surgical cases per day for each shared operating room during the third year of operation following completion of the project.

(c) A proposal to develop an additional operating room to be used as a dedicated C-section operating room shall not be approved unless the applicant documents that the average number of surgical cases per operating room to be performed in each facility owned by the applicant in the proposed service area, is reasonably projected to be at least 2.4 surgical cases per day for each inpatient operating room (excluding <u>dedicated</u> <u>open-heart and</u> dedicated C-section operating rooms), 4.8 surgical cases per day for each outpatient or ambulatory surgical operating room and 3.2 surgical cases per day for each shared operating room during the third year of operation following completion of the project.

(d) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently operating at 4.8 surgical cases per day for each outpatient or ambulatory surgical operating room, 7.2 gastrointestinal endoscopy cases per day for each gastrointestinal endoscopy procedure room, and 3.2 surgical cases per day for each shared operating room.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide documentation to show that each existing and approved ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty areas as proposed in the application is reasonably projected to be operating at 4.8 surgical cases per day for each outpatient or ambulatory surgical operating room, 7.2 <u>gastrointestinal</u> <u>endoscopy</u> cases per day for each <u>gastrointestinal</u> endoscopy procedure room, and 3.2 surgical cases per day for each shared surgical operating room prior to the completion of the proposed project.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. November 1, 1990;

Amended Eff. March 1, 1993;

Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Amended Eff. January 4, 1994;

Temporary Amendment Eff. January 1, 2002; July 1, 2001; Amended Eff. August 1, 2002;

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

Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005;

Amended Eff. November 1, 2005;

Temporary Amendment Eff. February 1, 2006.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility. facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination. stations.

(c) An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Temporary Adoption Eff. January 1, 2003; January 1, 2002; Eff. April 1, 2003; Amended Eff. August 1, 2004; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006.

SECTION .2500 – CRITERIA AND STANDARDS FOR SUBSTANCE ABUSE/CHEMICAL DEPENDENCY TREATMENT BEDS

10A NCAC 14C .2502 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish new intensive treatment beds or detoxification beds shall project resident origin by percentage by county of residence. All assumptions and the methodology for projecting occupancy shall be clearly stated.

(b) An applicant proposing to establish new intensive treatment beds or detoxification beds shall project an occupancy level for the entire facility for the first eight calendar quarters following the completion of the proposed project, including the average length of stay. All assumptions and the methodology for projecting occupancy shall be clearly stated.

(c) If the applicant is an existing chemical dependency treatment facility, the applicant shall document the percentage of patients discharged from the facility that are readmitted to the facility at a later date.

(d) An applicant shall document that the following items are currently available or will be made available following completion of the project:

- (1) admission criteria for clinical admissions to the facility or unit, including procedure for accepting emergency admissions;
- (2) client evaluation procedures, including preliminary evaluation and establishment of an individual treatment plan;
- (3) procedures for referral and follow-up of clients to necessary outside services;
- (4) procedures for involvement of family in counseling process;
- (5) provision of an aftercare plan; and
- (6) quality assurance/utilization review plan.

(e) An applicant proposing to establish new detoxification beds shall identify the location of each referral source for follow up outpatient, residential and rehabilitation services located in the proposed service area for clients who have completed detoxification.

(f)(e) An applicant shall document the attempts made to establish working relationships with the health care providers and others that are anticipated to refer clients to the proposed intensive treatment and detoxification beds.

 $(\underline{g})(\underline{f})$ An applicant shall provide copies of any current or proposed contracts or agreements or letters of intent to develop contracts or agreements for the provision of any services to the clients served in the chemical dependency treatment facility.

(h) An applicant shall identify the Area Authority that will serve as the Single Portal of Entry/Exit for the facility.

(i)(g) An applicant shall document the provisions that will be made to obtain services for patients with a dual diagnosis of chemical dependency and psychiatric problems.

(j)(h) An applicant proposing to establish new intensive treatment beds or detoxification beds shall specify the primary site on which the facility will be located. If such site is neither owned by nor under option by the applicant, the applicant shall provide a written commitment to diligently pursue acquiring the site if and when a certificate of need application is approved, shall specify at least one alternate site on which the facility could be located should acquisition efforts relative to the primary site

ultimately fail, and shall demonstrate that the primary site and alternate sites are available for acquisition.

(k)(i) An applicant proposing to establish new intensive treatment beds or detoxification beds shall document that the services will be provided in a physical environment that conforms with the requirements in 10A NCAC 27G .0300 which are incorporated by reference including all subsequent amendments.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996; <u>Temporary Amendment Eff. February 1, 2006.</u>

10A NCAC 14C .2503 PERFORMANCE STANDARDS

(a) An applicant shall not be approved unless the overall occupancy, over the nine months immediately preceding the submittal of the application, of the total number of intensive treatment beds and detoxification beds within the facility in which the beds are to be located, located except in facilities with only detoxification beds, has been:

- (1) 75 percent for facilities with a total of 1-15 intensive treatment beds and detoxification beds; or
- (2) 85 percent for facilities with a total of 16 or more intensive treatment beds and detoxification beds.

(b) An applicant shall not be approved unless the overall occupancy of the total number of intensive treatment beds and detoxification beds to be operated in the facility is projected, projected except in facilities with only detoxification beds, by the fourth quarter of the third year of operation following completion of the project, to be:

- (1) 75 percent for facilities with a total of 1-15 intensive treatment beds and detoxification beds; or
- (2) 85 percent for facilities with a total of 16 or more intensive treatment beds and detoxification beds.

(c) An applicant proposing to add detoxification beds to an existing facility that includes only detoxification beds shall not be approved unless the overall occupancy of the total number of detoxification beds in the facility has been at least 75 percent for the nine months immediately preceding the submittal of the application.

(d) An applicant proposing to establish a new detoxification facility or add detoxification beds to an existing facility that includes only detoxification beds shall demonstrate that the overall occupancy of the total number of detoxification beds in the facility is reasonably projected to be 75 percent by the fourth quarter of the third year of operation following completion of the project.

(e)(c) The applicant shall document the specific methodology and assumptions by which occupancies are projected, including the average length of stay and anticipated recidivism rate.

History Note: Authority G.S. 131E-177(1); 131E-183(b); Eff. November 1, 1996; Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003;

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .2505 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish new intensive treatment beds or detoxification beds shall document that clinical staff members will be:

- (1) currently licensed or certified by the appropriate state licensure or certification boards; or
- (2) supervised by staff who are licensed or certified by the appropriate state licensure or certification boards.

(b) An applicant proposing to establish new intensive treatment beds or detoxification beds shall document that the staffing pattern in the facility is consistent with the staffing requirements contained in 10A NCAC 27G .3102, .3202, or .3402, which are incorporated by reference including all subsequent amendments.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996; Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .2602 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish new psychiatric beds shall project resident origin by percentage by county of residence. All assumptions and the methodology for projecting occupancy shall be clearly stated.

(b) An applicant proposing to establish new psychiatric beds shall project an occupancy level for the entire facility for the first eight calendar quarters following the completion of the proposed project, including average length of stay. All assumptions and the methodology for projecting occupancy shall be clearly stated.

(c) The applicant shall provide documentation of the percentage of patients discharged from the facility that are readmitted to the facility at a later date.

(d) An applicant proposing to establish new psychiatric beds shall describe the general treatment plan that is anticipated to be used by the facility and the support services to be provided, including provisions that will be made to obtain services for patients with a dual diagnosis of psychiatric and chemical dependency problems.

(e) The applicant shall document the attempts made to establish working relationships with the health care providers and others that are anticipated to refer clients to the proposed psychiatric beds.

(f) The applicant shall provide copies of any current or proposed contracts or agreements or letters of intent to develop contracts or agreements for the provision of any services to the clients served in the psychiatric facility.

(g) The application shall identify the Area Authority that will serve as the Single Portal of Entry/Exit for the facility.

(h)(g) The applicant shall document that the following items are currently available or will be made available following completion of the project:

(1) admission criteria for clinical admissions to the facility or unit;

- (2) emergency screening services for the targeted population which shall include services for handling emergencies on a 24-hour basis or through formalized transfer agreements;
- (3) client evaluation procedures, including preliminary evaluation and establishment of an individual treatment plan;
- (4) procedures for referral and follow-up of clients to necessary outside services;
- (5) procedures for involvement of family in counseling process;
- (6) comprehensive services which shall include individual, group and family therapy; medication therapy; and activities therapy including recreation;
- (7) educational components if the application is for child or adolescent beds;
- (8) provision of an aftercare plan; and
- (9) quality assurance/utilization review plan.

(i)(h) An applicant proposing to establish new psychiatric beds shall specify the primary site on which the facility will be located. If such site is neither owned by nor under option by the applicant, the applicant shall provide a written commitment to diligently pursue acquiring the site if and when a certificate of need application is approved, shall specify at least one alternate site on which the facility could be located should acquisition efforts relative to the primary site ultimately fail, and shall demonstrate that the primary site and alternate sites are available for acquisition.

(j)(i) An applicant proposing to establish new psychiatric beds shall provide documentation to show that the services will be provided in a physical environment that conforms with the requirements in 10A NCAC 27G .0300.

History Note: Authority G.S. 131E-177(1); 131E-183; Eff. December 1, 1996;

Temporary Amendment Eff. February 1, 2006.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2701 DEFINITIONS

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

- (1) "Approved MRI scanner" means an MRI scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need.
- (2) "Capacity of fixed MRI scanner" means 100% of the procedure volume that the MRI scanner is capable of completing in a year, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm. Annual capacity of a fixed MRI scanner is 6,864 weighted MRI procedures, which assumes two weighted MRI procedures are performed per hour and the

scanner is operated 66 hours per week, 52 weeks per year.

- (3) "Capacity of mobile MRI scanner" means 100% of the procedure volume that the MRI scanner is capable of completing in a year, given perfect scheduling, no machine or room downtime, no cancellations, no patient transportation problems, no staffing or physician delays and no MRI procedures outside the norm. Annual capacity of a mobile MRI scanner is 4,160 weighted MRI procedures, which assumes two weighted MRI procedures are performed per hour and the scanner is operated 40 hours per week, 52 weeks per year.
- (4) "Dedicated breast MRI scanner" means an MRI scanner that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.
- (4)(5) "Existing MRI scanner" means an MRI scanner in operation prior to the beginning of the review period.
- (6) "Extremity MRI scanner" means an MRI scanner that is utilized for the imaging of extremities and is of open design with a field of view no greater than 25 centimeters.
- (5)(7) "Fixed MRI scanner" means an MRI scanner that is not a mobile MRI scanner.
- (6)(8) "Magnetic Resonance Imaging" (MRI) means a non-invasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.
- (7)(9) "Magnetic resonance imaging scanner" (MRI Scanner) is defined in G.S. 131E-176(14e).
- (8)(10) "Mobile MRI region" means either the eastern part of the State which includes the counties in Health Service Areas IV, V and VI, VI (Eastern Mobile MRI Region), or the western part of the State which includes the counties in Health Service Areas I, II, and HI. III (Western Mobile MRI Region). The counties in each Health Service Area are identified in Appendix A of the State Medical Facilities Plan.
- (9)(11) "Mobile MRI scanner" means an MRI scanner and transporting equipment which is moved at least weekly to provide services at two or more host facilities.
- (10)(12) "MRI procedure" means a single discrete MRI study of one patient.
- (11)(13) "MRI service area" means the Magnetic Resonance Imaging Planning Areas, as defined

in the applicable State Medical Facilities Plan, except for proposed new mobile MRI scanners for which the service area is a mobile MRI region.

- (12)(14) "MRI study" means one or more scans relative to a single diagnosis or symptom.
- (13) "Pediatric MRI patient" means a patient requiring an MRI scan who is under the age of 12 years or who is a special needs patient and is under the age of 21 years.
- (14)(15) "Related entity" means the parent company of the applicant, a subsidiary company of the applicant (i.e., the applicant owns 50% or more of another company), a joint venture in which the applicant is a member, or a company that shares common ownership with the applicant (i.e., the applicant and another company are owned by some of the same persons).
- (15) "Special Needs patient" means a patient who has cerebral palsy, encephalomyelopathy, central nervous system injuries, genetic and metabolic disorders, autism, and mental retardation.
- (16) "Temporary MRI scanner" means a an MRI scanner that the Certificate of Need Section has approved to be temporarily located in North Carolina at a facility that holds a certificate of need for a new fixed MRI scanner, but which is not operational because the project is not yet complete.
- (17) "Weighted MRI procedures" means MRI procedures which are adjusted to account for the length of time to complete the procedure, based on the following weights: one outpatient MRI procedure without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure with contrast or sedation is valued at 1.4 weighted MRI procedure without contrast or sedation is valued at 1.4 weighted MRI procedure without contrast or sedation is valued at 1.4 weighted MRI procedure without contrast or sedation is valued at 1.4 weighted MRI procedures; and one inpatient MRI procedure with contrast or sedation is valued at 1.8 weighted MRI procedures.
- "Weighted breast MRI procedures" means (18)MRI procedures which are performed on a dedicated breast MRI scanner and are adjusted to account for the length of time to complete the procedure, based on the following weights: one diagnostic breast MRI procedure is valued at 1.0 weighted MRI procedure (based on an average of 60 minutes per procedure), one MRI-guided breast needle localization MRI procedure is valued at 1.1 weighted MRI procedure (based on an average of 66 minutes per procedure), and one MRI-guided breast biopsy procedure is valued at 1.6 weighted MRI procedures (based on an average of 96 minutes per procedure).

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;

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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;

Amended Eff. August 1, 2002;

Temporary Amendment effective 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.

10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.

(b) Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the MRI service shall be named as co-applicants in the application form.

(c) An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:

- documentation that the proposed fixed MRI scanner, <u>excluding fixed extremity and breast</u> <u>MRI scanners</u>, shall be available and staffed for use at least 66 hours per week;
- (2) documentation that the proposed mobile MRI scanner shall be available and staffed for use at least 40 hours per week;
- (3) documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be available and staffed for use at least 40 hours per week;
- (3)(4) the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the professional fee is included in the charge, provide the dollar amount for the professional fee;

- (4)(5) if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the applicant to the contracting party for each of the first three years of operation;
- (5)(6) letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner and their estimate of the number of patients proposed to be referred per year; year, which is based on the physicians' historical number of referrals;
- (7) for each location at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed MRI scanners, projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project:
- (6)(8) for each location at which the service will be provided, applicant or a related entity will provide services, utilizing existing, approved, or proposed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of weighted MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;
- (7)(9) a detailed description of the methodology and assumptions used to project the number of <u>unweighted</u> weighted MRI procedures to be performed; performed at each location, including the number of contrast versus noncontrast procedures, sedation versus nonsedation procedures, and inpatient versus outpatient procedures;
- (8)(10) documentation to support each assumption used in projecting the number of procedures to be performed; a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;
- (9)(11) for each existing fixed or mobile MRI scanner owned by the applicant or a related entity and operated in North Carolina in the month the application is submitted, the vendor, tesla strength, serial number or vehicle CON identification number, project identification number, physical location for fixed MRI scanners, and host sites for mobile MRI scanners:
- (10)(12) for each approved fixed or mobile MRI scanner to be owned by the applicant or a related entity and approved to be operated in North Carolina, the proposed vendor, proposed tesla strength, CON project identification number, physical location for fixed MRI

scanners, and host sites for mobile MRI scanners;

- (11)(13) if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI scanner; and
- (14) identity of the accreditation authority the applicant proposes to use.

(d) An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner.

(e) An applicant proposing to acquire a dedicated fixed breast MRI scanner shall: shall demonstrate that:

- (1) provide a copy of a contract or working agreement with a radiologist or practice group that has experience interpreting images and is trained to interpret images produced by an MRI scanner configured exclusively for mammographic studies;
- (2) document that the applicant performed mammograms without interruption in the provision of the service during the last year; and
- (3) document that the applicant's existing mammography equipment is in compliance with the U.S. Food and Drug Administration Mammography Quality Standards Act.
- (1) it has an existing and ongoing working relationship with a specialized breast-imaging radiologist or radiology practice group that has experience interpreting breast images provided by mammography, ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI scanner configured exclusively for mammographic studies:
- (2) for the last twelve months it has performed the following services, without interruption in the provision of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms, breast ultrasound procedures, breast needle core biopsies, breast cyst aspirations, and pre-surgical breast needle localizations;
- (3) its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI scanner is in compliance with the federal Mammography Quality Standards Act;
- (4) it is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the geographic area proposed to be served by the applicant; and

(5) it has an existing relationship with an established collaborative team for the treatment of breast cancer that includes, radiologists, pathologists, radiation oncologists, hematologists/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

(f) An applicant proposing to acquire a dedicated fixed pediatric an extremity MRI scanner, <u>pursuant to a need determination in</u> the State Medical Facilities Plan for a demonstration project, shall:

- (1) provide a copy of a contract or working agreement with two pediatric radiologists qualified as described in 10A NCAC 14C .2705(f)(1);
- (2) provide a copy of the facility's emergency plan for pediatric and special needs patients that outline all emergency procedures including acute care transfers and a copy of a contract with an ambulance service for transportation during any emergencies;
- (3) commit that the proposed MRI scanner shall be used exclusively to perform procedures on pediatric MRI patients;
- (4) provide a description of the scope of the research studies that shall be conducted to develop protocols related to MRI scanning of pediatric MRI patients; which includes special needs patients, and
- (5) commit to prepare an annual report, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, which shall include the protocols for scanning pediatric MRI patients and the annual volume of weighted MRI procedures performed, by type.
- (1) provide a detailed description of the scope of the research studies that shall be conducted to demonstrate the convenience, cost effectiveness and improved access resulting from utilization of extremity MRI scanning;
- (2) provide projections of estimated cost savings from utilization of an extremity MRI scanner based on comparison of "total dollars received per procedure" performed on the proposed scanner in comparison to "total dollars received per procedure" performed on whole body scanners;
- (3) provide projections of estimated cost savings to the patient from utilization of an extremity MRI scanner;
- (4) commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
 - (A) a detailed description of the research studies completed;

- (B) a description of the results of the studies:
- (C) the cost per procedure to the patient and billing entity;
- (D) the cost savings to the patient attributed to utilization of an extremity MRI scanner;
- (E) an analysis of "total dollars received per procedure" performed on the extremity MRI scanner in comparison to "total dollars received per procedure" performed on whole body scanners; and
- (F) the annual volume of unweighted and weighted MRI procedures performed, by CPT code;
- (5) identify the operating hours of the proposed scanner;
- (6) provide a description of the capabilities of the proposed scanner;
- (7) provide documentation of the capacity of the proposed scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour;
- (8) identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;
- (9) provide copies of the operational and safety requirements set by the manufacturer; and
- (10) describe the specific criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.

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, 2003; January 1, 2002; 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.

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 <u>a controlling interest in</u> 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. 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.];
- (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 <u>a controlling interest in</u> 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 <u>a controlling interest in</u> and operates in the proposed mobile MRI region, <u>MRI service</u> <u>area</u> 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 <u>a controlling interest in</u> 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,

- (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,
- (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,
- (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
- (E) 4,805 weighted MRI procedures in <u>MI MRI</u> service areas in which the SMFP shows four or more fixed MRI scanners are located;
- (4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is 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,
 - (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,
 - (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,
 - (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
 - (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;
- (4)(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns <u>a controlling interest in</u> and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project. [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.];

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

(c) An applicant proposing to acquire a fixed <u>dedicated breast</u> magnetic resonance imaging (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:

- demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,716 1,664 weighted MRI procedures per year; which is .80 X 1 procedure per hour X 40 hours per week X 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 dedicated fixed pediatric 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:

- demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 2746 weighted MRI procedures (i.e., 80 percent of one procedure per hour, 66 hours per week, 52 weeks per year); 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(6), and
 - (2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

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;

Amended Eff. August 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.

10A NCAC 14C .2704 SUPPORT SERVICES

(a) An applicant proposing to acquire a mobile MRI scanner shall provide referral agreements between each host site and at least one other provider of MRI services in the proposed MRI service area geographic area to be served by the host site, to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site.

(b) An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall provide a written policy regarding pediatric sedation which outlines the criteria for sedating a pediatric patient, including the special needs patients, and identifies the staff that will administer and supervise the sedation process.

(c) An applicant proposing to acquire a dedicated fixed pediatric MRI scanner shall provide evidence of the availability of a pediatric code cart at the facility where the proposed pediatric MRI scanner will be located and a plan for emergency situations as described in 10A NCAC 14C .2702(f)(2).

(d)(b) An applicant proposing to acquire a fixed or mobile MRI scanner shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the American College of Radiology or a comparable accreditation authority, as determined by the Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.

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, 2005; Amended Eff. November 1 2005; Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .2705 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to provide the proposed services interpret the images who has had:

- (1) training in magnetic resonance imaging as an integral part of his or her residency training program; or
- (2) six months of supervised MRI experience under the direction of a certified diagnostic radiologist; or
- (3) at least six months of fellowship training, or its equivalent, in MRI; or
- (4) a combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule.

(b) An applicant proposing to acquire a dedicated fixed breast MRI scanner shall provide documentation that that: the radiologist is trained and has experience in interpreting images produced by an MRI scanner configured exclusively to perform mammographic studies.

- (1) the radiologist is trained and has specific expertise in breast imaging, including mammography, breast ultrasound and breast MRI procedures; and
- (2) two full time MRI technologists or two mammography technologists are available with specialized training in breast MRI imaging and that one of these technologists shall be present during the hours operation of the dedicated breast MRI scanner.

(c) An applicant proposing to acquire a MRI scanner, <u>including</u> <u>extremity but excluding dedicated breast MRI scanners</u>, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.

(d) An applicant proposing to acquire an MRI scanner, <u>including extremity and breast MRI scanners</u>, shall demonstrate that the following staff training is provided:

- American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and
- (2) the availability of an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel.

(e) An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraphs Paragraph (a) and (c) of this Rule shall be met at each host facility. facility, and that one full time MRI technologist-radiographer shall be present at each host facility during all hours of operation of the proposed mobile MRI scanner.

(f) An applicant proposing to acquire a dedicated fixed pediatric an extremity MRI scanner scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, also shall provide:

- (1) provide documentation of the availability of at least two radiologists, certified by the American Board of Radiology, with a pediatric fellowship or two years of specialized training in pediatrics;
- (2)(1) provide evidence that the applicant will have at least one licensed physician <u>shall be</u> on-site during the hours of operation of the proposed MRI scanner;
- (3) provide documentation that the applicant will employ at least two licensed registered nurses and that one of these nurses shall be present during the hours of operation of the proposed MRI scanner;
- (4)(2) provide a description of a research group for the project including a radiologist, neurologist, pediatric sedation specialist orthopaedic surgeon, and research coordinator; and
- (5) provide documentation of the availability of the research group to conduct research studies on the proposed MRI scanner; and

(6)(3) provide letters from the proposed members of the research group indicating their qualifications, experience and willingness to participate on the research team.

(g) An applicant proposing to perform cardiac MRI procedures shall provide documentation of the availability of a radiologist, certified by the American Board of Radiology, with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies.

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, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. January 1, 2005; Amended Eff. November 1, 2005; Temporary Amendment Eff. February 1, 2006.

SECTION .2800 - CRITERIA AND STANDARDS FOR REHABILITATION SERVICES

10A NCAC 14C .2801 DEFINITIONS

The definitions in this Rule will apply to all rules in this Section.

- (1) "Rehabilitation Facility" means a facility as defined in G.S. 131E-176.
- (2) "Rehabilitation" means the process to maintain, restore or increase the function of disabled individuals so that an individual can live in the least restrictive environment, consistent with his or her objective.
- (3) "Outpatient Rehabilitation Clinic" is defined as a program of coordinated and integrated outpatient services, evaluation, or treatment with emphasis on improving the functional level of the person in coordination with the patient's family.
- (4) "Rehabilitation Beds" means inpatient beds for which a need determination is set forth in 10 NCAC <u>14B</u> the current State Medical Facilities Plan and which are located in a hospital licensed pursuant to G.S. <u>131E 77 or a nursing facility licensed pursuant to G.S.</u> <u>131E 102.</u> G.S. <u>131E-77.</u>
- (5) "Traumatic Brain Injury" is defined as an insult to the brain that may produce a diminished or altered state of consciousness which results in impairment of cognitive abilities or physical functioning. It can also result in the disturbance of behavioral or emotional functioning. These impairments may be either temporary or permanent and cause partial or total functional disability or psychological maladjustment.
- (6) "Stroke" (cerebral infarction, hemorrhage) is defined as the sudden onset of a focal

neurologic deficit due to a local disturbance in the blood supply to the brain.

- (7) "Spinal Cord Injury" is defined as an injury to the spinal cord that results in the loss of motor or sensory function.
- (8) "Pediatric Rehabilitation" is defined as inpatient rehabilitation services provided to persons 14 years of age or younger.

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. May 1, 1991; Amended Eff. February 1, 1993; Temporary Amendment Effective February 1, 2006.

10A NCAC 14C .2806 QUALITY OF SERVICES

A proposal to add rehabilitation beds to an existing facility shall document that the facility has not operated on a provisional license beyond the effective date of the initial provisional license issued for a new operator, received an administrative penalty or had its admissions suspended within the 18 month period immediately preceding the submittal of the certificate of need application.

History Note: Authority G.S. 131E-177; 131E-183(b); Eff. May 1, 1991; Temporary Repeal Eff. February 1, 2006.

SECTION .3500 - CRITERIA AND STANDARDS FOR ONCOLOGY TREATMENT CENTERS

10A NCAC 14C .3501 DEFINITIONS

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

- (1) "Major medical equipment" is defined in G.S. 131E 176(14f).
- (2) "Medical equipment" means equipment used by the oncology treatment center to diagnose or treat disease or injury in patients, including major medical equipment.
- (3) "Medical oncologist" is a physician with a special interest in and competence in managing patients with cancer.
- (4) "Medicine Oncology" means a clinical medical specialty with a specific involvement with the treatment of tumors.
- (5) "Oncology diagnostic services" means those services which include, but are not limited to, procedures using diagnostic radiology and imaging techniques, clinical and pathological laboratory tests, or physical examination to obtain information from which a diagnosis is established.
- (6) "Oncology evaluation services" means the compilation of all diagnostic test results and consultation reports for the development of a patient specific treatment plan to provide curative or palliative cancer treatment.
- (7) "Oncology treatment center" is defined in G.S. 131E 176(18a).
- (8) "Oncology treatment center service area" means the geographic area defined by the applicant from which patients will originate who will receive the health services proposed.
- (9) "Oncology treatment services" means curative or palliative services provided to cancer patients which involve the use of radiation therapy, chemotherapy or other treatment techniques.
- (10) "Radiation oncologist" means a medical physician with a special interest, training and competence in managing patients with cancer who is certified by the American Board of Radiology or its equivalent.
- (11) "Radiology-Oncology" means a clinical medical specialty involving the treatment of tumors, particularly as they relate to treatment with ionizing radiation.

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994. <u>Temporary Repeal Eff. February 1, 2006.</u>

10A NCAC 14C .3502 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new oncology treatment center shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant shall also submit the following additional information:

- (1) documentation of the number of existing oncology treatment centers and other health service facilities which provide similar services in the proposed oncology treatment center's service area;
- (2) a list of the medical/surgical specialties in the existing oncology treatment centers and other health service facilities which provide similar services in the proposed oncology treatment center service area, such as Radiation-Oncology, Medicine Oncology, and surgical specialties;
- (3) a list of the medical equipment that is proposed to be acquired;
- (4) documentation verifying the actual cost or market value of each item of medical equipment, whichever is greater;
- (5) documentation that the proposed services shall result in an integrated multidisciplinary effort to diagnose and treat patients' clinical and psychosocial needs;
- (6) a list of all oncology diagnostic, oncology evaluation, and oncology treatment services that shall be available, and documentation demonstrating the means by which these services shall be provided;

- (7) documentation that coordination and referral agreements exist with a hospital, referring physicians, and surgical and medical specialists and subspecialists; and
- (8) documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

(c) An applicant proposing to acquire radiation therapy equipment shall document compliance with 10A NCAC 14C .1900, Criteria and Standards for Radiation Therapy Equipment.

(d) An applicant proposing to develop a new oncology treatment center shall provide:

- (1) the number of patients that are projected to use the service, by diagnosis;
- (2) the number of patients that are projected to use the service, by county of residence;
- (3) documentation of the maximum number of procedures that the equipment in the facility is capable of performing and the assumptions used to determine the maximum number of procedures;
- (4) quarterly projected utilization of the applicant's new equipment for each of the first three years after the completion of the project;
- (5) documentation of the effect the new oncology treatment center may have on existing oncology treatment centers and other health service facilities which provide similar services in the proposed oncology treatment center service area; and
- (6) all the assumptions and data supporting the methodology used to make the above projections.

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183; Eff. January 4, 1994; Amended Eff. November 1, 1996. Temporary Repeal Eff. February 1, 2006.

10A NCAC 14C .3504 SUPPORT SERVICES

(a) An applicant proposing to develop an oncology treatment center shall document that the following services will be available to the center:

(1)medical oncology services; (2)radiation oncology services; diagnostic radiology services; (3)nuclear medicine services; (4)(5)hospice and home health services; (6) psychology and social services; (7)pharmaceutical services; (8) pathology services; (9) transportation services; and (10)tumor registry services.

(b) An applicant proposing to develop an oncology treatment center shall specify whether any services other than those listed in Paragraph (a) of this Rule will be available to the center and shall list those additional services.

(c) An applicant proposing to develop an oncology treatment center shall list the types of surgical specialties which will be available to the center.

(d) An applicant proposing to develop an oncology treatment center for the provision of medical-oncology services shall document that the following services will be available in the center:

(1) pharmaceutical services; and

(2) pathology services.

(e) An applicant proposing to develop an oncology treatment center for the provision of radiation-oncology services shall document that diagnostic radiology services will be available in the center.

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994. Temporary Repeal Eff. February 1, 2006.

10A NCAC 14C .3505 STAFFING AND STAFF TRAINING

An applicant proposing to establish a new oncology treatment center shall provide the following information:

- (1) the medical specialties and board certification status of each physician who will provide services in the proposed center. An applicant shall also provide documentation of at least the following types of physicians:
 - (a) if proposing radiation therapy services, a radiation oncologist;
 - (b) if proposing radiation therapy services, access to a medical oncologist;
- (2) a description of the special training and specialty certification which will be required of all registered nurses who will be employed by the center;
- (3) documentation to show the types and numbers of staff, particularly qualified medical technologists and medical staff, that shall be available to support the services and an explanation as to why these staff are adequate to provide the proposed services; and
- (4) documentation to demonstrate that a formal training program exists to ensure the continued proficiency of the professional and technical staff.

History Note: Filed as a Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner; Authority G.S. 131E-177(1); 131E-183(b); Eff. January 4, 1994; Temporary Repeal Eff. February 1, 2006.

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

10A NCAC 14C .3702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated:

- (1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by clinical area (e.g., oncology, cardiology), and all methodologies and assumptions used in making the projections shall be provided.
- (2) Documentation that all of the following services were provided, at each facility where the PET scanner will be operated, continuously throughout the 12 months immediately prior to the date on which the application is filed:
 - (A) nuclear medicine imaging services;
 - (B) single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);
 - (C) magnetic resonance imaging scans;
 - (D) computerized tomography scans;
 - (E) cardiac angiography;
 - (F) cardiac ultrasound; and
 - (G) neuroangiography.
- (3) Documentation that the facility will:
 - (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate; and
 - (B) provide scheduled hours of operation for the PET scanner of a minimum of 12 hours per day, six days a week, except for mobile scanners; and scanners.
 - (C) implement a referral system which shall include a feedback mechanism of providing patient information to the referring physician and facility.
- (4) A description of the protocols that will be established to assure that all clinical PET procedures performed are medically necessary

and cannot be performed using other, less expensive, established modalities.

(c) An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.

(d) An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.

(e) An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.

(f) An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers manufacturer's specifications, and licensing requirements. The following shall be addressed:

- (1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents;
- (2) quality control measures and assurance of PET tomograph tomography and associated instrumentation;
- (3) radiation protection and shielding;
- (4) radioactive emission to the environment; and
- (5) radioactive waste disposal.

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;

Temporary Amendment Eff. January 1, 2002;

Temporary Amendment effective January 1, 2002 amends and replaces a permanent rulemaking originally proposed to be effective August 1, 2002;

Amended Eff. April 1, 2003;

Temporary Amendment Eff. February 1, 2006.

10A NCAC 14C .3703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:

- the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 3,200 2,080 PET procedures by the end of the third year following completion of the project;
- (2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of at least 3,200 2,080 PET procedures per PET scanner in the last year; and

(3) its existing and approved dedicated PET scanners shall perform an average of at least 3,200 2.080 PET procedures per PET scanner during the third year following completion of the project.

(b) The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.

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;

Temporary Amendment Eff. January 1, 2002; January 1, 2001; Amended Eff. August 1, 2002; Temporary Amendment effective 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.

10A NCAC 14C .3704 SUPPORT SERVICES

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document how medical emergencies within the PET scanner unit will be managed at each facility where the PET scanner will be operated.

(b)(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that radioisotopes shall be acquired from one or more of the following sources and shall identify the sources which will be utilized by the applicant:

- (1) an off-site medical cyclotron and radioisotope production facility that is located within two hours transport time to each facility where the PET scanner will be operated;
- (2) an on-site rubidium-82 generator; or
- (3) an on-site medical cyclotron for radio nuclide production and a chemistry unit for labeling radioisotopes.

(c)(b) An applicant proposing to acquire an on-site cyclotron for radioisotope production shall document that these agents are not available or cannot be obtained in an economically cost effective manner from an off-site cyclotron located within 2 hours total transport time from the applicant's facility.

(d)(c) An applicant proposing to develop new PET scanner services, including mobile PET scanner services, shall establish a clinical oversight committee at each facility where the PET scanner will be operated before the proposed PET scanner is placed in service that shall:

- (1) develop screening criteria for appropriate PET scanner utilization;
- (2) review clinical protocols;
- (3) review appropriateness and quality of clinical procedures;
- (4) develop educational programs; and

(5) oversee the data collection and evaluation activities of the PET scanning service.

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;

Temporary Amendment Eff. January 1, 2002; Amended Eff. April 1, 2003; Temporary Amendment Eff. February 1, 2006.

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

10A NCAC 14C .3901 DEFINITIONS

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

- (1) "Ambulatory surgical facility" means a facility as defined in G.S. 131E-176(1b).
- (2) "Gastrointestinal (GI) endoscopy room" means a room as defined in G.S. 131E-176(7d) that is used to perform one or more GI endoscopy procedures.
- (3) "Gastrointestinal (GI) endoscopy procedure" means a single procedure, identified by CPT code or ICD-9-CM procedure code, performed on a patient during a single visit to the facility for diagnostic or therapeutic purposes.
- (4) "Operating room" means a room as defined in G.S. 131E-176(18c).
- (5) "Related entity" means the parent company of the applicant, a subsidiary company of the applicant (i.e., the applicant owns 50 percent or more of another company), a joint venture in which the applicant is a member, or a company that shares common ownership with the applicant (i.e., the applicant and another company are owned by some of the same persons).
- (6) "Service area" means the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.

History Note: Authority G.S. 131E-177(1); 131E-183(b); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .3902INFORMATION REQUIRED OFAPPLICANT

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information:

(1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906;

- (2) with regard to services provided in the applicant's GI endoscopy rooms, identify:
 - (A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located;
 - (B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area;
 - (C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months;
 - (D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project
 - (E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months;
 - (F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project;
 - (G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months; and,
 - (H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project:
- (3) with regard to services provided in the applicant's operating rooms identify:
 - (A) the number of existing operating rooms in the facility;
 - (B) the number of procedures by type performed in the operating rooms in the last 12 months; and
 - (C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project;
- (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located;
- (5) if an applicant is an existing facility, the type and average facility charge for each of the ten GI endoscopy procedures most commonly

performed in the facility during the preceding 12 months;

- (6) the type and projected average facility charge for the ten GI endoscopy procedures which the applicant projects will be performed most often in the facility;
- (7) <u>a list of all services and items included in each</u> <u>charge, and a description of the bases on</u> <u>which these costs are included in the charge:</u>
- (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges;
- (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the ten GI endoscopy procedures most commonly performed in the facility during the preceding 12 months; and,
- (10) the average reimbursement projected to be received for each of the ten GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:

- (1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;
- (2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;
- (3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;
- (4) a written description of patient selection criteria including referral arrangements for high-risk patients;
- (5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;
- (6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.

History Note: Authority G.S. 131E-177; 131E-183(b); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .3903 PERFORMANCE STANDARDS

(a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.

(d) If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:

- (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or
 - (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.

(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.

History Note: Authority G.S. 131E-177; 131E-183(b); Temporary Adoption Eff. February 1, 2006.

10A NCAC 14C .3904 SUPPORT SERVICES

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.

(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.

(d) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:

- (1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county;
- (2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges; and
- (3) documentation of a transfer agreement with a hospital in case of an emergency.

History Note: Authority G.S. 131E-177; 131E-183(b); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas:

(1) administration;

- (2) pre-operative;
- (3) post-operative;
- (4) procedure rooms;
- (5) equipment cleaning, safety, and maintenance; and
- (6) other.

(b) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.

(c) The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility. (d) If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:

- (1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;
 - (2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;
 - (3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;
 - (4) at least one registered nurse shall be employed per procedure room;
 - (5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,
 - (6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.

History Note: Authority G.S. 131E-177; 131E-183(b); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .3906 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project.

(c) If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall:

- (1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.
- (2) provide a floor plan of the proposed facility identifying the following areas:

 (A) receiving/registering area;
 (B) waiting area;
 - (C) pre-operative area;

(D) procedure room by type; and

- (E) recovery area.
- (3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,
- (4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.

History Note: Authority G.S. 131E-177; 131E-183(b); <u>Temporary Adoption Eff. February 1, 2006.</u>

SECTION .4000 - CRITERIA AND STANDARDS FOR HOSPICE INPATIENT FACILITIES AND HOSPICE RESIDENTIAL CARE FACILITIES

10A NCAC 14C .4001 DEFINITIONS

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

- (1) "Bereavement counseling" means counseling provided to a hospice patient's family or significant others to assist them in dealing with issues of grief and loss.
- (2) "Caregiver" means the person whom the patient designates to provide the patient with emotional support, physical care, or both.
- (3) "Care plan" means a plan as defined in 10A NCAC 13K .0102 of the Hospice Licensing Rules.
- (4) "Home-like" means furnishings of a hospice inpatient facility or a hospice residential care facility as defined in 10A NCAC 13K .1110 or .1204 of the Hospice Licensing Rules.
- (5) "Hospice" means any coordinated program of home care as defined in G.S. 131E-176(13a).
- (6) "Hospice inpatient facility" means a facility as defined in G.S. 131E-176(13b).
- (7) "Hospice residential care facility" means a facility as defined in G.S. 131E-176(13c).
- (8) "Hospice service area" means for residential care facilities, the county in which the hospice residential care facility will be located and the contiguous counties for which the hospice residential care facility will provide services.
- (9) "Hospice services" means services as defined in G.S. 131E-201(5b).

(10) "Hospice staff" means personnel as defined in <u>10A NCAC 13K .0102 of the Hospice</u> <u>Licensing Rules.</u>

History Note: Authority G.S. 131E-177(1); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .4002 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall complete the application form for Hospice Inpatient and Hospice Residential Care Services.

(b) An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall provide the following information:

- (1) the projected number of hospice patients, by level of care (i.e., hospice residential care and hospice inpatient care), to be served in the facility by quarter for the first 24 months following completion of the project and the methodology and assumptions used to make the projections:
 - (2) the projected number of patient care days, by level of care (i.e., hospice residential care and hospice inpatient care), by quarter, to be provided in each of the first two years of operation following completion of the project and the methodology and assumptions used to make the projections shall be stated;
 - (3) the projected average annual cost per patient care day, by level of care (i.e., hospice residential care and hospice inpatient care) for each of the first two operating years following completion of the project and the methodology and assumptions used to project the average annual cost; and
 - (4) documentation of attempts made to establish working relationships with sources of referrals to the hospice facility including copies of proposed agreements for the provision of inpatient care and residential care.

(c) An applicant proposing to develop hospice inpatient or hospice residential care facility beds shall also provide the following information:

- (1) copies of the proposed contractual agreements, if the applicant is not a licensed hospice, with a licensed hospice or a licensed home care agency with a hospice designation on its license, for the provision of hospice services;
 - (2) documentation of the projected payor mix from the referring hospices, if the applicant is not a licensed hospice;
 - (3) a copy of the admission policies, including the criteria that shall be used to select persons for admission; and
 - (4) documentation that a home-like setting shall be provided in the facility.

TEMPORARY RULES

History Note: Authority G.S. 131E-177(1); 131E-183; Temporary Adoption Eff. February 1, 2006.

10A NCAC 14C .4003 PERFORMANCE STANDARDS

(a) An applicant proposing to develop hospice inpatient facility beds or hospice residential care facility beds shall demonstrate that:

- (1) the average occupancy rate of the licensed hospice beds in the facility is projected to be at least 50 percent for the last six months of the first operating year following completion of the project;
- (2) the average occupancy rate for the licensed hospice beds in the facility is projected to be at least 65 percent for the second operating year following completion of the project; and
- (3) if the application is submitted to address the need for a hospice residential care facility, each existing facility which is located in the hospice service area and which has licensed hospice beds of the type proposed by the applicant attained an occupancy rate of at least 65 percent for the 12 month period reported on that facility's most recent Licensure Renewal Application Form.

(b) An applicant proposing to add beds to an existing hospice inpatient facility or hospice residential care facility shall document that the average occupancy of the licensed hospice inpatient and hospice residential care facility beds in its existing facility was at least 65 percent for the nine months immediately preceding the submittal of the proposal.

History Note: Authority G.S. 131E-177(1); <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .4004 SUPPORT SERVICES

(a) An applicant proposing to develop a hospice inpatient facility beds or hospice residential care facility beds shall demonstrate that the following services will be provided directly by the applicant or by a contracted hospice to the patient and the patient's family or significant others:

- (1) nursing services;
- (2) social work services;
- (3) counseling services including dietary, spiritual, and family counseling;
- (4) bereavement counseling services;
- (5) volunteer services;
- (6) physician services; and
- (7) medical supplies.

(b) An applicant shall demonstrate that the nursing services listed in Paragraph (a) of this Rule will be available 24 hours a day, seven days a week.

(c) An applicant proposing to develop a hospice inpatient facility or a hospice residential care facility shall provide documentation that pharmaceutical services will be provided directly by the facility or by contract.

(d) For each of the services listed in Paragraphs (a) and (c) of this Rule which are proposed to be provided by contract, the applicant shall provide a copy of a letter from the proposed provider which expresses its interest in working with the proposed facility.

History Note: Authority G.S. 131E-177(1); 131E-183; <u>Temporary Adoption Eff. February 1, 2006.</u>

10A NCAC 14C .4005 STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop a hospice inpatient facility beds or hospice residential care facility beds shall document that staffing will be provided in a manner consistent with G.S. 131E, Article 10.

(b) The applicant shall demonstrate that:

- (1) the staffing pattern will be consistent with licensure requirements as specified in 10A NCAC 13K, Hospice Licensing Rules;
- (2) training for all staff will meet the requirements as specified in 10A NCAC 13K .0400, Hospice Licensing Rules.

History Note: Authority G.S. 131E-177(1); <u>Temporary Adoption Eff. February 1, 2006.</u>

RULES REVIEW COMMISSION

This Section contains information for the meeting of the Rules Review Commission on Thursday February 16, 2006, 10:00 a.m. at 1307 Glenwood Avenue, Assembly Room, Raleigh, NC. Anyone wishing to submit written comment on any rule before the Commission should submit those comments to the RRC staff, the agency, and the individual Commissioners. Specific instructions and addresses may be obtained from the Rules Review Commission at 919-733-2721. Anyone wishing to address the Commission should notify the RRC staff and the agency at least 24 hours prior to the meeting.

RULES REVIEW COMMISSION MEMBERS

Appointed by Senate Jim R. Funderburke - 1st Vice Chair David Twiddy - 2nd Vice Chair Thomas Hilliard, III Robert Saunders Jeffrey P. Gray Appointed by House Jennie J. Hayman - Chairman Graham Bell Lee Settle Dana E. Simpson John Tart

RULES REVIEW COMMISSION MEETING DATES

February 16, 2006 April 20, 2006

March 16, 2006 May 18, 2006

RULES REVIEW COMMISSION JANUARY 19, 2006 MINUTES

The Rules Review Commission met on Thursday, January 19, 2006, in the Assembly Room of the Methodist Building, 1307 Glenwood Avenue, Raleigh, North Carolina. Commissioners present were: Graham Bell, Jeffrey Gray, Jennie Hayman; Thomas Hilliard; Robert Saunders, Lee Settle, Dana Simpson, John Tart, and David Twiddy.

Staff members present were: Joseph DeLuca, Staff Counsel; Bobby Bryan, Rules Review Specialist, and Lisa Johnson, Administrative Assistant.

The following people attended:

Andy Ellen Sheila Coneen Gretchen Aycock Bridget Swan Jean Stanley David Kalbackon	NC Retail Merchants Department of Administration Department of Administration Department of Administration NC Board of Nursing NC Board of Nursing
Mike Lopazanski	Division of Coastal Management
Etta Maynard	Department of Insurance
Teresa Knowles	Department of Insurance
Nadine Pfeiffer	Division of Facility Services
Craig Smith	Division of Facility Services
Robert Privott	NC Home Builders Association
Mike Page	Department of Insurance
Julia Lohman	Sheriffs' Education & Training Standards Commission
Ellie Sprenkel	Department of Insurance
Julie Brincefield	OAH
Elkton Richardson	NC Commission of Indian Affairs
Garth Locklear	NC Commission of Indian Affairs
Greg Richardson	NC Commission of Indian Affairs
Mike Chapman	Office of State Personnel
Barry Gupton	Building Code Council
Nancy Pate	DENR
Delores Joyner	State Personnel Commission

RULES REVIEW COMMISSION

Jesse Chavis Frank Folger Nick Fountain Jack Nickols Denise Stanford Lisa Martin RDI Department of Insurance Young Moore and Henderson Allen & Pinnix Attorney/Pharmacy Board NC Home Builders Association

APPROVAL OF MINUTES

The meeting was called to order at 10:10 a.m. with Chairman Hayman presiding.

Chairman Hayman asked for any discussion, comments, or corrections concerning the minutes of the December 15, 2005 meeting. The minutes were approved as written.

FOLLOW-UP MATTERS

10A NCAC 09 .1701; .1718: Child Care Commission – No action was taken.

12 NCAC 10B .0905; .0915: Sheriffs' Education and Training Standards Commission – The Commission approved the rewritten rules submitted by the agency.

13 NCAC 15 .0705: Department of Labor – The Commission returned this temporary rule to the agency because it was notified by the agency that the agency would not be submitting additional findings.

21 NCAC 14O .0101: Cosmetic Art Examiners Board – The agency notified the Commission that they intend to satisfy the objection by beginning the rulemaking process with a Notice of Text in the NCR. Based on this, no action was taken and the rule will be removed from consideration as a follow-up matter.

21 NCAC 14P .0105: Cosmetic Art Examiners Board – The agency notified the Commission that they intend to satisfy the objection by beginning the rulemaking process with a Notice of Text in the NCR. Based on this, no action was taken and the rule will be removed from consideration as a follow-up matter.

21 NCAC 14P .0112: Cosmetic Art Examiners Board – The Commission approved the rewritten rule submitted by the agency.

21 NCAC 18B .0104; .1104: Board of Examiners of Electrical Contractors – The Commission approved the rewritten rules submitted by the agency.

21 NCAC 36 .0303; .0317: Board of Nursing – No action was taken.

051213 Item D-3 10.10; Article 100: Building Code Council – No action was taken.

LOG OF FILINGS

Chairman Hayman presided over the review of the log of permanent rules. All rules were approved unanimously with the following exceptions:

1 NCAC 30I .0309: Department of Administration – The Commission objected to the rule due to ambiguity. In (a), it is not clear what standards the Historically Underutilized Business Office will use in recognizing other certifying agencies.

Commissioner Twiddy did not participate in any discussion nor vote concerning rules from the Department of Insurance.

11 NCAC 8 .0713: Code Officials Qualification Board – The Commission objected to the rule due to ambiguity. Because there are no standards in the Rules for the approval of sponsors, it is not clear what is meant in (f) by "approved sponsors".

11 NCAC 8 .0718: Code Officials Qualification Board – The Commission objected to the rule due to ambiguity. It is not clear what the standards are for approving course sponsors.

15A NCAC 10D .0103: Wildlife Resources Commission – The Commission approved this rule contingent on a technical change being made. The change was not made and the rule will be carried forward to the next meeting.

12 NCAC 7D .0405: Private Protective Services Board – The Commission objected to the rule due to ambiguity and lack of statutory authority. There is no authority cited to make rules concerning who may or may not participate in a "ride-along." The authority cited, G.S. 74C-3(a)(8), is not authority for the general subject matter of this rule in (a), "an unlicensed and unregistered individual" who is "accompanying a licensed private investigator." As a general proposition, an occupational licensing board has no authority to regulate the conduct of non-licensed individuals. That is precisely what this rule purports to do in (b)(1) when it states that "an unlicensed

individual may accompany a licensed private investigator..." There may be authority to regulate the business conduct of licensees in regard to a "prospective employee" as found in (b)(1), line 8 through 10. If that is the intent of the rule, then the rule is unclear. Even if the rule did address only a "prospective employee," the authority cited is not broad enough to cover the prohibition. Commissioner Gray did not participate in any discussion nor vote on rules concerning the Private Protective Services Board.

12 NCAC 9E .0108: Criminal Justice Education and Training Standards Commission – The Commission approved this rule contingent upon a technical change. It was subsequently determined by staff that no technical change was required and that the rule should be added to the approved rule list.

21 NCAC 08: Board of Certified Public Accountant Examiners – Commissioner Gray did not participate in any discussion or vote on rules concerning the Board of Certified Public Accountant Examiners.

21 NCAC 26 .0207: Board of Landscape Architects – The Commission objected to the rule due to ambiguity. There is no authority cited to make rules concerning who may or may not participate in a "ride-along." The authority cited, G.S. 74C-3(a)(8), is not authority for the general subject matter of this rule in (a), "an unlicensed and unregistered individual" who is "accompanying a licensed private investigator." As a general proposition, an occupational licensing board has no authority to regulate the conduct of non-licensed individuals. That is precisely what this rule purports to do in (b)(1) when it states that "an unlicensed individual may accompany a licensed private investigator" There may be authority to regulate the business conduct of licensees in regard to a "prospective employee" as found in (b)(1), lines 8 through 10. If that is the intent of the rule, then the rule is unclear. Even if the rule did address only a "prospective employee," the authority cited is not broad enough to cover the prohibition.

21 NCAC 46 .1607: Board of Pharmacy – The Commission objected to the rule due to ambiguity. In (b)(5), line 27, it is unclear what is meant by the requirement that an out-of-state pharmacy "acknowledge the existence of policies governing" the following sub-items (A) - (D). Since immediately preceding this requirement is the separate requirement that these pharmacies "develop" these same policies, it would seem that they would be, and in any enforcement action could be charged with the knowledge of policies they had developed. It is unclear what this requirement adds. It may be that a slight revision in the language would satisfy the Board's concerns and the Commission's objection.

21 NCAC 46 .1612: Board of Pharmacy – The Commission objected to the rule due to lack of statutory authority and ambiguity. In setting the renewal fee for pharmacist licenses in (a), lines 5 and 6, at the "maximum original fee ... for licensure" it is unclear whether the Pharmacy Board is charging the maximum renewal fee allowed by G.S. 90-85.24 or whether it is attempting to charge the higher fee for the "examination of an applicant for license." It is only permitted to charge the maximum fee for license renewal. If they are attempting to charge a higher fee, there is no authority cited for that fee. In (a), lines 6 and 7 the rule refers to a renewal fee for "permits." It appears that this refers to the permit issued to a pharmacy for which the Board may charge an "original registration" fee of \$350.00 (G.S. 90-85.24). However the maximum renewal fee for that pharmacy registration is \$175.00. It does appear that the Board is attempting to charge a fee that is in excess of their statutory authority in setting the renewal fee at "the original registration fee." If that is not the case, the rule is unclear. If it is the case, there is no authority to charge such a fee.

21 NCAC 46 .2502: Board of Pharmacy – The Commission referred the rule to the Office of State Budget and Management for a determination of whether this rule has a substantial economic impact.

21 NCAC 46 .2511: Board of Pharmacy – The Commission objected to the rule due to lack of statutory authority and ambiguity. The authority cited for this rule, G.S. 150B-19(5), is general authority to charge a fee for certain services. Presumably this particular fee would be for either "b. a copy of part or all of a State ... document, the cost of mailing a document, or both ... [or] ... e. data processing services" in order to be covered by this general fee authority. This does not seem to be either one of these generally permitted fees. This is not an existing document, but rather an affidavit, a specific and unique one that is created for a particular need to meet a particular request. It is not the same as mailing out a copy of the license in question that might fall within the exception found in 150B-19(5). It also would not constitute a "data processing service," the exception found in 150B-19(5)e. It is "data processing" only in the most generic of senses that almost anything a Board does in regards to the paperwork or other work concerning licensees or permittees is "processing" that specific "data." This does not seem to be the exception envisioned by the APA. In addition the rule is unclear in what standards are to be applied in determining whether to "furnish such affidavits free of charge to governmental entities" as set out in the last sentence of the rule, lines 6 and 7. Since this could be considered a waiver of the fee provision, those standards must be set out as specific guidelines within the rule (G.S. 150B-19(6)). In addition there is no authority to set any standards for the Board's decisions, whether as a waiver or otherwise, outside rulemaking.

21 NCAC 46 .2601: Board of Pharmacy – The Commission objected to the rule due to lack of statutory authority. For the same reasons as set out in the previous rule, there is no authority to charge this "online renewal" fee in (d) as a "data processing" fee, although the justification might be somewhat easier to find. But if this were a renewal made by mail, with payment by check or credit card, they would have no authority to charge a "data processing" fee that is over and above the amount they are authorized by statute to charge for license renewals. It does not seem that they should have the authority to add the charge based on the method of renewal. As another approach to this issue it is hard to see how the Board has any additional costs with this online form of renewal that might be some "data processing" justification for it. While not grounds for the objection it does seem there may be a question of whether the Board can charge this additional fee if they have signed any agreement with the credit card company. There was the suggestion raised that it might be a contractual violation for the Board to charge a separate and additional fee for use of a credit card to make payment over the renewal fee if paid by check.

RULES REVIEW COMMISSION

041214 Items B-2, B-1, B-2D1 903.2.7: Building Code Council – The Commission objected to the rule due to failure to comply with the Administrative Procedure Act. It does not appear that the Council ever noticed the intent to specifically address this rule in the rulemaking process. The Notice of Rulemaking cited by the Council in its submission to the RRC to review this rule appears to be the Notice of Rulemaking that was given to adopt the entire Building Code for North Carolina. There is no specific reference to any public hearing on this specific section at issue or even this matter. However, it seems that the agency always intended to consider this specific rule separately from the remainder of the Building Code. The Submission for Filing form recites an adoption date of September 13, 2005. However the rule was not delivered to the RRC with the balance of the Code that was adopted on that date and delivered to the RRC and reviewed at the November RRC meeting. It does appear that the rule was further considered at the December meeting and the final version of the rule was adopted on that date. If the rule was "adopted" in September, and then further considered or reconsidered at the December meeting, that might violate the final paragraph of G.S. 150B-21.2(g) in that it was either not delivered within 30 days of its adoption (if the adoption date was September 13) or the agency took "further action" on the rule but they did not "follow the procedures in this [rulemaking procedures] part" of the APA. Essentially that would have required at least some further notice to the public. It appears that there were two different notices of what the text of this proposed rule would read that were put out on the web site of the Council. One was from the Building Code Committee that proposed to keep language from the 2002 code that was an exception to the International Code that is the basis for the N.C. Code. The other version, put out by the Fire Code Committee apparently proposed to delete that language that was in the previous N.C. Code and use the language of the International Code. This had the potential to mislead or confuse people as to what the Code Council was proposing. Even though the Submission form states that this rule has a substantial economic impact, it is unclear whether it was an analysis of this particular rule or the entire code that is the basis for that assertion. Although the RRC did not consider another fact, there were allegations that the note itself was not available for individual review by the time of the notice of the rule on the web or even until just shortly before or at the September meeting itself.

MEDICAL FACILITIES PLAN

The Commission reviewed the 2006 Medical Facilities Plan and determined that it had been adopted in compliance with G.S. 131E-176(25).

TEMPORARY RULES

Chairman Hayman presided over the review of the log of temporary rules. All rules were approved unanimously. COMMISSION PROCEDURES AND OTHER BUSINESS

No new business was discussed.

The meeting adjourned at 11:44 p.m.

The next scheduled meeting of the Commission is Thursday, February 16, 2006 at 10:00 a.m.

Respectfully submitted, Lisa Johnson

AGENDA *RULES REVIEW COMMISSION* February 16, 2006, 10:00 A.M.

- I. Reminder of Governor's Executive Order #1
- II. Communications from Board of Ethics
- III. Review of minutes of last meeting
- IV. Follow-Up Matters
 - A. Department of Administration 1 NCAC 30I .0309 (Bryan)
 - B. Child Care Commission 10A NCAC 09 .1701 and .1718 (Bryan)
 - C. Code Officials Qualification Board 11 NCAC 8 .0713; .0718 (Bryan)
 - D. Private Protective Services Board 12 NCAC 7D .0405 (DeLuca)
- 20:16

RULES REVIEW COMMISSION

- E. Cosmetic Art Examiners Board 21 NCAC 14O .0101 (DeLuca)
- F. Cosmetic Art Examiners Board 21 NCAC 14P .0105 (DeLuca)
- G. Board of Landscape Architects 21 NCAC 26.0207 (DeLuca)
- H. Board of Nursing 21 NCAC 36 .0303 and .0317 (Bryan)
- I. Board of Pharmacy 21 NCAC 46 .1607; .1612; .2511; .2601 (DeLuca)
- J. Board of Pharmacy 21 NCAC 46 .2502 (DeLuca)
- K. Building Code Council 041214 Items B-2, B-1, B-2D1 903.2.7
- L. Building Code Council 051213 Item D-3 10.10 and Article 100 (Bryan)
- V. Review of Rules (Log Report)
- VI. Review of Temporary Rules (If Any)
- VII. Commission Business
- VIII. Next meeting: March 16, 2006

This Section contains the full text of some of the more significant Administrative Law Judge decisions along with an index to all recent contested cases decisions which are filed under North Carolina's Administrative Procedure Act. Copies of the decisions listed in the index and not published are available upon request for a minimal charge by contacting the Office of Administrative Hearings, (919) 733-2698. Also, the Contested Case Decisions are available on the Internet at http://www.ncoah.com/hearings.

OFFICE OF ADMINISTRATIVE HEARINGS

Chief Administrative Law Judge JULIAN MANN, III

Senior Administrative Law Judge FRED G. MORRISON JR.

ADMINISTRATIVE LAW JUDGES

Sammie Chess Jr. Beecher R. Gray Melissa Owens Lassiter James L. Conner, II Beryl E. Wade A. B. Elkins II

AGENCY	CASE <u>NUMBER</u>	<u>ALJ</u>	DATE OF DECISION	PUBLISHED DECISION <u>REGISTER CITATION</u>
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Richard S Blazak, Park View Lounge v. ABC	96 ABC 0053	Gray	07/06/05	
ABC Comm. & City of Asheville v. Elijah Ulysses Jones T/A Jones Convenience Store	98 ABC 0962	Gray	07/12/05	
ABC Comm v. Rudean Robinson Harris T/A Rudean's Diner & Lounge 3	03 ABC 1214	Conner	06/28/05	
ABC Comm v. Desperado's Inc T/A Desperado's	04 ABC 1192	Wade	07/20/05	
ABC Commission v. Don Mariachi Ventures, Inc, T/A El Mariachi Gordo	05 ABC 0188	Morrison	02/01/06	
ABC Comm. v Nuntia Ester Davis T/A N and R Grocery 2	05 ABC 0209	Lassiter	09/13/05	
Cameron's One Stop, Sank Cameron v. ALE Agent B Haynes, Ann H. Johnson, Permit Comm Mgr.	05 ABC 0799	Elkins	07/28/05	
ABC Commission v Carlos Salas, T/A Boom Room Night Club	05 ABC 1831	Conner	01/11/06	
ABC Commission v. Loeffler Enterprises, Inc.,	05 ABC 1842	Conner	01/11/06	
ABC Commission v. Partnership, T/A John Boys County Store	05 ABC 1843	Conner	01/11/06	
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		-		
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Moreno Edoardo Lovejoy v. Crime Control & Public Safety, Victime Comp. Services Division, Crime Victims Compensation Commission	04 CPS 1176	Wade	09/22/05	
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Cecelia Reid v DCCPS, Div of Vic Comp Svcs, Crime Vic Comp Comm	05 CPS 0220	Lassiter	08/08/05	
Rhonda Lynnette Rhodes v. Crime Victims Compensation Program	05 CPS 0484	Gray	06/23/05	
Brenda Edwards, d/b/a B&H Wrecker Service v. Dept. of Crime Control &				
Public Safety, Div. of State Highway Patrol	05 CPS 0510	Lassiter	10/19/05	
Terry Ramey, d/b/a Ramey Wrecker Service v. Dept. of Crime Control & Public Safety, Division Of State Highway Patrol	05 CPS 0511	Lassiter	10/18/05	
Curtis Glenn Davis v. Crime Control and Public Safety Crime Victims Compensation Commission	05 CPS 0529	Bryan	10/10/05	
Jamaal O Staten v. Crime Victims Compensation Commission	05 CPS 0711	Elkins	07/28/05	
Sandra A. Tinsley v. Crime Victims Compensation Services	05 CPS 0850	Lassiter	12/02/05	
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Donald E. Cline, PH.D v. J.H. Lyall, PH.D, O'Berry Center	04 OSP 1247	DeLuca	10/05/05		
Loretta G Hooks v. Department of Corrections	04 OSP 1266 05 OSP 1343	Wade Lassiter	07/11/05 01/18/06		
Clayton R. Richardson v. Winston-Salem State University Melvin G. Cline., Jr., v. J. Iverson Riddle Development Center and the NC	04 OSP 1343	Wade	12/15/05		
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Wayne Pettit v Department of Correction	04 OSP 1458	Gray	08/04/05		
Carroll (ED) Swain v. UNC-Chapel Hill	04 OSP 1476	Gray	09/20/05		
Daisy L. Smith v. Cumberland Co Mental Health Center	04 OSP 1558	Elkins	07/28/05	20:05 NCR	291
Jacqueline Hightower v Wayne Co Dept of Social Services	04 OSP 1563	Lassiter	09/09/05		
Michael A. Kelly v. DENR	04 OSP 1572	Gray	12/28/05		
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Shelli Henderson Rice v. ESC of NC	04 OSP 1574	Gray	06/27/05		
James O. Mitchell v. DOT	04 OSP 1639	Elkins	11/28/05		
V Wayne Johnson v Department of Transportation	04 OSP 1716	Elkins	07/06/05		
Mimi Jakelsky v. DHHS	05 OSP 1731	Chess	01/13/06		
Beverly R Lee v. Employment Security Commission of NC	04 OSP 1742	Conner	08/03/05		
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Regina C Gaither v. Forsyth Co Department of Social Services	05 OSP 0047	Conner	06/27/05		
Thomas Freeman, Jr. v. DHHS/Murdoch Center	05 OSP 0071	Wade	08/15/05		
Percy L. Edwards v. Dept. of Juvenile Justice & Delinquency Prevention	05 OSP 0252	Lassiter	11/30/05		
Thomas A Horton v. Dept. of Crime Control and Public Safety	05 OSP 0389	Lassiter	06/02/05		
Anthony Bruce Allen v Department of Transportation	05 OSP 0418	Chess	06/09/05		
Peggy Anderson v. Whitaker School, NC DHHS	05 OSP 0427	Gray	10/25/05		
Angela Twitty v DOC, Marion Correctional Institution	05 OSP 0491	Wade	08/31/05		
Alan Bradford v. Avery Co. Derek H. Babson v. Department of Transportation	05 OSP 0493	Wade	10/06/05		
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Glendora Key v. UNC at Chapel Hill	05 OSP 0784	Gray	09/23/05		
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Milton W. Nobles v. DHHS/Dorothea Dix Hospital	05 OSP 0815	Gray	06/15/05
Sandra Thomas v Department of Correction	05 OSP 0824	Wade	07/21/05
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Mary F. Parker v. Wilson Technical Community College	05 OSP 1905	Lassiter	01/04/06
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Dawn B & John A Gladden v. UNC Hospitals via Dept. of Revenue	05 UNC 0608	Conner	07/26/05
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Audrey Ghia v UNC Hospitals	05 UNC 0856	Gray	09/14/05
De'Juana Middleton v UNC Chapel Hill Hospital	05 UNC 0701	Conner	07/26/05
Marjorie Hindsdale-Shouse v UNC Hospitals	05 UNC 1002	Elkins	09/15/05
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2 – Combined Cases 3 – Combined Cases 4 – Combined Cases 5 – Combined Cases

STATE OF NORTH CAROLINA

COUNTY OF WILSON

IN THE OFFICE OF ADMINISTRATIVE HEARINGS 03 DHR 2402

FRIENDLY ELM REST HOME (60), Petitioner,))	
v.)	DECISION
NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF FACILITY SERVICES, Respondent.)))	

This matter was heard before James L. Conner, II, Administrative Law Judge, on September 21, 2005 in Raleigh, North Carolina. Respondent filed its Proposed Decision November 14, 2005, and Petitioner filed its "Motion Proposing Corrections to Proposed Decision" on November 28, 2005.

APPEARANCES

Deborah A. Whitfield PO Box 480160 Charlotte, NC 28269 Counsel for Petitioner

June S. Ferrell Assistant Attorney General, North Carolina Department of Justice PO Box 629 Raleigh, NC 27602 Counsel for Respondent

ISSUE

Whether Respondent

- 1. failed to use proper procedure; or
- 2. failed to act as required by law or rule

when Respondent assessed an administrative penalty in the amount of \$10,000.00 against Petitioner for violations of the Adult Care Law and Rules.

APPLICABLE STATUTES AND RULES

N.C.G.S. §§ 131D-2, -21, -26 and -34 N.C.G.S. § 150B-23

DISPOSITIVE MOTION

At the hearing, prior to the taking of evidence, counsel for Petitioner moved that the case be dismissed for lack of subject matter jurisdiction. Petitioner argued that since the facility license had been surrendered, no decision could be entered affirming the penalty that had been assessed. Petitioner surrendered the facility license while the penalty assessment was on appeal through the contested case process. The Motion was denied, and the case proceeded to hearing.

EXHIBITS

The following exhibits were admitted into evidence:

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NORTH CAROLINA REGISTER

February 15, 2006

1. Petitioner's Exhibit #1 Wilson County Department of Social Services ("WCDSS") Adult Care Monitoring Report dated February 14, 2003

- 2. Petitioner's Exhibit #2 WCDSS Adult Care Monitoring Report dated April 30, 2003
- 3. Petitioner's Exhibit #3 WCDSS CAR dated April 30, 2003
- 4. Petitioner's Exhibit #4 WCDSS Adult Care Monitoring Report dated May 20, 2003
- 5. Petitioner's Exhibit #5 WCDSS Penalty Proposal Letter (with attachments) to Respondent dated June 3, 2003
- 6. Petitioner's Exhibit #6 Controlling Statutes, Regulations, Agency policies, 2003 Calendar

7. Petitioner's Exhibit #7 Respondent's November 19, 2003 Penalty Assessment Letter (with attachments) to Facility Administrator

- 8. Respondent's Exhibit #1 September 5, 2003 Letter (with attachments) from DFS to Facility Administrator
- 9. Respondent's Exhibit #2 November 19, 2003 Letter (with attachments) from DFS to Facility Administrator
- 10. Respondent's Exhibit #3 September 18, 2003 Letter (with Attachments) from Counsel for Petitioner to DFS
- 11. Respondent's Exhibit #4 Report Of Autopsy Examination dated April 22, 2003
- 12. Respondent's Exhibit #5 Respondent's Discovery Responses dated April 15, 2005 to Petitioner
- 13. Respondent's Exhibit #6 May 20, 2003 Letter (with attachments) from WCDSS to Petitioner
- 14. Respondent's Exhibit #8 FL-2 for Resident #1
- 15. Respondent's Exhibit #9 Medication Administration Record ("MAR") for Resident #1
- 16. Respondent's Exhibit #10 Accident/Incident Report dated January 28, 2003
- 17. Respondent's Exhibit #11 Accident/Incident Report dated January 30, 2003
- 18. Respondent's Exhibit #12 Certificate of Death for Resident #1
- 19. Respondent's Exhibit #13 Ambulance Call Report dated January 29, 2003
- 20. Respondent's Exhibit #14 Nurses Notes for Resident #1 dated January 28, 2003
- 21. Respondent's Exhibit #15 Nurses Notes dated January 28, 2003
- 22. Respondent's Exhibit #16 Report of Gross Autopsy Findings for Resident #1
- 23. Respondent's Exhibit #17 Nurses Notes for Resident #1 dated January 2-29, 2003
- 24. Respondent's Exhibit #18 FL-2 for Resident #2
- 25. Respondent's Exhibit #19 Nurses Notes for Resident #2 dated January 28, 2003
- 26. Respondent's Exhibit #20 Progress Notes from Wilson Medical Center dated June 27, 2002 through January 28,

2003

- 27. Respondent's Exhibit #21 Accident/Incident Report dated January 30, 2003
- 28. Respondent's Exhibit #23 Adult Care Monitoring Report dated May 21, 2003

- 29. Respondent's Exhibit #25 Scope and Severity Rebuttal submitted by Petitioner to Sandra Tatum
- 30. Respondent's Exhibit #26 Independent Audit of Administration Penalty Proposal submitted by Petitioner to Sandra Tatum
 - 31. Respondent's Exhibit #27 Note dated January 29, 2003 from Barbara Massey to Martha Johnson

STIPULATIONS - UNDISPUTED FACTS

1. On January 30, 2003, Wilson County DSS initiated an onsite complaint investigation of a resident's death that had occurred on or about January 29, 2003, at the Friendly Elm Rest Home. During the course of the investigation, DSS issued an Adult Care Monitoring Report dated February 14, 2003. This February 14, 2003, monitoring report was signed by the Wilson County DSS Adult Home Specialist and by Mr. Edwin Pettis, administrator of Friendly Elm Rest Home. Page two (2) of the February 14, 2003, monitoring report states that "the incident being investigated is considered a penalty situation and could result in a Type A Penalty."

2. On April 30, 2003, DSS completed its complaint investigation and delivered a Corrective Action Report ("CAR") to Mr. Pettis. Included in the CAR was a directed plan addressing the Type A violations. On May 20, 2003, a Type A penalty proposal was hand-delivered to Mr. Pettis. By letter dated June 3, 2003, Wilson County DSS recommended to Respondent an administrative penalty proposal against Friendly Elm Rest Home.

3. By letter dated November 19, 2003, the Adult Care Licensure Section notified Petitioner of its intent to assess an administrative penalty in the amount of \$10,000.00 against Petitioner. In accordance with its appeal rights, on December 18, 2003, Petitioner timely filed a Petition for a Contested Case Hearing with the Office of Administrative Hearings in which it challenged the penalty assessment.

4. On November 19, 2003, the date that Respondent assessed the administrative penalty at issue in this contested case, Petitioner was licensed by Respondent to operate an adult care licensure facility. The license number assigned to Petitioner was HAL-098-002. Petitioner operated its adult care facility under the name of Friendly Elm Rest Home. The facility was located at 416 North Parker Street, Elm City, North Carolina. Mr. Edwin Pettis was identified by Petitioner as the administrator of the facility.

Based upon the documents filed in this matter, exhibits admitted into evidence, stipulations of the parties, and the sworn testimony of the witnesses, the undersigned makes the following:

FINDINGS OF FACT

1. At all times relevant to this matter, Lisa Craven was employed as the Supervisor-in-Charge at Friendly Elm Rest Home.

2. At all times relevant to this matter, Martha Johnson was employed as an adult home specialist by the WCDSS as an adult home specialist. Tr pp 49-50; P Ex 5

3. At all times relevant to this matter, Barbara Massey was employed as an enhanced care worker with the WCDSS. Tr p 54

4. At all times relevant to this matter, Ellen Walls was employed by Respondent as the Assistant Section Chief of the Adult Care Licensure Section. Tr p 111

5. At all times relevant to this matter, James B. Upchurch, Jr., was employed by Respondent as Chief of the Adult Care Licensure Section. Tr pp 40-41

6. At all times relevant to this matter, Resident #1 was a resident at Friendly Elm Rest Home. R Ex 1

7. At all times relevant to this matter, Resident #2 was a resident at Friendly Elm Rest Home. R Ex 1

8. At all times relevant to this matter, Resident #1 and Resident #2 were roommates at Friendly Elm Rest Home. T p 87; R Ex 1

9. Resident #1 was admitted to Friendly Elm Rest Home on December 10, 2002. At the time of admission, Resident #1 had the following diagnoses: Undifferentiated Schizophrenia, Deep Vein Thrombosis and Pulmonary Embolus, Hypertension, Obesity, and Adult Onset Diabetes Mellitus. R Ex 1 and 8

10. Resident #2 was admitted to Friendly Elm Rest Home on July 25, 2001. At the time of admission, Resident #2 has the following diagnosis: schizophrenia-paranoid type and alcohol abuse. Additionally, Resident #2 was known to be aggressive and injurious to others. R Ex 1 and 18

11. On or about January 28, 2005, Resident #1 and Resident #2 became involved in a verbal and physical altercation in their bedroom. As a result of the altercation, both residents received physical injuries. T pp 87-91; R Ex 10, 11, 17, 18, 20, and 27

12. Following the altercation, Resident #2 was moved to another room. Resident #1 remained in her same room. She was seen up and about during that day. Staff asked her to let them take her to the doctor, but she refused. T p 87; R Ex 10

13. During the early morning hours of January 29, 2003, an employee entered Resident #1's room. Upon entry, Resident #1 appeared non-responsive. Employees of Petitioner sought emergency medical services for Resident #1; however, Resident #1 was deceased. R Ex 10, 11, 17, and 27

14. The cause of death for Resident #1 was determined to be the result of large left subdural hematoma as a consequence of blunt force injury to the head. R Ex 4, 12, and 16.

15. As an adult home specialist in Wilson County, Ms. Johnson monitors Petitioner's facility. Monitoring includes monthly visits to facilities, investigation of regulatory violations, complaint investigations and follow-up visits for regulatory compliance. Tr pp 83-84; P Ex 5; R Ex 1

16. Petitioner was required to report the incident between Residents #1and #2 to Ms. Johnson.

17. When Ms. Johnson arrived at work on January 30, 2003, she found a note from Ms. Massey. The note informed Ms. Johnson of the January 28, 2003, altercation between Residents #1 and #2. Ms. Johnson telephoned Petitioner to inquire about the alleged altercation. Tr pp 54; R Ex 27

18. Ms. Craven informed Ms. Johnson that Residents #1 and #2 had had an argument, not a fight. Tr p 73

19. Ms. Johnson visited the Petitioner's facility on January 30, 2003, and began an inquiry into the events of the previous two days. During the time period from January 30 through April 30, 2003, Ms. Johnson conducted her investigation of the altercation between Residents #1 and #2 and as well as Resident #1's subsequent death. Tr pp 55-65; P Ex 1-3 and 5

20. Ms. Johnson interviewed a number of Petitioner's employee's and other persons with knowledge of either the altercation or Residents #1 and #2. In addition to the interviews, Ms. Johnson also obtained medical records for Residents #1 and #2, death certificate for Resident #1, autopsy results for Resident #1 and photos of Resident #1. P Ex 5; R Ex 4 and 8-21

21. Upon completion of the interviews and receipt of the documents referenced in Finding of Fact 23 above, Ms. Johnson determined that Petitioner had violated N.C. Gen. Stat. § 131D-21(2) and (4) and 10 NCAC 42D.1701 and -.1827. P Ex 5; R Ex 6

22. Ms. Johnson testified that she needed the autopsy results from the medical examiner in order to know the cause of death for Resident #1. Ms. Johnson further testified that if Resident #1 had died of natural causes, there would not have been a regulatory violation. T pp 57-59

23. N.C. Gen. Stat. § 131D-26(a1) provides as follows:

(a1) When the department of social services in the county in which a facility is located receives a complaint alleging a violation of the provisions of this Article pertaining to patient care or patient safety, the department of social services shall initiate an investigation as follows:

(1) Immediately upon receipt of the complaint if the complaint alleges a life-threatening situation.

(2) Within 24 hours if the complaint alleges abuse of a resident as defined by G.S. 131D-20(1).

(3) Within 48 hours if the complaint alleges neglect of a resident as defined by G.S. 131D-20(8).

(4) Within two weeks in all other situations.

The investigation shall be completed within 30 days. The requirements of this section are in addition to and not in lieu of any investigatory requirements for adult protective services pursuant to Article 6 of Chapter 108A of the General Statutes.

24. The timeline of events occurred as follows:

January 28, 2003 Altercation occurred between Residents #1 and #2

January 30, 2003 Ms. Johnson learned of altercation and began investigation

February 3, 2003 Ms. Johnson continued the investigation

February 7, 2003 Ms. Johnson continued the investigation

February 13, 2003 Ms. Johnson continued the investigation

February 14, 2003 Ms. Johnson continued the investigation

March 21, 2003 Ms. Johnson received Gross Autopsy Report

April 30, 2003 Ms. Johnson completed the investigation

P Ex 5; R Ex 4 and 8-21

25. Following receipt of the gross autopsy report on March 21, 2003, Ms. Johnson completed her investigation report and the corrective action report. She then visited Petitioner's facility and informed the administrator of her findings. T p 64

26. By letter, dated May 1, 2003, Mr. Pettis informed Ms. Johnson that he needed additional time to respond to her findings. T p 66

27. Following the conference with Mr. Pettis on June 3, 2003, Ms. Johnson submitted the penalty proposal to Ms. Walls. T p 68; P Ex 5

28. At its November 13, 2003, meeting, the Penalty Review Committee considered the penalty proposal against the Petitioner. By a 6-0 vote, the Committee recommended that a \$10, 000 penalty be assessed against Petitioner. R Ex 2

29. By letter dated November 19, 2003, Mr. Upchurch informed Petitioner that he had assessed a \$10,000 penalty against Petitioner. R Ex 2

30. At the contested case hearing, Petitioner conceded that the violations underlying the penalty were not at issue in the hearing and that it was proceeding only on procedural issues. T pp 28-39

31. Among other things, Petitioner contends that since N.C. Gen. Stat. § 131D-26 states that an investigation must be completed within 30 days and Ms. Johnson's investigation exceeded the 30 day deadline, Respondent was barred from assessing an administrative penalty against Petitioner. T pp 166-167

Based upon the foregoing Findings of Fact, the undersigned Administrative Law Judge makes the following:

CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has jurisdiction over the parties and the subject matter pursuant to Chapters 131D and 150B of the North Carolina General Statutes.

2. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder.

3. The North Carolina Department of Health and Human Services, Division of Facility Services, Adult Care Licensure Section is authorized by N.C. Gen. Stat. § 131D-34 to assess administrative penalties against operators of adult care facilities.

4. Ms. Johnson promptly commenced her investigation as required by N.C. Gen. Stat. §131D-26.

5. Between January 30, and April 30, 2003, Ms. Johnson actively pursued the investigation of Petitioner.

6. N.C. Gen. Stat. § 131D-26 states in part: "The investigation shall be completed within 30 days."

7. Although the statute sets forth a 30-day time limit for completion of a complaint investigation, the statute does not provide a remedy if the 30-day deadline is not met. Likewise, the statute does not state that DFS cannot assess a penalty if the deadline is not met.

8. The record is devoid of any evidence of purposeful delay on the part of Ms. Johnson. Ms. Johnson followed a reasonable schedule in her work and upon receipt of the first autopsy report (March 21, 2003) promptly completed the investigation.

9. Where the Legislature has not fashioned a remedy, I decline to do so.

10. Respondent did not fail to use proper procedure or fail to act as required by law or rule in assessing an administrative penalty against Petitioner for violation of N.C. Gen. Stat. § 131D-21(2) and (4) and 10 NCAC 42D.1701 and -.1827.

DECISION

That the North Carolina Department of Health and Human Services, Division of Facility Services, Adult Care Licensure Section did not fail to use proper procedure or fail to act as required by law or rule when it assessed an administrative penalty in the amount of \$10,000.00 against Petitioner.

ORDER

It is hereby ordered that the agency serve a copy of the FINAL DECISION on the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, NC 27699-6714, in accordance with N.C. Gen. Stat. § 150B-36(b).

NOTICE

The Agency making the FINAL DECISION in this contested case is required to give each party an opportunity to file exceptions to this decision and to present written arguments to those in the agency who will make the final decisions. N.C. Gen. Stat. § 150-36(a).

The Agency is required by N.C. Gen. Stat. § 150B-36(b) to serve a copy of the FINAL DECISION on all parties and to furnish a copy to the parties' attorney of record and to the Office of Administrative Hearings.

The agency that will make the FINAL DECISION in this contested case is the North Carolina Department of Health and Human Services, Division of Facility Services.

This the 3rd day of January 2006.

James L. Conner, II Administrative Law Judge

STATE OF NORTH CAROLINA

COUNTY OF CUMBERLAND

20:16

IN THE OFFICE OF ADMINISTRATIVE HEARINGS 04 EHR 1562

Yvonne D Bledsoe	
Bledsoe Construction Co.)
Petitioner)
)
VS.) DECISION
)
N. C. Department of Environment and)
Natural Resources)
Respondent)

THIS CAUSE coming on for hearing before the undersigned Administrative Law Judge, on July 18 and 19 and August 31 and October 14, 2005, Cumberland County, North Carolina. The Petitioner appeared in Court represented by its counsel, J. Thomas Neville of Thorp, Clarke & Neville, P.A., Stormie D. Forte, Assistant Attorney General, represented the Respondents.

No matters were stipulated to by the parties.

This matter involves a civil penalty assessment for violation of the Sedimentation Pollution Control Act of 1973 which was assessed by the Department of Environmental and Natural Resources, Division of Land Resources (DENR) on August 11, 2004 upon Yvonne D. Bledsoe d/b/a Bledsoe Construction Company and Bledsoe Properties, L.L.C. (hereinafter referred to as "Petitioners".)

The Respondent alleged in the above described civil penalty assessment (Assessment) that from April 12, 2004 through June 24, 2004 the Petitioners violated applicable statutes on a tract of land comprising 5.3 acres and located in subdivision known as Fox Meadows II, Cumberland County, as follows:

a. N.C.G.S. § 113A-54(d)(4), N.C.G.S. 113A-57(4), and 15A NCAC 04B.0107(c) were violated where on a tract larger than 1 acre, an erosion and sedimentation plan was not filed at least 30 days before the initiation of land disturbing activity and/or land disturbing activity was begun prior to plan approval;

b. N.C.G.S. § 113A-57(3) was violated for failure on a tract of more than one acre, where more than one acre is uncovered, to install such sedimentation and erosion control devices and practices as are sufficient to retain sediment generated by land-disturbing activity within the boundaries of the tract during construction;

c. 15A NCAC 04B .0105 was violated for failure to take all reasonable measures to protect all public and private property caused by land-disturbing activity.

The Assessment was for a total penalty of \$65,120.00 based upon \$880.00 per day for a 74 day period.

The Petitioner presented 7 witnesses including the Petitioners, Yvonne Bledsoe and Chris Bledsoe, the developer of the subject site, Rajan Shamdasani, the developer=s engineer, Jimmy Kizer, subcontractors, J.D. Gunther, and Dwayne Parker, and Amy Campbell, an employee of Bledsoe Properties LLC and landowner of the subject property. The Respondent presented 3 witnesses including, Francis M. Nevils, Jr., Chief, Land Quality Section, DLR, Raleigh, North Carolina and Wendy R. Dunaway, DLR, Environmental Technician, Fayetteville, North Carolina. Both the Petitioner and the Respondent presented numerous exhibits.

Based upon the testimony of the witnesses and the exhibits presented, the Court, having had the opportunity to hear witnesses, examine the exhibits and determine matters relating to credibility and weight, makes the following finding of fact:

FINDINGS OF FACT

1. The Petitioner, Yvonne Bledsoe, is a citizen and resident of Cumberland County, North Carolina and doing business as Bledsoe Construction Company.

2. Chris Bledsoe, the husband of the Petitioner, Yvonne Bledsoe, is a citizen and resident of Cumberland County, North Carolina and doing business as Bledsoe Construction Company.

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3. Bledsoe Properties, L.L.C. is a limited liability company organized in the State of North Carolina and doing business in Cumberland County, North Carolina.

4. The Respondent, North Carolina Department of Environmental and Natural Resources, Division of Land Resources (DENR), assessed the heretofore described civil penalty assessment upon Yvonne and Chris Bledsoe doing business as Bledsoe Construction Company and Bledsoe Properties, LLC on August 11, 2004.

5. On September 23, 2004, the Petitioners denied liability to the Assessment and filed a Preliminary Statement on December 14, 2004.

6. The Petitioner's Preliminary Statement asserted that the actions of the Respondent were arbitrary, capricious and erroneous as follows:

a. the Respondent had named the wrong party;

b. any alleged liability on the part of the Petitioner was based upon the negligence of others in that erosion was caused by the developer, Rajan Shamdasani and the engineer had mistakenly failed to file the required erosion control plan;

c. the alleged erosion was caused by natural forces of nature not within the control of the Petitioner;

d. the Petitioner had, in good faith, attempted to implement erosion control measures believed to have been defined in the plan as evidenced by the Petitioner expending a sum in excess of \$120,000.00 for erosion control measures;

e. Mr. Chris Bledsoe was ill during the subject time period and unable to correspond effectively with the DENR local office.

7. Additionally, the Petitioner's Preliminary Statement alleged that the Respondent had incorrectly determined that Chris Bledsoe was liable as he was not the record owner of the subject properties nor had he executed a Financial Responsibility/Ownership (F.R.O.) Form.

8. The Respondent filed its Preliminary Statement on or about March 16, 2004. The Respondent contended that the civil penalty assessment was lawful. The Respondent did not respond to the Petitioner's allegations that the wrong parties were named.

9. The Respondent did name the correct parties as the parties were so closely related and the Respondent communicated to all parties and accepted the Petitioner's allegations from all of the parties assessed.

10. Prior to beginning a land disturbing activity of the subject property of the assessment, the Petitioners met with employees of the Respondent, including Wendy Dunaway, on December 9, 2004 at the subject site. Also present were Rajan Shamdasani, developer of the subject property, and the developer's engineer, Jimmy Kizer.

11. Prior to the above described meeting and the subject civil penalty assessment, the Respondent had not fined or assessed a civil penalty assessment upon builders such as the Petitioner in Cumberland County. The local DENR office had determined that the applicable statues did not apply to said builders but applied to developers and had communicated said determination to developers, builders and engineers working in the subject area.

12. The purpose of the December 9, 2003 meeting was to discuss the erosion problems that were being experienced at the subject property.

13. Additionally, the purpose of the meeting was to discuss the requirements and liabilities of individuals conducting soil disturbance. Specifically, at what time an erosion control plan was required and by whom.

14. Prior to this time period, builders, such as the Petitioners, were not required by the local DENR agency to submit erosion control plans. Consequently, builders, such as the Petitioners, were not submitting said erosion control plans and they were not being assessed by the local DENR agency.

15. At this meeting and prior thereto, Jimmy Kizer of Moorman, Kizer & Reitzel, Inc. the civil engineer for the developer, Rajan Shamdasani, discussed and requested a determination from the local and home DENR offices concerning liabilities

and requirements of builders such as the Petitioner in regards to submitting an erosion control plan. Much of Mr. Kizer's concern centered on the agency's failure to require said plans from builders previously and the interpretation of the rule requiring disturbance of one contiguous acre.

16. The above described DENR offices were unable to effectively respond to Mr. Kizer as to a builder's requirements and liabilities and consequently, Mr. Kizer, and other engineers similarly situated were unable to effectively inform builders such as the Petitioner as to their liabilities and requirements relative to DENR rules.

17. The above described statute requiring the submission of an erosion control plan was made unclear and ambiguous by the Respondent's prior failure to require said plans and their ineffective response to Jimmy Kizer, Rajan Shamdasani and the Petitioners.

18. The subject statute, N.C.G.S. § 113A-54(d)(4), N.C.G.S. § 113A-57(4), and 15A NCAC 04B.0107(c), as applied by the local DENR office are ambiguous.

19. Prior to the above described meeting the subject site had been "clear-cut" by the developer, Raja Shamdasani. The effect of clear-cutting, combined with steep grades present on the site, adversely affected the developer's ability to control or prevent erosion. During the meeting Wendy Dunaway and other employees of the Respondent acknowledged and discussed with the other individuals present at the meeting the erosion control problems then experienced at the site and the developers inability to effectively control erosion.

20. The Respondent did not assess the developer with a civil penalty assessment for his inability to control erosion at the subject site.

21. At the December 9, 2003 meeting at which it was determined by the Respondent that the site was experiencing severe erosion control problems, the Petitioners were not record owners of the property, nor had they executed a Financial Responsibility Ownership (F.R.O.) form or performed any land disturbing activity on the property.

22. At the December 9, 2003 meeting the Petitioner was informed by the Respondent that the Petitioner would not be responsible for the subject property until the Petitioner began a soil disturbing activity on the subject lots comprising the property. The Respondent further informed the Petitioner that the Petitioner was required to submit an erosion control plan once the Petitioner had disturbed an area greater than one acre.

23. At same said meeting and in the presence of the Respondent, the Petitioner requested that Mr. Kizer complete and submit the required erosion control plan for the Petitioner. Mr. Kizer, in the presence of the Respondent, agreed to complete and submit said erosion control plan.

24. Subsequently, but prior to the Petitioner disturbing an area greater than 1 acre, the Petitioner telephoned Mr. Kizer and asked him if he had yet submitted the erosion control plan. Mr. Kizer responded that he had not yet done so, but that he would and he would hand deliver the erosion control plan to the local DENR office.

25. Mr. Kizer further instructed the Petitioner that they could begin their construction in the subject development pursuant to the erosion control plan submitted for Fox Meadows I as the required implementation of erosion control measure under both plans were essentially the same.

26. Mr. Kizer failed to complete and deliver the erosion control plan to the local DENR office and failed to inform the Petitioner of such.

27. The Petitioner understood that Mr. Kizer had submitted the erosion control plan and that it had been approved and pursuant to his instructions they implemented erosion control measures pursuant to the plan submitted for Fox Meadows I and believed to be contained in Fox Meadows II.

28. Prior to, during and subsequent to the penalty period the Petitioner implemented reasonable and sufficient erosion control measures called for and in excess of those required under the approved erosion control plan.

29. The erosion control measures implemented by the Petitioner were rendered futile not because they were unreasonable or insufficient, but because of the prior soil disturbance of the developer coupled with the adverse weather conditions in excess of that which is reasonably anticipated within a 10 year period.

30. The erosion control measures implemented by the Petitioners were reasonable and sufficient to control erosion during a typical year as by the above described standard.

31. Both prior to the beginning of the penalty period and during the penalty period the subject property experienced adverse weather conditions rendering the erosion control measures implemented and called for under the approved erosion control plan futile primarily due to the clear-cutting instituted by the developer and the steep slopes encountered on the property.

32. The local DENR office was aware of the effect that the above described clear-cutting caused by the developer and the steep grades rendered futile the erosion control measures implemented by the Petitioner and called for by the Petitioner's erosion control plan.

33. The Petitioners expended in excess of \$290,000.00 in labor and material in an attempt to control erosion on the subject property. Said expended sum reflects efforts beyond reasonable and measures that were more than sufficient under the usual climatic conditions.

34. The Petitioner, on numerous occasions, provided labor through employees and subcontractors in an effort to control erosion.

35. Both Chris and Yvonne Bledsoe and their children on occasion provided labor in an effort to control erosion.

36. The above described efforts of the Petitioners were reasonable.

37. The Petitioners did not willfully or intentional conduct soil disturbance on the subject property.

38. The Petitioners did not willfully or intentionally fail to submit an erosion control plan 30 days prior to conducting a soil disturbance activity.

39. The erosion control measures implemented by the Petitioner were reasonable.

40. The Respondent alleged that the Petitioner had disturbed 5.3 acres and of that acreage an amount of 1 acre or more was contiguous. The Respondent determined the amount of 5.3 acres by conducting a physical observation of the subject property to determine if any soil disturbance had occurred. The Respondent then determined what, if any, permits had been pulled by Petitioners.

41. The developer, Raja Shamdasani and the engineer, Jimmy Kizer, testified that it was impossible, if not extremely difficult, at the time the Respondent made the above described determination, to determine who or what entity had disturbed the soil to the subject property because of the soil disturbance and the attempted erosion control measures by the developer.

42. The Respondent incorrectly determined that the Petitioners had disturbed 5.3 acres of which 1 acre or more was contiguous on the above described observation date.

43. The degree of off-site damage was slight and the benefit to the Petitioners for not timely submitting an erosion control plan was minimal.

44. The Petitioners were previously assessed a civil penalty for failure to submit an erosion control plan due to the local DENR offices practice of not requiring builders to submit erosion control plans.

- 45. The \$880.00 daily fine was comprised of the following:
 - a. \$30 per day for the heretofore described violations;
 - b. \$50.00 per day for slight harm;
 - c. \$200.00 per day for adherence to the plan or effectiveness of the plan;
 - d. \$200.00 per day for prior record of the violator;
 - e. \$400.00 per day for willful violation;

46. The \$880.00 fine period began on April 12, 2004 and ended on June 24, 2004.

47. The Petitioner first submitted the erosion control plan on May 24, 2004. Said plan was rejected by the Respondent because the F.R.O. was not signed by both a qualified individual and for Bledsoe Properties LLC and Yvonne and Chris Bledsoe d/b/a Bledsoe Construction Company. This delay was caused by the Respondent. The original F.R.O. was appropriately executed by Bledsoe Properties L.L.C. Bledsoe Properties L.L.C. was the record owner of the subject property during the time of the assessment period. The plan was resubmitted on June 9, 2004. Although the Respondent required that the Petitioner resubmit the F.R.O., the Respondent had the submitted plan in its possession.

48. The Respondent failed to name the developer, Raja Shamdasani, as the party responsible for the erosion occurring at the subject property.

CONCLUSIONS OF LAW

1. The findings of fact in Paragraphs 1 through 48 are incorporated and reasserted as if fully set forth.

2. The Respondent failed to name the developer, Raja Shamdasani, as the party responsible for the erosion occurring at the subject property and incorrectly assessed the Petitioners.

3. The subject statute, N.C.G.S. § 113A-54(d)(4), N.C.G.S. § 113A-57(4), and 15A NCAC 04B.0107(c), as applied by the local DENR office are unclear and ambiguous.

4. The actions of the Respondent were arbitrary, capricious and erroneous as follows:

a. determining that the Petitioners had disturbed 5.3 acres of which 1 acre or more was contiguous by failing to use reasonable efforts to determine who or what entity had actually disturbed the subject property ;

b. assessing the Petitioners \$400.00 per day upon a determination that the Petitioners had willfully failed to submit an erosion control plan with full knowledge that the Petitioners had retained an engineer to submit said plan;

c. assessing the Petitioners \$400.00 per day upon a determination that the Petitioners had willfully failed to implement sufficient erosion control measures with full knowledge of the failed erosion control measures of the developer and the effect those said failed measures had upon the measure implemented by the Petitioners;

d. assessing the Petitioners \$400.00 per day upon a determination that the Petitioners had willfully failed to take all reasonable measures with full knowledge of the erosion control measures implemented by the Petitioners and the adverse weather encountered by the Petitioners coupled with the failed erosion control measures attempted by the developer.

e. assessing \$30.00 per day upon a finding that the Petitioners had committed the heretofore described violations;

f. assessing \$50.00 per day upon a finding that the Petitioners caused slight harm without offering proof as the extent of the off-site damage and agreeing that the Petitioners did not benefit from failing to submit timely a plan;

g. assessing \$200.00 per day for adherence to the plan with knowledge that the Petitioner implemented the erosion control measures called for in the plan and knowledge that said erosion control measures were futile;

h. assessing the Petitioners \$200.00 per day, based, in part, upon a finding that the Petitioners had previously failed to submit an erosion control plan with full knowledge that the previous assessment was caused by the local DENR offices practice of not requiring builders, such as the Petitioners, to file erosion control plans;

i. requiring the Petitioners resubmit the F.R.O. and assessing the Petitioners for 74 number of days of delay caused by said re-submittal.

NOW, THEREFORE, in accordance with the foregoing, IT IS DECIDED as follows:

That the Respondent have and recover nothing of Chris Bledsoe, Yvonne Bledsoe, Chris and Yvonne Bledsoe doing business as Bledsoe Construction Company or Bledsoe Properties, LLC.

ORDER AND NOTICE

The Secretary of the Department of Environment and Natural Resources will make the Final Decision in this contested case. N.C.G.S. § 150B-36(b), (b1), (b2) and (b3) enumerate the standard of review and procedures the agency must follow in making its Final Decision, and adopting and/or not adopting the Findings of Fact and Decision of the Administrative Law Judge.

Pursuant to N.C.Gen. Stat. § 150B-36(a), before the agency makes a Final Decision in this case, it is required to give each party an opportunity to file exceptions to this decision, and to present written arguments to those in the agency who will make the Final Decision. N.C.G.S. § 150B-36(b)(3) requires the agency to serve a copy of its Final Decision on each party, and furnish a copy of its Final Decision to each party's attorney or record and to the Office of Administrative Hearings, 6714 mail Service Center, Raleigh, N.C. 27699-6714.

This the 5th day of January, 2006.

William A. Creech Temporary Administrative Law Judge