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The **NORTH CAROLINA REGISTER**

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ISSUE DATE: September 15, 1993

Volume 8 • Issue 12 • Pages 1007 - 1184



INFORMATION ABOUT THE NORTH CAROLINA REGISTER AND ADMINISTRATIVE CODE

NORTH CAROLINA REGISTER

The *North Carolina Register* is published twice a month and contains information relating to agency, executive, legislative and judicial actions required by or affecting Chapter 150B of the General Statutes. All proposed administrative rules and notices of public hearings filed under G.S. 150B-21.2 must be published in the Register. The Register will typically comprise approximately fifty pages per issue of legal text.

State law requires that a copy of each issue be provided free of charge to each county in the state and to various state officials and institutions.

The *North Carolina Register* is available by yearly subscription at a cost of one hundred and five dollars (\$105.00) for 24 issues. Individual issues may be purchased for eight dollars (\$8.00).

Requests for subscription to the *North Carolina Register* should be directed to the Office of Administrative Hearings, P. O. Drawer 27447, Raleigh, N. C. 27611-7447.

ADOPTION AMENDMENT, AND REPEAL OF RULES

The following is a generalized statement of the procedures to be followed for an agency to adopt, amend, or repeal a rule. For the specific statutory authority, please consult Article 2A of Chapter 150B of the General Statutes.

Any agency intending to adopt, amend, or repeal a rule must first publish notice of the proposed action in the *North Carolina Register*. The notice must include the time and place of the public hearing (or instructions on how a member of the public may request a hearing); a statement of procedure for public comments; the text of the proposed rule or the statement of subject matter; the reason for the proposed action; a reference to the statutory authority for the action and the proposed effective date.

Unless a specific statute provides otherwise, at least 15 days must elapse following publication of the notice in the *North Carolina Register* before the agency may conduct the public hearing and at least 30 days must elapse before the agency can take action on the proposed rule. An agency may not adopt a rule that differs substantially from the proposed form published as part of the public notice, until the adopted version has been published in the *North Carolina Register* for an additional 30 day comment period.

When final action is taken, the promulgating agency must file the rule with the Rules Review Commission (RRC). After approval by RRC, the adopted rule is filed with the Office of Administrative Hearings (OAH).

A rule or amended rule generally becomes effective 5 business days after the rule is filed with the Office of Administrative Hearings for publication in the *North Carolina Administrative Code* (NCAC).

Proposed action on rules may be withdrawn by the promulgating agency at any time before final action is taken by the agency or before filing with OAH for publication in the NCAC.

TEMPORARY RULES

Under certain emergency conditions, agencies may issue temporary rules. Within 24 hours of submission to OAH, the Codifier of Rules must review the agency's written statement of findings of need for the temporary rule pursuant to the provisions in G.S. 150B-21.1. If the Codifier determines that the findings meet the criteria in G.S. 150B-21.1, the rule is entered into the NCAC. If the Codifier determines that the findings do not meet the criteria, the rule is returned to the agency. The agency may supplement its findings and resubmit the temporary rule for an additional review or the agency may respond that it will remain with its initial position. The Codifier, thereafter, will enter the rule into the NCAC. A temporary rule becomes effective either when the Codifier of Rules enters the rule in the Code or on the sixth business day after the agency resubmits the rule without change. The temporary rule is in effect for the period specified in the rule or 180 days, whichever is less. An agency adopting a temporary rule must begin rule-making procedures on the permanent rule at the same time the temporary rule is filed with the Codifier.

NORTH CAROLINA ADMINISTRATIVE CODE

The *North Carolina Administrative Code* (NCAC) is a compilation and index of the administrative rules of 25 state agencies and 38 occupational licensing boards. The NCAC comprises approximately 15,000 letter size, single spaced pages of material of which approximately 35% of is changed annually. Compilation and publication of the NCAC is mandated by G.S. 150B-21.18.

The Code is divided into Titles and Chapters. Each state agency is assigned a separate title which is further broken down by chapters. Title 21 is designated for occupational licensing boards.

The NCAC is available in two formats.

- (1) Single pages may be obtained at a minimum cost of two dollars and 50 cents (\$2.50) for 10 pages or less, plus fifteen cents (\$0.15) per each additional page.
- (2) The full publication consists of 53 volumes, totaling in excess of 15,000 pages. It is supplemented monthly with replacement pages. A one year subscription to the full publication including supplements can be purchased for seven hundred and fifty dollars (\$750.00). Individual volumes may also be purchased with supplement service. Renewal subscriptions for supplements to the initial publication are available.

Requests for pages of rules or volumes of the NCAC should be directed to the Office of Administrative Hearings.

CITATION TO THE NORTH CAROLINA REGISTER

The *North Carolina Register* is cited by volume, issue, page number and date. 1:1 NCR 101-201, April 1, 1986 refers to Volume 1, Issue 1, pages 101 through 201 of the *North Carolina Register* issued on April 1, 1986.

FOR INFORMATION CONTACT: Office of
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NORTH CAROLINA REGISTER



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NORTH CAROLINA REGISTER

Publication Schedule

(July 1993 - May 1994)

Volume and Issue Number	Issue Date	Last Day for Filing	Last Day for Electronic Filing	Earliest Date for Public Hearing <i>15 days from notice</i>	* End of Required Comment Period <i>30 days from notice</i>	Last Day to Submit to RRC	** Earliest Effective Date
8:7	07/01/93	06/10/93	06/17/93	07/16/93	08/02/93	08/20/93	10/01/93
8:8	07/15/93	06/23/93	06/30/93	07/30/93	08/16/93	08/20/93	10/01/93
8:9	08/02/93	07/12/93	07/19/93	08/17/93	09/01/93	09/20/93	11/01/93
8:10	08/16/93	07/26/93	08/02/93	08/31/93	09/15/93	09/20/93	11/01/93
8:11	09/01/93	08/11/93	08/18/93	09/16/93	10/01/93	10/20/93	12/01/93
8:12	09/15/93	08/24/93	08/31/93	09/30/93	10/15/93	10/20/93	12/01/93
8:13	10/01/93	09/10/93	09/17/93	10/18/93	11/01/93	11/22/93	01/04/94
8:14	10/15/93	09/24/93	10/01/93	11/01/93	11/15/93	11/22/93	01/04/94
8:15	11/01/93	10/11/93	10/18/93	11/16/93	12/01/93	12/20/93	02/01/94
8:16	11/15/93	10/22/93	10/29/93	11/30/93	12/15/93	12/20/93	02/01/94
8:17	12/01/93	11/05/93	11/15/93	12/16/93	01/03/94	01/20/94	03/01/94
8:18	12/15/93	11/24/93	12/01/93	12/30/93	01/14/94	01/20/94	03/01/94
8:19	01/03/94	12/08/93	12/15/93	01/18/94	02/02/94	02/21/94	04/01/94
8:20	01/14/94	12/21/93	12/30/93	01/31/94	02/14/94	02/21/94	04/01/94
8:21	02/01/94	01/10/94	01/18/94	02/16/94	03/03/94	03/21/94	05/01/94
8:22	02/15/94	01/25/94	02/10/94	03/02/94	03/17/94	03/21/94	05/01/94
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8:24	03/15/94	02/22/94	03/10/94	03/30/94	04/14/94	04/20/94	06/01/94
9:1	04/04/94	03/11/94	03/18/94	04/19/94	05/04/94	05/20/94	07/01/94
9:2	04/15/94	03/24/94	03/31/94	05/02/94	05/16/94	05/20/94	07/01/94
9:3	05/02/94	04/11/94	04/18/94	05/17/94	06/01/94	06/20/94	08/01/94
9:4	05/16/94	04/25/94	05/02/94	05/31/94	06/15/94	06/20/94	08/01/94

Note: Time is computed according to the Rules of Civil Procedure, Rule 6.

* An agency must accept comments for at least 30 days after the proposed text is published or until the date of any public hearing, whichever is longer. See G.S. 150B-21.2(f) for adoption procedures.

** The "Earliest Effective Date" is computed assuming that the agency follows the publication schedule above, that the Rules Review Commission approves the rule at the next calendar month meeting after submission, and that RRC delivers the rule to the Codifier of Rules five (5) business days before the 1st business day of the next calendar month.

Revised 07/93

**EXECUTIVE ORDER NUMBER 23
PUBLIC SCHOOL ADMINISTRATOR
TASK FORCE**

WHEREAS, this Administration has a goal of doing more with less in our public schools by increasing effectiveness and efficiency;

WHEREAS, business and industry leaders have built up valuable expertise in using this strategy;

WHEREAS, the most effective and efficient ratio of local public school administrators to teachers and students is not known;

NOW, THEREFORE, by the power vested in me as Governor by the Constitution and laws of North Carolina, **IT IS ORDERED:**

Section 1. Recission of Executive Order.

Executive Order 12, dated May 12, 1993, is hereby rescinded.

Section 2. Establishment.

There is hereby established a Public School Administrator Task Force ("Task Force").

Section 3. Membership and Chair.

The Task Force shall consist of the following members:

- (a) twelve business and industry leaders with experience in improving effectiveness and efficiency in their organizations appointed by the Governor;
- (b) nine representatives of the public school system, appointed by the Governor, consisting of: three superintendents, three principals, and three teachers. A small, medium, and large public school system shall be represented in each category;
- (c) the Director of State Personnel, or his designee;
- (d) the State Auditor, or his designee;
- (e) the Superintendent of Public Instruction, or his designee; and
- (f) the State Budget Officer, or his designee.

The chair shall be designated by the Governor, and the Task Force shall meet at the call of the Chair.

Section 4. Duties.

The Task Force shall have the following duties:

- (a) Analyze existing ratios of local public

school administrators to teachers and students;

- (b) Determine the ratio necessary to effectively and efficiently administer quality education at the local level;
- (c) Develop guidelines for local public school administrators to follow in implementing more effective and efficient administration; and
- (d) Report its findings and recommendations to the Joint Legislative Education Oversight Committee and to the State Board of Education by May 1, 1994.

Section 5. Administration and Expenses.

The Task Force members shall be reimbursed for reasonable travel and other expenses as allowed by North Carolina law. Administrative and staff support for the Task Force shall be principally provided by the Office of the Governor. Additional staff support may be provided by other state agencies as required.

This order is effective immediately, and shall terminate upon completion of the Task Force's reported findings and recommendations.

Done in the Capital City of Raleigh, North Carolina, this 26th day of August, 1993.

**TITLE 1 - DEPARTMENT OF
ADMINISTRATION**

Notice is hereby given in accordance with G.S. 150B-21.2 that the State Employees Combined Campaign Advisory Committee intends to amend rules cited as 1 NCAC 35 .0101 - .0103, .0201 - .0204, .0301 - .0307 and repeal rule cited as 1 NCAC 35 .0303. Existing Rules 1 NCAC 35 .0301 - .0302, .0401 - .0407 are proposed to be recodified as .0203 - .0204, .0301 - .0307. This notice reflects those recodification changes.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on October 4, 1993 at the State Library Building, Room 211, 109 East Jones Street, Raleigh, NC.

Reason for Proposed Action: To clarify and consolidate rules applying to charitable organizations applying for inclusion in the State Employees Combined Campaign.

Comment Procedures: Written comments should be submitted to: Secretary Betty Ray McCain, Department of Cultural Resources, 109 East Jones Street, Raleigh, NC 27603.

**CHAPTER 35 - STATE EMPLOYEES
COMBINED CAMPAIGN**

**SECTION .0100 - PURPOSE AND
ORGANIZATION**

.0101 DEFINITIONS

~~The purpose of the State Employees Combined Campaign is to allow state employees the opportunity to contribute to charitable non-partisan organizations in an orderly and uniform process. The contributions are in turn granted to those charities selected by the S.E.C.C. Advisory Committee.~~

~~These Regulations apply only to those campaigns in which employees are asked to make charitable donations using payroll deduction as method of payment.~~

(a) "Charitable organization." A non-partisan organization that is tax-exempt for both the IRS and N.C. tax purposes. The organization must

receive contributions that are tax deductible by the donor.

(b) "Audit" or "audited financial statement." An examination of financial statements of an organization by a CPA, conducted in accordance with generally accepted auditing standards, to determine whether, in the CPA's opinion, the statements conform with generally accepted accounting principles or, if applicable, with another comprehensive basis of accounting.

(c) "State Employees Combined Campaign" or "SECC." The official name of the state employees charitable fund-raising drive.

(d) "Federation" or "Federated Group" means a group of voluntary charitable human health and welfare agencies organized for purposes of supplying common fund-raising, administrative, and management services to its constituent members.

Statutory Authority G.S. 143-3.3; 143B-10.

.0102 PURPOSE

~~The official name of the state employees charitable fundraising drive is the State Employees Combined Campaign (SECC).~~

The purpose of the State Employees Combined Campaign is to allow state employees the opportunity to contribute to charitable non-partisan organizations in an orderly and uniform process. The contributions are in turn granted to those charities selected by the SECC Advisory Committee. The SECC is authorized to conduct a payroll deduction fund-raising effort among state employees.

Statutory Authority G.S. 143-3.3; 143B-10.

**.0103 ORGANIZATION OF THE
CAMPAIGN**

The Campaign Organization is as follows:

- (1) Chair. Each year the ~~governor~~ Governor may appoint a ~~State~~ Statewide Combined Campaign ~~Director~~ Chair from one of the Executive Cabinet, Council of State, System of Community Colleges, or University Administration agencies. The Campaign ~~Director~~ Chair or the Campaign ~~Director's~~ Chair's designee will serve as ~~chair~~ director of the campaign. The responsibilities of the ~~chair~~ Chair include setting the dates and approving the published materials for the Combined Campaign, contracting for the Statewide Campaign Manager, and appointing and serving as chair of the ~~S.E.C.C. advisory committee~~ SECC Advisory Committee.

For the purposes of selecting a Statewide Campaign Manager, the Statewide Combined Campaign Chair will consider the following criteria:

- (a) The organization must have demonstrated ability to manage large-scale fund-raising campaigns.
 - (b) The organization must have the ability and willingness to work with a statewide system of local organizations capable of effectively managing local combined campaigns and relating to the Statewide Campaign Manager.
 - (c) The organization must have an acceptable record of financial accountability.
 - (d) The organization must be a tax-exempt organization under the Internal Revenue Code.
 - (e) The organization must be willing and able to provide a bond in an amount satisfactory to the SECC Advisory Committee to protect the participant organizations and donors.
- (2) SECC Advisory Committee. This ongoing committee serves as a central application point for all charitable organizations applying to participate in the S.E.C.C. SECC. The committee recommends overall policy for the campaign to the Governor, the Statewide Campaign ~~Director~~ Chair, and necessary state agencies and recommends the criteria for participation by charitable organizations. The committee reviews the recommendations made by the Statewide Campaign Manager and accepts or rejects its recommendations. The committee may, in its discretion, require the Statewide Campaign Manager to provide a bond, as provided in Item (1)(e) of this Rule. The committee is composed of 10 state employee members appointed by the Statewide Campaign ~~Director~~ Chair. ~~Members of the committee will initially serve staggered terms of one, two, and three calendar years determined by the Campaign Director. As each member's term expires, the replacement members will serve a three year calendar appointment. Members serve three-year staggered terms at the pleasure of the Statewide Campaign Chair. If a vacancy occurs, the Statewide Campaign Chair shall appoint a replacement to fill the unexpired term. Any member may be reap-~~

pointed at the end of his or her term.

- (3) Statewide Campaign Manager. The Statewide Campaign Manager is selected by the Statewide Campaign Chair. The duties of the Statewide Campaign Manager include, but are not limited to, the following:
 - (a) serving as the financial administrator of the SECC;
 - (b) determining if the applicant agencies meet the requirements of Rule .0202 of this Chapter;
 - (c) submitting to the Statewide Campaign Chair the name of an organization to serve as Local Campaign Manager;
 - (d) providing the necessary supervision of data processing services in order to process all payroll deduction pledge forms of state employees;
 - (e) receiving reports from the Local Campaign Manager;
 - (f) transmitting to each Local Campaign Manager its share of the state employees payroll deduction funds;
 - (g) printing and distributing the pledge form, the campaign report form and collection envelopes to the Local Campaign Manager;
 - (h) maintaining an accounting of all funds raised and submitting an interim unaudited end-of-campaign report of the following:
 - (i) amounts contributed and pledged;
 - (ii) number of contributions; and
 - (iii) amounts distributed to each participating agency;
 - (i) Once applications for acceptance into the campaign have been recommended to the SECC Advisory Committee by the Statewide Campaign Manager, a list of all accepted organizations will be prepared by the Statewide Campaign Manager and distributed to all applicants.
- ~~Serves as the financial administrator for the Combined Campaign and as such is responsible for receiving reports from the local Combined Campaigns, for transmitting to each local campaign its share of the state employees payroll deduction funds, and for preparing an end-of-campaign report which summarizes all fiscal campaign activity including local audits. The Statewide Campaign Manager is also responsible for~~

- ~~the printing and distribution of the pledge form, campaign report form, and collection envelopes.~~
- (4) Local Campaign Chair. The Governor, if asked by the local charitable organizations accepted into the Combined Campaign, may appoint an area representative from either state government or the University of North Carolina system to serve as the ~~local chair~~ Local Chair. This person will be responsible for forming a ~~local advisory committee~~ Local Advisory Committee for recruitment of volunteer state employees. The Local Chair and the Local Advisory Committee are jointly responsible for the approval of local campaign literature, the establishment of local goals as needed, and the distribution of any undesignated funds made available for distribution.
- (5) Local Campaign Manager. ~~Once applications for acceptance into the campaign have been recommended to the Committee by the Statewide Campaign Manager, a list of all accepted organizations will be prepared by the Statewide Campaign Manager and distributed to all applicants. The State Campaign Manager will submit to the State Combined Campaign Director the name of an agency to serve as the local campaign manager. The Campaign Director Chair will approve or reject the State Campaign Manager's recommendation and has the right to name the Local Campaign Manager. The Local Campaign Manager must identify itself on all printed materials as the local manager of the SECC rather than of any other organization.~~
- (a) For the purpose of selecting a Local Campaign Manager, the Statewide Campaign Chair and Statewide Campaign Manager will consider the following criteria:
- (i) be a local organization willing to conduct a local SECC;
 - (ii) comply with the terms of the State/Local Managers contract;
 - (iii) have a broad base of community and state employee support and volunteer involvement;
 - (iv) have a demonstrated ability and successful history of managing fund-raising campaigns that include:
 - (A) development of campaign strategy;
 - (B) development of campaign materials;
 - (C) development of volunteer campaign structures;
 - (D) training of volunteer solicitors;
 - (E) have a financial structure and resources that can efficiently manage, account for, and disburse funds;
 - (F) be a participant organization of the campaign;
 - (G) must be able to develop financial relationships with a network of statewide organizations so as to ensure the orderly transmittal, disbursement, accounting of, and reporting of donations and pledges.
- (b) The local manager Local Campaign Manager is responsible for assisting the Local Campaign Chair and Local Campaign Advisory Committee in the printing and distribution of campaign literature, the collection of pledge reports and envelopes from the state agency volunteers, the development of campaign reports, and the forwarding of one copy of each payroll deduction pledge to the Statewide Campaign Manager. In addition, an end of campaign report shall be sent to the Statewide Campaign Manager for inclusion in the required fiscal reports.
- (c) The Local Campaign Manager is responsible for the following:
- (i) establishing an account with a bank in order to receive deposits of collected funds; and
 - (ii) distributing the funds from the contributions in accordance with designations made by state employees. Undesignated funds will be distributed according to APA regulations governing the SECC.

Note: A contract between the state and the Statewide Campaign Manager, and the ~~state~~ Statewide and ~~local manager~~ Local Campaign Managers, will be executed in order to develop an acceptable audit trail. The contracts will allow a reasonable charge for campaign expenses to be claimed by the Statewide Campaign Manager and the ~~local manager~~ Local Manager. All terms and conditions of these contracts are subject to review and approval by the Statewide Campaign Director Chair.

Statutory Authority G.S. 143-3.3; 143B-10.

SECTION .0200 - APPLICATION PROCESS AND SCHEDULE

.0201 APPLICATIONS

To be eligible to participate in the State Employees Combined Campaign, an organization must apply annually for consideration, either as an independent organization or as a group of organizations federation.

Statutory Authority G.S. 143-3.3; 143B-10.

.0202 CONTENT OF APPLICATIONS

(a) All organizations seeking inclusion in the campaign must submit an application to the state campaign. The application must include a completed State Employees Combined Campaign Certificate of Compliance, provided by the State-wide Campaign Manager. Included in or attached to the Certificate of Compliance must be:

- (1) A letter from the board of directors requesting inclusion in the campaign.
- (2) A complete description of services provided, the service area of the organization, and fund-raising/administrative costs.
- (3) The most recent audited financial statement prepared by a CPA within the past two years. The year end of such audited financial statement must be no earlier than two years prior to the current year's campaign date. The SECC Advisory Committee may grant an exception to this requirement if an organization has filed its Articles of Incorporation with the Secretary of State's Office since March 1 of the preceding year of the current campaign.
- (4) A board statement of assurance of non-discrimination of employment, board membership and client services.
- (5) A description of the origin, purpose and structure of the organization.
- (6) A list of the current members of the board, including their addresses.
- (7) A letter from the board of directors certifying compliance with the eligibility standards listed in Paragraph (b) of this Rule.
- (8) When a federated fund-raising organization submits an application they may submit the credentials of the federation only, not each member agency. By the

submission of such, the federations certify that all of their member agencies comply with all the SECC regulations, unless there are exceptions. If there are exceptions to the requirements, the federations must disclose such and explain to the satisfaction of the State-wide Combined Campaign Advisory Committee the reasons for the exception.

(b) Organizations must meet the following criteria to be accepted as participants in the Combined Campaign:

- (1) The organization must be licensed to solicit funds in North Carolina if a license is required by law.
- (2) ~~Have~~ Must provide written proof of tax exempt status for both ~~the IRS~~ federal and N.C. tax purposes. Organizations must certify that contributions from state employees are tax deductible by the donor under N.C. and federal law.
- (3) Must prepare and make available to the general public an annual audited financial statement, report or IRS Form 990. The SECC Advisory Committee may grant an exception to this requirement if an organization has filed its Articles of Incorporation with the Secretary of State's Office since March 1 of the preceding year of the current campaign. ~~An exception to this requirement is provided for any organization which has filed its Articles of Incorporation with the Secretary of State's Office as of March 1, of the preceding year of the current campaign.~~
- (4) If fund-raising and administrative expenses are in excess of 25 percent of total revenue, the organization must demonstrate to the satisfaction of the SECC that those expenses for this purpose are reasonable under all the circumstances of the case.
- (5) Must certify that all publicity and promotional activities are truthful and non-deceptive and that all material provided to the SECC is truthful and non-deceptive.
- (6) Must agree to maintain the confidentiality of the contributor list.
- (7) Must permit no payments of commissions, kickbacks, finders fees, percentages, bonuses, or overrides for fund-raising, and permit no paid solicitations

- of the public.
- (8) Must have a policy of non-discrimination on the basis of race, color, religion, sex, age, national origin or physical or mental ~~handicap~~ disability for clients of the agency, employees of the agency and members of the governing board.
- (9) Must provide benefits or services within the local community, meaning that employees in the solicitation area or their families should be able to receive benefits or services from the agency within a reasonable distance, ~~or receive benefits from voluntary agencies.~~ Examples of services ~~are~~ include:
- (a) (A) research and education in the health and welfare or education fields;
 - (b) (B) family and child care services;
 - (c) (C) protective services for children and adults;
 - (d) (D) services for children and adults in foster care;
 - (e) (E) services related to the management and maintenance of the home;
 - (f) (F) day care services for adults and children;
 - (g) (G) transportation services, information referral and counseling services;
 - (h) (H) the preparation and delivery of meals;
 - (i) (I) adoption services;
 - (j) (J) emergency shelter care and relief services;
 - (k) (K) safety services;
 - (l) (L) neighborhood and community organization services;
 - (m) (M) recreation services;
 - (n) (N) social adjustment and rehabilitation services;
 - (o) (O) health support services; or
 - (p) (P) a combination of services designed to meet the needs of special groups such as the elderly or ~~handicapped~~ disabled.

However, an international organization which provides health and welfare services overseas, whose activities do not require a local presence and which meet other eligibility criteria, may be accepted for participation in the campaign.

Statutory Authority G.S. 143-3.3; 143B-10.

.0301 .0203 SCHEDULE

Complete applications must be submitted to the

~~State~~ Statewide Combined Campaign Advisory Committee by February 15 annually to be included in the fall campaign. Incomplete applications may not be considered by the committee. The Chair will forward all application materials to the Statewide Campaign Manager within three working days after the closing deadline. The Statewide Campaign Manager will report to the Committee its recommendation on each application within three weeks of the closing deadline. The Committee shall affirm or reject each recommendation by the Statewide Campaign Manager and will inform the Statewide Campaign Manager of its decisions.

Statutory Authority G.S. 143-3.3; 143B-10.

.0302 .0204 RESPONSE

All applicants will be notified by the Statewide Campaign Manager of the Committee's decision within ~~30~~ 45 days of the closing deadline. An applicant who is dissatisfied with the determination of its application may file an appeal to the State Advisory Committee within 10 days of the notification ~~dispatch~~ postmark date. An applicant who is dissatisfied with either the ~~committee's~~ Committee's decision or the appeal determination of the ~~committee~~ Committee may commence a contested case by filing a petition under 150B-23 within 60 days of notification ~~dispatch~~ postmark date of the Committee's decision.

Statutory Authority G.S. 143-3.3; 143B-10.

.0303 FORM AND CONTENT OF APPLICATION

~~All organizations seeking funding must submit an application to the state campaign. The application must include the State Employees Combined Campaign Certificate of Compliance. Included in or attached to the Certificate of Compliance must be:~~

- (1) ~~A letter from the board of directors indicating interest.~~
- (2) ~~A complete description of services provided, and the service area of the organization.~~
- (3) ~~The most recent audited financial statement prepared by a CPA. An exception to this requirement is provided for any organization which has filed its Articles of Incorporation with the Secretary of State's Office as of March 1, of the preceding year of the current campaign.~~
- (4) ~~A board statement of assurance of non-discrimination.~~

- ~~(5) A description of the origin, purpose and structure of the organization.~~
- ~~(6) A list of the current members of the board, including addresses.~~
- ~~(7) A letter certifying compliance with the eligibility standards listed in Rule .0202 of this Chapter including tax exempt status, licensing, and showing the percentage of funds expended in the categories of Program and Service, Management and General (Administrative) and Fundraising.~~

Statutory Authority G.S. 143-3.3; 143B-10.

SECTION .0400 .0300 - GENERAL PROVISIONS

~~.0401~~ .0301 OTHER SOLICITATION PROHIBITED

Not more than one on-the-job solicitation for funds will be made in any year at any location on behalf of participating SECC agencies. The prohibition does not include Red Cross sponsored Bloodmobiles or employee association solicitations. ~~The State Employee Combined Campaign is the only authorized payroll deduction fund raising effort among state employees.~~

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0402~~ .0302 COERCIVE ACTIVITIES PROHIBITED

(a) In order to insure that donations are made on a voluntary basis, actions that do not allow free choice or that create an impression of required giving are prohibited. Peer solicitation is encouraged. Employee Employees gifts are kept confidential, except that employees may opt to have their designated contributions acknowledged by the recipient organizations.

(b) The following activities are not permitted:

- (1) The Providing providing and using of contributor lists for purposes other than the routine collection, ~~and forwarding,~~ and acknowledgement of contributions.
- (2) The establishment of personal dollar goals or quotas.
- (3) The developing and using of lists of non-contributors.

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0403~~ .0303 PAYMENT METHOD AND TERMS OF CONTRIBUTION

Payment may be made by payroll deduction, cash, ~~pledge,~~ or personal check. If an employee chooses to use the payroll deduction method of contributing, he/she must agree to ~~having~~ have the deduction continue for one year with equal amounts ~~being taken~~ deducted from each check (monthly or biweekly depending on the payroll). All deductions will start with the January payroll and continue through December. If the employee discontinues employment, or actively chooses to discontinue payment, the state will not be responsible for the collection of the unpaid pledge. No deduction will be made for any period in which the employee's net pay, after all legal and previously authorized deductions, is insufficient to cover the allotment. No adjustments will be made in subsequent periods to make up for deductions missed.

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0404~~ .0304 CAMPAIGN LITERATURE

Each charitable organization accepted as a part of the campaign, must provide adequate information about its services, including administrative/fund-raising costs, to the ~~local campaign manager~~ Local Campaign Manager for use in the local campaign.

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0405~~ .0305 DESIGNATION CAMPAIGN

Each employee will be given the opportunity to designate which agency or group of agencies should benefit from his or her contribution to the State Employees Combined Campaign. Each employee will be given a listing list of the approved agencies in the campaign in order to help them make the decision.

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0406~~ .0306 DISTRIBUTION OF UNDESIGNATED FUNDS

All contributions made through the ~~S.E.C.C.~~ SECC should be designated to a particular recipient. Any monies not designated to a particular recipient shall be deemed as undesignated funds. Undesignated funds shall be allocated by the ~~S.E.C.C.~~ SECC to the ~~county/local S.E.C.C.~~ SECC committees. The ~~county/local S.E.C.C.~~ SECC shall distribute these funds within their communities.

Statutory Authority G.S. 143-3.3; 143B-10.

~~.0407~~ .0307 EFFECTIVE DATE OF

AMENDED RULES

These amended rules shall ~~become effective as specified by statute and shall apply to all applications then pending or thereafter approved be effective for the 1994 SECC and thereafter.~~

Statutory Authority G.S. 143-3.3; 143B-10.

TITLE 10 - DEPARTMENT OF HUMAN RESOURCES

Notice is hereby given in accordance with G.S. 150B-21.2 that the Division of Facility Services intends to adopt the rules cited as 10 NCAC 3R .0214, .1213 - .1219, .1413 - .1419, .1619, .1720, .1912 - .1918, .2120, .2314 - .2320, .2713 - .2719, .3101 - .3108, .3201 - .3207, .3301 - .3306, .3401 - .3407, .3501 - .3507, .3601 - .3607, .3701 - .3707, .3801 - .3807, .3901 - .3908, .4001 - .4012, .4101 - .4107; amend rules cited as 10 NCAC 3R .0304, .0309, .0321, .1613 - .1618, .1713 - .1715, .1717 - .1719, .2113 - .2119; and repeal rules cited as 10 NCAC 3R .1202 - .1209, .1402, .1404 - .1409, .1716, .1902, .1904 - .1908, .2702 - .2707, .2710 - .2711.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 29, 1993 at the Council Building, Room 201, 701 Barbour Drive, Raleigh, North Carolina 27603.

Reason for Proposed Action:

10 NCAC 3R .1202 - .1209, .1213 - .1219, .1617 - .1619, .1716, .1720, .2120, 4101 - .4107 - Repeal existing "intensive care service", "open heart surgical services" rules and adopt rules which would incorporate current medical practices and technologies. Amend existing and establish criteria and standards for review of CON applications for Pediatric Intensive Care Services, Cardiac Catheterization Services and Ambulatory Surgery Services.

10 NCAC 3R .1614, .1615 - .1616, .2115, .2117, .2118 - To adopt as permanent rules amendments to the temporary rules adopted effective September 1, 1993, which amend existing criteria and standards for Cardiac Catheterization Services and Ambulatory Surgical Services.

10 NCAC 3R .0214, .2314 - .2320, .3101 - .3108,

.3201 - .3207, .3301 - .3306, .3401 - .3407, .3501 - .3507, .3601 - .3607, .3701 - .3707, .3801 - .3807, .3901 - .3908, .4001 - .4012 - To adopt as permanent rules the temporary rules adopted effective September 1, 1993, which amend existing and establishes criteria and standards pursuant to Senate Bill 10 which was ratified on March 18, 1993.

10 NCAC 3R .1402, .1404 - .1409, .1413 - .1419, .1902, .1904 - .1908, .1912 - .1918, .2702 - .2707, .2710 - .2711, .2713 - .2719 - To repeal existing rules and adopt as permanent rules the temporary rules adopted effective September 1, 1993 which establishes criteria and standards pursuant to Senate Bill 10 which was ratified on March 18, 1993.

10 NCAC 3R .0304, .0309, .0321, .1613, .1713 - .1715, .1717 - .1719, .2113 - .2114, .2116, .2119 - To adopt as permanent rules the temporary rules adopted September 1, 1993 which amends existing and establishes criteria and standards pursuant to Senate Bill 10 which was ratified on March 18, 1993.

Comment Procedures: All written comments must be submitted to Jackie Sheppard, APA Coordinator, Division of Facility Services, P. O. Box 29530, Raleigh, NC 27626-0530, telephone (919) 733-2342, up to and including October 29, 1993. Written comments submitted after the deadline will not be considered.

Editor's Note: Temporary rules have been filed effective September 1, 1993 with the exception of Rules 10 NCAC 3R .1202 - .1209, .1213 - .1219, .1617 - .1619, .1716, .1720, .2120 and .4101 - .4107. The text of the temporary rules may differ from the proposed permanent rules published in this notice. The temporary rules can be obtained by contacting the Office of Administrative Hearings, Rules Division at (919) 733-2678.

CHAPTER 3 - FACILITY SERVICES

SUBCHAPTER 3R - CERTIFICATE OF NEED REGULATIONS

SECTION .0200 - EXEMPTIONS

.0214 REPLACEMENT EQUIPMENT

(a) The purpose of this Rule is to define the terms used in the definition of "replacement equipment" set forth in G.S.131E-176(22a).

(b) "Activities essential to acquiring and making operational the replacement equipment" means those activities which are indispensable and requisite; absent which the replacement equipment could not be acquired or made operational.

(c) "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

(d) Replacement equipment is comparable to the equipment being replaced if:

- (1) it has the same basic technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired; and
- (4) it will be located on the same site or campus as the equipment currently in use.

(e) Replacement equipment is not comparable to the equipment being replaced if:

- (1) the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- (2) the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- (3) the replacement equipment is permanently fixed equipment and the existing equipment is one piece of mobile equipment which is shared between two or more facilities.

Statutory Authority G.S. 131E-177(1).

SECTION .0300 - APPLICATION AND REVIEW PROCESS

.0304 DETERMINATION OF REVIEW

(a) After receipt of a letter of intent, the agency shall determine whether the proposed project requires a certificate of need. ~~In making this decision the agency shall consider the obligation of a capital expenditure on behalf of or for a health service facility to be:~~

- ~~(1) an expenditure to be obligated or incurred by the facility;~~
- ~~(2) an expenditure to be obligated or incurred by any person, board or organization having ownership or control of the facility, or over which the facility has ownership or control and which relates to the provision of a health service;~~
- ~~(3) an expenditure to be obligated or incurred by any person, board or organization with which the facility has a contractual relationship to provide or purchase services, or share space, profit or expenses in connection with the provision of a health service; or~~
- ~~(4) an expenditure to be obligated or incurred by any person, board or organization developing a health service on property owned or leased to or by the facility.~~

(b) If it is determined that the project requires a certificate of need, the agency will determine the appropriate review category or categories for the proposed project, the type or types of application forms to be submitted, the number of separate applications to be submitted, the applicable review period for each application, and the deadline date for submitting each application.

(c) Copies of the application forms may be obtained from the agency.

(d) Proposals requiring review will be reviewed according to the categories and schedule set forth in the duly adopted State Medical Facilities Plan in effect at the time scheduled review period commences.

(e) Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.

Statutory Authority G.S. 131E-177; 131E-182.

.0309 REVIEW PERIOD

(a) The review of an application for a certificate of need shall be completed within 90 days from the beginning date of the review period for the appli-

cation, except as provided in Paragraph (b) of this Rule.

(b) Except in the case of an expedited review, The the period for review may be extended for up to 60 days by the agency if it determines that, for one or more of the following reasons, it cannot complete the review within 90 days:

- (1) the extension is necessary to consider conflicting, contradictory, or otherwise relevant matters;
- (2) the total number of applications assigned to the project analyst for review, including those in other review periods, preclude the project analyst from completing the review within 90 days;
- (3) the complexity of the application or applications to be reviewed make it necessary to extend the review period;
- (4) the review of an applicant's response to the agency's request for additional information has not been completed;
- (5) the timing of the public hearing which was held for the application or applications under review does not allow sufficient time to consider the information presented;
- (6) extension of previous reviews necessitated that the project analyst delay the commencement of the review; or
- (7) the unavailability of the project analyst due to illness, annual leave, litigation associated with other reviews, or other duties and responsibilities.

(c) In the case of an expedited review, the review period may be extended only if the Agency has requested additional substantive information from the applicant in accordance with G.S. 131E-185(c).

(d) (e) Applicants will be provided written notice of the extension of the review period after the agency determines that an extension is necessary. Failure to receive such notice prior to the last day of the scheduled review period, however, does not entitle an applicant to a certificate of need nor authorize an applicant to proceed with a project without one.

Statutory Authority G.S. 131E-177; 131E-185.

.0321 EXPEDITED REVIEW

(a) An applicant which desires an expedited review shall submit a petition for an expedited review with the Certificate of Need Section when

the application is submitted.

(b) The Certificate of Need Section shall review the petition within 15 days from the beginning of the review and shall notify the applicant if the Agency has determined that a public hearing is in the public interest.

(c) If the Certificate of Need Section decides that it is not in the public interest to hold a public hearing, a final determination on the request for an expedited review shall not be issued until after the thirty day written comment period has expired.

(d) If a request for a public hearing is received by the Agency during the 30 day written comment period, which is defined in G.S. 131E-185, the request for an expedited review shall be denied.

(e) After the thirty day written comment period, the Certificate of Need Section shall notify the applicant that its petition for an expedited review is approved or denied.

Statutory Authority G.S. 131E-177(1).

SECTION .1200 - CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

.1202 DEFINITIONS

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

- (1) ~~"Intensive care services" means those services provided by an acute care care hospital to patients who require continuous, comprehensive observation and a high level of nursing care.~~
- (2) ~~"Intensive care unit" means a separate self-sufficient entity within which all necessary supplies and equipment essential to provide intensive care services are available to patients requiring them. This does not include post-operative recovery rooms, post-delivery rooms, or emergency observation units.~~

Statutory Authority G.S. 131E-177(1).

.1204 CAPACITY IN THE FACILITY AND IN THE HEALTH SERVICE AREA

(a) ~~Proposals filed by or on behalf of hospital facilities for intensive care services must be consistent with the applicable North Carolina State Medical Facilities Plan, with the applicable North Carolina State Health Plan (the one in effect at time of final agency decision) and with the applicable health systems plan.~~

(b) ~~Proposals involving new or expanded intensive care beds must specify the numbers of intensive care beds to be operated following the completion of the proposed project.~~

(c) ~~A proposal involving additional intensive care beds shall not be approved unless the overall average annual occupancy, over the 12 months immediately preceding the submittal of the proposal, of the total number of functional existing intensive care beds in the facility in which the proposed beds are to be operated is at least 70 percent in units with 20 or more intensive care beds, 65 percent in units with 10-19 intensive care beds, and 60 percent in units with 1-9 intensive care beds.~~

Statutory Authority G.S. 131E-177(1).

.1205 SCOPE OF SERVICES OFFERED

~~A proposal to provide new or expanded intensive care services must document the extent to which the following will be available. If any item will not be available, then substantive information must be given obviating the need for that item before approval for a new or expanded service can be given:~~

- ~~(1) a distinct, identifiable area for the provision of intensive care services;~~
- ~~(2) twenty-four hour on-call availability of laboratory and radiology services;~~
- ~~(3) O₂/air/suction capability;~~
- ~~(4) electronic cardiovascular monitoring capability;~~
- ~~(5) capabilities for endotracheal intubation, mechanical ventilatory assistance, and cardiac pacemaker insertion;~~
- ~~(6) cardiac arrest management plan;~~
- ~~(7) twenty-four hour blood bank.~~

Statutory Authority G.S. 131E-177(1).

.1206 PROJECTED UTILIZATION/ OCCUPANCY

~~(a) A proposal to provide new or expanded intensive care services must project an occupancy level for the total intensive care services for each of the first eight calendar quarters following the completion of the proposed project. An occupancy level must also be projected for each specialized type of intensive care service to the extent that specialized types of service are proposed to be operated. All assumptions, including the specific methodologies by which occupancies are projected, must be clearly stated.~~

~~(b) A proposal to provide new or expanded~~

~~intensive care services shall not be approved unless occupancy is projected to be at least 75 percent for the total number of intensive care beds proposed to be operated, no later than three years following the completion of the proposed project. All assumptions, including the specific methodologies by which occupancies are projected, must be clearly stated.~~

~~(c) A proposal to establish a new intensive care or coronary care unit shall not be approved unless the utilization of the unit is projected to be at least at a rate of 4 beds at 75 percent occupancy no later than three years following the completion of the proposed project.~~

Statutory Authority G.S. 131E-177(1).

.1207 PROJECTED PATIENT ORIGIN

~~(a) A proposal to provide new or expanded intensive care services must project patient origin by percentage by county of residence. All assumptions, including the specific methodology by which patient origin is projected, must be clearly stated.~~

~~(b) A proposal to provide new or expanded intensive care services must show that at least 90 percent of the anticipated patient population is within 45 minutes automobile driving time (one-way) from the facility, with the exception that there may be variance from the 90 percent standard for institutions traditionally offering very specialized levels of intensive care to a large and geographically diverse population.~~

Statutory Authority G.S. 131E-177(1).

.1208 SITE AND EQUIPMENT

~~(a) A proposal to provide new or expanded intensive care services must provide documentation to show that the services will be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.~~

~~(b) A proposal to provide new or expanded intensive care services must document the extent to which the following, required by the Joint Commission on Accreditation of Hospitals, will be available. If any item will not be available, then substantive information must be given obviating the need for that item before approval for a new or expanded service can be given:~~

- ~~(1) oxygen and compressed air and the means of administration;~~
- ~~(2) mechanical ventilatory assistance equipment including airways, manual~~

- ~~breathing bag and ventilator/respirator;~~
- ~~(3) cardiac defibrillator with synchronization capability;~~
- ~~(4) respiratory and cardiac monitoring equipment;~~
- ~~(5) thoracentesis and closed thorostomy sets;~~
- ~~(6) tracheostomy set;~~
- ~~(7) tourniquets;~~
- ~~(8) vascular cutdown sets;~~
- ~~(9) infusion pumps;~~
- ~~(10) laryngoscopes and endotracheal tubes;~~
- ~~(11) tracheobronchial and gastric suction equipment;~~
- ~~(12) portable x-ray;~~
- ~~(13) patient weighing device for bed patients.~~

Statutory Authority G.S. 131E-177(1).

.1209 STAFFING

~~(a) A proposal to offer new or expanded intensive care services must provide documentation to show that the appropriate types and numbers of staff, particularly qualified medical and nursing staff, will be available to support the services.~~

~~(b) A proposal to offer new or expanded intensive care services must provide documentation to show that such services will be coordinated by a registered nurse who has formal training in intensive care nursing.~~

Statutory Authority G.S. 131E-177(1).

.1213 DEFINITIONS

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

- (1) "Intensive care services" means those services provided by an acute care hospital to patients with a wide variety of illnesses of a life-threatening nature, including patients with highly unstable conditions which require sophisticated medical and surgical intervention and a high level of nursing care and those patients which require continuous, comprehensive observation.
- (2) "Intensive care unit" means a separate self-sufficient entity which has all supplies, equipment, and staff necessary to offer intensive care services twenty-four hours a day, seven days a week. The term does not include post-operative recovery rooms, post-delivery rooms, or emergency observation units.

Statutory Authority G.S. 131E-177(1).

.1214 INFORMATION REQUIRED OF APPLICANT

(a) Applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form.

(b) Applicant proposing new or expanded intensive care services shall also submit the following additional information:

- (1) the number of intensive care beds currently operated by the applicant and the number of intensive care beds to be operated following completion of the proposed project;
- (2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including:
 - (A) the number of inpatient days of care provided to intensive care patients;
 - (B) the number of patients initially treated at the facility and referred to other facilities for intensive care services; and
 - (C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services.
- (3) the number of patients from the proposed service area who are projected to require intensive care services by the patients' county of residence in each of the first 12 quarters of operation, including all assumptions and methodologies;
- (4) the projected number of patients to be served and inpatient days of care to be provided by county of residence by specialized type of intensive care for each of the first twelve calendar quarters following completion of the proposed project, including all assumptions and methodologies;
- (5) correspondence from the proposed referral sources documenting their intent to refer patients to the applicant's facility;
- (6) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies;
- (7) documentation of written policies and procedures regarding the provision of care within the intensive care unit.

which includes, but is not limited to the following:

- (A) the admission and discharge of patients;
- (B) infection control; and
- (C) safety procedures;
- (8) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access;
- (9) documentation to show that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;
- (10) a detailed floor plan of the proposed area drawn to scale; and
- (11) documentation of a means for observation by unit staff of all patients in the unit from one vantage point.

Statutory Authority G.S. 131E-177(1).

.1215 REQUIRED PERFORMANCE STANDARDS

The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

- (1) the overall average annual occupancy rate of all intensive care beds in the facility, excluding neonatal and pediatric intensive care beds, over the 12 months immediately preceding the submittal of the proposal, shall have been at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds;
- (2) the projected occupancy rate for all intensive care beds in the applicant's facility, exclusive of neonatal and pediatric intensive care beds, shall be at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds, in the third operating year following the completion of the proposed project; and
- (3) all assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided.

Statutory Authority G.S. 131E-177(1).

.1216 REQUIRED SUPPORT SERVICES

(a) An applicant proposing new or additional intensive care services shall document the extent to which the following items are available:

- (1) twenty-four hour on-call laboratory services including microspecimen chemistry techniques and blood gas determinations;
- (2) twenty-four hour on-call radiology services, including portable radiological equipment;
- (3) twenty-four hour blood bank services;
- (4) twenty-four hour on-call pharmacy services;
- (5) twenty-four hour on-call coverage by respiratory therapy;
- (6) oxygen and air and suction capability;
- (7) electronic cardiovascular monitoring capability;
- (8) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
- (9) endotracheal intubation capability;
- (10) cardiac pacemaker insertion capability;
- (11) cardiac arrest management plan;
- (12) patient weighing device for bed patients; and
- (13) isolation capability.

(b) If any item in Subparagraphs (a)(1) - (13) of this Rule will not be available, the applicant shall document the reason why the item is not needed for the provision of the proposed services.

Statutory Authority G.S. 131E-177(1).

.1217 REQUIRED STAFFING AND STAFF TRAINING

The applicant shall demonstrate the ability to meet the following staffing requirements, in accordance with recommendations and standards from the Society of Critical Care Medicine for intensive care units:

- (1) nursing care shall be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support;
- (2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care;
- (3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available; and
- (4) appropriate inservice training or continuing education programs shall be

provided for the intensive care staff.

Statutory Authority G.S. 131E-177(1).

.1218 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and specifically stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

.1219 DATA REPORTING REQUIREMENTS

The facility shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .1400 - CRITERIA AND STANDARDS FOR NEONATAL SERVICES

.1402 DEFINITIONS

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

(1) ~~"Normal newborn services" means those routine services provided by an acute care hospital to normal full term and normal pre-term infants weighing at least 2000 grams at birth. Routine care within this context includes increased observation, screening, and stabilization of infants within the first four to twenty four hours following birth.~~

(2) ~~"Neonatal continuing care services" means those services provided by an acute care hospital to low birth weight infants who are not sick but who require frequent feeding, infants who no longer require neonatal intermediate care services but who still require more nursing hours than normal infants, and infants who require close observation for any reason.~~

(3) ~~"Neonatal intermediate care services" means those services provided by an acute care hospital to sick infants who do not require neonatal intensive care but who do require six to twelve nursing hours per day.~~

(4) ~~"Neonatal intensive care services" means those services provided by an acute care hospital to severely ill infants who require constant nursing care, as well as continuous cardiopulmonary and other supportive care. Neonatal intensive care differs from neonatal intermediate care with regard to the complexity or multiplicity of patient problems, e.g. care required for neonatal surgery patients.~~

(5) ~~"Neonatal services" means any of the services defined in this Rule.~~

Statutory Authority G.S. 131E-177(1).

.1404 CAPACITY IN THE FACILITY AND IN THE HEALTH SERVICE AREA

(a) ~~Proposals filed by or on behalf of hospital facilities for neonatal services must be consistent with the applicable North Carolina State Medical Facilities Plan, with the applicable North Carolina State Health Plan (the one in effect at time of final agency decision), and with the applicable health systems plan.~~

(b) ~~Proposals involving new or expanded neonatal bassinets/beds must specify the numbers of neonatal bassinets/beds to be operated following the completion of the proposed project. Such specification must be in terms of normal newborn services, neonatal continuing care services,~~

neonatal intermediate care services, and neonatal intensive care services. If levels of care other than that for normal newborns are involved, the proponent must define the manner in which the proponent designates beds for such levels.

(c) A proposal involving a net increase in the total number of a facility's existing neonatal intermediate care beds and neonatal intensive care beds shall not be approved unless the overall average annual occupancy, over the 12 months immediately preceding the submittal of the proposal, of the functional existing neonatal intermediate care beds in the facility in which the proposed beds are to be operated is at least 80 percent.

(d) No proposal for additional neonatal intermediate care or neonatal intensive care beds shall be approved unless it is determined that an unmet need exists in the health service area or in the proponent's defined service area in which the proposed beds are to be operated. Need for neonatal intermediate care beds and neonatal intensive care beds shall be computed for each of the six established health service areas in North Carolina by:

- (1) identifying the annual number of live births occurring at all hospitals located within the health service area, using the latest available data compiled by the Division of Health Services;
- (2) identifying the low birth weight rate (percent of live births below 2500 grams) for the births identified in (1) of this Subparagraph, using the latest available data compiled by the Division of Health Services;
- (3) dividing the low birth weight rate identified in (2) of this Subparagraph by .08 and subsequently multiplying the resulting quotient by four; and
- (4) determining need for neonatal intensive care beds and neonatal intermediate care beds in the health service area as the product of:
 - (A) the product derived in (3) of this Subparagraph, and
 - (B) the quotient resulting from the division of the number of live births in the initial year of the projection identified in (1) of this Subparagraph by the number 1000.

(a) A proposal to provide new normal newborn services or neonatal continuing care services must document the extent to which the following will be available. If any item will not be available, then substantive information must be given obviating the need for that item before approval for a new or expanded service can be given:

- (1) a distinct, identifiable area for the provision of the proposed service;
- (2) competence to manage uncomplicated labor and delivery of normal term newborn;
- (3) capability for continuous fetal monitoring;
- (4) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;
- (5) availability of obstetric services;
- (6) capability for cesarean section within 30 minutes at any hour; and
- (7) twenty four hour on-call availability of blood, anesthesia service, radiology service, clinical laboratory service.

(b) A proposal to provide new or expanded neonatal intermediate care services or neonatal intensive care services must meet the requirements of (a) of this Rule as well as document the extent to which the following will be available. If any item will not be available, then substantive information must be given obviating the need for that item before approval for a new or expanded service can be given:

- (1) a distinct, identifiable area for the provision of the proposed service;
- (2) competence to manage labor and delivery of premature newborns and newborns with complications;
- (3) twenty four hour coverage of microchemistry hematology and blood gases;
- (4) twenty four hour coverage by respiratory therapy;
- (5) twenty four hour coverage with portable radiographic capability;
- (6) O₂/air/suction capability;
- (7) electronic cardiovascular and respiration monitoring capability;
- (8) capabilities for endotracheal intubation and mechanical ventilatory assistance;
- (9) cardio-respiratory arrest management plan.

Statutory Authority G.S. 131E-177(1).

.1405 SCOPE OF SERVICES OFFERED

Statutory Authority G.S. 131E-177(1).

.1406 PROJECTED UTILIZATION/ OCCUPANCY

(a) ~~Proponents proposing new normal newborn and neonatal continuing care services must perform, or project to perform, at least 500 deliveries, per year except that a variance from this standard will be allowed to the extent that a substantial portion of the population to be served reside more than 45 minutes automobile driving time (one way) from existing inpatient neonatal services.~~

(b) ~~A proposal to provide new normal newborn or neonatal continuing care services, or new or expanded intermediate care services or neonatal intensive care services, or any combination of the four must project an occupancy level for each of the services for each of the first eight calendar quarters following the completion of the proposed project. All assumptions, including the specific methodologies by which occupancies are projected, must be clearly stated.~~

(c) ~~A proposal to provide new normal newborn and neonatal continuing care services shall not be approved unless for the total number of beds proposed to be operated annual occupancy is projected to be 50 percent. Occupancy is projected to be 60 percent for a 1-10 bed unit, 65 percent for a 11-20 bed unit, 70 percent for a 21-30 bed unit, and 75 percent for a unit of 31 beds or more after two years following the completion of the proposed project. All assumptions, including the specific methodologies by which occupancies are projected, must be clearly stated.~~

(d) ~~A proposal to provide new neonatal intermediate care services or new neonatal intensive care services shall not be approved unless occupancy is projected to be at least 75 percent for the total number of neonatal intermediate care beds and neonatal intensive care beds proposed to be operated, no later than three years following the completion of the proposed projects. All assumptions, including the specific methodologies by which occupancies are projected, must be clearly stated.~~

Statutory Authority G.S. 131E-177(1).

.1407 PROJECTED PATIENT ORIGIN

(a) ~~A proposal to provide new normal newborn or neonatal continuing care services, or new or expanded intermediate care services or neonatal intensive care services, or any combination of the four must project patient origin for each proposed~~

~~service by percentage by county of residence. All assumptions, including the specific methodology by which patient origin is projected, must be clearly stated.~~

(b) ~~A proposal to provide new normal newborn or neonatal continuing care services must document that at least 90 percent of the anticipated patient population is within 45 minutes driving time (one way) from the facility.~~

(c) ~~A proposal to provide new or expanded neonatal intermediate care services or new or expanded neonatal intensive care services must document that at least 90 percent of the anticipated patient population is within 90 minutes driving time (one way) from the facility, with the exception that there may be a variance from the 90 percent standard for institutions with very specialized levels of neonatal care to a large and geographically diverse population.~~

Statutory Authority G.S. 131E-177(1).

.1408 SITE AND EQUIPMENT

~~A proposal to provide new or expanded neonatal services must provide documentation to show that the services will be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.~~

Statutory Authority G.S. 131E-177(1).

.1409 STAFFING

(a) ~~A proposal to offer new or expanded neonatal services must provide documentation to show that the appropriate types and numbers of staff, particularly qualified medical and nursing staff, will be available to support the services.~~

(b) ~~A proposal to offer new or expanded neonatal intermediate care or neonatal intensive care services must provide documentation to show that such services will:~~

- ~~(1) be coordinated by a registered nurse who has completed an organized educational program in neonatal intermediate and intensive care, and~~
- ~~(2) be under the direction of a physician with training and experience in neonatal intermediate and intensive care.~~

Statutory Authority G.S. 131E-177(1).

.1413 DEFINITIONS

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

- (1) "Approved neonatal service" means a

neonatal service that was not operational prior to the beginning of the review period but that had been issued a certificate of need or for which development had been initiated prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.

- (2) "Existing neonatal service" means a neonatal service in operation prior to the beginning of the review period.
- (3) "High-risk obstetric patients" means those patients requiring specialized services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery. The services are characterized by specialized facilities and staff for the intensive care and management of high-risk maternal and fetal patients before and during delivery.
- (4) "Level I neonatal service" means those routine services provided by an acute care hospital to normal full-term and pre-term infants weighing at least 2000 grams at birth. Level I neonatal services include the observation, screening, and stabilization of: infants following birth who are served in a bassinet; infants who are not sick but who require special care and frequent feedings; infants who no longer require Level II or Level III neonatal services, but who still require more nursing hours than normal infants; and infants who require close observation in a licensed acute care bed.
- (5) "Level II neonatal service" means the performance of Level I neonatal services, plus the management of high-risk, small, and sick neonates with a moderate degree of illness that are admitted within the hospital or transferred from another facility. Level II neonatal services involve the management of newborns weighing between approximately 1,500-2,500 grams (or approximately 32 and less than 36 completed weeks of gestational age) that are relatively healthy, or involve intermediate care services for sick infants who do not require intensive care but who do require six to twelve nursing hours per day. Level II neonatal services are provided in a licensed acute care bed.
- (6) "Level III neonatal service" means the performance of Level I and Level II

neonatal services plus the management of high-risk newborns weighing less than 1,500 grams (or approximately under 32 weeks of gestational age), which requires neonatal expertise. Level III neonates require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care, care required for neonatal surgery patients and other intensive care services. Level III neonatal services are provided in a licensed acute care bed.

- (7) "Neonatal intensive care services" is defined in G.S. 131E-176(15b).
- (8) "Neonatal service area" means a geographic area defined by the applicant from which the patients to be admitted to the service will originate.
- (9) "Neonatal services" means any of the Level I, Level II or Level III services defined in this Rule.
- (10) "Obstetric services" means any normal or high-risk services provided by an acute care hospital to the mother and fetus during pregnancy, labor, delivery and to the mother after delivery.
- (11) "Perinatal services" means services provided during the period shortly before and after birth.
- (12) "Perinatal regions" mean a geographic area of the state as established by the Perinatal Council. A copy of the perinatal regions may be obtained from the Division of Maternal and Child Health, Department of Environment, Health and Natural Resources, 1330 St. Mary's Street, Raleigh, NC, 27605-3248.

Statutory Authority G.S. 131E-177(1).

.1414 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new neonatal service or to add a bed to an existing neonatal service shall use the Acute Care Facility/Medical Equipment application form.

(b) The applicant shall provide the following additional information:

- (1) the current number of Level I bassinets, Level I beds, Level II beds and Level III beds operated by the applicant;
- (2) the proposed number of Level I bassinets, Level I beds, Level II beds and Level III beds to be operated following completion of the proposed

- project;
- (3) evidence of the applicant's experience in treating the following patients at the facility during the past twelve months, including:
 - (A) the number of obstetrical patients treated at the acute care facility;
 - (B) the number of neonatal patients treated in Level I bassinets, Level I beds, Level II beds and Level III beds, respectively;
 - (C) the number of inpatient days at the facility provided to obstetrical patients;
 - (D) the number of inpatient days provided in Level I beds, Level II beds and Level III beds, respectively;
 - (E) the number of high-risk obstetrical patients treated at the applicant's facility and the number of high-risk obstetrical patients referred from the applicant's facility to other facilities or programs; and
 - (F) the number of neonatal patients referred to other facilities for services, identified by required level of neonatal service (i.e. Level I, Level II or Level III);
 - (4) the projected number of neonatal patients to be served identified by Level I, Level II and Level III neonatal services and by county of residence for each of the first twelve quarters of operation following the completion of the project, including the methodology and assumptions used for the projections;
 - (5) the projected utilization of the Level I bassinets, Level I beds, Level II beds and Level III beds, respectively, by county of residence for each of the first twelve quarters of operation following completion of the project, including the methodology and assumptions used for the projections;
 - (6) if proposing to provide Level I neonatal services, documentation that at least 90 percent of the anticipated patient population is within 45 minutes driving time one-way from the facility;
 - (7) if proposing to provide Level I neonatal services, documentation of a written plan to transport infants to Level II or Level III neonatal services as the infant's care requires;
 - (8) if proposing to provide Level II or Level III neonatal services, documentation that at least 90 percent of the anticipated patient population is within 90 minutes driving time one-way from the facility, with the exception that there shall be a variance from the 90 percent standard for facilities which demonstrate that they provide very specialized levels of neonatal care to a large and geographically diverse population, or facilities which demonstrate the availability of air ambulance services for neonatal patients;
 - (9) evidence that existing and approved neonatal services and obstetric services in the applicant's perinatal region and in the applicant's defined neonatal service area are unable to accommodate the applicant's projected need for additional Level II and Level III services;
 - (10) documentation of the availability of existing obstetric services, and the identification of all obstetrics programs and neonatal services which currently serve patients from the applicant's primary service area;
 - (11) an analysis of the proposal's impact upon existing and approved neonatal services in the same perinatal region(s) and those perinatal regions adjacent to the perinatal region(s) in which the applicant proposes to provide services, including but not limited to the proposal's effect on the utilization of existing neonatal services, except when an applicant demonstrates that they provide very specialized levels of neonatal care to a large and geographically diverse population;
 - (12) evidence that the applicant shall have access to a transport service with at least the following components:
 - (A) trained personnel;
 - (B) transport incubator;
 - (C) emergency resuscitation equipment;
 - (D) oxygen supply and the means of administration;
 - (E) portable cardiac and temperature monitors; and
 - (F) a ventilator;
 - (13) documentation that the new or additional neonatal service shall be

coordinated with the existing statewide perinatal network, including but not limited to:

- (A) the Division of Maternal and Child Health of the Department of Environment, Health and Natural Resources,
- (B) the physicians' statewide neonatal bed locator system,
- (C) existing neonatal services,
- (D) existing obstetrical services,
- (E) home health care agencies,
- (F) other hospitals, and
- (G) local Departments of Social Services;
- (14) copies of written policies which provide for parental participation in the care of their infant, as the infant's condition permits, in order to facilitate family adjustment and continuity of care following discharge; and
- (15) copies of written policies and procedures regarding the scope and provision of care within the neonatal service, including but not limited to the following:
 - (A) the admission and discharge of patients;
 - (B) infection control;
 - (C) pertinent safety practices; and
 - (D) the triaging of patients requiring consultations, including the transfer of patients to another facility.
- (c) An applicant proposing to provide new or additional neonatal services shall provide the following:
 - (1) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity with controlled access;
 - (2) documentation to show that the new or additional Level I, Level II or Level III neonatal services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;
 - (3) a detailed floor plan of the proposed area drawn to scale;
 - (4) documentation of direct or indirect visual observation by unit staff of all patients from one or more vantage points; and
 - (5) documentation that the floor space allocated to each bed and bassinet shall accommodate equipment and personnel to meet anticipated contingencies.

Statutory Authority G.S. 131E-177(1).

.1415 REQUIRED PERFORMANCE STANDARDS

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

- (1) applicants proposing new or additional Level I services shall perform or project to perform, at least 500 deliveries per year, except that a variance from this standard shall be allowed to the extent that a major portion of the population to be served reside more than 45 minutes automobile driving time one-way from existing inpatient neonatal services;
- (2) applicants proposing new or additional Level I services shall demonstrate that the following standards will be met:
 - (A) the occupancy of the applicant's total number of neonatal beds is projected to be 50% or more during the first year of operation following completion of the proposed project. Provide all assumptions and data supporting the methodology used for the projections;
 - (B) if an applicant is proposing additional Level I services and does not currently provide Level II or Level III services, the projected occupancy of the proposed service shall be at least 75% after the second year of operation following completion of the proposed project and provide all assumptions and data supporting the methodology used for the projections;
 - (C) if an applicant is proposing additional Level I services and currently provides Level II or Level III services, the projected occupancy of all neonatal services in the facility shall be at least 65% after the second year of operation following completion of the proposed project, and provide all assumptions and data supporting the methodology used for the projections;
 - (D) the total number of Level I neonatal bassinets and Level I neonatal beds projected to be operated in the facility shall exceed the number of obstetric beds in the facility by at least 25%; and

- (E) the total number of Level I neonatal bassinets and Level I neonatal beds projected to be operated in the facility shall exceed the number of obstetric beds in the facility by at least 35% if Level II or Level III services will be provided in the facility;
- (3) if an applicant proposes an increase in the number of the facility's existing Level II or Level III beds, the overall average annual occupancy of the total number of existing Level II and Level III beds in the facility is at least 75%, over the 12 months immediately preceding the submittal of the proposal; and
- (4) if an applicant is proposing to develop a new or additional Level II or Level III beds, the projected occupancy of the total number of Level II and Level III beds proposed to be operated after the second year of operation of the proposed project shall be at least 75%. The applicant shall document the assumptions and provide data supporting the methodology used for the projections.
- (b) If an applicant proposes to develop a new Level II or Level III service the applicant shall document that an unmet need exists in the perinatal region or in the applicant's defined neonatal service area. The need for Level II and Level III beds shall be computed for each of the perinatal regions in North Carolina or in the applicant's neonatal service area by:
 - (1) identifying the annual number of live births occurring at all hospitals within the perinatal region or proposed neonatal service area, using the latest available data compiled by the State Center for Health and Environmental Statistics;
 - (2) identifying the low birth weight rate (percent of live births below 2,500 grams) for the births identified in (1) of this Paragraph, using the latest available data compiled by the State Center for Health and Environmental Statistics;
 - (3) dividing the low birth weight rate identified in (2) of this Paragraph by .08 and subsequently multiplying the resulting quotient by four; and
 - (4) determining the need for Level II and Level III beds in the perinatal region or

proposed neonatal service area as the product of:

- (A) the product derived in (3) of this Paragraph, and
- (B) the quotient resulting from the division of the number of live births in the initial year of the determination identified in (1) of this Paragraph by the number 1000.

Statutory Authority G.S. 131E-177(1).

.1416 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to provide new or additional Level I, Level II or Level III services shall document that the following items shall be available, unless an item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) competence to manage uncomplicated labor and delivery of normal term newborn;
- (2) capability for continuous fetal monitoring;
- (3) a continuing education program on resuscitation to enhance competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn and of the mother;
- (4) obstetric services;
- (5) anesthesia services;
- (6) capability of cesarean section within 30 minutes at any hour of the day; and
- (7) twenty-four hour on-call blood bank, radiology, and clinical laboratory services.

(b) An applicant proposing to provide new or additional Level II or Level III services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) competence to manage labor and delivery of premature newborns and newborns with complications;
- (2) twenty-four hour availability of microchemistry hematology and blood gases;
- (3) twenty-four hour coverage by respiratory therapy;
- (4) twenty-four hour radiology coverage with portable radiographic capability;
- (5) oxygen and air and suction capability;
- (6) electronic cardiovascular and

- (7) respiration monitoring capability;
- (8) vital sign monitoring equipment which has an alarm system that is operative at all times;
- (9) capabilities for endotracheal intubation and mechanical ventilatory assistance;
- (10) cardio-respiratory arrest management plan;
- (11) isolation capabilities;
- (12) social services staff;
- (13) occupational or physical therapies with neonatal expertise; and
- (14) a registered dietician or nutritionist with training to meet the special needs of neonates.

(c) An applicant proposing to provide new or additional Level III services shall document that the following items shall be available, unless any item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) pediatric surgery services;
- (2) ophthalmology services;
- (3) pediatric neurology services;
- (4) pediatric cardiology services;
- (5) on-site laboratory facilities;
- (6) computed tomography and pediatric cardiac catheterization services;
- (7) emergency diagnostic studies available 24 hours per day;
- (8) designated social services staff; and
- (9) serve as a resource center for the statewide perinatal network.

Statutory Authority G.S. 131E-177(1).

.1417 REQUIRED STAFFING AND STAFF TRAINING

An applicant shall demonstrate that the following staffing requirements for hospital care of newborn infants shall be met:

- (1) If proposing to provide new or additional Level I services the applicant shall provide documentation to demonstrate that:
 - (a) the nursing care shall be supervised by a registered nurse in charge of perinatal facilities;
 - (b) a physician is designated to be responsible for neonatal care; and
 - (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (2) If proposing to provide new or additional Level II services the applicant shall provide documentation to demonstrate that:

- (a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;
- (b) the service shall be staffed by a board certified pediatrician with certification, special interest, experience, or training in neonatology; and
- (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (3) If proposing to provide new or additional Level III services the applicant shall provide documentation to demonstrate that:
 - (a) the nursing care shall be supervised by a registered nurse with educational preparation and advanced skills for maternal-fetal and neonatal services;
 - (b) the service shall be staffed by a full-time board certified pediatrician with certification in neonatal medicine; and
 - (c) the medical staff will provide physician coverage to meet the specific needs of patients on a 24 hour basis.
- (4) All applicants shall submit documentation which demonstrates the availability of appropriate inservice training or continuing education programs for neonatal staff.
- (5) All applicants shall submit documentation which demonstrates the proficiency and ability of the nursing staff in teaching parents how to care for neonatal patients following discharge to home.
- (6) All applicants shall submit documentation to show that the proposed neonatal services will be provided in conformance with the requirements of federal, state and local regulatory bodies.

Statutory Authority G.S. 131E-177(1).

.1418 DATA REPORTING REQUIREMENTS

The facility shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.1419 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that shall be used to insure that the projected number of medically underserved shall be served in the unit.

(b) The applicant shall provide a copy of the written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admissions requirements for each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit collection policies, that shall be utilized by the facility.

(d) The applicant shall document that the health care community in the applicants neonatal service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

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

.1613 DEFINITIONS

The following definitions ~~will~~ 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 or had been acquired prior to March 18, 1993 in accordance with G.S.131E-175, et. al.
- (2) (+) "Capacity" of a an item of cardiac catheterization room equipment or cardiac angioplasty equipment is considered to be 1000 means 1270 diagnostic-equivalent procedures per year. One PTCA therapeutic cardiac catheterization procedure is valued at two 1.67 diagnostic-equivalent procedures. One pediatric cardiac catheterization procedure performed on a patient age five or under is

valued at two diagnostic-equivalent procedures. All other procedures are valued at one diagnostic-equivalent procedure.

- (3) "Cardiac angioplasty equipment" is defined in G.S.131E-176(2e).

- (4) (2) "Cardiac catheterization" is means a diagnostic, electrophysiology or therapeutic procedure performed using cardiac catheterization equipment or cardiac angioplasty equipment in a cardiac catheterization room, whereby a flexible tube is inserted into the patient's body, usually through an extremity blood vessel, and advanced under fluoroscopic guidance into the heart chambers to perform a hemodynamic or angiographic examination or therapeutic intervention of the left and or right heart chamber, or coronary arteries; therapeutic intervention in a coronary artery may also be performed using cardiac catheterization. By this definition 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 as an isolated procedure, or cardiac pacing through a right electrode catheter. It does include angiographic procedures to evaluate the coronary arteries, and aortic root injections to examine the degree of aortic regurgitation or deformity of aortic valve.

- (5) "Cardiac catheterization equipment" is defined in G.S.131E-176(2f).

- (6) (3) "Cardiac catheterization procedure" means a single episode of diagnostic, electrophysiology or therapeutic catheterization which occurs during one visit to a cardiac catheterization room.

- (7) (4) "Cardiac catheterization room" means a room in a hospital or a mobile unit in which has the there is cardiac catheterization or cardiac angioplasty equipment required to perform angiographic and physiologic for the provision of cardiac catheterization procedures, and which has been approved by the Certificate of Need Section as a cardiac catheterization room services.

- (8) (11) "Cardiac catheterization Sservice area" means a geographical area defined by the proponent 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.

(9) "Cardiac catheterization services" means the provision of diagnostic cardiac catheterization procedures, therapeutic cardiac catheterization procedures or electrophysiology catheterization procedures.

(10) (5) "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, emergency treatment of cardiovascular illnesses, non-invasive diagnostic imaging modalities, diagnostic and ~~interventional~~ therapeutic cardiac catheterization procedures, open heart surgery and cardiac rehabilitation services. Community outreach and cardiac rehabilitation services ~~may~~ 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 ~~must~~ shall be provided within a single facility.

(11) (6) "Diagnostic cardiac catheterization procedure" means a cardiac catheterization procedure performed using cardiac catheterization or cardiac angioplasty equipment for the purpose of detecting and identifying defects or diseases in the great arteries or veins of the heart, or abnormalities in the heart structure.

(7) ~~"Expanded cardiac catheterization service" means the addition or conversion of a room to be dedicated to cardiac catheterization procedures; or the purchase of additional equipment specially designed to perform cardiac catheterizations.~~

(12) "Electrophysiology catheterization procedure" means a diagnostic or therapeutic cardiac catheterization procedure performed to study the electrical conduction activity of the heart and characterization of atrial ventricular arrhythmias utilizing cardiac catheterization equipment or cardiac

angioplasty equipment.

(13) "Existing" means the equipment was in operation prior to the beginning of the review period.

(14) "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 Cardiac Catheterization and Cardiac Catheterization Laboratories (1991) report.

(15) "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.

(8) ~~"Pediatric cardiac catheterization procedure" means a cardiac catheterization procedure performed on a patient age five or under.~~

(16) (9) "Percutaneous transluminal coronary angioplasty (PTCA)" is a ~~interventional~~ 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.

(17) (40) "Primary cardiac catheterization service area" means a geographical area defined by the ~~proponent~~ 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.

(18) "Therapeutic cardiac catheterization procedure" means a cardiac catheterization procedure performed for the purpose of treating or resolving certain anatomical or physiological conditions which have been determined to exist in the heart or great arteries or veins of the heart.

Statutory Authority G.S. 131E-177(1).

.1614 INFORMATION REQUIRED OF

APPLICANT

(a) An applicant that proposes ~~a new or expanded cardiac catheterization service to acquire cardiac catheterization or cardiac angioplasty equipment must provide the information requested on~~ shall use the acute care facility/medical equipment application form.

(b) ~~In addition to information requested on the acute care application form, the~~ The applicant ~~must~~ shall provide the following additional information based on the population residing within the applicant's proposed cardiac catheterization service area:

- (1) the projected number of cardiac catheterization procedures, by CPT or ICD-9-CM by type classification of cardiac catheterization procedure, to be ~~completed~~ performed in each cardiac catheterization room for each of the first 12 calendar quarters 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 twelve months, including:
 - (A) the number of patients receiving stress tests;
 - (B) the number of patients receiving intravenous ~~thrombolytic~~ thrombolytic therapies;
 - (C) the number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction; and
 - (D) the number of patients referred to other facilities for cardiac catheterization procedures and/or ~~or~~ open heart surgery procedures, by type of procedure;
- (3) the number of patients from the proposed service area who are projected to receive cardiac catheterization services by patient's county of residence in each of the first 12 quarters of operation, including the methodology and assumptions used for these projections;
- (4) the number of patients from the proposed primary service area who are projected to receive cardiac catheterization services by patient's county of residence in each of the first

12 quarters of operation, including the methodology and assumptions used for these projections;

- (5) documentation of the applicant's projected ~~referral~~ sources of patients referrals that are located in the proposed service area, including letters from the referral sources that demonstrate their intent to refer patients to the applicant for cardiac catheterization services;
- (6) evidence of the applicant's capability to communicate ~~efficiently~~ with emergency transportation agencies and with an established comprehensive cardiac services program;
- (7) the number and composition of cardiac catheterization teams available to the applicant;
- (8) ~~a brief description of~~ documentation of the applicant's in-service training or continuing education programs for cardiac catheterization team members;
- (9) a written agreement with a comprehensive cardiac services program ~~specifying that~~ specifies the arrangements for referral and transfer of patients seen by the ~~proponent applicant which and that includes a process to~~ alleviates the need for duplication in catheterization studies;
- (10) a written description of patient selection criteria including referral arrangements for high-risk patients-;
- (11) 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
- (12) documentation that the cardiac catheterization equipment and cardiac angioplasty equipment and the procedures for operation of the equipment are designed and developed based on the American College of Cardiology/American Heart Association Guidelines for Cardiac Catheterization Laboratories (1991) report.

Statutory Authority G.S. 131E-177(1).

.1615 REQUIRED PERFORMANCE STANDARDS

- (a) ~~To be approved the State Agency must~~

~~determine~~ The applicant shall demonstrate that the project is capable of meeting the following standards:

- (1) each proposed item of cardiac catheterization room equipment or cardiac angioplasty equipment, including mobile equipment ~~will~~ shall be utilized at an annual rate of at least ~~40~~ 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project;
- (2) if the ~~facility applicant has a comprehensive cardiac services program or the proponent intends~~ proponent ~~proposes~~ to perform elective PTCA therapeutic cardiac catheterization procedures, ~~each of the proponent applicant's therapeutic cardiac catheterization teams will be performing~~ shall be performing at an annual rate of at least ~~50 PTCA 100~~ therapeutic cardiac catheterization procedures, ~~measured during the fourth quarter of the third year of operation~~ following completion of the project;
- (3) at least 50 percent of the projected cardiac catheterization procedures ~~will~~ shall be performed on patients residing within the primary service area;
- (4) each existing item of cardiac catheterization room equipment and cardiac angioplasty equipment in each facility which has a primary service area that overlaps the proposed primary service area ~~shall have been~~ shall operated at a level of at least ~~50~~ 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Facility Services;
- (5) the utilization of each existing or approved item of cardiac catheterization programs equipment and cardiac catheterization angioplasty equipment ~~whose in each facility which has a primary service area that overlaps the proposed primary service area is not~~ shall not be expected to fall below ~~40~~ 60 percent of capacity due to the ~~institution of the new or expanded program~~ acquisition of the proposed cardiac catheterization, cardiac angioplasty, or mobile equipment;
- (6) if the applicant proposes to perform

diagnostic cardiac catheterization procedures, ~~the applicant's projected utilization and proposed staffing patterns are such that~~ each diagnostic cardiac catheterization team will shall be performing at an annual rate of at least 150 diagnostic-equivalent catheterization procedures by the end of the third year following completion of the project;

- (7) each item of existing mobile equipment in the proposed cardiac catheterization service area shall have been performing at least an average of four diagnostic-equivalent catheterization procedures per day per site in the proposed cardiac catheterization service area in the twelve month period preceding the submittal of the application; and
 - (8) each item of existing or approved mobile equipment to be operating in the proposed cardiac catheterization service area shall be performing at least an average of four diagnostic-equivalent catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation.
- (b) If the ~~proponent intends~~ applicant proposes to perform pediatric cardiac catheterization procedures on patients age five and under, the ~~State Agency must determine that the proponent the applicant shall demonstrate that it~~ meets the following additional criteria:
- (1) the facility has the capability to perform both pediatric diagnostic and therapeutic cardiac catheterization services procedures and pediatric open heart surgery services on patients age five and under;
 - (2) the proposed project ~~will~~ shall be performing at an annual rate of at least ~~80~~ 150 pediatric cardiac catheterization procedures on patients age five or under during the fourth quarter of the third year following initiation of pediatric the proposed cardiac catheterization service for patients age five and under.
- (c) An applicant shall provide documentation of all assumptions and data used in the development of the projections required in this Rule.

Statutory Authority G.S. 131E-177(1).

.1616 REQUIRED SUPPORT SERVICES

(a) ~~If the proponent intends applicant proposes to perform elective PTCA therapeutic cardiac catheterization procedures, the State Agency must determine that the proponent the applicant shall demonstrate that has access to an open heart surgery services are provided within the same facility.~~

(b) If the applicant proposes to perform diagnostic cardiac catheterization procedures, the applicant shall document that its patients will have access to a facility which provides open heart surgery services, in close proximity, and that the patients can be transported to that facility with no greater risk than if the procedure had been performed in a hospital which provides open heart surgery services.

(c) ~~To be approved the State Agency must determine~~ The applicant shall provide documentation to demonstrate that the following services will shall be available in the facility:

- (1) electrocardiography laboratory and testing services including stress testing and continuous cardiogram monitoring;
- (2) echocardiography service;
- (3) blood gas laboratory;
- (4) pulmonary function unit;
- (5) staffed blood bank;
- (6) hematology laboratory/coagulation laboratory;
- (7) microbiology laboratory;
- (8) clinical pathology laboratory with facilities for blood chemistry;
- (9) immediate endocardiac catheter pacemaking in case of cardiac arrest; and
- (10) nuclear medicine services including nuclear cardiology.

Statutory Authority G.S. 131E-177(1).

.1617 REQUIRED STAFFING AND STAFF TRAINING

(a) ~~To be approved, the State Agency must determine that the proponent~~ The applicant shall provide documentation to demonstrate that can meet 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 ~~and—board eligibility~~ 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 special training and current experience in cardiovascular disease and radiation sciences;
 - (B) one nurse with special training and current experience in critical care of cardiac patients, cardiovascular medication, and catheterization equipment; and
 - (C) at least three technicians with current specialized training in cardiac care who are capable of performing the duties of a radiologic technologist, cardiopulmonary technician, monitoring and recording technician, and darkroom technician.

(b) ~~To be approved, the State Agency must determine that the proponent~~ The applicant shall provide documentation to demonstrate that can provide 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.

Statutory Authority G.S. 131E-177(1).

.1618 DATA REPORTING REQUIREMENTS

The facility ~~must shall~~ agree to provide, upon the request of the Division of Facility Services, the following types of data and information—to the Division of Facility Services, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.1619 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to ensure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES

.1713 DEFINITIONS

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

- (1) "Capacity" of an open heart surgical suite surgery room is considered to be means 400 adult-equivalent open heart surgical procedures per year. One pediatric open heart surgical procedure on persons age 5 and under is valued at two adult open heart surgical procedures. For purposes of determining capacity, one open heart surgical procedure is defined to be one visit or trip by a patient to the open heart surgical suite surgery room for an open heart operation.
- (2) "Cardiac Surgical Intensive Care Unit"

means a distinct intensive care unit as defined in 10 NCAC 3R .1213(2) and which is for exclusive use by post-surgical open heart patients.

- ~~(2) "Expanded open heart surgical suite" means the addition or conversion of an operating room to be dedicated for open heart surgical procedures.~~
- (3) "Heart-lung bypass machine is defined in G.S. 131E-176(10a).
- ~~(5) "Pediatric open heart surgical procedure" means an open heart surgical procedure performed on a patient age five or under.~~
- (4) ~~(9) "Open heart Service surgery service area" means a geographical area defined by the proponent applicant, which has boundaries that are not farther than 90 road miles from the facility.~~
- (5) "Open heart surgery services" is defined in G.S. 131E-176(18b).
- (6) ~~(3) "Open heart surgical procedures" means are highly specialized surgical procedures which utilize a heart lung bypass machine (the "pump") to perform extra-corporeal circulation and oxygenation during surgery. Open heart surgical procedures include a wide range of procedures those surgical procedures which are identified by Diagnostic Related Group ("DRG") numbers 104, 105, 106, 107, and 108, and which are designed to correct congenital and acquired cardiac and coronary artery disease.~~
- (7) ~~(4) "Open heart surgical suite surgery room" means an operating room dedicated to open heart surgical procedures, which has been approved for this use by the Certificate of Need Section as reported on the most current hospital licensure application, along with any related rooms used for preparation and immediate post operative recovery of patients receiving an open heart surgical procedure.~~
- (8) ~~(6) "Open heart surgical surgery program" includes means all of the open heart surgical suites surgery rooms operated in one hospital.~~
- ~~(7) "Percutaneous transluminal coronary angioplasty (PTCA) procedure" means an interventional 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.~~

- (9) ~~(8)~~ "Primary open heart surgery service area" means a geographical area defined by the ~~proponent~~ applicant, which has boundaries that are not farther than 45 road miles from the facility.

Statutory Authority G.S. 131E-177(1).

.1714 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes ~~a new or expanded to add an~~ open heart ~~surgical suite surgery room or to acquire a~~ heart-lung ~~bypass machine must provide the information requested on~~ shall use the acute care facility/medical equipment application form.

(b) ~~In addition to information requested on the acute care application form, the~~ The applicant ~~must shall also~~ provide the following additional information:

- (1) the projected number of open heart surgical procedures to be completed in each open heart ~~surgical suite~~ surgery room and the projected number of open heart surgical procedures to be performed on each heart-lung bypass machine for each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used ~~for~~ to make these projections;
- (2) the projected number of cardiac catheterization procedures to be completed in the facility for each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections;
- (3) 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 cardiac catheterization procedures performed, by type of procedure;
 - (E) the number of patients referred to

other facilities for cardiac catheterization or open heart surgical procedures, by type of procedure;

- (F) the number of patients referred to ~~proponent's~~ the applicant's facility for cardiac catheterization or open heart surgical procedures, by type of procedure;
- (4) the number of patients from the proposed open heart surgery service area who are projected to receive open heart surgical procedures by patient's county of residence in each of the first 12 quarters of operation ~~for these projections including the methodology and assumptions used to make the projections;~~
- (5) the number of patients from the proposed primary open heart surgery service area who are projected to receive open heart surgical procedures by patient's county of residence in each of the first 12 quarters, including the methodology and assumptions used ~~for~~ to make these projections;
- (6) the projected patient referral sources ~~of patients;~~
- (7) evidence of the applicant's capability to communicate efficiently with emergency transportation agencies and with all hospitals serving the proposed service area;
- (8) the number and composition of open heart surgical teams available to the applicant;
- (9) a brief description of the applicant's in-service training or continuing education programs for open heart surgical team members; and
- (10) evidence of applicant's the capability to perform both cardiac catheterization and open heart surgical procedures ~~on a 24 hours per day, 7 days per week basis.~~

Statutory Authority G.S. 131E-177(1).

.1715 REQUIRED PERFORMANCE STANDARDS

~~To be approved, the State Agency must determine~~ The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

- (1) each open heart ~~surgical suite~~ surgery room ~~will shall~~ be utilized at an annual

rate of at least 50 percent of capacity, measured during the fourth ~~twelfth~~ quarter of the third year following completion of the project;

(2) ~~the proponent will be performing a sufficient number of~~ applicant shall perform at least 4 diagnostic catheterizations to generate the projected number of per open heart surgical procedures procedure during each quarter;

(3) ~~the proponent will be performing at an annual rate of at least 50 PTCA procedures, measured during the fourth quarter of the third year following completion of the project;~~

(3) a new or additional heart-lung bypass machine shall be utilized at 200 open heart surgical procedures per year, measured during the twelfth quarter following completion of the project;

(4) at least 50 percent of the projected open heart surgical procedures will shall be performed on patients residing within the primary open heart surgery service area;

(5) each existing open heart surgical suite surgery program in each facility which has a primary open heart surgery service area that overlaps the proposed primary open heart surgery service area 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;

(6) the utilization of existing open heart surgical surgery programs whose primary open heart surgery service area overlaps the proposed primary open heart surgery service area is not expected to fall below 50 percent of capacity due to the institution of the new or expanded open heart surgical program; and surgery program;

(7) the applicant's projected utilization and proposed staffing patterns are such that each open heart surgical team will be performing shall perform at an annual rate of at least 150 open heart surgical procedures by the end of the third year following completion of the project project;

(8) the applicant shall document the assumptions and provide data supporting the methodology used to make these projections; and

(9) heart-lung bypass machines that have been acquired for non-surgical use shall

not be utilized in the performance of open heart surgical procedures.

Statutory Authority G.S. 131E-177(1).

.1716 HOURS OF OPERATION

~~To be approved, the State Agency must determine applicant shall demonstrate that the proponent has the capability of providing open heart surgical procedures 24 hours per day, seven days per week.~~

Statutory Authority G.S. 131E-177(1).

.1717 REQUIRED SUPPORT SERVICES

(a) ~~To be approved, the State Agency must determine~~ The applicant shall demonstrate that the following services will shall be available on a in the facility 24 hours per day, 7 days per week basis in the facility:

- (1) electrocardiography laboratory and testing services, including stress testing and continuous cardiogram monitoring;
- (2) echocardiography service;
- (3) blood gas laboratory;
- (4) nuclear medicine laboratory;
- (5) pulmonary function unit;
- (6) staffed blood bank;
- (7) hematology laboratory or coagulation laboratory;
- (8) microbiology laboratory;
- (9) clinical pathology laboratory with facilities for blood chemistry;
- (10) dedicated cardiac surgical intensive care unit that shall be a distinct intensive care unit and shall meet the requirements of 10 NCAC 3R .1200;
- (11) emergency room with full-time director, staffed for cardiac emergencies with acute coronary suspect surveillance area and voice communication linkage to the ambulance service and the coronary care unit; and
- (12) cardiac catheterization services including both diagnostic and interventional cardiac catheterization capabilities.

(b) ~~To be approved the State Agency must determine~~ The applicant shall demonstrate that the following services will shall be available to the proponent applicant:

- (1) a preventive maintenance program for all biomedical devices, electrical installations and environmental controls;
- (2) a cardiac rehabilitation program; and
- (3) a community outreach and education

program.

Statutory Authority G.S. 131E-177(1).

.1718 REQUIRED STAFFING AND STAFF TRAINING

(a) ~~To be approved the State Agency must determine~~ The applicant shall demonstrate that the proponent ~~it~~ can meet the following staffing requirements:

- (1) one cardiovascular surgeon who has been designated to serve as director of the open heart ~~surgical surgery~~ program and who has the following special ~~credentials~~ qualifications:
 - (A) ~~certified~~ certification by the American Board of Thoracic Surgery; and
 - (B) ~~special qualification in cardiac surgery~~ thorough understanding of and experience in basic medical and surgical knowledge and techniques of cardiac surgery, cardiopulmonary bypass and methods of myocardial management;
- (2) at least one specialized open heart surgical team ~~to perform open heart surgical procedures~~ composed of at least the following professional and technical personnel:
 - (A) one cardiovascular surgeon board certified (~~or board eligible~~) by the American Board of Thoracic Surgery;
 - (B) one assistant surgeon, preferably a cardiovascular or thoracic surgeon;
 - (C) one board certified (~~or board eligible~~) anesthesiologist trained in open heart surgical procedures;
 - (D) one certified registered nurse anesthetist;
 - (E) one circulating nurse or scrub nurse, with recent specialized training in open heart surgical procedures;
 - (F) one operating room technician or nurse with recent specialized training in open heart surgical procedures;
 - (G) ~~two one~~ one certified pump ~~technicians~~ technician per operational heart lung bypass machine and an additional certified pump technician on standby;
 - (H) staff for the dedicated cardiac ~~surgery~~ surgical intensive care unit ~~sufficient~~ to ensure the availability of 1 RN for every 2 patients during the first 48 hours of post-operative care;
- (3) at least two fully-qualified cardiac

surgeons on the staff, at least one of whom is board-certified, ~~and the other at least board eligible~~; one of these surgeons ~~must~~ shall be on-call at all times; if pediatric open heart surgical procedures are performed, one of these surgeons ~~must~~ shall be specially trained and clinically competent to perform pediatric open heart surgical procedures.

(b) ~~To be approved, the State Agency must determine~~ The applicant shall demonstrate that the proponent ~~it~~ can provide the following staff training for members of open heart surgical terms:

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

Statutory Authority G.S. 131E-177(1).

.1719 DATA REPORTING REQUIREMENTS

The facility ~~must~~ shall provide, upon the request of the Division of Facility Services, the following types of data and information ~~to the Division of Facility Services~~, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.1720 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that shall be used to insure that the projected number of medically underserved shall be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent

and charity care); and

(7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that shall be utilized by the facility.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

.1902 DEFINITION

The following definition will apply to all rules in this Section:

"Radiation oncology services" means those services provided by health care facilities to treat malignant disease through the use of ionizing radiation with energy in excess of 1MeV (million electron volts). This includes the use of cobalt machines, linear accelerators (with and without electron beam capacity), and betatrons.

Statutory Authority G.S. 131E-177(1).

.1904 CAPACITY IN THE FACILITY AND IN THE HEALTH SERVICE AREA

(a) A proposal involving new or expanded radiation oncology services must be consistent with the applicable North Carolina State Health Plan (the one in effect at time of the final agency decision) and with the applicable health systems plan.

(b) A proposal involving new or expanded radiation oncology services must specify:

- (1) the current capabilities and capacities of the proponent's aggregate radiation oncology services;
- (2) the capabilities and capacities of the proponent's aggregate radiation oncology services following the completion of the proposed project.

(c) A proposal involving new or expanded radiation oncology services shall not be approved unless existing services of the type being proposed are demonstrated to be currently utilized at 80 percent of annual capacity. For purposes of

capacity—determinations, minimal—service availability shall be considered to be eight hours per day, five days per week. In no case shall a proposal involving an additional cobalt, megavoltage, or supervoltage unit be approved unless each existing cobalt, megavoltage, or supervoltage unit currently performs at least 6000 treatments per year with the exception that units performing less than 6000 treatments per year shall be acceptable if:

- (1) the units are dedicated primarily for special purposes, e.g., electron beam, research, teaching;
- (2) the units, having attained their useful life, are retained and operated for emergency backup; or
- (3) the existing unit is not meeting a need which exists in the health service area.

Statutory Authority G.S. 131E-177(1).

.1905 SCOPE OF SERVICES OFFERED

A proposal to provide new or expanded radiation oncology services must document the extent to which the following will be available. If any item will not be available, then substantive information must be given obviating the need for that item before approval for a new or expanded service can be given:

- (1) distinct, identifiable area for the provision of the proposed service;
- (2) a program of radiation oncology continuing education for technologists and medical staff;
- (3) a program developed and implemented for the collection of utilization data relative to the proponent's provision of radiation oncology services.

Statutory Authority G.S. 131E-177(1).

.1906 PROJECTED UTILIZATION

(a) A proposal to provide new or expanded radiation oncology services must project patient utilization for each of the first eight calendar quarters following the completion of the proposed project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

(b) A proposal to provide new or expanded radiation oncology services shall not be approved unless all services of the type being proposed are projected to be utilized at 80 percent of the annual capacity within three years of initiation. In no case shall a proposal involving new or additional

~~supervoltage, cobalt, or megavoltage linear accelerator units be approved unless utilization of the equipment is projected to be at least 6000 procedures per year no later than three years following the activation of usage of the equipment.~~

Statutory Authority G.S. 131E-177(1).

.1907 SITE

~~A proposal to provide new or expanded radiation oncology services must provide documentation to show that the services will be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.~~

Statutory Authority G.S. 131E-177(1).

.1908 STAFFING

~~A proposal to provide new or expanded radiation oncology services must provide documentation to show that the appropriate types and numbers of staff, particularly qualified technologists and medical staff, will be available to support the services. A proponent must have available, or committed to be available a physician licensed to practice medicine in North Carolina, who is qualified and authorized by the proponent's facility to perform radiation oncology procedures, to supervise all radiation oncology procedures.~~

Statutory Authority G.S. 131E-177(1).

.1912 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 but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (2) "Existing linear accelerator" means a linear accelerator in operation prior to the beginning of the review period.
- (3) "Linear accelerator" means MRT equipment which is used to deliver a beam of electrons or photons in the treatment of cancer patients.
- (4) "Linear accelerator service area" means a geographical area, defined by the applicant, in which a linear accelerator provides services and in which no less than 120,000 persons reside.
- (5) "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.

- (6) "Megavoltage radiation therapy (MRT)" means the use of ionizing radiation in excess of one million electron volts in the treatment of cancer.
- (7) "MRT equipment" means a machine or energy source used to provide megavoltage radiation therapy including linear accelerators and other particle accelerators.
- (8) "Radiation therapy equipment" means medical equipment which is used to provide radiation therapy services.
- (9) "Radiation therapy services" means those services which involve the delivery of precisely controlled and monitored doses of radiation to a well 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.
- (10) "Radiation therapy service area" means the geographic area in which radiation therapy services are proposed to be provided by the applicant.
- (11) "Simulator" means a machine that produces high quality diagnostic radiographs and that is capable of precisely reproducing the geometric relationships of the MRT equipment to the patient.

Statutory Authority G.S. 131E-177(1).

.1913 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire radiation therapy equipment shall also provide the following additional information:

- (1) a description of the boundaries of the proposed radiation therapy service area or the proposed linear accelerator service area if the applicant proposes to acquire a linear accelerator;
- (2) a list of the existing radiation therapy

equipment in the proposed radiation therapy service area or linear accelerator service area;

- (3) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;
- (4) documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment proposed to be acquired;
- (5) the projected number of patient treatments to be performed on each piece of radiation therapy equipment for each of the first eight calendar quarters following the completion of the proposed project and documentation of all assumptions by which utilization is projected;
- (6) documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;
- (7) documentation that no more than one simulator is available for every two linear accelerators in the applicant's facility, except that an applicant that has only one linear accelerator may have one simulator; 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.

Statutory Authority G.S. 131E-177(1).

.1914 REQUIRED PERFORMANCE STANDARDS

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

- (1) each existing linear accelerator in the proposed service area served at least 250 patients or provided 6,400 treatments in the twelve months prior to the date the application was submitted, with the exception that existing linear accelerators that performed less than 6,400 treatments per year shall not be held to this standard if the applicant can provide documentation that:

- (A) the patient characteristics or tumor types treated by the existing linear

accelerator are complex and require more treatment time per patient; and

- (B) the existing linear accelerator is committed to clinical research and teaching;

- (2) each proposed new linear accelerator shall be utilized at an annual rate of 250 patients or 6,400 treatments during the third year of operation of the new equipment; and

- (3) each existing and approved linear accelerator shall be projected to be utilized at an annual rate of 250 patients or 6,400 treatments during the third year of operation of the new equipment.

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

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

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

Statutory Authority G.S. 131E-177(1).

.1915 REQUIRED SUPPORT SERVICES

An applicant proposing to acquire radiation therapy equipment shall document that the following items shall be available; and if any item shall not be available, the applicant shall provide substantive information obviating the need for that item:

- (1) a program of radiation therapy continuing education for technologists and medical staff;
- (2) a program for the collection of utilization data relative to the applicant's provision of radiation therapy services;
- (3) medical laboratory services;
- (4) pathology services; and
- (5) pharmaceutical support services.

Statutory Authority G.S. 131E-177(1).

.1916 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire radiation therapy equipment shall document that:

- (1) the appropriate types and numbers of staff, particularly qualified radiation therapists and medical staff, shall be available to support the proposed services; and
- (2) a board-certified Radiation-Oncologist licensed to practice medicine in North Carolina shall be available to perform radiation therapy procedures and supervise all radiation therapy procedures.

(b) An applicant proposing to acquire radiation therapy equipment shall provide documentation to demonstrate the availability of the following staff:

- (1) Radiation-Oncologist;
- (2) Radiation Physicist;
- (3) Dosimetrist or Physics Assistant;
- (4) Physics Technologist;
- (5) Radiation Therapist;
- (6) Radiation-Oncology Administrator;
- (7) Registered Nurse or LPN;
- (8) Physical Therapist;
- (9) Dietician;
- (10) Pharmacist;
- (11) Social Worker; and
- (12) Maintenance Engineer.

Statutory Authority G.S. 131E-177(1).

.1917 ACCESSIBILITY

(a) The applicant shall document the mechanism that will be used to insure that the projected number of medically underserved will be served by the applicant.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the proposed services and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the applicant.

(d) The applicant shall document that the health care community in the service area, including the

Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the applicant's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

.1918 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .2100 - CRITERIA AND STANDARDS FOR AMBULATORY SURGICAL SERVICES

.2113 DEFINITIONS

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

- (1) "Ambulatory surgical case" means an individual who receives one or more ambulatory surgical procedures in an ambulatory surgical operating room during a single operative encounter.
- (2) "Ambulatory surgical service area" means a single or multi-county area as used in the development of 10 NCAC 3R .3030.
- (3) ~~(2)~~ "Ambulatory surgical services" means those surgical services provided to patients as part of an ambulatory surgical program within a licensed ambulatory surgical facility or a general acute care hospital licensed under G.S. Chapter 131E, Article 5, Part A.
- (4) ~~(3)~~ "Ambulatory surgical facility" means a facility as defined in G.S. 131E-176~~(4)~~ (1a).
- (5) ~~(6)~~ "Ambulatory surgical operating room" means a dedicated or shared operating room in a licensed ambulatory surgical facility, or a general acute care hospital licensed under G.S. 131E, Article 5, Part A, that is fully equipped to perform surgical procedures and is constructed to meet the specifications and

standards, including fire and life safety code requirements, appropriate to the type of facility as utilized by the Construction Section of the Division of Facility Services. Ambulatory surgical operating rooms exclude operating rooms dedicated for the performance of inpatient surgical procedures, cast rooms, procedures rooms that do not meet operating room specifications, suture rooms, YAG laser rooms, and cystoscopy and endoscopy procedure rooms that do not meet the specifications of an operating room.

- (6) (4) "Ambulatory surgical program" means a program as defined in G.S. 131E-176(4a) (1b).
- (7) (5) "Ambulatory surgical procedure" means a surgical procedure performed in a surgical operating room which requires local, regional or general anesthesia and a period of post-operative observation of less than 24 hours. Ambulatory surgical procedures exclude those procedures which are generally performed more than 50 percent of the time in a physician's office.
- (8) (7) "Existing ambulatory surgical operating rooms" means only the those ambulatory surgical operating rooms in ambulatory surgical facilities and hospitals which were reported on 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.
- (9) (8) "Approved ambulatory surgical operating rooms" means only the those ambulatory surgical operating rooms that ~~have been~~ 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, ~~and ambulatory surgical~~ The term also means those operating rooms which the Certificate of Need Section determined were not subject to certificate of need review and ~~are~~ which were under construction prior to the date the

applicant's proposal was submitted to the Agency.

- (10) (9) "Dedicated ambulatory surgical operating room" means an ambulatory surgical operating room used solely for the performance of ambulatory surgical procedures.
- (11) "Multispecialty ambulatory surgical program" means a program as defined in G.S. 131E-176(15a).
- (12) (10) "Shared surgical operating room" means an ambulatory surgical operating room that is used for the performance of both ambulatory and inpatient surgical procedures.
- (13) (11) "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.
- (14) "Specialty ambulatory surgical program" means a program as defined in G.S. 131E-176(24c).
- (15) (12) "Practical utilization" is 4.3 surgical cases per day for a dedicated ambulatory surgical operating room and 3.5 surgical cases per day for a shared surgical operating room.
- (13) ~~"Service area" means a single or multi-county area as designated in 10 NCAC 3R .3020.~~

Statutory Authority G.S. 131E-177(1).

.2114 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new ambulatory surgical facility, to increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital, 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 identify each of the following specialty areas that will be provided in the facility:

- (1) gynecology;
- (2) otolaryngology;
- (3) plastic surgery;
- (4) general surgery;

- (5) ophthalmology;
- (6) orthopedic;
- (7) oral surgery; and
- (8) other specialty area identified by the applicant.

(b) An applicant proposing to establish a new ambulatory surgical facility, ~~or to increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital,~~ 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 the following information regarding the services to be offered in the facility following completion of the project:

- (1) the number and type of existing and proposed dedicated ambulatory surgical operating rooms; ;
- (2) the number and type of existing and proposed shared ambulatory surgical operating rooms; ;
- (3) the number and type of shared ambulatory surgical operating rooms that are proposed to be converted to dedicated ambulatory surgical operating rooms;
- (4) ~~(3)~~ the current and projected number of surgical procedures, identified by CPT code or ICD-9-CM procedure code, to be performed in the ambulatory surgical operating rooms; ;
- (5) ~~(4)~~ the fixed and movable equipment to be located in each ambulatory surgical operating room; ;
- (6) ~~(5)~~ the hours of operation of the ambulatory surgical program; ;
- (7) if the applicant is an existing ambulatory surgical facility, the average charge for the 20 surgical procedures most commonly performed in the facility during the preceding twelve months and a list of all services and items included in each charge;
- (8) the projected average charge for the 20 surgical procedures which the applicant projects will be performed most often in the proposed ambulatory surgical program and a list of all services and items in each charge;
- ~~(6) the projected average charge for the 20 most common surgical procedures currently performed and proposed to be performed in the ambulatory surgical program and a list of all services and items included in each charge.~~

- (9) ~~(7)~~ identification of providers of pre-operative services and procedures which will not be included in the facility's charge; ; and
- (10) ~~(8)~~ other information as required in the application.

Statutory Authority G.S. 131E-177(1).

.2115 REQUIRED PERFORMANCE STANDARDS

(a) In projecting utilization for existing, approved, ~~and~~ proposed and expanded ambulatory surgical programs, a program shall be considered to be open five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, ~~or to increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital,~~ 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 ambulatory surgical cases per each ambulatory surgical operating room in the applicant's proposed ambulatory surgical program are projected to be ~~at practical utilization operating at~~ 4.3 surgical cases per day for each dedicated ambulatory surgical operating room and 3.5 surgical cases per day for each shared surgical operating room during the fourth quarter of the third year of operation following completion of the project.

(c) 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 ambulatory surgical service area that performs ambulatory surgery in the same specialty areas as proposed in the application is currently operating at 4.3 surgical cases per day for each dedicated ambulatory surgical operating room and 3.5 surgical cases per day for each shared surgical operating room.

(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 and approved ambulatory surgery program in the ambulatory surgical service area that performs ambulatory surgery in the same specialty areas as

proposed in the application is projected to be operating at 4.3 surgical cases per day for each dedicated ambulatory surgical operating room and 3.5 surgical cases per day for each shared surgical operating room prior to the completion of the proposed project. The applicant shall document the assumptions and provide data supporting the methodology used for the projections.

Statutory Authority G.S. 131E-177(1).

.2116 FACILITY

(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that 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 a licensed ambulatory surgical facility shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

(c) An applicant proposing to establish a new ambulatory surgical facility, ~~or to~~ increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital, 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 document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

(d) In competitive reviews, an applicant proposing to perform ambulatory surgical procedures in at least three specialty areas will be considered more favorably than an applicant proposing to perform ambulatory surgical procedures in fewer than three specialty areas.

(e) The applicant shall provide a floor plan of the proposed facility clearly identifying the following areas:

- (1) receiving/registering area;
- (2) waiting area;
- (3) pre-operative area;
- (4) operating room by type;
- (5) recovery area; and

(6) observation area.

(f) An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:

- (1) physicians;
- (2) ancillary services;
- (3) support services;
- (4) medical equipment;
- (5) surgical equipment;
- (6) receiving/registering area;
- (7) clinical support areas;
- (8) medical records;
- (9) waiting area;
- (10) pre-operative area;
- (11) operating rooms by type;
- (12) recovery area; and
- (13) observation area.

Statutory Authority G.S. 131E-177(1).

.2117 ACCESSIBILITY

(a) An applicant proposing to establish a new ambulatory surgical facility, ~~or to~~ increase the number of ambulatory surgical operating rooms in an existing ambulatory facility or hospital, 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 assurance that the facility, unless solely designated as a birthing center, will be certified for Medicaid and Medicare reimbursement upon completion of the project.

(b) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(c) The applicant shall provide a copy of the written admissions policies identifying any prepayment or deposit requirements for the facility and clearly stating the admission requirements for the following payor categories:

- (1) ~~private pay;~~ Medicare;
- (2) ~~medicaid beneficiaries;~~ Medicaid;
- (3) ~~medicare beneficiaries;~~ Blue Cross and Blue Shield;
- (4) ~~uninsured indigent patients;~~ Commercial Insurance;
- (5) ~~underinsured indigent patients; and~~ State Employees Health Plan;

- (6) ~~fully insured patients.~~ Self-Pay (includes self-pay, indigent and charity care); and

- (7) Other as identified by the applicant.

(d) The applicant shall provide a written description of the billing procedures, including the credit collection policies, that will be utilized by the facility.

(e) The applicant shall document that the health care community in the ambulatory surgical service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

(f) The applicant shall provide documentation that the facility will match or exceed the average percent of patients in the combined categories of Medicare, Medicaid, charity care and bad debt provided by the existing and approved ambulatory surgical programs in the proposed ambulatory surgical service area in which the applicant's facility is, or will be, located.

Statutory Authority G.S. 131E-177(1).

.2118 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new ambulatory surgical facility, ~~or to~~ to increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital, 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 identify, ~~and~~ justify and document the availability of the number of current and proposed staff to be utilized in the following areas:

- (1) administration; ;
- (2) pre-operative; ;
- (3) post-operative; ;
- (4) operating room; ; and
- (5) other.

(b) The applicant shall ~~estimate~~ identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.

(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed ambulatory surgical service area in which the

facility is, or will be, located or will have written referral procedures with a physician who is an active member in good standing at a general acute care hospital in the proposed ambulatory surgical service area.

Statutory Authority G.S. 131E-177(1).

.2119 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to establish a new ambulatory surgical facility, ~~or~~ to increase the number of ambulatory surgical operating rooms in an existing ambulatory surgical facility or hospital, convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or add a specialty to a specialty ambulatory surgical program shall provide written policies and procedures demonstrating that the facility will have patient referral, transfer, and followup procedures.

(b) The applicant shall provide documentation showing the proximity of the proposed facility to the following services:

- (1) emergency services; ;
- (2) support services; ;
- (3) ancillary services; ; and
- (4) public transportation.

Statutory Authority G.S. 131E-177(1).

.2120 DATA REPORTING REQUIREMENTS

The facility shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .2300 - CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

.2314 DEFINITIONS

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

- (1) "Approved computed tomography (CT) scanner" means a CT scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.

- (2) "Computed tomography" means a technique whereby a sharply collimated X-ray beam is passed through the human body from a source which rotates around the body in a specific arc. As the beam passes through the body from its perimeter, its intensity is reduced. The transmitted intensity of the beam varies in accordance with the density of the tissue it passes through and is measured by sensitive detectors and, from this information, two-dimensional cross-sectional pictures or other images may be generated. A computer is used to generate the image from the measurements of X-ray beam intensity. Tissue images can be done with or without contrast agents. Computed tomography services are rendered by CT scanners.
- (3) "Computed tomography (CT) scanner" means an imaging machine which combines the information generated by a scanning X-ray source and detector system with a computer to reconstruct an cross-sectional image of the full body, including the head.
- (4) "Computed tomography (CT) service area" means a geographical area defined by the applicant, which has boundaries that are not farther than 40 road miles from the facility.
- (5) "CT scan" means one discrete image of a patient produced by a CT scanner.
- (6) "Existing CT scanner" means a computed tomography scanner in operation prior to the beginning of the review period.
- (7) "Fixed CT scanner" means a CT Scanner that is used at only one location or campus.
- (8) "HECT unit" means a unit that is equivalent to one CT scan which is derived by applying a weighted conversion factor to a CT scan in accordance with the Head Equivalent Computed Tomography studies formula developed by the National Electric Manufacturers, based on the "Leonard Methodology".
- (9) "Mobile CT scanner" means a CT scanner and transporting equipment which is moved to provide services at two or more host facilities.

Statutory Authority G.S. 131E-177(1).

.2315 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form.

(b) An applicant proposing to acquire a CT scanner shall provide the number of CT scans that have been performed on its existing CT scanners for each type of CT scan listed below for the previous 12 month period:

- (1) head scan without contrast;
- (2) head scan with contrast;
- (3) head scan without and with contrast;
- (4) body scan without contrast;
- (5) body scan with contrast; and
- (6) body scan without contrast and with contrast.

(c) The applicant shall project the number of CT scans to be performed on the new CT scanner for each type of CT scan listed below for the first 12 quarters the new CT scanner is proposed to be operated:

- (1) head scan without contrast;
- (2) head scan with contrast;
- (3) head scan without and with contrast;
- (4) body scan without contrast;
- (5) body scan with contrast; and
- (6) body scan without contrast and with contrast.

(d) The applicant shall convert the historical and projected number of CT scans to HECT units as follows:

	Type of CT Scan	No. of Scans		Conver. Factor		HECT Units
<u>1</u>	<u>Head without contrast</u>		<u>X</u>	<u>1.00</u>	<u>=</u>	
<u>2</u>	<u>Head with contrast</u>		<u>X</u>	<u>1.25</u>	<u>=</u>	
<u>3</u>	<u>Head without and with contrast</u>		<u>X</u>	<u>1.75</u>	<u>=</u>	
<u>4</u>	<u>Body without contrast</u>		<u>X</u>	<u>1.50</u>	<u>=</u>	
<u>5</u>	<u>Body with contrast</u>		<u>X</u>	<u>1.75</u>	<u>=</u>	
<u>6</u>	<u>Body without contrast and with contrast</u>		<u>X</u>	<u>2.75</u>	<u>=</u>	

(e) An applicant proposing to acquire a mobile CT scanner shall provide the information requested in Paragraphs (b), (c), and (d) of this Rule for each proposed host facility.

(f) The applicant shall provide all projected direct and indirect operating costs and all projected revenues for the provision of CT services for the first 12 quarters the new CT scanner is proposed to be operated.

(g) The applicant shall provide projected costs and projected charges by CPT code for the first 12 quarters the new CT scanner is proposed to be operated.

(h) If an applicant that has been utilizing a mobile CT scanner proposes to acquire a fixed CT scanner for its facility, the applicant shall demonstrate that its projected charge per CPT code shall not increase more than 10% over its current charge per CPT code on the mobile CT scanner.

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

(j) An applicant proposing to acquire a CT scanner shall demonstrate that it has a written commitment from the radiology group of a hospital that it will accept CT readings from the applicant.

(k) An applicant proposing to acquire a CT scanner shall demonstrate that the applicant has the capability of performing CT scan procedures 12 hours per day, six days per week.

Statutory Authority G.S. 131E-177(1).

.2316 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire a CT Scanner shall demonstrate each of the following:

- (1) each fixed or mobile CT Scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;
- (2) each existing fixed CT scanner in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application;
- (3) each existing and approved fixed CT scanner in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;
- (4) each existing mobile CT scanner in the proposed CT service area performed at least an average of 20 HECT units per day per site in the CT scanner service area in the 12 months prior to submittal of the application; and
- (5) each existing and approved mobile CT scanner shall perform at least an average of 20 HECT units per day per site in the CT scanner service area in the third year of operation of the proposed equipment.

Statutory Authority G.S. 131E-177(1).

.2317 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to acquire a CT scanner shall document the availability of the following diagnostic services:

- (1) diagnostic radiology services;
- (2) therapeutic radiology services;
- (3) nuclear medicine services; and
- (4) diagnostic ultrasound services.

(b) An applicant proposing to acquire a CT scanner shall document the availability of services to treat patients with the following conditions:

- (1) neurological conditions;
- (2) thoracic conditions;
- (3) cardiac conditions;
- (4) abdominal conditions;
- (5) medical oncological conditions;
- (6) radiological oncological conditions;
- (7) gynecological conditions;
- (8) neurosurgical conditions; and
- (9) genitourinary and urogenital conditions.

(c) An applicant proposing to acquire a mobile CT scanner shall provide:

- (1) referral agreements between each host site and at least one other provider of CT services in the proposed CT service area to document the availability of CT services if patients require them when the mobile unit is not in service at that host site; and
- (2) documentation that each of the services listed in Paragraphs (a) and (b) of this Rule shall be available at each host facility.

Statutory Authority G.S. 131E-177(1).

.2318 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements:

- (1) one Board certified radiologist who has had:
 - (A) training in computed tomography as an integral part of his or her residency training program; or
 - (B) six months of supervised CT experience; or
 - (C) at least three months of fellowship training, or its equivalent, in CT; or
 - (D) an appropriate combination of CT experience and fellowship training equivalent to Parts (a)(1) (A), (B), or (C) of this Rule;
- (2) at least one radiology technologist registered by the American Society of Radiologic Technologists shall be present during the hours of operation of the CT unit; and
- (3) a radiation physicist with training in medical physics shall be available for consultation for the calibration and maintenance of the equipment. The radiation physicist may be an employee or an independent contractor.

(b) An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided:

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

(c) An applicant proposing to acquire a mobile

CT scanner shall document that the requirements in Paragraphs (a) and (b) of this Rule shall be met at each host facility.

Statutory Authority G.S. 131E-177(1).

.2319 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information to the in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.2320 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the unit.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the unit and stating the admissions requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit collection policies, that will be utilized by the unit.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the unit's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

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

.2702 DEFINITIONS

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

- (1) ~~"Magnetic Resonance Imaging (MRI)" is defined as a non-invasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI unit 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.~~
- (2) ~~"MRI Procedure" is defined as a discrete MRI study of one patient.~~
- (3) ~~"MRI Unit" is defined as all of the essential equipment and facilities necessary to operate one MRI suite.~~
- (4) ~~"Primary Service Area" is defined as the geographic area in which 75 percent of the projected patient population resides.~~

Statutory Authority G.S. 131E-177(1).

.2703 CAPACITY IN THE FACILITY AND IN THE HEALTH SERVICE AREA

~~(a) A proposal to provide new or expanded MRI services must be consistent with the applicable North Carolina State Health Plan.~~

~~(b) A proposal involving a new or additional MRI unit must specify the type and estimated number of other diagnostic procedures which MRI will replace or complement in the facility.~~

~~(c) A proposal involving a new or additional MRI unit must provide documentation that the applicant has or is developing policies to establish the MRI unit as a regional resource that will have no administrative or clinical requirements which would impede physician referrals of patients for whom MRI testing would be appropriate. These policies must prescribe that services or scheduled testing will be available up to 12 hours per day, six days a week as required by the patient.~~

Statutory Authority G.S. 131E-177(1).

.2704 SCOPE OF SERVICES

~~(a) The proponent must demonstrate that the proposed MRI unit will function as a component of a comprehensive diagnostic imaging service in a facility which currently has the following diagnostic modalities on site and operational for at least one year:~~

- (1) ~~radioisotopic imaging studies;~~

- (2) ~~diagnostic X Ray studies;~~
- (3) ~~angiograms, including digital;~~
- (4) ~~diagnostic ultrasound studies; and~~
- (5) ~~computed tomography.~~

(b) ~~The proponent must make appropriate provisions for quality assurance and utilization review in connection with MRI services.~~

Statutory Authority G.S. 131E-177(1).

.2705 PROJECTED UTILIZATION

~~A proposal to provide new or expanded magnetic resonance imaging must:~~

- (1) ~~project an annual utilization of at least eight MRI procedures per eight hour shift for the first eight calendar quarters beginning with the operation of the new or expanded MRI service;~~
- (2) ~~initiate MRI services no later than 18 months after issuance of the certificate of need; and~~
- (3) ~~for the projections provided in (1) of this Paragraph, calculate the portion of procedures expected to be clinical and that expected to be for research purposes. The applicant must also provide documentation which directly relates the delineation of clinical and research procedures to actual discharge or out-patient diagnoses recorded in the applicant's facility during the most recent 12 month period for which this information has been compiled.~~

Statutory Authority G.S. 131E-177(1).

.2706 SITE AND EQUIPMENT

(a) ~~A proposal to provide new or expanded magnetic resonance imaging must provide documentation to show that the services will be offered in a physical environment that conforms to the requirements of federal, state and local regulatory bodies.~~

(b) ~~A proponent must provide evidence that the proposed MRI equipment has been certified for clinical use by the U.S. Food and Drug Administration.~~

Statutory Authority G.S. 131E-177(1).

.2707 STAFFING

(a) ~~The proponent must have available, or committed to be available, a physician licensed to practice medicine in North Carolina with evidence of training in magnetic resonance imaging who is~~

~~qualified and authorized by the proponent's facility to perform and to supervise magnetic imaging procedures. The authorization process and criteria to be applied in determining the qualifications of this physician must be specified.~~

(b) ~~The proponent must provide evidence of the availability of two full time technologists specially trained to operate the MRI unit.~~

Statutory Authority G.S. 131E-177(1).

.2710 COOPERATIVE AGREEMENTS

~~The proponent must submit evidence of cooperative agreements with facilities and appropriate individuals to assure efficient equipment utilization and availability of service. Such evidence shall include:~~

- (1) ~~letters from appropriate physicians indicating their intent to use the magnetic resonance imaging service of the proponent and to comply with all relevant criteria and guidelines; and~~
- (2) ~~designation of the provisions that have been established to accommodate all referrals from other facilities in the primary service area.~~

Statutory Authority G.S. 131E-177(1).

.2711 DATA FORMAT: REPORTING

~~The proponent must agree to share upon request validated results of its research and utilization of MRI with the department, in accordance with data format and reporting requirements that will be formulated by the department.~~

Statutory Authority G.S. 131E-177(1).

.2713 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 or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (2) "Existing MRI scanner" means an MRI scanner in operation prior to the beginning of the review period.
- (3) "Magnetic Resonance Imaging" (MRI) means a non-invasive diagnostic modality in which electronic equipment is used to create tomographic images of body struc-

ture. 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.

- (4) "Magnetic resonance imaging scanner" (MRI Scanner) is defined in G.S. 131E-176(14e).
- (5) "Mobile MRI Scanner" means an MRI scanner and transporting equipment which is moved to provide services at two or more host facilities.
- (6) "MRI Procedure" means a single discrete MRI study of one patient.
- (7) "MRI Service Area" means the geographic area defined by the applicant.
- (8) "MRI study" means one or more scans relative to a single diagnosis or symptom.

Statutory Authority G.S. 131E-177(1).

.2714 INFORMATION REQUIRED OF APPLICANT

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

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

- (1) documentation that the MRI scanner shall be available for use a minimum of 12 hours per day, six days per week. Mobile MRI scanners are not subject to this criterion;
- (2) projections of the number of procedures to be performed by type of service and the average charge for each proposed procedure for each of the first twelve quarters after completion of the project. This information shall be provided separately for each proposed host facility if the application proposes the acquisition of a mobile MRI scanner;
- (3) documentation of the need for an additional MRI scanner in the proposed MRI service area and description of the methodology used to project need, including all assumptions regarding the population to be served;
- (4) documentation that the proposed MRI scanner, including a mobile MRI scan-

ner, shall function as a component of a comprehensive diagnostic imaging service in a facility which has the following diagnostic modalities on-site. The applicant shall demonstrate further that the following diagnostic modalities have been continuously available on-site for at least 12 months prior to the date the application was filed:

- (A) radioisotopic imaging studies,
- (B) diagnostic X-Ray studies,
- (C) angiograms, including digital,
- (D) diagnostic ultrasound studies, and
- (E) computed tomography (full body);
- (5) except for proposed MRI scanners to be used exclusively for research purposes, documentation that all equipment, supplies and pharmaceutical proposed for the service have been certified for clinical use by the U.S. Food and Drug Administration or shall be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Service regulations;
- (6) letters from physicians indicating their intent to use the proposed magnetic resonance imaging scanner and to comply with all relevant criteria and guidelines; and
- (7) copies of agreements that have been established to accommodate referrals from other facilities in the MRI service area.

(c) 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.

Statutory Authority G.S. 131E-177(1).

.2715 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall:

- (1) demonstrate that all existing MRI scanners, except mobile MRI scanners, operating in the proposed MRI service area performed at least 2,032 MRI procedures in the last year;
- (2) project annual utilization in the third year of operation of at least 2,032 MRI procedures per year, for each proposed MRI scanner or mobile MRI scanner to be

operated by the applicant in the proposed MRI service area;

- (3) demonstrate that all of the existing MRI scanners operating in the proposed MRI service area shall be performing at least 2,032 MRI procedures per year in the applicant's third year of operation;
- (4) demonstrate that all of the approved MRI scanners in the proposed MRI service area shall be performing at least 2,032 MRI procedures per year in the applicant's third year of operation;
- (5) demonstrate that all existing mobile MRI scanners operating in the proposed MRI service area performed at least an average of 8 procedures per day per site in the proposed MRI service area in the last year and shall be performing at least an average of 8 procedures per day per site in the proposed MRI service area in the applicant's third year of operation;
- (6) demonstrate that all approved mobile MRI scanners to be operating in the proposed MRI service area shall be performing at least an average of 8 procedures per day per site in the proposed MRI service area in the applicant's third year of operation; and
- (7) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

Statutory Authority G.S. 131E-177(1).

.2716 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following on-site services and specialists or shall provide formal referral agreements that ensure that the following services are otherwise available:

- (1) anesthesiology,
- (2) radiology,
- (3) oncology,
- (4) neurology,
- (5) internal medicine,
- (6) orthopedics,
- (7) neurosurgery,
- (8) pathology, and
- (9) surgery.

(b) 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 to document the availability of MRI

services if patients require them when the mobile unit is not in service at that host site.

Statutory Authority G.S. 131E-177(1).

.2717 REQUIRED STAFFING AND STAFF TRAINING

(a) The applicant shall document that the proposed MRI scanner shall be operated under the supervision of a medical director who shall be a North Carolina licensed radiologist, nuclear medicine imaging physician, or other physician whose primary responsibility for the three years immediately prior to the date of the filing of the application has been the interpretation of images. This physician shall have knowledge of MRI through training, experience, or documented post-graduate education. An applicant for an MRI scanner shall identify one or more qualified physicians who are interested in becoming, or are available to serve as, medical director.

(b) The applicant shall provide evidence of the availability of two full-time MRI technologist-radiographers or technologists who have had equivalent education, training, and experience. One of the technologists shall be on-site at all times during operating hours. This individual shall demonstrate experience in computed tomography, nuclear medicine or other cross-sectional imaging methods.

(c) The applicant shall submit documentation which demonstrates the availability of appropriate inservice training or continuing education programs for all staff.

(d) The applicant shall submit documentation which demonstrates that at least one staff member who is certified in CPR and basic cardiac life support shall be present in the facility at all times.

Statutory Authority G.S. 131E-177(1).

.2718 ACCESSIBILITY

(a) An applicant that proposes to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide documentation describing the mechanism that will be used to assure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements which states the admissions requirements for the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;

- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

.2719 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

.3101 PURPOSE AND SCOPE

The rules set forth in this Section shall apply to applications for major medical equipment, including new major medical technology, for which specific criteria and standards have not otherwise been promulgated in 10 NCAC 3R.

Statutory Authority G.S. 131E-177(1).

.3102 DEFINITIONS

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

- (1) "Essential" means those items which are indispensable, the absence of which renders the equipment useless.
- (2) "Major Medical Equipment" is defined in G.S. 131E-176(14f).
- (3) "Mobile Major Medical Equipment" means major medical equipment and transporting equipment which is moved

to provide services at two or more host facilities.

- (4) "New Major Medical Technology" means major medical equipment that:

- (a) has been approved for clinical use by the U.S. Food and Drug Administration or shall be operated in accordance with protocols approved by an institutional review board whose membership is consistent with the U.S. Department of Health and Human Services regulations;
- (b) is intended for use in the diagnosis or treatment of medical conditions;
- (c) which meets the definition of major medical equipment in G.S. 131E-176(14f);
- (d) which is so new that no state or national utilization data is readily available to the Agency for the development of specific criteria and standards.

Statutory Authority G.S. 131E-177(1).

.3103 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.

(c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.

(d) An applicant shall document the estimated productive life of the specific equipment and whether any improvements can be expected during its productive life that would reduce its capital cost, operating cost, or increase its productivity.

(e) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human

Services regulations.

(f) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:

- (1) receiving/registering area;
- (2) waiting area;
- (3) pre-procedure area;
- (4) procedure area or rooms;
- (5) post-procedure areas, including observation areas; and
- (6) administrative and support areas.

(g) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and standards for the type of major medical equipment to be installed.

Statutory Authority G.S. 131E-177(1).

.3104 NEED FOR SERVICES

(a) An applicant proposing to acquire major medical equipment shall provide the following information:

- (1) the number of patients who will use the service, classified by diagnosis and by county of residence;
- (2) documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;
- (3) quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and
- (4) all the assumptions and data supporting the methodology used for the projections in this Rule.

(b) An applicant proposing to acquire new major medical technology shall provide the following information:

- (1) the number of patients who will use the service, classified by diagnosis and by county of residence;
- (2) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;
- (3) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;
- (4) documentation of the effect the new

major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and

- (5) all the assumptions and data supporting the methodology used for the projections in this Rule.

Statutory Authority G.S. 131E-177(1).

.3105 REQUIRED SUPPORT SERVICES

An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.

Statutory Authority G.S. 131E-177(1).

.3106 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:

- (1) trained and qualified clinical staff shall be employed, and
- (2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.

(b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.

(c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:

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

Statutory Authority G.S. 131E-177(1).

.3107 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served by the major medical equipment.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the major medical equipment and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the major medical equipment.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

.3108 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .3200 - CRITERIA AND STANDARDS FOR LITHOTRIPTOR EQUIPMENT

.3201 DEFINITIONS

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

- (1) "Approved lithotripter" means a lithotripter which was not operational prior to the beginning of the review

period but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.

- (2) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes but is not limited to a urologist skilled and experienced in both percutaneous and retrograde endoscopic stone removal procedures, and experienced interventional radiologic support.

- (3) "Existing lithotripter" means a lithotripter in operation prior to the beginning of the review period.

- (4) "Host facility" means the site at which a mobile lithotripter is parked for the provision of SWL procedures.

- (5) "Lithotripter" means equipment as defined in G.S. 131E-176(14d).

- (6) "Lithotripter service area" means a geographical area defined by the applicant and which has boundaries that encompass at least 1,000,000 of the state's residents.

- (7) "Mobile lithotripter" means a lithotripter and transporting equipment that is moved to provide services at two or more host facilities.

- (8) "Shock wave lithotripsy (SWL) procedure" means a procedure for the removal of kidney stones which involves focusing shock waves on kidney stones so that they are pulverized into sand-like particles which may then be passed through the urinary tract.

Statutory Authority G.S. 131E-177(1).

.3202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire a lithotripter shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire a lithotripter shall also provide the following additional information:

- (1) the boundaries of the proposed lithotripter service area;
- (2) documentation that 1,000,000 persons reside in the proposed lithotripter service area based on population data provided by the North Carolina State

- (3) Office of Management and Budget; documentation that all equipment, supplies and pharmaceuticals proposed for the service have been certified for clinical use by the U.S. Food and Drug Administration or will be operated and used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations;
- (4) the number of patients from the proposed lithotripter service area who are projected to receive SWL procedures by patient's county of residence in each of the first 12 quarters after completion of the project. This information shall be provided separately for each proposed host facility in those applications which propose the acquisition of a mobile lithotripter;
- (5) documentation from the applicant's projected referral sources which indicates their intent to refer to the applicant's lithotripter; and
- (6) the locations at which existing and approved lithotripter, including mobile units, operate or have been approved to operate in the lithotripter service area.

(c) An applicant proposing to acquire a mobile lithotripter shall also provide the following information:

- (1) copies of letters of intent from, and proposed contracts with, all of the proposed host facilities;
- (2) the proposed schedule for the provision of SWL procedures at each host facility;
- (3) the projected method for staffing the service, including whether personnel will travel with the lithotripter or will be supplied at each host facility where services are provided and whether personnel will be dedicated to providing lithotripter services; and
- (4) documentation of the means by which patients will receive follow-up care after the lithotripter leaves the site where the services are provided.

Statutory Authority G.S. 131E-177(1).

.3203 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire a lithotripter,

including a mobile lithotripter, shall demonstrate that the following standards are met:

- (1) each existing lithotripter in the proposed lithotripter service area, except mobile lithotriptors, performed 1,000 procedures in the last year;
- (2) each proposed lithotripter shall be projected to perform 1,000 procedures per year in the third year of operation of the proposed lithotripter;
- (3) each existing and approved lithotripter, except mobile lithotriptors, in the proposed lithotripter service area shall be projected to perform at least 1000 procedures per year in the third year of operation of the proposed lithotripter;
- (4) each existing mobile lithotripter providing services in the proposed lithotripter service area performed an average of 4.0 procedures per day per site in the proposed lithotripter service area;
- (5) each existing and approved mobile lithotripter providing services in the proposed lithotripter service area shall perform an average of 4.0 procedures per day per site in the proposed lithotripter service area in the applicant's third year of operation.

Statutory Authority G.S. 131E-177(1).

.3204 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to acquire a lithotripter shall document the availability of the following services:

- (1) an active radiology service and an established referral urological practice; and
- (2) the availability and accessibility of acute inpatient services for patients who experience complications.

(b) An applicant proposing to acquire a mobile lithotripter shall provide referral agreements between each host site and at least one other provider of lithotripter services in the proposed lithotripter service area to document the availability of lithotripter services if patients require them when the mobile lithotripter is not in service at that host facility.

Statutory Authority G.S. 131E-177(1).

.3205 REQUIRED STAFFING AND STAFF TRAINING

(a) The applicant shall demonstrate that the following staff shall be available at each location at which the lithotripter will be operated:

- (1) one certified general surgeon;
- (2) one certified urologist skilled and experience in complicated stone disease treatment capability; and
- (3) one certified radiologist with experience in X-ray, CT and Ultrasound Imaging.

(b) All individuals using the lithotripter equipment shall meet the training and proficiency guidelines and standards in the American Urological Association Guidelines and Standards, which are hereby incorporated by reference, including all subsequent amendments and editions of the referenced materials. A list of the American Urological Association's approved training sites may be obtained free of charge from American Urological Association, 1120 North Charles Street, Baltimore, Maryland, 21201.

(c) The applicant shall demonstrate that the following staff training shall be provided at each location where the lithotripter will be operated:

- (1) certification in cardiopulmonary resuscitation and basic cardiac life support; and
- (2) an organized program of staff education and training specific to lithotripter services that ensures improvements in technique and the proper training of new personnel.

Statutory Authority G.S. 131E-177(1).

.3206 DATA REPORTING REQUIREMENTS

The applicant offering lithotripter services shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.3207 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the

admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.

(d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .3300 - CRITERIA AND STANDARDS FOR AIR AMBULANCE

.3301 DEFINITIONS

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

- (1) "Air ambulance" as defined in G.S. 131E-176(1a).
- (2) "Air ambulance service" means an entity engaged in the operation of an air ambulance transporting patients.
- (3) "Air ambulance service area" means a geographic area defined by the applicant from which the project's patients originate.
- (4) "Approved air ambulance" means either a rotary air ambulance or a fixed wing air ambulance which was not operational prior to the beginning of the review period but which had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (5) "Audit and review panel" as defined in 21 NCAC 32H .0100.
- (6) "Capacity of fixed wing air ambulance" means the maximum number of hours the aircraft can be operated as defined by the aircraft manufacturer.
- (7) "Category IV (A) ambulance" as defined in 10 NCAC 3D .0801(b)(4)(A).
- (8) "Category IV (B) ambulance" as defined

- in 10 NCAC 3D .0801(b)(4)(B).
- (9) "Existing air ambulance" means either a rotary air ambulance or a fixed wing air ambulance in operation prior to the beginning of the review period.
 - (10) "Ground mobile intensive care ambulance service" means a ground based emergency vehicle that meets the definition of a 'mobile intensive care unit' as defined in 21 NCAC 32H .0100.
 - (11) "Inter-facility patient transport" means the transport of a patient from one facility to another facility.
 - (12) "Level 2 trauma center" as defined in North Carolina's Trauma Center Criteria developed by the OEMS pursuant to G.S. 131E-162(7a).
 - (13) "Medical crew member" as defined in 10 NCAC 3D .0800.
 - (14) "Medical director" as defined in 21 NCAC 32H .0100.
 - (15) "Office of Emergency Medical Services" (OEMS) as defined in 10 NCAC 3D .0800 and 21 NCAC 32H .0100.
 - (16) "Patient" as defined in G.S. 131E-155(6).
 - (17) "Scene transport" means the transport of a patient from the scene of a medical emergency.
 - (18) "Sponsor hospital" as defined in 21 NCAC 32H .0102.

Statutory Authority G.S. 131E-177(1).

.3302 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire an air ambulance shall use the Acute Care Facility/Medical Equipment Application Form.

(b) The applicant shall also provide the following additional information:

- (1) the number of air ambulance aircraft by type and make currently operated and to be operated in the "air ambulance" service area following completion of the proposed project;
- (2) if the applicant is a current air ambulance service provider, documentation of the applicant's experience in transporting patients via air ambulance during the past 12 months, including:
 - (A) the number of scene transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing); and
 - (B) the number of inter-facility patient

- transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing);
- (3) if the applicant is a health service facility proposing to establish a new air ambulance service, the applicant shall provide documentation of:
 - (A) the number of scene transports to their facility by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) during the past 12 months; and
 - (B) the number of inter-facility patient transports during the past 12 months by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) to their facility from other facilities and from their facility to other facilities;
- (4) the number of patients from the proposed air ambulance service area that are projected to require air ambulance service by type of aircraft and the patient's county of residence and county from which transported in each of the first 12 calendar quarters of operation following completion of the project, including the methodology and assumptions used for the projections;
- (5) the projected utilization of the air ambulance service per aircraft for each of the first 12 calendar quarters following completion of the proposed project by type of patient (e.g., neonatal, pediatric, cardiac), including the methodology and assumptions used for these projections;
- (6) documentation which demonstrates that existing air ambulance services in the State are unable to accommodate the applicant's projected need for an additional air ambulance;
- (7) as appropriate to the type of aircraft proposed, documentation of referral sources for air ambulance patients and evidence of the willingness of hospitals to participate;
- (8) documentation which demonstrates the applicant's capability to communicate with and access emergency transportation resources including, but not limited to ground mobile intensive care ambulance services;
- (9) evidence of the applicant's capability to provide air ambulance services on a 24

- hour per day, 7 day per week basis except as precluded by weather, maintenance and other factors as applicable;
- (10) documentation of appropriate inservice training or continuing education programs for staff;
- (11) documentation of written policies and procedures for the operation of the air ambulance service, which shall be in effect at the time the proposed air ambulance becomes operational, for at least the following:
- (A) arrangements for transport of a patient when patient transport cannot be provided by the applicant or a current Mutual Aid Agreement with the NC Aeromedical Affiliation and other agreements as appropriate with adjoining states;
- (B) written criteria for patient transport;
- (C) medical crew contact with medical control;
- (D) operation of an audit and review panel;
- (E) patient treatment protocols;
- (F) patient transfer protocols;
- (G) communication, including incoming calls, dispatch, and on-going communication with air ambulance flight and medical crew and other emergency medical service providers;
- (H) role in disaster plans;
- (I) if the applicant proposes a Category IV (A) ambulance, the proposed role and responsibility of participating hospitals as outlined in 21 NCAC 32H;
- (J) if the applicant proposes a Category IV (A) ambulance, medical control as outlined in 21 NCAC 32H; and
- (K) coordination with local emergency medical service systems in the proposed air ambulance service area or other providers as appropriate given the type of aircraft and service proposed;
- (12) if the applicant is an existing air ambulance service provider, copies of the following, as applicable:
- (A) the current permit(s) issued by the OEMS and evidence that the permit(s) has not been denied or revoked,
- (B) the current FAA Part 135 or Part 91 Certificate, and
- (C) the current FCC radio license;

- (13) if an applicant does not currently operate an air ambulance, evidence that the OEMS, FCC and FAA are aware of the proposed air ambulance and that the applicant expects to be able to obtain all required permits, licenses or certifications and an indication of the category of ambulance proposed, i.e., Category IV (A) or Category IV (B) ambulance;
- (14) documentation of the aircraft selection analysis used by the applicant and reason for selection of the aircraft proposed;
- (15) documentation of a financial analysis of a lease versus purchase option for acquisition of the proposed aircraft and the method (e.g., hire own versus contract) of providing personnel to fly the aircraft and the reason for selection of the option proposed;
- (16) if the applicant proposes a Category IV (A) ambulance, evidence of the existence of a sponsor hospital that meets criteria set forth in 21 NCAC 32H; and
- (17) if the applicant proposes the acquisition of a fixed wing air ambulance, documentation of the capacity of each existing fixed wing air ambulance based in the state.

Statutory Authority G.S. 131E-177(1).

.3303 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire an air ambulance shall demonstrate that the project meets the following standards:

- (1) For the acquisition of a rotary air ambulance (unless 10 NCAC 3R .3303(4) is applicable):
- (a) existing rotary air ambulances based in the State of North Carolina shall have flown an average of 60 patient flights per month per rotary aircraft for the last year [calculated as follows: (total number of patient flights in the last year flown in the state by rotary air ambulances based in the state) divided by (total number of rotary air ambulances based in the state) divided by (twelve)]; and
- (b) each rotary air ambulance proposed to be acquired by the applicant shall be utilized at an average rate of at least 60 patient requests per month, measured

- during the fourth quarter of the second year following completion of the project (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and
- (c) existing or approved rotary air ambulances based in the state are projected to be utilized at an average of no less than 60 patient requests per month per rotary aircraft measured during the fourth quarter of the third year after the operation of the new air ambulance [calculated as follows: (total projected number of patient requests in the fourth quarter of the third year after the operation of the new air ambulance by existing or approved rotary air ambulances based in the state) divided by (total number of existing or approved rotary air ambulances based in the state in the fourth quarter of the third year after the operation of the new air ambulance) divided by (three)] (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and
- (d) an applicant proposing to add a rotary air ambulance to an existing rotary air ambulance service shall demonstrate that all of its existing rotary air ambulances have had at least 60 patient requests per month in the last year.
- (2) For the acquisition of a fixed wing air ambulance (unless 10 NCAC 3R .3303(4) is applicable):
- (a) existing fixed wing air ambulances based in the State of North Carolina were utilized at an average of 60% of capacity transporting patients for the last year [calculated as follows: (total utilized capacity transporting patients in the last year of fixed wing air ambulances based in the state) divided by (total potential capacity of fixed wing air ambulances based in the state in the last year) times (100)]; and
- (b) each fixed wing air ambulance proposed to be acquired by the applicant shall be utilized at an average of no less than 60% of capacity transporting patients (determined based on the type aircraft), measured during the fourth quarter of the second year following completion of the project (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and
- (c) existing or approved fixed wing air ambulances based in the state are not projected to fall below an average 60% of capacity transporting patients measured during the fourth quarter of the third year after the operation of the new air ambulance [calculated as follows: (total projected utilized capacity transporting patients in the fourth quarter of the third year after the operation of the new air ambulance of existing or approved fixed wing air ambulances based in the state) divided by (total potential capacity of existing or approved fixed wing air ambulances based in the state in the fourth quarter of the third year after the operation of the new air ambulance) times (100)] (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and
- (d) an applicant proposing to add a fixed wing air ambulance to an existing fixed wing air ambulance service shall demonstrate that all of its existing fixed wing air ambulances have been utilized at no less than 60% of capacity transporting patients for the last year.
- (3) For all proposed projects involving the development of a new air ambulance service (rotary or fixed wing), the new service shall be developed in conjunction with at least a level 2 designated trauma center and another air ambulance service shall not be based within 60 air miles of the base of the proposed new service.
- (4) For acquisition of an air ambulance that shall be utilized less than 25% of the time flown for purposes defined in G.S. 131E-176(1a), the applicant shall provide the following information:
- (a) documentation that the aircraft shall be utilized less than 25% of the time flown in any given quarter for purposes defined in G.S. 131E-176(1a) (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and
- (b) a detailed description of all circumstances and conditions under which the aircraft will be utilized including the number of hours the aircraft will be

flown for each of these circumstances; and

- (c) if the proposal is for a rotary wing aircraft, existing rotary air ambulances based in the State are projected to be utilized at an average of no less than 60 patient requests per month per rotary aircraft measured during the fourth quarter of the first year after the operation of the new air ambulance [calculated as follows: (total projected number of patient requests in the fourth quarter of the first year after the operation of the new air ambulance by existing or approved rotary air ambulances based in the state) divided by (total number of existing or approved rotary air ambulances based in the state in the fourth quarter of the first year after the operation of the new air ambulance) divided by (three)] (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and

- (d) if the proposal is for a fixed wing air ambulance, the utilization of existing fixed wing air ambulances based in the State are not projected to fall below an average 60% of capacity transporting patients measured during the fourth quarter of the first year after the operation of the new air ambulance [calculated as follows: (total projected utilized capacity transporting patients in the fourth quarter of the first year after the operation of the new air ambulance of existing or approved fixed wing air ambulances based in the state) divided by (total potential capacity of existing or approved fixed wing air ambulances based in the state in the fourth quarter of the first year after the operation of the new air ambulance) times (100)](the applicant shall document the assumptions and provide data supporting the methodology used for the projections).

Statutory Authority G.S. 131E-177(1).

.3304 REQUIRED SUPPORT SERVICES/EQUIPMENT

- (a) The applicant shall demonstrate that the following services or equipment shall be available on a 24 hour per day, 7 day per week basis:

- (1) two-way voice radio licensed by the

FCC that meets the capabilities outlined in 10 NCAC 3D;

- (2) internal voice communication system as outlined in 10 NCAC 3D;
(3) aircraft and patient compartment that meet standards of 10 NCAC 3D; and
(4) equipment as outlined in 10 NCAC 3D.

- (b) The applicant shall demonstrate that a community outreach and aircraft related accident prevention education program shall be provided on an ongoing basis.

Statutory Authority G.S. 131E-177(1).

.3305 REQUIRED STAFFING AND STAFF TRAINING

- (a) The applicant shall demonstrate that the following staff shall be available to provide air ambulance services:

- (1) a North Carolina licensed physician who is designated as the medical director and who meets the requirements of 21 NCAC 32H;
(2) medical crew members trained in accordance with 10 NCAC 3D and available in accordance with 10 NCAC 32H;
(3) flight crew members to fly the aircraft in accordance with 10 NCAC 3D;
(4) if applicable, personnel available as needed for transport of special care patients (e.g., neonatal, cardiac);
(5) appropriately trained personnel to operate the ground communication network.

- (b) The applicant shall provide an organized program of staff education and training approved by the OEMS which is integral to the air ambulance service and ensures improvements in technique and the proper training of personnel including flight and medical crew members as required by 10 NCAC 3D and 21 NCAC 32H.

Statutory Authority G.S. 131E-177(1).

.3306 DATA REPORTING REQUIREMENTS

- The applicant shall provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients transported;
(2) financial data; and
(3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .3400 - CRITERIA AND STANDARDS FOR BURN INTENSIVE CARE SERVICES

.3401 DEFINITIONS

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

- (1) "Approved burn intensive care unit" means a burn intensive care unit which was not operational prior to the beginning of the review period but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (2) "Burn care technician" means:
 - (a) a licensed practical nurse;
 - (b) a operating room technician;
 - (c) a operating room corpsman; or
 - (d) a high school graduate with basic nurse aide training who has received special education or experience in burn treatment care.
- (3) "Burn intensive care services" as defined in G.S. 131E-176(2b).
- (4) "Burn intensive care service area" means a geographic area defined by the applicant from which the patients to be admitted to the unit will originate.
- (5) "Burn intensive care unit" means a designated area within a hospital dedicated to the provision of burn intensive care services to severely burned patients.
- (6) "Burn specialist" means a registered nurse who possesses experience in general nursing and experience in or knowledge of intensive nursing care and burn treatment care.
- (7) "Existing burn intensive care unit" means a burn intensive care unit in operation prior to the beginning of the review period.
- (8) "Severely burned patient" means a patient that has burns covering more than 20 percent of the body area or that has burns which require intensive treatment, such as, but not limited to: inhalation injuries; chemical and electrical burns; burns with complications, such as fractures; burns to the face; full thickness burns to the hands and feet; burns on patients whose pre-burned health was known to be poor, such as patients with diabetes or heart disease; and, burns on patients who are under 5 and over 60 years of age.

Statutory Authority G.S. 131E-177(1).

.3402 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new burn intensive care unit or to add beds to an existing or approved burn intensive care unit shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to develop a new burn intensive care unit or to add beds to an existing or approved burn intensive care unit shall also provide the following additional information:

- (1) the number of beds in the burn intensive care unit currently operated in the applicant's facility and the total to be operated following completion of the proposed project;
- (2) documentation of the applicant's experience in treating severely burned patients at its facility during the last year, including:
 - (A) the number of severely burned patients treated through emergency room services;
 - (B) the number of severely burned patients referred to the applicant's facility from other facilities;
 - (C) the number of inpatient days of care provided to severely burned patients; and
 - (D) the number of severely burned patients the applicant referred to other facilities for burn treatment;
- (3) the number of severely burned patients from the proposed burn intensive care service area that are projected to require burn intensive care services, by the patient's county of residence, in each of the first 12 quarters of operation following completion of the project. The applicant shall state the methodology and assumptions used to make the projections;
- (4) the projected utilization of the beds in the applicant's burn intensive care unit for each of the first twelve calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections;
- (5) evidence that existing and approved burn intensive care units in the state are unable to accommodate the applicant's projected need for additional burn

- intensive care services;
- (6) letters from physicians or other evidence that document the referral sources of patients to the burn intensive care unit;
- (7) evidence of the applicant's capability to communicate with and access emergency transportation resources including, but not limited to air ambulance services;
- (8) evidence of the applicant's capability to provide burn treatment services in the burn intensive care service unit on a 24 hour per day, 7 day per week basis;
- (9) description of inservice training or continuing education programs specific to burn intensive care services that shall be provided to unit staff; and
- (10) copies of written policies and procedures for the operation of the burn intensive care unit that shall be in effect at the time the unit becomes operational, for at least the following:
 - (A) arrangements for treatment of a patient when patient load exceeds optimal operational capacity;
 - (B) patient admission and discharge policies that are developed with input from the medical staff and the nursing service;
 - (C) infection control and prevention, including handling of contaminated items, decontamination, transportation of patients outside of the unit, house-keeping and cleaning schedule, solid and liquid waste systems, staff and visitor traffic control, and aseptic isolation;
 - (D) the inclusion of the unit in the facility's external and internal disaster plans;
 - (E) performance of special procedures; and
 - (F) acquisition and storage of homograft and heterograft skin.

(c) The applicant shall provide documentation, including a detailed floor plan of the proposed unit drawn to scale, to demonstrate that the proposed unit shall:

- (1) be organized as a physically and functionally distinct entity with controlled access;
- (2) provide an effective means of isolation for patients suffering from communicable or infectious disease, for patients

requiring protective isolation, and for disoriented or emotionally disturbed patients who require the services of the unit until placement elsewhere becomes possible;

- (3) provide a means for observation by unit staff of all patients from at least one vantage point; and
- (4) contain no fewer than 6 licensed acute care beds.

Statutory Authority G.S. 131E-177(1).

.3403 REQUIRED PERFORMANCE STANDARDS

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that:

- (1) the existing burn intensive care units in the state had an overall average occupancy rate of at least 80 percent for the last year, which shall be calculated by dividing the total number of bed days utilized in the last year by severely burned patients in all facilities in the state that have burn intensive care units, by the total number of burn intensive care unit beds in all facilities in the state that have burn intensive care units multiplied by 365 days;
- (2) the average occupancy rate of the applicant's existing unit for the last year was at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds;
- (3) the applicant's unit shall be utilized at an annual occupancy rate of at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds, no later than 2 years following completion of the proposed project; and
- (4) each existing or approved burn intensive care unit shall be projected to be utilized at an annual occupancy rate of at least 70% in units with 20 or more beds, 65% in units with 10 to 19 beds, and 60% in units with 1 to 9 beds, no later than 2 years following completion of the applicant's proposed project.

(b) The calculation of occupancy rates in this Rule shall be based only on severely burned patients.

(c) The applicant shall document all assumptions and data supporting the methodology used for all occupancy rates projected in this Rule.

Statutory Authority G.S. 131E-177(1).

.3404 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that the following services, equipment and supplies shall be available to the burn intensive care unit 24 hours per day, 7 days per week:

- (1) monitoring devices which allow nurses at a nursing station to monitor patients around-the-clock;
- (2) ventilator capability at each bed in the unit;
- (3) a tub, tank or table for the cleaning of burn wounds located in an area of the unit separate from the general patient care area;
- (4) temperature control equipment or capability which allows for independent temperature control for each patient area;
- (5) renal dialysis;
- (6) an operating room;
- (7) a clinical laboratory which is capable of performing tests and reporting the results on a timely basis, including blood chemistries, blood gas analyses, Ph levels, electrolyte determinations, and serum and urine osmolalities;
- (8) microbiology services;
- (9) blood bank services;
- (10) diagnostic radiologic services;
- (11) a direct intercommunication/alarm system between the nurses' station and the patient's bedside, with connections to treatment, work, lounge, or other areas from which additional personnel would be summoned;
- (12) oxygen and compressed air and the means of administration;
- (13) mechanical ventilatory assistance equipment;
- (14) cardiac defibrillator with synchronization capability;
- (15) respiratory and cardiac monitoring equipment;
- (16) thoracentesis and closed thoracostomy sets;
- (17) tracheostomy sets;

- (18) tourniquets;
- (19) vascular cutdown sets;
- (20) infusion pumps;
- (21) laryngoscopes and endotracheal tubes;
- (22) tracheobronchial and gastric suction equipment;
- (23) portable x-ray equipment; and
- (24) a patient weighing device for bed patients.

(b) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall also demonstrate that the following services shall be available:

- (1) aftercare services to burn unit patients for post hospitalization including social services, vocational counseling and physical rehabilitation; and
- (2) a community outreach and prevention education program, which shall include, but not be limited to, coordination with emergency medical service authorities in training in the assessment, care, triage and transfer of severely burned patients.

Statutory Authority G.S. 131E-177(1).

.3405 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that the following staff shall be available to provide the proposed services:

- (1) a designated physician in charge of the unit with board certification in general or plastic surgery and at least one year of experience in a burn unit;
- (2) in-house physician coverage by either a staff physician or a member of the house staff assigned to the unit 24 hours per day, 7 days per week;
- (3) a registered nurse administratively responsible for the nursing service in the unit who has at least two years of intensive care or equivalent experience and experience working with burn patients;
- (4) a burn specialist 24 hours per day, 7 days per week;
- (5) a burn care technician 24 hours per day, 7 days per week;
- (6) designated support staff available to the unit, including:

- (A) anesthetist,
- (B) chaplain,
- (C) dietician,
- (D) inhalation therapist,
- (E) microbiologist,
- (F) occupational therapist,
- (G) pharmacist,
- (H) physical therapist, and
- (I) social worker;
- (7) other non-surgical support services staff available for consultation, including:
 - (A) anesthesiology,
 - (B) cardiology,
 - (C) gastroenterology,
 - (D) hematology,
 - (E) infectious disease,
 - (F) internal medicine,
 - (G) nephrology,
 - (H) neurology,
 - (I) nutrition,
 - (J) ophthalmology,
 - (K) pathology,
 - (L) pediatrics,
 - (M) psychiatry,
 - (N) pulmonary,
 - (O) radiology, and
 - (P) special education; and
- (8) surgical support specialists available for consultation, including:
 - (A) cardiothoracic,
 - (B) neurologic,
 - (C) OB-GYN,
 - (D) ophthalmic,
 - (E) oral and maxillofacial,
 - (F) orthopaedic,
 - (G) otorhinolaryngologic,
 - (H) pediatric,
 - (I) plastic (if not the director of the burn unit),
 - (J) urologic, and
 - (K) vascular.

(b) An applicant proposing to develop a new burn intensive care unit or to add a bed to an existing or approved burn intensive care unit shall demonstrate that an organized staff education and training program shall be provided which is integral to the burn intensive care service unit and which ensures improvements in technique and the proper training of new personnel.

Statutory Authority G.S. 131E-177(1).

.3406 DATA REPORTING REQUIREMENTS

The applicant shall provide, upon the request of the Division of Facility Services, the following

types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.3407 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that shall be used to ensure that the projected number of medically underserved shall be served in the unit.

(b) The applicant shall provide a copy of the written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admissions requirements for the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit collection policies, that shall be utilized by the facility.

(d) The applicant shall document that the health care community in the "burn intensive care" service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .3500 - CRITERIA AND STANDARDS FOR ONCOLOGY TREATMENT CENTERS

.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.

Statutory Authority G.S. 131-177(1).

.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 10 NCAC 3R .1900, Criteria and Standards for Radiation Therapy Equipment.

Statutory Authority G.S. 131-177(1).

.3503 NEED FOR SERVICES

An applicant proposing to develop an oncology treatment center shall provide the following information:

- (1) the number of patients that are projected to use the service, classified by diagnosis and by county of residence;
- (2) documentation of the maximum number of procedures that the equipment in the facility is capable of performing;
- (3) quarterly projected utilization of the applicant's new equipment for each of the

- first three years after the completion of the project;
- (4) 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
 - (5) all the assumptions and data supporting the methodology used for the projections.

Statutory Authority G.S. 131E-177(1).

.3504 REQUIRED 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;
- (3) diagnostic radiology services;
- (4) nuclear medicine services;
- (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.

Statutory Authority G.S. 131-177(1).

.3505 REQUIRED 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 of 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 that the appropriate types and numbers of staff, particularly qualified medical technologists and medial staff, shall be available to support the services; and
- (4) documentation to demonstrate that a formal training program exists to ensure the continued proficiency of the professional and technical staff.

Statutory Authority G.S. 131-177(1).

.3506 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131-177(1).

.3507 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;

- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.
- (c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.
- (d) The applicant shall document that the health care community in the service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131-177(1).

SECTION .3600 - CRITERIA AND STANDARDS FOR GAMMA KNIFE

.3601 DEFINITIONS

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

- (1) "Approved gamma knife" means a gamma knife which was not operational prior to the beginning of the review period but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (2) "Existing gamma knife" means a gamma knife in operation prior to the beginning of the review period.
- (3) "Gamma knife" is defined in G.S. 131E-176(7c).
- (4) "Gamma knife procedure" means a radiation dosage delivered in one treatment session.
- (5) "Gamma knife service area" means the geographic area defined by the applicant.

Statutory Authority G.S. 131E-177(1).

.3602 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant proposing the acquisition of a gamma knife shall use the Acute Care Facility/Medical Equipment application form.
- (b) The applicant shall also provide the following additional information:
 - (1) copies of written policies that establish the gamma knife as a regional resource having no administrative, clinical or charge requirements which would impede physician referrals of patients

- for whom gamma knife procedures would be appropriate;
- (2) documentation that the following diagnostic modalities have been operational in the facility in which the gamma knife will be used for at least 12 months prior to the submittal of the application:
 - (A) magnetic resonance imaging (MRI);
 - (B) angiography, including digital;
 - (C) neuro angiography and CT services; and
 - (D) linear accelerator;
- (3) if the proposed gamma knife will be used for clinical use or for clinical trials, documentation that all equipment, supplies and pharmaceuticals proposed for the service have been certified for clinical use by the U.S. Food and Drug Administration or that the gamma knife shall be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Service regulations;
- (4) if the proposed gamma knife will be used for experimental or research activities, documentation of the sources of funds to be used to finance the capital cost and operational costs of the gamma knife;
- (5) documentation of the projected number of procedures, by type, to be performed in each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections;
- (6) documentation of the type and estimated number of procedures performed in the facility that the gamma knife will replace or complement;
- (7) evidence that protocols will be established to assure that all clinical gamma knife procedures performed are medically necessary and that alternative treatment modalities have been considered; and
- (8) evidence of cooperative agreements with facilities and appropriate individuals to assure efficient equipment utilization and availability of the gamma knife, including:
 - (A) letters from qualified physicians indicating their intent to use the

gamma knife proposed by the applicant and to comply with all relevant gamma knife criteria and guidelines; and

- (B) the provisions that have been established to accommodate referrals from other facilities in the gamma knife service area.

Statutory Authority G.S. 131E-177(1).

.3603 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire a gamma knife shall:

- (1) demonstrate that all existing gamma knives in the applicant's gamma knife service area performed at least 408 procedures during the twelve month period immediately preceding submittal of the application;
- (2) project an annual utilization of at least 326 procedures per year by the end of the third year of operation and provide all assumptions and data supporting the methodology used for the projections;
- (3) for the projections provided in response to Item (2) of this Rule, calculate the number of procedures projected to be performed for clinical purposes and the number of procedures projected to be performed for research purposes; and
- (4) demonstrate that all of the existing and approved gamma knives in the applicant's gamma knife service area shall be performing at least 326 gamma knife procedures per year in the third year of operation of the new gamma knife, and provide all assumptions and data supporting the methodology used for the projections.

Statutory Authority G.S. 131E-177(1).

.3604 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to acquire a gamma knife shall provide documentation, such as formal consultation agreements or letters of commitment, that physicians certified in the following specialty areas shall be available for consultation:

- (1) neurological surgery,
- (2) radiation oncology,
- (3) medical physicist,
- (4) diagnostic radiology,
- (5) anesthesiology,

(6) otolaryngology, and

(7) neurology.

(b) An applicant proposing to acquire a gamma knife shall demonstrate how medical emergencies within the gamma knife unit will be managed in conformity with accepted medical practice.

Statutory Authority G.S. 131E-177(1).

.3605 REQUIRED STAFF AND STAFF TRAINING

(a) The applicant shall demonstrate that the following persons shall be available to provide the proposed services:

- (1) a neurological surgeon who is familiar with the principles of craniospinal irradiation and has expertise in conventional stereotactic surgery, microsurgery, and selection of target volumes defined by neuroimaging;
- (2) a radiation oncologist who is familiar with the principles of stereotactic imaging and has experience with precise single fraction irradiation of small target volumes;
- (3) qualified radiophysicist with documented training in radiosurgery; and
- (4) qualified gamma knife nurse with documented training in radiosurgery.

(b) The applicant shall provide documentation that each staff member as identified in Paragraph (a) of this Rule who will be initiating gamma knife procedures shall have specific, documented training in radiosurgery prior to the operation of the gamma knife, including attendance at specific courses or symposia and a site visit at a center that is currently performing radiosurgery. The documentation shall confirm that each team member has had education that includes:

- (1) analysis of prior results,
- (2) patient selection,
- (3) stereotactic head frame application,
- (4) stereotactic neurodiagnostic imaging using all pertinent modalities,
- (5) target selection,
- (6) dose determination,
- (7) dose prescription,
- (8) treatment delivery, and
- (9) instructions regarding radiation effects and protection.

(c) The applicant shall submit documentation which demonstrates the availability of inservice training or continuing education programs for its staff specific to the provision of gamma knife

services.

(d) The applicant shall submit documentation which demonstrates that at least one staff member who is certified in CPR and basic life support shall be present in the facility at all times.

Statutory Authority G.S. 131E-177(1).

.3606 ACCESSIBILITY

(a) An applicant that proposes to acquire a gamma knife shall provide documentation describing the mechanism that will be used to assure that the projected number of medically underserved will be served by the applicant.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements which state the admissions requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the applicant.

(d) The applicant shall document that the health care community in the gamma knife service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the applicant's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

.3607 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

SECTION .3700 - CRITERIA AND

STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

.3701 DEFINITIONS

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

- (1) "Approved positron emission tomography (PET) scanner" means a PET scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.
- (2) "Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.
- (3) "Existing PET scanner" means a PET scanner in operation prior to the beginning of the review period.
- (4) "PET procedure" means a single discrete study of one patient involving one or more PET scans.
- (5) "PET scan" means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure.
- (6) "PET scanner service area" means a geographic area defined by the applicant from which patients to be admitted to the service will originate.
- (7) "Positron emission tomographic scanner" (PET) is defined in G.S. 131E-176(19a).
- (8) "Radioisotope" means a radiochemical which directly traces biological processes when introduced into the body.

Statutory Authority G.S. 131E-177(1).

.3702 INFORMATION REQUIRED OF APPLICANT

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

(b) The applicant shall also provide the following additional information:

- (1) The projected number of scans, the projected number of procedures, and the projected number of patients for each of the first 12 calendar quarters following completion of the proposed

project. Projections shall be listed by clinical area (i.e. oncology, cardiology). The applicant shall include all methodologies and assumptions used.

- (2) Documentation that the applicant has provided all of the following services continuously throughout the twelve 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) If the PET scanner will be used for experimental or research purposes, the applicant shall document how capital costs and service operations will be funded.
- (4) If the PET scanner will be used for clinical purposes, the applicant shall specify the type and estimated number of other diagnostic procedures that the PET scanner will replace or complement in the facility.
- (5) If the PET scanner will be used for clinical purposes, the applicant shall develop and submit policies which:
 - (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;
 - (B) prescribe that services or scheduled testing will be available a minimum of 12 hours per day, six days a week; and
 - (C) implement a referral system which shall include a feedback mechanism of providing patient information to the referring physician and facility.
- (6) If the PET scanner will be used for clinical purposes, the applicant shall identify those 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.

Statutory Authority G.S. 131E-177(1).

.3703 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to acquire a PET scanner shall demonstrate that:

- (1) 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;
- (2) each PET scanner proposed for clinical use shall be utilized at an annual rate of at least 1,524 clinical procedures within its proposed PET scanner service area by the end of the third year following completion of the project. The applicant shall describe all assumptions and methodologies used in making these projections;
- (3) if the PET scanner will be used for clinical purposes, all existing clinical PET scanners in the applicant's PET scanner service area performed 1,524 clinical procedures during the twelve months immediately prior to the date on which the application was filed;
- (4) if the PET scanner will be used for clinical purposes, all existing and approved clinical PET scanners in the applicant's PET scanner service area will perform at least 1,524 clinical procedures during the third year following completion of the project. All assumptions and methodologies used in making these projections shall be described in the application; and
- (5) each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed:
 - (a) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents;
 - (b) quality control measures and assurance of PET tomograph and associated

- instrumentation;
- (c) radiation protection and shielding;
- (d) radioactive emission to the environment; and
- (e) radioactive waste disposal.

Statutory Authority G.S. 131E-177(1).

.3704 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to acquire a PET scanner shall document how medical emergencies within the PET scanner unit will be managed in conformity with accepted medical practice.

(b) An applicant proposing to acquire a 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 the facility;
- (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) 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) An applicant proposing to acquire a PET scanner shall document that a clinical oversight committee will be created before the proposed PET scanner is placed in service and that the committee 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.

Statutory Authority G.S. 131E-177(1).

.3705 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire to acquire a PET scanner shall document that the scanner will be staffed by the following personnel:

- (1) One or more full-time nuclear medicine imaging physicians who:
 - (A) are licensed by the State to handle medical radioisotopes;
 - (B) have specialized in the acquisition and interpretation of nuclear images, including tomographic studies, for at least one year;
 - (C) have acquired knowledge about PET through experience or postdoctoral education; and
 - (D) have had practical training with an operational PET scanner.
- (2) Engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment;
- (3) Radiation safety personnel with training and experience in the handling of short-lived positron emitting nuclides; and
- (4) Certified nuclear medicine technologists with training and experience in positron emission computed tomographic nuclear medicine imaging procedures.

(b) An applicant proposing to acquire a cyclotron shall document that the cyclotron shall be staffed by radiochemists or radiopharmacists who:

- (1) have at least one year of training and experience in the synthesis of short-lived positron emitting radioisotopes; and
- (2) have at least one year of training and experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical synthesis.

(c) An applicant proposing to acquire a PET scanner, a cyclotron, or both, shall document that the personnel described in Paragraphs (a) and (b) of this Rule shall be available at all times that the scanner and cyclotron are operating.

(d) An applicant proposing to acquire a PET scanner shall document that it shall develop and offer a program of continuing staff education which will insure the proper training of new personnel and the maintenance of staff competence as clinical PET applications, techniques and technology continue to develop and evolve.

Statutory Authority G.S. 131E-177(1).

.3706 DATA REPORTING REQUIREMENTS

An applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information in

accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.3707 ACCESSIBILITY

(a) An applicant shall provide documentation describing the mechanism that will be used to ensure that the projected number of medically underserved will be served in the facility.

(b) An applicant shall provide written admissions policies identifying any prepayment or deposit requirements and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) An applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the applicant.

(d) An applicant shall document that the health care community in the PET scanner service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the applicant's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .3800 - CRITERIA AND STANDARDS FOR BONE MARROW TRANSPLANTATION SERVICES

.3801 DEFINITIONS

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

- (1) "Allogeneic bone marrow transplantation services" means the procedure by which the bone marrow of a person other than the patient is infused after treating the patient for disease.
- (2) "Approved bone marrow transplantation service" means an allogeneic or an autolo-

gous bone marrow transplantation service which was not operational prior to the beginning of the review period but which had been issued a certificate of need or had been developed and offered prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.

- (3) "Autologous bone marrow transplantation services" means the process of reinfusing the patient's own bone marrow after treating the patient for disease.
- (4) "Bone marrow transplantation service area" means a geographic area defined by the applicant from which patients to be admitted to the service will originate.
- (5) "Bone marrow transplantation services" is defined in G.S. 131E-176(2a).
- (6) "Cryopreservation" means the process of preserving tissue by freezing at very low temperatures.
- (7) "Existing bone marrow transplantation service" means an allogeneic or an autologous bone marrow transplantation service in operation prior to the beginning of the review period.

Statutory Authority G.S. 131E-177(1).

.3802 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing new or expanded autologous or allogeneic bone marrow transplantation services shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing new or expanded autologous or allogeneic bone marrow transplantation services shall also provide the following additional information:

- (1) the projected number of autologous and allogeneic transplant patients by disease type (e.g. Hodgkin's lymphoma Stage III) to be performed in each of the first 12 calendar quarters following completion of the proposed project, including the methodology and assumptions used for these projections; and
- (2) a copy of the applicant's proposed policy and guidelines for participation in peer-reviewed clinical trials or research protocols.

(c) An applicant that proposes new autologous or allogeneic bone marrow transplantation services shall provide documentation that the applicant will participate in approved clinical trials or research

protocols and also participate in a National Cancer Institute approved cooperative research group.

(d) An applicant that proposes expanded autologous or allogeneic bone marrow transplantation services shall provide documentation that the applicant is participating in approved clinical trials or research protocols, and is participating in a National Cancer Institute approved cooperative research group.

(e) An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services for clinical purposes shall:

- (1) provide documentation of existing referral networks and other referral sources for patients to be treated with bone marrow transplantation, and
- (2) identify the sources of reimbursement for the procedures and demonstrate the availability of these sources for treatment of the specific diseases proposed to be treated with bone marrow transplantation.

(f) An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services for experimental or research purposes shall demonstrate how capital costs and service operations will be funded.

Statutory Authority G.S. 131E-177(1).

.3803 REQUIRED PERFORMANCE STANDARDS

(a) An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services shall demonstrate that:

- (1) all existing facilities within the applicant's bone marrow transplantation service area which have been offering bone marrow transplantation services for at least two years shall have performed at least 20 transplants during the most recent 12 month period;
- (2) all existing and approved facilities within the applicant's bone marrow transplantation service area will provide at least 20 transplants during the second year of operation following completion of the project; and
- (3) the projected utilization for the new or expanded bone marrow transplantation program shall perform at least 20 transplants during the second year of operation following completion of the project.

(b) An applicant that proposes to provide new or

expanded autologous or allogeneic bone marrow transplantation services shall describe all of the assumptions and methodologies used to calculate the projections requested in Subparagraphs (a)(2) and (3) of this Rule.

(c) An applicant that proposes the use of bone marrow transplantation services for clinical use shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the service have been certified for clinical use by the U.S. Food and Drug Administration or will be operated under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

Statutory Authority G.S. 131E-177(1).

.3804 REQUIRED SUPPORT SERVICES

(a) An applicant that proposes to provide new or expanded autologous or allogeneic bone marrow transplantation services shall demonstrate that the following will be available in the facility upon initiation of bone marrow transplantation services:

- (1) accommodations which offer 24 hour critical support and which are appropriate for patients whose immune systems are depressed from the effects of the treatment;
- (2) air handling systems which are appropriate for patients whose immune systems are depressed from the effects of the treatment;
- (3) if processing autologous bone marrow transplantation services, cryopreservation equipment for the storage of bone marrow;
- (4) laboratory services which are available to the bone marrow transplant patient on a twenty-four hour basis;
- (5) radiology services, including CT scanning and nuclear medicine, which are available to the bone marrow transplant patient on a twenty-four hour basis;
- (6) total body radiotherapy for patients whose treatment protocols require total body irradiation;
- (7) irradiated red cells, platelets and other blood products available on a twenty-four hour basis;
- (8) access to blood bank services which are accredited by the American Association of Blood Banks;
- (9) operating and recovery room resources;
- (10) microbiology and virology laboratories;

- (11) a multidisciplinary plan for providing rehabilitative services;
- (12) basic and clinical laboratory research;
- (13) an active, formal research program related to the proposed organ transplantation program; and

(b) An applicant that proposes to provide new or expanded allogeneic bone marrow transplantation services shall also demonstrate that the following will be available in the facility upon initiation of allogeneic bone marrow transplantation services:

- (1) if proposing allogeneic bone marrow transplantation services, laboratory facilities for histocompatibility testing which are certified by the American Society for Histocompatibility and Immunogenetics; and
- (2) if proposing allogeneic bone marrow transplantation services, an established on-site program to promote organ donation.

(c) A proposal to provide new or expanded bone marrow transplantation services shall provide evidence that, prior to the operation of the service, the applicant will develop a clinical oversight committee for bone marrow transplant services. The clinical oversight committee shall be responsible for the following activities:

- (1) developing screening criteria for appropriate bone marrow transplantation utilization;
- (2) reviewing clinical protocols;
- (3) reviewing appropriateness and quality of clinical procedures;
- (4) developing educational programs; and
- (5) overseeing the data collection, evaluation, and reporting activities of the bone marrow transplantation service.

Statutory Authority G.S. 131E-177(1).

.3805 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant shall demonstrate that it can meet each of the following staffing requirements:

- (1) a bone marrow transplant clinical coordinator;
- (2) a physician licensed to practice medicine in North Carolina who will be designated as the director of the program and who has documented experience within the past year in:
 - (A) pretransplant evaluation;
 - (B) bone marrow processing;

- (C) the provision of medical care services to hospitalized bone marrow transplant patients; and
- (D) post-transplant care;

(3) availability of physician in the following specialties to the bone marrow transplantation program on a 24 hour basis:

- (A) hematology or oncology;
- (B) gastroenterology;
- (C) nephrology;
- (D) infectious diseases;
- (E) pulmonary diseases; and
- (F) pediatrics (if pediatric patients will be treated).

(4) laboratory or nursing personnel staffed who are trained in the processing of bone marrow;

(5) a state certified social worker with a master's degree in social work who is available for inpatient and outpatient ongoing support of both the patient and family;

(6) a licensed practicing psychologist or licensed psychological associate who is available for inpatient and outpatient ongoing support of both the patient and family;

(7) a board-certified or equivalently qualified psychiatrist who is available for inpatient and outpatient ongoing support of both the patient and family;

(b) An applicant shall demonstrate that a program of staff education and training which is integral to the bone marrow transplantation service and which ensures improvements in technique and the proper training of new personnel will be provided.

Statutory Authority G.S. 131E-177(1).

.3806 DATA REPORTING REQUIREMENTS

(a) An applicant shall agree to report the results of all transplants to the appropriate transplant registry (e.g. International Bone Marrow Transplant Registry [IBMTR] for allogeneic transplants and the North American Autologous Bone Marrow Transplant Registry [NAABMTR] for autologous transplants).

(b) An applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;

- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.3807 ACCESSIBILITY

(a) An applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(b) An applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) An applicant shall provide a written description of the billing procedures, including the credit and collection policies, that will be utilized by the facility.

(d) An applicant shall document that the health care community in the bone marrow transplantation service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .3900 - CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS

.3901 PURPOSE AND SCOPE

The rules set forth in this Section shall apply to applications for diagnostic centers for which specific criteria and standards have not otherwise been promulgated in 10 NCAC 3R.

Statutory Authority G.S. 131E-177(1).

.3902 DEFINITIONS

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

- (1) "Approved diagnostic center" means a diagnostic center that was not operational prior to the beginning of the review

period but that had been issued a certificate of need or had been acquired prior to March 18, 1993 in accordance with G.S. 131E-175, et. al.

- (2) "Diagnostic center" is defined in G.S. 131E-176(7a).
- (3) "Diagnostic center service area", unless otherwise defined by the State Medical Facilities Plan, means the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.
- (4) "Diagnostic procedure" means a discrete diagnostic procedure with a distinct CPT code or ICD-9-CM procedure code performed on one patient during one visit to a diagnostic suite.
- (5) "Diagnostic suite" means a single room or group of rooms in a diagnostic center which is used for the purpose of conducting diagnostic procedures.
- (6) "Essential" means those items which are indispensable, the absence of which renders the equipment useless.
- (7) "Existing diagnostic center" means a diagnostic center in operation prior to the beginning of the review period.
- (8) "Freestanding diagnostic center" means a diagnostic center that is not operated as a part of another health service facility but rather as a discrete business entity. A freestanding diagnostic center may be owned by another health service facility and may be located on the campus of another health service facility.
- (9) "Medical diagnostic equipment" means a single piece of diagnostic equipment or a single component of a multi-component diagnostic system which costs ten thousand dollars (\$10,000) or more, or whose fair market value is ten thousand dollars (\$10,000) or more.
- (10) "Mobile medical diagnostic equipment" means medical diagnostic equipment and transporting equipment which is moved to provide services at two or more host facilities.
- (11) "Mobile diagnostic program" means the provision of diagnostic services using mobile medical diagnostic equipment and transporting equipment at two or more host facilities.
- (12) "Radiologic technologist or X-Ray technician" means a person who, under the supervision of a physician radiologist,

operates radiologic equipment and assists radiologists and other health professionals, and whose competence has been tested and approved by the American Registry of Radiologic Technologists.

Statutory Authority G.S. 131E-177(1).

.3903 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall use the Acute Care Facility/Medical Equipment application form.

(b) The applicant shall also provide the following additional information:

- (1) the number, type, cost, condition, useful life and depreciation schedule of all medical diagnostic equipment that either is proposed to be acquired or is currently owned or operated by the applicant, and will be part of the diagnostic center following completion of the project;
- (2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;
- (3) the maximum number of procedures that each piece of medical diagnostic equipment in the diagnostic center is capable of performing and the assumptions used to project capacity;
- (4) a list all health service facilities that operate existing and have been approved to operate medical diagnostic equipment and diagnostic suites by type and location in the proposed medical diagnostic service area;
- (5) the hours of operation of the proposed diagnostic center and each proposed diagnostic service;
- (6) the patient origin by percentage by county of residence for each diagnostic service provided by the applicant in the 12 month period immediately preceding the submittal of the proposal;
- (7) the projected patient origin by percentage by county of residence for each service proposed, and all the assumptions and data supporting the methodology used for the projections;
- (8) drawings or schematics of the proposed diagnostic center that identifies a dis-

tinct, identifiable area for each of the proposed services; and

(9) a three year capital budget.

(c) An applicant proposing to establish a new mobile diagnostic program shall also provide the following information:

- (1) the number, type and cost of all proposed mobile medical diagnostic equipment including the cost of the transporting equipment;
- (2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;
- (3) the number and type of all existing and approved mobile diagnostic equipment in the proposed mobile diagnostic center service area;
- (4) the maximum number of procedures that each proposed piece of medical diagnostic equipment is capable of performing and the assumptions used to project capacity;
- (5) the name, address and hours of service at each host facility that is proposed to be served by the mobile diagnostic program; and
- (6) copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the mobile diagnostic program.

(d) An applicant proposing to establish a new or to expand an existing diagnostic center shall identify which of the following services will be available:

- (1) computerized tomography (CT) services;
- (2) fluoroscopy services;
- (3) laboratory services;
- (4) mammography screening;
- (5) magnetic resonance imaging (MRI);
- (6) nuclear medicine;
- (7) positron emission tomography (PET);
- (8) diagnostic radiology;
- (9) diagnostic ultrasound imaging; and
- (10) other diagnostic services.

(e) An applicant proposing to establish a new or to expand an existing diagnostic center shall demonstrate that the diagnostic services will be offered in a physical environment that conforms to the requirements of federal, state and local regulatory bodies.

(f) An applicant shall demonstrate that all equipment, supplies and pharmaceuticals proposed

for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration or will be operated or used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services regulations.

Statutory Authority G.S. 131E-177(1).

.3904 NEED FOR FACILITY

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

- (1) the projected number of patients to be served, classified by diagnosis and by county of residence for each of the first twelve calendar quarters following completion of the project;
- (2) the projected number and type of diagnostic procedures proposed to be provided by CPT code or ICD-9-CM procedure code for each of the first twelve calendar quarters following completion of the project;
- (3) documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;
- (4) documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation after initiation of diagnostic services;
- (5) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and
- (6) all the assumptions and data supporting the methodologies used for the projections in this Rule.

Statutory Authority G.S. 131E-177(1).

.3905 REQUIRED SUPPORT SERVICES

An applicant shall provide documentation show-

ing the proximity of the proposed diagnostic center to the following services:

- (1) emergency services;
- (2) support services;
- (3) ancillary services; and
- (4) public transportation.

Statutory Authority G.S. 131E-177(1).

.3906 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall identify the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff that are projected to be involved in providing each of the proposed diagnostic services.

(b) An applicant proposing to provide ionizing and nonionizing radiation procedures shall demonstrate that a physician, licensed to practice medicine in North Carolina who is qualified and authorized to perform radiation procedures, shall be available to perform and supervise all radiation procedures.

(c) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.

Statutory Authority G.S. 131E-177(1).

.3907 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with the data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients receiving services;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.3908 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that will be used to insure that the projected number of medically underserved will be served in the facility.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the

admission requirements for the patients in each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies that will be utilized by the facility.

(d) The applicant shall document that the health care community in the diagnostic center service area, including existing current providers of diagnostic services, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

SECTION .4000 - CRITERIA AND STANDARDS FOR SOLID ORGAN TRANSPLANTATION SERVICES

.4001 DEFINITIONS

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

- (1) "Solid organs" mean the heart, lung, liver, kidney, pancreas and islet cells and intestines.
- (2) "Pediatric Patient" means a patient under the age of 17.
- (3) "Solid Organ Transplantation Service Area" means a geographical area defined by the applicant from which patients projected to receive the services originate.
- (4) "Solid Organ Transplantation Services" is defined in G.S. 131E-176(16)(24b).
- (5) "UNOS" or the "United Network for Organ Sharing" means the organization contracted by the Department of Health and Human Services to operate both the organ procurement and transplantation network and the scientific registry of information on organ donors and recipients.

Statutory Authority G.S. 131E-177(1).

.4002 INFORMATION REQUIRED OF

APPLICANT

(a) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall demonstrate that it meets one of the following:

- (1) the applicant is an academic medical center teaching hospital with accredited residencies or fellowships related to solid organ transplantation, including but not limited to: general surgery, thoracic surgery, internal medicine, and urology; or
- (2) the applicant has a written agreement with such an academic medical center teaching hospital under which the academic medical center teaching hospital will provide technical assistance to the applicant.

(c) The applicant shall provide a copy of its procedures for selecting transplant candidates and for distributing organs which are consistent with UNOS guidelines.

(d) The applicant shall provide letters of agreement or contracts with either an independent organ procurement organization or a hospital-based organ procurement organization. The letters shall demonstrate the capability to provide sufficient numbers of organs to support the minimum activity level for the applicable type of organ transplantation proposed in the application.

(e) The applicant shall document collaboration with experts in the fields of hepatology, cardiology, pediatrics, infectious disease, nephrology, renal dialysis, pulmonary medicine, respiratory therapy, pathology, immunology, anesthesiology, physical therapy, and rehabilitation. The documentation shall include, but not be limited to, a plan of operation detailing the interaction of the transplant service and the stated specialty areas.

(f) An applicant that proposes to establish a joint sharing arrangement for organ transplantation services which involves more than one hospital shall demonstrate all of the following:

- (1) all hospitals in the joint sharing arrangement are geographically proximate to permit cost-effective sharing of resources; and
- (2) a single hospital site has been designated where the organ transplant surgical procedures will be performed

which involves both adult and pediatric organ transplant procedures, except one hospital site may be designated where all adult organ transplant procedures will be performed and another hospital site may be designated where all pediatric organ transplant procedures will be performed if both hospital sites are part of the joint sharing arrangement.

(g) The applicant shall demonstrate that transplantation services will be offered in a physical environment that conforms to the requirements of federal, state and local bodies.

(h) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall include drawings or schematics of the proposed project that identify the location of the operating rooms in the hospital where transplantation procedures will be performed.

(i) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall project the number and type of transplantations by CPT code or ICD-9-CM procedure code by distinct transplantation service for each of the first twelve calendar quarters following completion of the proposed project.

(j) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall project patient origin by state and by county for North Carolina residents and shall indicate the percentage of total patients to originate from each State and county.

Statutory Authority G.S. 131E-177(1).

.4003 REQUIRED SUPPORT SERVICES

An applicant proposing to establish a new or to expand an existing solid organ transplantation service shall demonstrate that it offers all of the following items:

- (1) operating and recovery room resources;
- (2) intensive care facilities allowing reverse isolation;
- (3) microbiology and virology laboratory;
- (4) laboratory facilities for histocompatibility testing that are certified by the American Society for Histocompatibility and Immunogenetics;
- (5) a multidisciplinary plan for providing rehabilitation;
- (6) CT scanning;

- (7) nuclear medicine;
- (8) magnetic resonance imaging;
- (9) duplex ultrasound scanning for liver, pancreas and kidney transplantation;
- (10) pulmonary medicine;
- (11) cardiology;
- (12) an acute hemodialysis unit;
- (13) a state certified social worker with a master's degree in social work who is available for inpatient and outpatient ongoing support of both the patient and family;
- (14) a licensed practicing psychologist or licensed psychological associate who is available for inpatient and outpatient ongoing support of both the patient and family;
- (15) a psychiatrist who is available for inpatient and outpatient ongoing support of both the patient and family;
- (16) full-time organ transplant coordinator(s);
- (17) an on-going program of community-based post-transplantation care;
- (18) basic and clinical laboratory research;
- (19) an active, formal research program related to the proposed organ transplantation service;
- (20) an established organ donation protocol, with brain death protocol, consistent with North Carolina law; and
- (21) an established program to promote organ donation at the applicant's hospital.

Statutory Authority G.S. 131E-177(1).

.4004 ADDTL REQ. FOR HEART, HEART/LUNG OR LUNG TRANSPLANTATION SERVICES

(a) An applicant proposing to establish a new heart, heart/lung or lung transplantation service shall document that no more than two (2) heart, heart/lung or lung transplantation services shall be located in the same solid organ transplantation service area following completion of the project.

(b) An applicant that proposes to establish a new heart, heart/lung or lung transplantation service shall project a cumulative minimum of 20 heart, heart/lung or lung transplantation procedures by the end of the second full year of operation following the date on which the first heart, heart/lung or lung transplant procedure is performed.

(c) An applicant proposing to establish a new heart, heart/lung or lung transplantation service or to expand an existing heart, heart/lung or lung

transplantation service shall demonstrate that it offers all of the following services:

- (1) a histocompatibility laboratory, or a written agreement with such a laboratory;
- (2) anatomic and clinical pathology with an approved residency program;
- (3) 24-hour angiography;
- (4) an intensive care unit with 24-hour per day resident coverage;
- (5) a continuously available coagulation laboratory; and
- (6) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on demand.

Statutory Authority G.S. 131E-177(1).

.4005 ADDITIONAL REQUIREMENTS FOR LIVER TRANSPLANTATION SERVICES

(a) An applicant proposing to establish a new liver transplantation service or to expand an existing liver transplantation service shall document that no more than 2 liver transplantation services shall be located in the same solid organ transplantation service area following completion of the project.

(b) An applicant proposing to establish a new liver transplantation service shall project a cumulative minimum of 15 liver transplantation procedures by the end of the second full year of operation following the date on which the first liver transplant procedure is performed.

(c) An applicant proposing to establish a new liver transplantation service or to expand an existing liver transplantation service shall demonstrate that it either:

- (1) operates an existing renal transplant service; or
- (2) has a written agreement with a renal transplant service that ensures that the professional expertise of the renal transplant service is readily available to the proposed liver transplantation service.

(d) An applicant proposing to establish a new liver transplantation service or to expand an existing liver transplantation service shall demonstrate that it offers all of the following items:

- (1) a histocompatibility laboratory, or a written agreement with such a laboratory;
- (2) anatomic and clinical pathology with an approved residency program;

- (3) 24-hour angiography;
- (4) an intensive care unit with 24-hour per day resident coverage;
- (5) veno-venous bypass equipment that does not require heparin;
- (6) adult and pediatric (as appropriate) gastroenterologists and hepatologists on the active medical staff who meet UNOS criteria for transplant physicians and surgeons;
- (7) endoscopic retrograde cholangiopancreatography (ERCP) availability;
- (8) percutaneous cholangiogram availability;
- (9) a rapid blood infusion system;
- (10) percutaneous liver biopsy capability;
- (11) hemoperfusion;
- (12) a rapid red blood cell (RBC) saver system; and
- (13) duplex ultrasound.

(e) The applicant shall establish and maintain all of the following:

- (1) nuclear HID biliary scan availability;
- (2) continuously available coagulation laboratory; and
- (3) a blood bank system capable of providing 200 units of blood or packed cells, 100 units of plasma on demand, 24 units (or four adult doses) of platelet concentrates and 30 units of cryoprecipitate on demand.

Statutory Authority G.S. 131E-177(1).

.4006 ADDITIONAL REQUIREMENTS FOR PANCREAS TRANSPLANTATION SERVICES

(a) An applicant proposing to establish a new pancreas transplantation service or to expand an existing pancreas transplantation service shall document that no more than 2 pancreas transplantation services shall be located in the same solid organ transplantation service area following completion of the project.

(b) An applicant proposing to establish a new pancreas transplantation service or to expand an existing pancreas transplantation service shall project a cumulative minimum of 10 pancreas transplantation procedures by the end of the second full year of operation following the date on which the first pancreas transplant procedure is performed.

(c) An applicant proposing to establish a new pancreas transplantation service or to expand an existing pancreas transplantation service shall

demonstrate that it offers all of the following services:

- (1) a histocompatibility laboratory, or a written agreement with such a laboratory;
- (2) anatomic and clinical pathology;
- (3) 24-hour angiography;
- (4) an intensive care unit with 24-hour per day resident coverage;
- (5) approved on-site renal transplant services;
- (6) physicians with rehabilitation expertise;
- (7) both adult and pediatric surgeons, as appropriate; and
- (8) both adult and pediatric diabetologists, as appropriate, on the active medical staff.

(d) The applicant shall establish and maintain all of the following:

- (1) insulin,
- (2) C-peptide,
- (3) glycosylated hemoglobin assays; and
- (4) glucometer glucose assays.

Statutory Authority G.S. 131E-177(1).

.4007 ADDITIONAL REQUIREMENTS FOR KIDNEY TRANSPLANTATION SERVICES

(a) An applicant proposing to establish a new kidney transplantation service or to expand an existing kidney transplantation service shall document that no more than 2 kidney transplantation services shall be located in the same solid organ transplantation service area following completion of the project.

(b) An applicant proposing to establish a new kidney transplantation service shall project a cumulative minimum of 50 transplantation procedures by the end of the second full year of operation following the date on which the first transplant procedure is performed.

(c) An applicant proposing to establish a new kidney transplantation service or to expand an existing kidney transplantation service shall demonstrate that it provides all of the following:

- (1) a histocompatibility laboratory, or a written agreement with such a laboratory;
- (2) an intensive care unit with 24-hour per day resident coverage;
- (3) inpatient renal dialysis services;
- (4) available freestanding renal dialysis clinic services;
- (5) pre-dialysis, dialysis and post-

transplantation nutritional services;

(6) bacteriologic services;

(7) biochemical services;

(8) pathological services;

(9) radiologic services; and

(10) ophthalmology retinal eye services.

Statutory Authority G.S. 131E-177(1).

.4008 ADDITIONAL REQUIREMENTS FOR INTESTINE TRANSPLANTATION SERVICES

An applicant proposing to establish a new intestine transplantation service or to expand an existing intestine transplantation service shall document that no more than two intestine transplantation services shall be located in the same solid organ transplantation service area following completion of the project.

Statutory Authority G.S. 131E-177(1).

.4009 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new heart, heart/lung or lung transplantation service or to expand an existing heart, heart/lung or lung transplantation service shall demonstrate that the following persons shall provide the proposed services:

- (1) anesthesiologists with expertise in transplantation anesthesia;
- (2) cardiologists and surgeons trained in endocardial biopsy and immunosuppression techniques;
- (3) cardiologists and surgeons for both adult and pediatric patients, as appropriate;
- (4) surgeons and physicians that meet UNOS criteria as transplant physicians and surgeons; and
- (5) a nursing team trained in immunosuppression management including isolation techniques and infection control methods.

(b) An applicant proposing to establish a new liver transplantation service or to expand an existing liver transplantation service shall demonstrate that the following persons shall provide the proposed services:

- (1) anesthesiologists with expertise in transplantation anesthesia;
- (2) surgeons and physicians who meet UNOS criteria as liver transplant surgeons and physicians;

- (3) a veno-venous bypass team immediately available for liver transplant recipient operation, a requirement which may be satisfied by a written agreement which ensures that a veno-venous bypass team will always be on site throughout the entire liver transplant recipient operation; and

- (4) a nursing team trained in immunosuppression management including isolation techniques and infection control methods.

(c) An applicant proposing to establish a new pancreas transplantation service or to expand an existing pancreas transplantation service shall demonstrate that the following persons shall provide the proposed services:

- (1) anesthesiologists with expertise in transplantation anesthesia;
- (2) transplant surgeons and physicians experienced with renal transplantation in diabetics;
- (3) surgeons and physicians who meet UNOS criteria as pancreatic transplant surgeons and physicians;
- (4) adult and pediatric diabetologists, as appropriate, actively participating in the transplant service; and
- (5) a nursing team trained in immunosuppression management including isolation techniques and infection control methods.

(d) An applicant proposing to establish a new kidney transplantation service or to expand an existing kidney transplantation service shall demonstrate that the following persons shall provide the proposed services:

- (1) surgeons and physicians that meet UNOS criteria as kidney transplant surgeons and physicians;
- (2) the transplant team performing kidney transplantation shall include physicians in the areas of anesthesiology, nephrology, psychiatry, vascular surgery and urology;
- (3) additional support personnel shall be available including but not limited to a nephrology nurse with experience in the nursing care of patients with permanent kidney failure and a renal dietician;
- (4) adult and pediatric diabetologists, as appropriate, actively participating in the transplant service;
- (5) a nursing team trained in immunosuppression management including isola-

tion techniques and infection control methods.

(e) An applicant proposing to establish a new intestine transplantation service or to expand an existing intestine transplantation service shall demonstrate that the following persons shall provide the proposed services:

- (1) anesthesiologists with expertise in transplantation anesthesia;
- (2) surgeons and physicians that meet UNOS criteria as transplant surgeons and physicians;
- (3) a physician who meets UNOS criteria in the sub-specialty of Gastroenterology;
- (4) a pathologist who is certified by the American Board of Pathology or who has equivalent qualifications; and
- (5) a nursing team trained in immunosuppression management including isolation techniques and infection control methods.

Statutory Authority G.S. 131E-177(1).

.4010 NEED FOR SERVICES

The applicant shall provide a description of the data sources used to project utilization, assessments of the accuracy of the data, the statistical method used to make the projections, the expected volume of organs that will be available for transplantation and the anticipated relationship between projected volumes and patient outcomes. This information shall be set out separately for each type of solid organ transplantation service that the applicant proposes to offer.

Statutory Authority G.S. 131E-177(1).

.4011 DATA REPORTING REQUIREMENTS

The applicant shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.4012 ACCESSIBILITY

(a) An applicant proposing to establish a new solid organ transplantation service or expand an existing solid organ transplant service shall docu-

ment the procedures that will be used to ensure that patient selection criteria is public, fair and equitable with primary screening based on medical suitability which is designed to offer transplantation to those who can benefit the most from it in terms of probability of living for a significant period of time with a reasonable prospect of rehabilitation.

(b) The applicant shall provide written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admission requirements for patients in each of the following payor categories:

- (1) Medicaid;
- (2) Medicare;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit and collection policies, that will be utilized by the facility.

(d) The applicant shall describe the procedures for the referral of patients from one institution to another institution when space, personnel or other limitations prevent the referring institution from timely serving the patient's needs.

(e) The applicant shall document that the health care community in the solid organ transplantation service area, including all providers of solid organ transplantation services and organ procurement organizations in North Carolina have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

(f) An applicant proposing to establish a new solid organ transplantation service or to expand an existing solid organ transplantation service shall provide documentation describing the mechanism for donor/patient compatibility that will be used to ensure that the uninsured and medically underserved will have access to solid organ transplantation services.

Statutory Authority G.S. 131E-177(1).

SECTION .4100 - CRITERIA AND STANDARDS FOR PEDIATRIC INTENSIVE CARE SERVICES

.4101 DEFINITIONS

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

- (1) "Pediatric intensive care service area" means a geographic area defined by the applicant from which the patients to be admitted to the unit will originate.
- (2) "Pediatric intensive care services" means those services provided by an acute care hospital to children with a wide variety of illnesses of a life-threatening nature, including children with highly unstable conditions requiring sophisticated medical and surgical intervention, children requiring a high level of nursing care and those children requiring continuous, comprehensive observation.
- (3) "Pediatric intensive care unit" means a separate self-sufficient entity that contains supplies and equipment essential to provide treatment on a 24-hour basis to children who need pediatric intensive care services. It does not include post-operative recovery rooms, post-delivery rooms, or emergency observation units.
- (4) "Perinatal region" means a geographic area of the state as established by the Perinatal Council. A list of the perinatal regions may be obtained from the Division of Maternal and Child Health, Department of Environment, Health and Natural Resources, 1330 St. Mary's Street, Raleigh, NC, 27605-3248.

Statutory Authority G.S. 131E-177(1).

.4102 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to develop a new pediatric intensive care unit or to add a bed to an existing pediatric intensive care unit shall use the Acute Care Facility/Medical Equipment application form.

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

- (1) the number of designated pediatric intensive care beds currently operated by the applicant and the number of designated pediatric intensive care beds to be operated following completion of the proposed project;
- (2) documentation of the applicant's experience in treating pediatric patients at its facility during the past twelve months, including:
 - (A) the number of pediatric trauma

- patients provided emergency room services;
- (B) the number of pediatric patients provided ambulatory surgery services;
- (C) the number of inpatient days of care provided to pediatric patients; and
- (D) the number of pediatric patients treated and referred to a pediatric intensive care unit in another facility;
- (3) the number of patients, by county of residence, in the proposed pediatric intensive care service area that are projected to need pediatric intensive care services in each of the first twelve quarters of operation following the completion of the project; also, all assumptions and methodologies for projecting need shall be stated;
- (4) the projected number, by county of residence, of those patients identified in response to item (3) of this Rule that are projected to be served in the applicant's facility in each of the first twelve calendar quarters following completion of the proposed project; also, all assumptions and methodologies for projecting utilization shall be stated;
- (5) documentation that at least 90 percent of the anticipated patient population is within 90-minute automobile driving time one-way from the facility, unless the applicant demonstrates that its facility provides:
- (A) specialized levels of pediatric intensive care services to a large and geographically diverse population, or
- (B) air ambulance services;
- (6) documentation that the existing and approved pediatric intensive care units in the same perinatal region and adjacent perinatal regions are unable to accommodate the projected need for pediatric intensive care services;
- (7) documentation that the services shall be offered in conformance with the requirements of federal, state, and local regulatory bodies;
- (8) correspondence from physicians, hospitals, or other health care facilities documenting their intent to refer patient's to the applicant's pediatric intensive care unit;
- (9) evidence of the applicant's capability to communicate effectively with emergency transportation agencies;
- (10) copies of written policies that provide for parental participation in the care of the child, as the child's condition permits, in order to facilitate family adjustment and continuity of care following discharge;
- (11) copies of written policies and procedures regarding the operation of the pediatric intensive care unit, including but not limited to the following:
- (A) the admission and discharge of patients;
- (B) infection control;
- (C) safety procedures; and
- (D) the triaging of patients requiring consultations, including the transfer of patients to another facility;
- (12) documentation that the proposed service shall be operated in an area of the facility that is organized as a physically and functionally distinct entity and that has controlled access;
- (13) a detailed floor plan of the proposed area drawn to scale; and
- (14) documentation that unit staff shall be able to observe all patients from one vantage point.

Statutory Authority G.S. 131E-177(1).

.4103 REQUIRED PERFORMANCE STANDARDS

An applicant proposing to develop a new pediatric intensive care unit or to add a bed to an existing pediatric intensive care unit shall demonstrate that the following standards are met:

- (1) the overall average annual occupancy rate for the twelve months immediately preceding the submittal of the proposal of the number of beds in the applicant's existing pediatric intensive care unit shall have been at least 70 percent in units with 20 or more pediatric intensive care beds, 65 percent in units with 10-19 pediatric intensive care beds, and 60 percent in units with 1-9 pediatric intensive care beds;
- (2) the projected annual occupancy rate of the applicant's proposed pediatric intensive care unit in the third year of operation following completion of the proposed project shall be at least 70 percent in units with 20 or more pediatric intensive care beds, 65 percent in units

with 10-19 pediatric intensive care beds, and 60 percent in units with 1-9 pediatric intensive care beds; and

- (3) the applicant shall document all assumptions and provide data supporting the methodology used for each of the projections required in this Rule.

Statutory Authority G.S. 131E-177(1).

.4104 REQUIRED SUPPORT SERVICES

(a) An applicant proposing to develop a new pediatric intensive care unit or to add a bed to an existing pediatric intensive care unit shall document that the following items shall be available; except that if an item shall not be available, then documentation shall be provided obviating the need for that item:

- (1) twenty-four hour laboratory services including microspecimen chemistry techniques and blood gas determinations;
- (2) twenty-four hour radiology services, including portable radiological equipment;
- (3) twenty-four hour blood bank services;
- (4) twenty-four hour pharmacy services;
- (5) twenty-four hour respiratory therapy services;
- (6) twenty-four hour CT scanning services;
- (7) EEG testing capability;
- (8) oxygen and air and suction capability;
- (9) cardiovascular monitoring capability with alarm capacity;
- (10) mechanical ventilatory assistance equipment including airways, manual breathing bag, ventilator and respirator of pediatric patient size;
- (11) endotracheal intubation capability;
- (12) a cardiac arrest management plan;
- (13) a patient weighing device for bed patients;
- (14) isolation capability;
- (15) a designated social worker;
- (16) consultation with the following medical subspecialties:
 - (A) Pediatric Cardiology and cardiology diagnostic services;
 - (B) Pediatric Surgery or surgeons with training or interest in pediatrics, including neurosurgery, otolaryngology and cardiothoracic surgery;
 - (C) Pediatric Neurology; and
 - (D) other pediatric subspecialties as required; and

- (17) pediatric expertise in the following areas:

- (A) physical therapy;
- (B) occupational therapy;
- (C) speech therapy; and
- (D) dietary support.

(b) An applicant shall describe the types of patient care monitoring that shall be available to meet the specific needs of each type of patient that the applicant proposes to serve.

Statutory Authority G.S. 131E-177(1).

.4105 REQUIRED STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop a new pediatric intensive care unit or to add a bed to an existing pediatric intensive care unit shall demonstrate that the following staffing requirements will be met:

- (1) nursing care shall be supervised by a registered nurse with specialized training in patient care monitoring and life support;
- (2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care; and
- (3) documentation from the medical staff confirming that pediatricians and surgeons of at least the resident or staff level shall be in the facility twenty-four hours per day.

(b) An applicant shall document that inservice training or continuing education programs specific to pediatric intensive care services shall be provided to the pediatric intensive care staff and shall describe the inservice training and continuing care programs which shall be offered.

Statutory Authority G.S. 131E-177(1).

.4106 DATA REPORTING REQUIREMENTS

The facility shall agree to provide, upon the request of the Division of Facility Services, the following types of data and information, in accordance with data format and reporting requirements formulated by the Division of Facility Services:

- (1) demographic data on patients treated;
- (2) financial data; and
- (3) clinical data.

Statutory Authority G.S. 131E-177(1).

.4107 ACCESSIBILITY

(a) The applicant shall provide documentation describing the mechanism that shall be used to insure that the projected number of medically underserved shall be served in the unit.

(b) The applicant shall provide a copy of the written admissions policies identifying any prepayment or deposit requirements for the facility and stating the admissions requirements for each of the following payor categories:

- (1) Medicare;
- (2) Medicaid;
- (3) Blue Cross and Blue Shield;
- (4) Commercial Insurance;
- (5) State Employees Health Plan;
- (6) Self-Pay (includes self-pay, indigent and charity care); and
- (7) Other as identified by the applicant.

(c) The applicant shall provide a written description of the billing procedures, including the credit collection policies, that shall be utilized by the facility.

(d) The applicant shall document that the health care community in the "pediatric intensive care" service area, including the Departments of Social Services and Health, have been invited to comment on the proposed project, particularly with regard to the facility's referral mechanisms and admissions policies for the medically underserved.

Statutory Authority G.S. 131E-177(1).

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Notice is hereby given in accordance with G.S. 150B-21.2 that the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services intends to amend rules cited as 10 NCAC 14J .0206 and 10 NCAC 14L .0602, with changes from the proposed text of 10 NCAC 14J .0206 noticed in the Register, Volume 8, Issue 7, pages 545 - 549 and 10 NCAC 14L .0602 noticed in Volume 8, Issue 5, pages 413 - 414.

The proposed effective date of this action is January 4, 1994.

Reason for Proposed Action:

10 NCAC 14J .0206 - To reinsert a portion of the Rule which was inadvertently omitted during 30-day notice of initial amendment, clarifying procedures for use of Seclusion, Restraints, or Isolation time out.

10 NCAC 14L .0602 - To provide public notice of

changes made during the public hearing regarding licensure of Residential Treatment Facilities.

Comment Procedures: Written comments may be submitted to Charlotte Tucker, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, Albemarle Building, 325 N. Salisbury Street, Raleigh, NC 27603. These comments will be accepted from September 15, 1993 through October 15, 1993.

Editor's Note: An agency may not adopt a rule that differs substantially from the text of a proposed rule published in the Register, unless the agency publishes the text of the proposed different rule and accepts comments on the new text for at least 30 days after the publication of the new text.

CHAPTER 14 - MENTAL HEALTH: GENERAL

SUBCHAPTER 14J - TREATMENT OR HABILITATION RIGHTS

SECTION .0200 - PROTECTIONS REGARDING CERTAIN PROCEDURES

.0206 PROCEDURES: SECLUSION, RESTRAINTS, OR ISOLATION TIME OUT

(a) ~~The interventions specified in this Rule present a significant risk to the client and therefore require additional safeguards. These procedures shall be followed in addition to the procedures specified in Rule .0203 of this Section.~~

(b) ~~The following interventions are designed for the primary purpose of reducing the incidence of aggressive, dangerous or self-injurious behavior to a level which will allow the use of less intrusive treatment/habilitation procedures. Such interventions include the use of:~~

- (1) ~~seclusion, restraints, or isolation time out employed as a measure of therapeutic treatment;~~
- (2) ~~seclusion, restraints, or isolation time out used on an emergency basis more than 40 hours in a calendar month or more than one episode of 24 hours;~~
- (3) ~~unpleasant tasting foodstuffs;~~
- (4) ~~planned non-attention to specific undesirable behaviors when the target behavior is health threatening;~~

- ~~(5) contingent deprivation of any basic necessity;~~
- ~~(6) contingent application of any noxious substances which include but are not limited to noise, bad smells or splashing with water; and~~
- ~~(7) any potentially physically painful procedure or stimulus which is administered to the client for the purpose of reducing the frequency or intensity of a behavior.~~

~~(e) Such interventions shall never be the sole treatment modality for the elimination of target behavior. The intervention shall always be accompanied by positive treatment or habilitation methods which include the deliberate teaching and reinforcement of behaviors which are non-injurious; the improvement of conditions associated with non-injurious behaviors such as an enriched educational and social environment; and the alteration or elimination of environmental conditions which are reliably correlated with self injury.~~

~~(d) Prior to the implementation of any planned use of the intervention the following written approvals and notifications shall be obtained and documented in the client record:~~

- ~~(1) the treatment/habilitation team shall approve the plan;~~
- ~~(2) each client whose treatment/habilitation plan includes interventions with reasonably foreseeable physical consequences shall receive an initial medical examination and periodic planned monitoring by a physician;~~
- ~~(3) the treatment/habilitation team shall inform the internal client advocate that the intervention has been planned for the client and the rationale for utilization of the intervention.~~
- ~~(4) the treatment/habilitation team shall explain the intervention and the reason for the intervention to the client and the legally responsible person, if applicable. The prior written consent of the client or his legally responsible person shall be obtained except for those situations specified in Rule .0204 (h)(1) in this Section. If the client or legally responsible person, if applicable, refuses the intervention, the State Facility Director shall follow the right to refuse treatment procedures as specified in this Subchapter.~~
- ~~(5) The plan shall be reviewed and approved by a review committee~~

~~designated by the State Facility Director. At least one member of the review committee shall be qualified through experience and training to utilize the planned intervention. No member of the review committee shall be a member of the client's treatment team.~~

- ~~(6) The treatment/habilitation plan may be reviewed and approved by the State Facility Director, at his option.~~

- ~~(7) If any of the persons or committees specified in Subparagraphs (d)(1), (2), (4), (5), or (6) of this Rule do not approve the continued use of a planned intervention, the planned intervention shall be terminated. The State Facility Director shall establish an appeal mechanism for the resolution of any disagreement over the use of the intervention.~~

~~(e) Neither the consents nor the approvals specified in Paragraph (d) of this Rule shall be considered valid for more than six months. The treatment/habilitation team shall re-evaluate the use of the intervention and obtain the client's and legally responsible person's consent for continued use of the intervention.~~

~~(f) The plan shall be reviewed at the next meeting of the Human Rights Committee within the constraints of 10 NCAC 14G .0209. The Committee, by majority vote, may recommend approval or disapproval of the plan to the State Facility Director or may abstain from making a recommendation. If the State Facility Director does not agree with the decision of the Committee, the Committee may appeal the issue to the Division in accordance with the provisions of 10 NCAC 14G .0208.~~

~~(g) The intervention shall be used only when the treatment/habilitation team has determined and documented in the client record the following:~~

- ~~(1) that the client is engaging in behaviors that are likely to result in injury to self or others;~~
- ~~(2) that other methods of treatment or habilitation employing less intrusive interventions are not appropriate;~~
- ~~(3) the frequency, intensity and duration of the target behavior, and the behavior's probable antecedents and consequences; and~~
- ~~(4) it is likely that the intervention will enable the client to stop the target behavior.~~

~~(h) The treatment/habilitation team shall designate a state facility employee to maintain accurate~~

and up-to-date written records on the application of the intervention and accompanying positive procedures. These records shall include at a minimum the following:

- (1) ~~data which reflect the frequency, intensity and duration with which the targeted behavior occurs (scientific sampling procedures are acceptable);~~
- (2) ~~data which reflect the frequency, intensity and duration of the intervention and any accompanying positive procedures; and~~
- (3) ~~data which reflect the state facility employees who administered the interventions.~~

(i) ~~The interventions shall be evaluated at least weekly by the treatment team or its designee and at least monthly by the Director of Clinical Services or the State Facility Director. The designee of the State Facility Director or Director of Clinical Services shall not be a member of the client's treatment/habilitation team. Reviews shall be documented in the client record.~~

(j) ~~During the use of the intervention, the Human Rights Committee shall be given the opportunity to review the treatment/habilitation plan within the constraints of 10 NCAC 14G .0209.~~

(a) This Rule delineates the procedures to be followed for use of seclusion, restraints, or isolation time out in addition to the procedures specified in Rule .0203 of this Section.

(b) This Rule governs the use of physical or behavioral interventions which are used to terminate a behavior or action in which a client is in imminent danger of injury to self or other persons or when substantial property damage is occurring, or which are used as a measure of therapeutic treatment. Such interventions include seclusion, isolation time out, and mechanical restraints listed in Subparagraphs (a)(1), (2) and (3) of Rule .0203 of this Section.

(c) Seclusion, restraints, or isolation time out may only be used when other less restrictive alternatives are not feasible, as delineated in Rules .0204 and .0205 of this Section.

(d) If determined to be acceptable for use within the state facility, the State Facility director shall establish written policies and procedures that govern the use of seclusion, restraints, or isolation time out which shall include the following:

- (1) techniques for seclusion, restraints, or isolation time out which are written and approved;
- (2) provision, to both new clinical and

habilitation staff as part of in-service training, and as a condition of continued employment, for those authorized to use or apply intrusive interventions which shall include, but not be limited to:

- (A) competency-based training and periodic reviews on the use of seclusion, restraints, or isolation time out; and
- (B) skills for less intrusive interventions specified in Rules .0203 and .0204 of this Section;
- (3) process for identifying and privileging state facility employees who are authorized to use such interventions;
- (4) provisions that a qualified or responsible professional shall:
 - (A) meet with the client and review the use of the intervention as soon as possible but at least within one hour after the initiation of its use;
 - (B) verify the inadequacy of less restrictive intervention techniques;
 - (C) document in the client record evidence of approval or disapproval of continued use; and
 - (D) inspect to ensure that any devices to be used are in good repair and free of tears and protrusions;
- (5) procedures for documenting the intervention which occurred to include, but not be limited to:
 - (A) the rationale for the use of the intervention which addresses attempts at and inadequacy of less restrictive intervention techniques; this shall contain a description of the specific behaviors justifying the use of seclusion, restraints, or isolation time out;
 - (B) notation of the frequency, intensity, and duration of the behavior and any precipitating circumstances contributing to the onset of the behavior;
 - (C) description of the intervention and the date, time and duration of its use;
 - (D) estimated amount of additional time needed in seclusion, restraint or isolation time out;
 - (E) signature and title of the state facility employee responsible for the use of the intervention; and
 - (F) the time that the client was met with by the responsible professional;
- (6) procedures for the notification of others to include:

(A) those to be notified as soon as possible but no more than one working day after the behavior has been controlled to include:

- (i) the treatment/habilitation team, or its designee, after each use of the intervention;
- (ii) a designee of the State Facility Director; and
- (iii) the internal client advocate, in accordance with the provisions of G.S. 122C-53(g); and

(B) notification in a timely fashion of the legally responsible person of a minor client or an incompetent adult client when such notification has been requested.

(e) Seclusion, restraint and isolation time out shall not be employed as punishment or for the convenience of staff or used in a manner that causes harm or undue physical or mental discomfort or pain to the client.

(f) Whenever a client is in seclusion, restraint or isolation time out for more than 24 continuous hours, the client's rights, as specified in G.S. 122C-62, are restricted. The documentation requirements in this Rule shall satisfy the requirements specified in G.S. 122C-62(e) for restriction of rights.

(g) Whenever seclusion, restraint or isolation time out is used more than three times in a calendar month:

- (1) a pattern of behavior has developed and future emergencies can be reasonably predicted; and
- (2) dangerous behavior can no longer be considered unanticipated; and
- (3) emergency procedures shall be addressed as a planned intervention in the treatment/habilitation plan.

(h) In addition to the requirements in this Rule, additional safeguards as specified in Rule .0210 of this Section shall be initiated whenever:

- (1) a client exceeds spending 40 hours, or more than one episode of 24 or more continuous hours of time in emergency seclusion, restraint or isolation time out within a 30-day period; or
- (2) seclusion, restraint or isolation time out is:
 - (A) used as a measure of therapeutic treatment as specified in G.S. 122C-60; and
 - (B) limited to specific planned behavioral interventions designed for the extinc-

tion of dangerous, aggressive or undesirable behaviors.

(i) The written approval of the State Facility Director or designee shall be required when seclusion, restraint or isolation time out is utilized for longer than 24 continuous hours.

(j) Standing orders or PRN orders shall not be used to authorize the use of seclusion, restraint or isolation time out.

(k) The client shall be removed from seclusion, restraint or isolation time out when:

- (1) the client no longer demonstrates the behavior which precipitated the seclusion, restraint or isolation time out; however,
- (2) in no case shall the client remain in seclusion, restraint or isolation time out longer than an hour after gaining behavioral control; and
- (3) if the client is unable to gain self-control within the time frame specified in the authorization, a new authorization must be obtained.

(l) Whenever seclusion, restraints, or isolation time out are used on an emergency basis prior to inclusion in the treatment/ habilitation plan, the following procedures shall be followed:

- (1) A state facility employee authorized to administer emergency interventions may employ such procedures for up to 15 minutes without further authorization.
- (2) A qualified professional may authorize the continued use of seclusion, restraints, or isolation time out for up to one hour from the initial employment of the intervention if the qualified professional:
 - (A) has experience and training in the use of seclusion, restraints, or isolation time out; and
 - (B) has been privileged to employ such interventions.
- (3) If a qualified professional is not immediately available to conduct a face-to-face assessment of the client, but after discussion with the state facility employee, the qualified professional concurs that the intervention is justified for longer than 15 minutes, then the qualified professional:
 - (A) may verbally authorize the continuation of the intervention for up to one hour;
 - (B) shall meet with and assess the client within one hour after authorizing the

- continued use of the intervention; and
- (C) shall immediately consult with the professional responsible for the client's treatment/habilitation plan, if the intervention needs to be continued for longer than one hour.
- (4) The responsible professional shall authorize the continued use of seclusion, restraints, or isolation time out for periods over one hour.
- (5) If the responsible professional is not immediately available to conduct a clinical assessment of the client, but after discussion with the qualified professional concurs that the intervention is justified for longer than one hour the responsible professional:
- (A) may verbally authorize the continuation of the intervention until an onsite assessment of the client can be made; however,
- (B) if such authorization cannot be obtained, the intervention shall be discontinued.
- (6) If the responsible professional and the qualified professional are the same person, the documentation requirements of this rule can be done at the time of the documentation required by Subparagraph .0206(d)(5) of this Section.
- (7) The responsible professional, or if the responsible professional is unavailable, the on-service or covering professional, shall meet with and assess the client within three hours after the client is first placed in seclusion, restraints, or isolation time out, and document in detail:
- (A) the reasons for continuing seclusion, restraints, or isolation time out; and
- (B) the client's response to the intervention. In addition, the responsible professional shall provide an evaluation of the episode and propose recommendations regarding specific means for preventing future episodes. Clients who have been placed in seclusion, restraints, or isolation time out and released in less than three hours shall be examined by the responsible professional who authorized the intervention no later than 24 hours after the episode.
- (8) Each incident shall be reviewed by the treatment team, which shall include possible alternative actions and specific means for preventing future episodes.
- (m) While the client is in seclusion, restraint or isolation time out, the following precautions shall be followed:
- (1) Whenever a client is in seclusion:
- (A) periodic observation of the client shall occur at least every 15 minutes, or more often as necessary, to assure the safety of the client. Observation may include direct line of sight or the use of video surveillance;
- (B) appropriate attention shall be paid to the provision of regular meals, bathing and the use of the toilet; and
- (C) such observation and attention shall be documented in the client record.
- (2) Whenever a client is in restraint, the facility must provide:
- (A) the degree of observation needed to assure the safety of those placed in restraint. The degree of observation needed is determined at the time of application of the restraint after consideration of the following:
- (i) the type of restraint used;
- (ii) the individual patient situation; and
- (iii) the existence of any specific manufacturer's warning concerning the safe use of a particular product;
- Observation may include direct line of sight or the use of video surveillance. In no instance should observation be less frequent than at 15-minute intervals.
- (B) appropriate attention to the provision of regular meals, bathing and the use of the toilet; and
- (C) documentation of the above observation and attention in the client record.
- (3) Whenever a client is in isolation time out there shall be:
- (A) a state facility employee in attendance with no other immediate responsibility than to monitor the client who is placed in isolation time out;
- (B) continuous observation and verbal interaction with the client when appropriate to prevent tension from escalating; and
- (C) documentation of such observation and verbal interaction in the client record.

(n) Reviews and reports on the use of seclusion, restraints, or isolation time out shall be conducted as follows:

- (1) the State Facility Director or designee shall review all uses of seclusion, restraints, or isolation time out in a timely fashion and investigate unusual or possibly unwarranted patterns of utilization; and
- (2) each State Facility Director shall maintain a log which includes the following information on each use of seclusion, restraints, or isolation time out:
 - (A) name of the client;
 - (B) name of the responsible professional;
 - (C) date of each intervention;
 - (D) time of each intervention;
 - (E) duration of each intervention.

(o) Nothing in this Rule shall be interpreted to prohibit the use of voluntary seclusion, restraints, or isolation time out at the client's request; however, the procedures in Paragraphs (a) through (m) of this Rule shall apply.

Statutory Authority G.S. 122C-51; 122C-53; 122C-57; 122C-60; 122C-62; 131E-67; 143B-147.

SUBCHAPTER 14L - LICENSURE RULES FOR MENTAL HEALTH FACILITIES

SECTION .0600 - RESIDENTIAL TREATMENT FOR CHILDREN AND ADOLESCENTS WHO ARE MENTALLY ILL

.0602 CAPACITY

- (a) ~~Each facility shall serve no more than:~~
- (1) ~~nine children; or~~
 - (2) ~~nine adolescents.~~
- (b) ~~Any facility currently licensed as a Residential Treatment Center under this Section on the effective date of this Rule, and providing services to more than nine children or nine adolescents, may continue to provide services at no more than the facility's license capacity as of the effective date of this Rule.~~
- (c) ~~At no time shall a Residential Treatment Center serve more than 24 children or 24 adolescents.~~
- (a) Each facility shall serve no more than a total of 12 children and adolescents, except as set forth in Paragraphs (b) and (c) of this Rule.
- (b) Any facility currently licensed as a Residential Treatment Facility under this Section on the effective date of this Rule, and providing services

to more than a total of 12 children and adolescents, is exempt from the provision in Paragraph (a) of this Rule and may continue to provide services at no more than the facility's licensed capacity, providing that the capacity does not exceed 24.

(c) Any Child Caring Institution which is currently licensed by the Division of Social Services on the effective date of this Rule, may seek licensure as a Residential Treatment Facility as follows:

- (1) the capacity of each residential unit in the Residential Treatment Facility shall be limited to 12 children and adolescents;
- (2) each residential unit will be administered, staffed, and located to function separately from all other residential units in the facility; and
- (3) the overall capacity shall be limited to the current capacity of the institution at the time of licensure as a Residential Treatment Facility.

(d) The two former Child Caring Institutions that are currently licensed as Residential Treatment Facilities under this Section on the effective date of this Rule shall be:

- (1) exempt from the capacity limit of 24;
- (2) exempt from the provisions in Subparagraphs (c)(1) and (2) of this Rule; and
- (3) limited to the licensed capacity existing on July 1, 1993.

Statutory Authority G.S. 122C-26; 143B-147.

Notice is hereby given in accordance with G.S. 150B-21.2 that the Social Services' Commission intends to amend rules cited as 10 NCAC 42W .0001 and .0002.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on October 19, 1993 at the Albemarle Building, Conference Room 844, 325 North Salisbury Street, Raleigh, NC.

Reason for Proposed Action: The current rules of the Social Services' Commission regarding eligibility criteria for the State Abortion Fund have been

preempted by recent legislation of the North Carolina General Assembly and must be immediately amended. ("Current Operations Appropriations Act of 1993", Chapter 321, Senate Bill 27, Section 259.1 ratified July 9, 1993.)

Comment Procedures: Comments may be presented in writing anytime before or at the public hearing or orally at the hearing. Time limits for oral remarks may be imposed by the Commission Chairman. Any person may request copies of these rules by calling or writing to Special Assistant, Division of Social Services, 325 North Salisbury Street, Raleigh, NC 27603, 919/733-3055.

Editor's Note: These Rules were filed as temporary amendments effective August 13, 1993 for a period of 180 days or until the permanent rules become effective, whichever is sooner.

CHAPTER 42 - INDIVIDUAL AND FAMILY SUPPORT

SUBCHAPTER 42W - STATE ABORTION FUND

.0001 NATURE AND SCOPE

(a) The State Abortion Fund is a financial resource ~~to pay for abortion procedures for North Carolina residents who meet Title XX eligibility criteria for health support services and specific eligibility criteria as established in Chapter 479, Section 93 of the 1985 Session Laws.~~ need the procedure and who meet the eligibility criteria established in Chapter 321, Section 259.1 of the 1993 Session Laws and the criteria in 10 NCAC 35E .0106 for Health Support Services including all subsequent amendments and editions. A copy of this Rule may be obtained from the Office of Administrative Hearings, Post Office Drawer 27447, Raleigh, NC 27611-7447, (919) 733-2678, at a cost of two dollars and fifty cents (\$2.50) for up to ten pages and fifteen cents (\$.15) for each additional page at the time of adoption of this Rule.

(b) (4) The State Abortion Fund is administered by the Division of Social Services.

(2) ~~The State Abortion Fund pays a maximum rate of one hundred fifty dollars (\$150.00) for first trimester abortions and five hundred dollars (\$500.00) for second trimester abortions.~~

(3) ~~Abortions performed after the 135th day~~

~~of gestation are not reimbursable under the State Abortion Fund.~~

(c) (4) Only abortions performed in accordance with applicable state laws are reimbursable under the State Abortion Fund.

Statutory Authority G.S. 14-45.1; 143B-153; 1985 S.L., c. 479, s. 93; 1993 S.L. c. 321, s. 259.

.0002 ELIGIBILITY

(a) State Abortion Funds are administered uniformly in every political subdivision of the state. Applications are made to county departments of social services. A county other than the client's county of residence may authorize State Abortion Funds for individuals who do not want to apply for services in their own counties for reasons of confidentiality.

(b) Applicants must be residents of North Carolina and meet the eligibility criteria established in Chapter 321, Section 259.1a of the 1993 Session Laws and the criteria in 10 NCAC 35E .0106 for Health Support Services including all subsequent amendments and editions. A copy of this Rule may be obtained from the Office of Administrative Hearings, Post Office Drawer 27447, Raleigh, NC 27611-7447, (919) 733-2678, at a cost of two dollars and fifty cents (\$2.50) for up to ten pages and fifteen cents (\$.15) for each additional page at the time of adoption of this Rule.

(c) ~~Applicants who meet the specific eligibility criteria established in the 1985 Session Laws Chapter 479, Section 93, and who are recipients of aid to families with dependent children, or who are receiving health support services in conjunction with protective services for children or disabled adults, or whose income is four thousand, two hundred and twenty six dollars (\$4,226.00) per year for a one person household (which is 50 percent of the state's established income for social services) will be eligible for the State Abortion Fund.~~

(d) Marital status and age will not affect eligibility for the State Abortion Fund except as specified in 1985 Session Laws Chapter 479, Section 93.

Statutory Authority G.S. 14-45.1; 143B-153; 1985 S.L., c. 479, s. 93; 1993 S.L., c. 321, s. 259.1.

TITLE 11 - DEPARTMENT OF INSURANCE

Notice is hereby given in accordance with G.S.

150B-21.2 that the N.C. Department of Insurance intends to adopt rule cited as 11 NCAC 11H .0011.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on September 30, 1993 at the Dobbs Building, 3rd Floor Hearing Room, 430 North Salisbury Street, Raleigh, NC 27611.

Reason for Proposed Action: Establishes a financial review process in determining if Continuing Care Facilities are insolvent.

Comment Procedures: Written comments may be sent to Bill Darden at P.O. Box 26387, Raleigh, NC 27611. Oral presentations may be made at the public hearing. Anyone having questions should call Bill Darden at (919) 733-5060 or Ellen Sprengel at (919) 733-4529.

CHAPTER 11 - FINANCIAL EVALUATION DIVISION

SUBCHAPTER 11H - CONTINUING CARE FACILITIES

.0011 INSOLVENCY OR HAZARDOUS FINANCIAL CONDITION

(a) The Commissioner may deem a provider or facility that has a negative fund balance to be insolvent. A negative fund balance is a financial position in which provider's or facility's assets do not exceed its liabilities as required under generally accepted accounting principles.

(b) The Commissioner may also deem a provider or facility to be in imminent danger of becoming insolvent if any of the following hazardous financial condition standards or factors are applicable or present:

- (1) There are adverse findings or conditions reported in the provider's or facility's financial statements.
- (2) The current or projected ratios of total assets, including required reserve levels, to total liabilities indicate an impairment or a deterioration of the provider's or facility's operations or equity; or demonstrate a trend that could lead to an impairment or a deterioration

of the provider's or facility's operations, working capital, or equity.

- (3) The current or projected ratios of current assets to current liabilities indicate an impairment or a deterioration of the provider's or facility's operations, working capital, or equity; or demonstrate a trend that could lead to an impairment or a deterioration of the provider's or facility's operations, working capital, or equity.
- (4) The provider or facility is unable to perform normal daily activities and meet its obligations as they become due, considering the provider's or facility's current or projected cash flow and liquidity position.
- (5) The provider's or facility's operating losses for the past year or projected operating losses are of such magnitude as to jeopardize normal daily activities or continued provider or facility operations.
- (6) The insolvency of an affiliated provider or facility or other affiliated person results in legal liability of the provider or facility for payments and expenses of such magnitude as to jeopardize the provider's or facility's ability to meet its obligations as they become due, without substantial disposition of assets outside the ordinary course of business, any restructuring of debt, or externally forced revisions of its operations.
- (7) The provider or facility has receivables that are more than 90 days old.
- (8) The insolvency is not temporary and the provider or facility can not demonstrate that the insolvency is materially reduced or eliminated over the next fiscal quarter.
- (9) There is an adverse effect on the provider or facility of reporting entrance fees as deferred revenues, with consideration given to all reporting requirements required under generally accepted accounting principles and the ultimate net income component of those revenues.
- (10) A start-up provider or facility or any operational provider or facility undergoing plant expansion or refinancing of its debt has a financial condition as a result of such action that could otherwise seriously jeopardize present or

future operations.

(c) The provider or facility shall prepare a plan to address and correct any condition that has led to a determination of insolvency or imminent danger of insolvency by the Commissioner. The plan must be presented to the Commissioner within 90 days after the date of the insolvency determination. If the plan to correct the condition is disapproved by the Commissioner, the plan does not correct the condition leading to the Commissioner's determination of insolvency, or the provider's or facility's hazardous condition is such that it cannot be significantly corrected or eliminated by the end of the next fiscal quarter, the Commissioner may then proceed under G.S. 58-64-10 or G.S. 58-64-45.

Statutory Authority G.S. 58-2-40; 58-64-10; 58-64-45; 58-64-65.

Notice is hereby given in accordance with G.S. 150B-21.2 that the N. C. Department of Insurance intends to amend rule cited as 11 NCAC 12 .1004 and adopt rule cited as 11 NCAC 12 .1022.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on September 30, 1993 at the Dobbs Building, 3rd Floor Hearing Room, 430 North Salisbury Street, Raleigh, NC 27611.

Reason for Proposed Action: To comply with standards established by the National Association of Insurance Commissioners through the Long-Term Care Model Act as adopted January 1993.

Comment Procedures: Written comments may be sent to T. N. Shackelford at P.O. Box 26387, Raleigh, NC 27611. Oral presentations may be made at the public hearing. Anyone having questions should call T. N. Shackelford at (919) 733-5060 or Ellen Sprenkel at (919) 733-4529.

CHAPTER 12 - LIFE AND HEALTH DIVISION

SECTION .1000 - LONG-TERM CARE INSURANCE

.1004 POLICY PRACTICES AND PROVISIONS

(a) The terms "guaranteed renewable" or "non-cancellable" may not be used in any individual policy without further explanatory language in accordance with the disclosure requirements of 11 NCAC 12 ~~.1005~~ .1006. No such policy issued to an individual shall contain renewal provisions other than "guaranteed renewable" or "noncancel-able".

(b) The term "guaranteed renewable" may be used only when the insured has the right to continue the policy in force by timely payments of premiums; during which period the insurer has no unilateral right to make any change in any provision of the policy while the policy is in force and can not refuse to renew: Provided that rates may be revised by the insurer on a class basis.

(c) The word "noncancellable" may be used only when the insured has the right to continue the policy in force by timely payments of premiums; during which period the insurer has no right to unilaterally make any change in any provision of the policy or in the premium rate.

(d) No policy may limit or exclude coverage by type of illness, treatment, medical condition, or accident, except as follows:

- (1) preexisting conditions as specified in G.S. 58-55-30;
- (2) mental or nervous disorders, except for Alzheimer's Disease;
- (3) alcoholism and drug addiction;
- (4) illness, treatment, or medical condition arising out of:
 - (A) war or act of war (whether declared or undeclared);
 - (B) participation in a felony, riot, or insurrection;
 - (C) service in the armed forces or units auxiliary thereto;
 - (D) suicide, attempted suicide, or intentionally self-inflicted injury; or
 - (E) aviation activity as a nonfare-paying passenger;
- (5) treatment provided in a government facility (unless otherwise required by law); services for which benefits are available under Medicare, under any other governmental program (except Medicaid), or under any state or federal workers' compensation, employer's liability, or occupational disease law; services provided by a member of the insured's immediate family; and services for which no charge is normally

- made in the absence of insurance;
- (6) exclusions and limitations for payment for services provided outside the United States; and
- (7) legitimate variations in benefit levels to reflect differences in provider rates.

(e) Termination of a policy shall be without prejudice to any benefits payable for institutionalization if the institutionalization began while the policy was in force and continues without interruption after termination. Such extension of benefits beyond the period during which the policy was in force may be limited to the duration of the benefit period, if any, or to payment of the maximum benefits; and may be subject to any policy waiting period and all other applicable provisions of the policy.

Statutory Authority G.S. 58-2-40(1); 58-55-30(a).

.1022 PROTECTION AGAINST UNINTENTIONAL LAPSE

(a) No individual policy shall be issued until the insurer has received from the applicant either a written designation of at least one person, in addition to the applicant, who is to receive notice of lapse or termination of the policy for nonpayment of premium; or a written waiver dated and signed by the applicant electing not to designate additional persons to receive notice. Every applicant has the right to so designate at least one person. Designation does not constitute acceptance of any liability on the part of the designated person or persons for services provided to the insured. The form used for the designation must provide space clearly designated for listing at least one person. The designation shall include each person's full name and home address. If an applicant elects not to designate any person, a written, signed waiver shall state:

"Protection against unintended lapse. I understand that I have the right to designate at least one person other than myself to receive notice of lapse or termination of this long-term care insurance policy for nonpayment of premium. I understand that notice will not be given until thirty (30) days after a premium is due and unpaid. I elect NOT to designate any person to receive such notice."

The insurer shall notify the insured of the right to

change this written designation no less often than once every two years.

(b) When a policyholder pays premium for a policy through a payroll or pension deduction plan, the requirements contained in Paragraph (a) of this Rule need not be met until 60 days after the policyholder is no longer on such a payment plan. The application or enrollment form for such policies shall clearly indicate the payment plan selected by the applicant.

(c) No individual policy shall lapse or be terminated for nonpayment of premium unless the insurer, at least 30 days before the effective date of the lapse or termination, has given notice to the insured and to any person or persons designated under Paragraph (a) of this Rule, at the addresses provided by the insured. Notice shall be given by first class United States mail, postage prepaid; and notice may not be given until 30 days after a premium is due and unpaid. Notice shall be deemed to have been given as of five days after the date of mailing.

(d) In addition to the requirement in Paragraph (a) of this Rule, each policy shall provide for reinstatement of coverage if the insurer is furnished proof of cognitive impairment or the loss of functional capacity of the insured. This option is available to the insured if requested within five months after lapse or termination; and the insurer may require payment of past due premium before reinstatement, where appropriate. The standard of proof of cognitive impairment or loss of functional capacity shall not be more stringent than the benefit eligibility criteria on cognitive impairment or the loss of functional capacity, if any, contained in the policy.

Statutory Authority G.S. 58-2-40(1); 58-55-30(a).

Notice is hereby given in accordance with G.S. 150B-21.2 that the N. C. Department of Insurance intends to amend rules cited as 11 NCAC 13 .0318 and .0319.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on September 30, 1993 at the Dobbs Building, 3rd Floor Hearing Room, 430 N. Salisbury Street, Raleigh, NC 27611.

Reason for Proposed Action: To clarify language in these rules.

Comment Procedures: Written comments may be sent to Fred Mohn at P.O. Box 26387, Raleigh, NC 27611. Oral presentations may be made at the public hearing. Anyone having questions should call Fred Mohn at (919) 733-2200 or Ellen Sprenkel at (919) 733-4529.

CHAPTER 13 - SPECIAL SERVICES DIVISION

SECTION .0300 - INSURANCE PREMIUM FINANCE COMPANIES

.0318 NOTICE OF CANCELLATION

The ~~request for cancellation notice~~ notice of cancellation as described in General Statute 58-35-85(2) shall be signed by the owner or an officer of the premium finance company (the owner or officer's facsimile signature may be used), shall have in bold print at its top the wording "~~Request for Cancellation Notice~~" "Notice of Cancellation" and shall include the name and address of the insured; the name and address of the insurance company; the name and address of the premium finance company; the insurance company policy number; a certification that the ten-days notice of intent to cancel has been furnished to the insured; the authority under which the policy is to be cancelled; the date the ~~request for cancellation notice~~ notice of cancellation is mailed to the insured and to the insurance company; the effective date of cancellation; a notice stating, "If automobile liability insurance is included, you are cautioned that financial responsibility is required to be maintained continuously throughout the registration period and that operation of a motor vehicle without maintaining such financial responsibility is a misdemeanor, the penalty for which is loss of registration plate, and fine or imprisonment, in accordance with the motor vehicle laws of the State of North Carolina as they may be amended from time to time"; and all other pertinent information.

Statutory Authority G.S. 58-2-40; 58-35-85(2).

.0319 EFFECTIVE DATE OF CANCELLATION

When an insurance premium finance company cancels an insurance policy by using a power of

attorney signed by the insured, the effective date of cancellation as stated in the ~~request for cancellation notice~~ notice of cancellation shall be no earlier than the date the request for cancellation notice is mailed to the insurance company.

Statutory Authority G.S. 58-2-40; 58-35-85(2).

TITLE 12 - DEPARTMENT OF JUSTICE

Notice is hereby given in accordance with G.S. 150B-21.2 that the North Carolina Department of Justice intends to adopt rule cited as 12 NCAC 1 .0106.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on October 4, 1993 at the N.C. Department of Justice, Olivia Raney Building, 1st Floor Conference Room, Raleigh, NC 27602.

Reason for Proposed Action: To implement procedures for filing grievance under the Americans with Disabilities Act.

Comment Procedures: Interested persons may present their views either orally or in writing at the hearing. In addition, the record of hearing will be open for receipt of written comments from September 15, 1993 through October 15, 1993. Such written comments must be delivered or mailed to Melissa L. Trippe, Rulemaking Coordinator, 104 Fayetteville Street Mall, P.O. Box 629, Raleigh, NC 27602.

CHAPTER 1 - DEPARTMENTAL RULES

SECTION .0100 - GENERAL PROVISIONS

.0106 ADA DISPUTE RESOLUTION PROCEDURE

(a) The North Carolina Department of Justice has established a grievance procedure to provide for prompt and equitable resolution of complaints alleging any action prohibited by the U.S. Department of Justice regulations implementing Title II of the Americans with Disabilities Act. Title II states in part that "no otherwise qualified individual with a disability shall, solely by reasons of the

disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination" in programs or activities sponsored by a public entity.

(b) Individuals seeking to initiate a grievance against the Department under Title II may initiate such grievance by following the steps below:

- (1) Step 1. A complaint shall be filed in writing or orally, contain the name and address of the person filing it, and contain a brief description of the alleged violation of the regulations. It shall be filed within 30 days after the complainant becomes aware of the alleged violation and must be submitted to:

Charlotte W. Clark, ADA Coordinator
North Carolina Department of Justice
P.O. Box 629
Raleigh, North Carolina 27602-0629
(919)733-5837

- (2) Step 2. An investigation, as may be appropriate, shall follow a filing of the complaint and shall be conducted by the ADA Coordinator. The investigation will be thorough, and all interested parties, and their representatives if any, shall have an opportunity to submit evidence relevant to the complaint. If the complainant fails to comply with a request for information from the ADA Coordinator, he may be deemed to have abandoned his complaint.
- (3) Step 3. A written determination of the validity of the complaint, and a description of the resolution if any, shall be issued by the ADA Coordinator with a copy to the complainant mailed via certified mail, return receipt requested, to the complainant's address of record no later than fifteen working days after the filing, or the complainant will be informed in writing of the reasons for delay and advised as to when a determination may be expected. Should the complainant have a known disability that renders a different form of communication necessary, the ADA Coordinator will make reasonable efforts to effectively communicate her determination.
- (4) Step 4. The complainant may request a reconsideration of the case in instances of dissatisfaction with the resolution, within fifteen days of receipt of the

written determination. The request shall be made to the ADA Coordinator. The ADA Coordinator shall forward the request to the North Carolina Department of Justice Personnel Officer. The Personnel Officer shall appoint a Committee consisting of at least three Departmental employees including the individual ultimately selected by the other committee members to be the Chair of the Committee. Selected employees must agree to serve before they will be placed on the Committee. Employees serving on a Committee shall inform the Departmental Personnel Officer of any conflict of interest in their serving on a Committee reviewing a particular complainant's case. The Committee shall review the ADA Coordinator's determination and respond to the complainant no later than fifteen working days after the Committee is appointed. Alternatively, the complainant shall be informed, in writing, of the reasons for delay and advised as to when a determination may be expected. Should the complainant have a known disability that renders a different form of communication necessary, the Committee Chair will make reasonable efforts to effectively communicate the Committee's determination. If the complainant fails to comply with a request for information from the Committee, than he may be deemed to have abandoned his complaint.

- (5) Step 5. The Committee's determination shall be simultaneously submitted to the Attorney General as a written report containing a recommended course of action. The Attorney General or his designated agent shall review the Committee's determination and recommendations. The Attorney General may secure additional information that he deems necessary to render his decision. This may involve meeting with the parties. If the complainant fails to comply with a request for information from the Attorney General, he may be deemed to have abandoned his complaint. The Attorney General may adopt the Committee's recommendation in whole or in part or may choose any

other course of action that he deems appropriate. The Attorney General's decision shall constitute the final Departmental decision. It shall be in writing and mailed via certified mail, return receipt requested, to the complainant's address of record. Should the complainant have a known disability that renders a different form of communication necessary, the Department shall make reasonable efforts to effectively communicate its determination. The final Departmental decision shall be communicated to the complainant within 30 calendar days from the date the Committee's report is received in the Attorney General's office. If more time is needed by the Attorney General the complainant shall be notified.

(c) A complainant also has the right during this process to pursue other remedies, such as filing an ADA complaint with the responsible federal agency. In addition, the complainant may pursue such remedies or court action if he continues to be dissatisfied after step 5 in Subparagraph (a)(5) of this Rule.

(d) The ADA Coordinator shall maintain the files and records of the North Carolina Department of Justice relating to the complaints filed for a period of three years after the final Departmental decision.

Authority G.S. 114-1; 114-1.1; 28 C.F.R. 35.107.

TITLE 15A - DEPARTMENT OF ENVIRONMENT, HEALTH, AND NATURAL RESOURCES

Notice is hereby given in accordance with G.S. 150B-21.2 that EHNHR - Commission for Health Services intends to adopt rules cited as 15A NCAC 13B .1701 - .1710.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N.C.

Reason for Proposed Action: *These Rules establish requirements for siting, design, construction, operation and closure of coal combustion by-product structural fill projects and its other uses.*

Comment Procedures: *All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.*

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 13 SOLID WASTE MANAGEMENT

SUBCHAPTER 13B - SOLID WASTE MANAGEMENT

SECTION .1700 - REQUIREMENTS FOR BENEFICIAL USE OF COAL COMBUSTION BY-PRODUCTS

.1701 DEFINITIONS

The following definitions shall apply throughout

this Section:

- (1) "Beneficial and beneficial use" means projects promoting public health and environmental protection, offering equivalent success relative to other alternatives, and preserving natural resources.
- (2) "Coal combustion by-products" means residuals, including fly ash, bottom ash, boiler slag and flue gas desulfurization residue produced by coal fired electrical or steam generation units.
- (3) "Jurisdictional wetland" means those areas that meet the criteria established by the United States Environmental Protection Agency for delineating wetlands and are considered by the Division to be waters of the United States.
- (4) "Structural fill" means an engineered fill with a projected beneficial end use constructed using coal combustion by-products properly placed and compacted.
- (5) "Use or reuse of coal combustion by-products" means the procedure whereby coal combustion by-products are directly used as follows:
 - (a) As an ingredient in an industrial process to make a product, unless distinct components of the coal combustion by-products are recovered as separate end products; or
 - (b) In a function or application as an effective substitute for a commercial product or natural resource.

Statutory Authority G.S. 130A-294.

.1702 GENERAL PROVISIONS FOR STRUCTURAL FILL FACILITIES

The provisions of this Section shall apply to the siting, design, construction, operation, closure and recordation of projects which utilize coal combustion by-products as structural fill material or as specified in Item (4) of Rule .1708 of this Section and shall apply to structural fills other than those which received written approval from the Division prior to the effective date of this Section. A solid waste management permit is not required for coal combustion by-products structural fills which meet the requirements listed in this Section.

Statutory Authority G.S. 130A-294.

.1703 NOTIFICATION FOR STRUCTURAL FILL FACILITIES

- (a) A minimum of 30 days before using coal

combustion by-products in structural fill projects, the person proposing the use shall submit a written notice to the Division. The notice shall contain, at a minimum:

- (1) A description of the nature, purpose and location of the project, including the name of the United States Geological Survey seven and one-half minute map on which the project is located and a Department of Transportation map or an eight and one-half by 11 inch topographic map showing the project.
 - (2) The estimated start and completion dates for the project.
 - (3) An estimate of the volume of coal combustion by-products to be used for the project.
 - (4) A Toxicity Characteristic Leaching Procedure (TCLP) analysis from a representative sample of each different coal combustion by-product source to be used in the project. The TCLP analysis shall be conducted and certified by the generator to be representative of each coal combustion by-product source used in the project. A TCLP analysis shall be conducted at least annually. A minimum analysis shall include: arsenic, barium, cadmium, lead, chromium, mercury, selenium and silver.
 - (5) A signed and dated statement by the owner(s) of the land on which the structural fill is to be placed, acknowledging and consenting to the use of coal combustion by-products as structural fill and agreeing to record the fill in accordance with Rule .1707 of this Section.
 - (6) The notification shall include:
 - (A) Name of coal combustion by-products generator;
 - (B) Physical location of the generating facility;
 - (C) Address of generator;
 - (D) Name of contact for generator;
 - (E) Telephone number of generator; and
 - (F) Changes that occur will require subsequent notification of the Division of Solid Waste Management.
- (b) In addition to the notification requirements under Paragraph (a) of this Rule, at least 30 days before using coal combustion by-products as a structural fill in projects with a volume of more than 10,000 cubic yards, the person proposing the use shall submit a written notice to the Division containing construction plans for the structural fill

facility, including a stability analysis when necessary, which shall be prepared, signed and sealed by a registered professional engineer in accordance with sound engineering practices. The Department of Transportation is not required to submit construction plans with the written notice. The Department of Transportation shall maintain a complete set of construction plans and shall notify the Division where the construction plans are located.

Statutory Authority G.S. 130A-294.

.1704 SITING FOR STRUCTURAL FILL FACILITIES

(a) Coal combustion by-products used as a structural fill shall not be placed:

- (1) Within 50 horizontal feet of a jurisdictional wetland or from the top of the bank of any regularly flowing water body or stream;
- (2) Within two feet of the seasonal high ground-water table;
- (3) Within 100 horizontal feet of any source of drinking water, such as a well, spring or other groundwater source of drinking water;
- (4) Within an area subject to a one-hundred year flood, unless it can be demonstrated to the Division that the facility will be protected from inundation, and washout, and the flow of water is not restricted and the storage volume of the flood plain will not be significantly reduced;
- (5) Within 25 feet of any property boundary; and
- (6) Within 25 feet of a bedrock outcrop.

(b) The Division and the Department of Transportation may agree on specific structural fill siting criteria that may be used on Department of Transportation projects.

Statutory Authority G.S. 130A-294.

.1705 DESIGN, CONSTRUCTION, AND OPERATION FOR STRUCTURAL FILL FACILITIES

(a) The structural fill facility must be designed, constructed, operated, closed, and maintained in such a manner as to minimize the potential for harmful release of constituents of coal combustion by-products to the environment or create a nuisance to the public.

(b) Coal combustion by-products shall be col-

lected and transported in a manner that will prevent nuisances and hazards to public health and safety. Coal combustion by-products shall be moisture conditioned, as necessary, and transported in covered trucks to prevent dusting.

(c) Coal combustion by-products shall be placed uniformly and compacted in lifts not exceeding one foot in thickness and shall be compacted to standards, including in-situ density, compaction effort and relative density, specified by a registered professional engineer for a specific end use purpose.

(d) Equipment shall be provided which is capable of placing and compacting the coal combustion by-products and handling the earthwork required during the periods that coal combustion by-products are received at the fill area.

(e) The coal combustion by-product structural fill facility shall be effectively maintained and operated as a non-discharge system to prevent discharge to surface water resulting from the operation of the facility.

(f) The coal combustion by-product structural fill facility shall be effectively maintained and operated to ensure no violations of ground water standards, 15A NCAC 2L.

(g) Surface waters resulting from precipitation shall be diverted away from the active coal combustion by-product placement area during filling and construction activity.

(h) Site development shall comply with the North Carolina Sedimentation Pollution Control Act of 1973, as amended.

(i) The structural fill project must be operated with sufficient dust control measures to minimize airborne emissions and to prevent dust from creating a nuisance or safety hazard and must not violate applicable air quality regulations.

(j) All structural fills shall be covered with a minimum of 12 inches compacted earth, and an additional surface six inches of soil capable of supporting the growth of suitable vegetation.

(k) Compliance with these standards does not insulate any of the owners or operators from claims for damages to surface waters, ground-water or air resulting from the operation of the structural fill facility. If the facility fails to comply with the requirements of this Section, the constructor, generator, owner or operator shall notify the Division and shall take such immediate corrective action as may be required by the Department.

(l) Coal combustion by-products utilized on an exterior slope of a structural fill shall not be placed with a slope greater than 3.0 horizontal to

1.0 vertical.

(m) The Division and the Department of Transportation may agree on specific design, construction, and operation criteria that may apply to the Department of Transportation projects.

Statutory Authority G.S. 130A-294.

.1706 CLOSURE OF STRUCTURAL FILL FACILITIES

(a) No later than 30 working days or 60 calendar days, whichever is less after coal combustion by-product placement has ceased, the final cover shall be applied over the coal combustion by-product placement area.

(b) The final surface of the structural fill shall be graded and provided with drainage systems that:

- (1) Minimize erosion of cover materials; and
- (2) Promote drainage of area precipitation, minimize infiltration and prevent ponding of surface water on the structural fill.

(c) Other erosion control measures, such as temporary mulching, seeding, or silt barriers shall be installed to ensure no visible coal combustion by-product migration to adjacent properties until the beneficial end use of the project is realized.

(d) The constructor or operator shall submit a certification to the Division signed and sealed by a registered professional engineer or signed by the Secretary of the Department of Transportation or his designee certifying that all requirements in the Rules of this Section have been met. The report shall be submitted within 30 days of application of the final cover.

(e) The Division and the Department of Transportation shall agree on specific closure criteria that apply to Department of Transportation projects.

Statutory Authority G.S. 130A-294.

.1707 RECORDATION OF STRUCTURAL FILL FACILITIES

(a) The owners of land where coal combustion by-products have been utilized in volumes of more than 1,000 cubic yards shall file a statement of the volume and locations of the coal combustion by-products with the Register of Deeds in the county or counties where the property is located. The statement shall identify the parcel of land according to the complete legal description on the recorded deed, either by metes and bounds, or by refer-

ence to a recorded plat map. The statement shall be signed and acknowledged by the landowners(s) in the form prescribed by G.S. 47-38 through 47-43.

(b) Recordation shall be required within 90 days after completion of coal combustion by-product fill project.

(c) The Register of Deeds in accordance with G.S. 161-14 shall record the notarized statement and index it in the Grantor Index under the name of the owner(s) of the land. The original notarized statement with the Register's seal and the date, book and page number of recording shall be returned to the Division after recording.

(d) When property with more than 1,000 cubic yards of coal combustion by-products is sold, leased, conveyed or transferred in any manner, the deed or other instrument of transfer shall contain in the description section in no smaller type than used in the body of the deed or instrument a statement that coal combustion by-products have been used as fill material on the property.

Statutory Authority G.S. 130A-294.

.1708 OTHER USES FOR COAL COMBUSTION BY-PRODUCTS

Coal combustion by-products may be beneficially used on one or more of the following applications or when handled, processed, transported or stockpiled for such beneficial use applications and do not require a solid waste permit provided the uses are consistent with the requirements identified below:

- (1) Coal combustion by-products used as soil nutrient additives or other agricultural purposes under the authority of the North Carolina Department of Agriculture;
- (2) Coal combustion bottom ash or boiler slag used as a traction control material or road surface material if the use is approved by the North Carolina Department of Transportation;
- (3) Coal combustion by-products used as material in the manufacturing of another product, such as concrete products, lightweight aggregate, roofing materials, plastics, paint, flowable fill and roller compacted concrete or as a substitute for a product or material resource, including but not limited to, blasting grit, roofing granules, filter cloth precoat for sludge dewatering and pipe bedding;
- (4) Coal combustion by-products used as a structural fill for the base, sub-base,

under a structure or the footprint of a paved road, a parking lot, sidewalk, walkway or similar structure;

- (5) Coal combustion by-products used for the extraction or recovery of materials and compounds contained within the coal combustion by-products. Residuals from the processing operations shall remain solid waste and be subject to this Section and Section .1600 of this Subchapter; and
- (6) Coal combustion by-products processed with a cementitious binder to produce a stabilized structural fill product which is spread and compacted for the construction of a project with a planned end use.

Statutory Authority G.S. 130A-294.

.1709 STORAGE AND CONTAINMENT OF COAL COMBUSTION BY-PRODUCTS

(a) Coal combustion by-products may not be stored or speculatively accumulated at the immediate area where they will be put to beneficial use for a longer period of time than necessary to complete the project. Coal combustion by-products are not being speculatively accumulated when a minimum of 75 percent of the coal combustion by-products are removed from the facility and beneficially used annually.

(b) Compliance with this Section does not exempt the owner or operator of the structural fill facility from applicable North Carolina Water Pollution Control Regulations (15A NCAC 2H), the North Carolina Air Pollution Control Regulations (15A NCAC 2D) and all other federal, state and local laws and regulations.

Statutory Authority G.S. 130A-294.

.1710 ANNUAL REPORTING

No later than October 1, 1993 and each October 1 thereafter, the generators of coal combustion by-products shall submit an annual summary to the Division. The annual summary shall be for the period July 1 through June 31 and shall include:

- (1) Volume of coal combustion by-products produced;
- (2) Volume of coal combustion by-products disposed;
- (3) Volume of coal combustion by-products used in structural fill facilities; and
- (4) Volume of coal combustion by-products used for other uses as described in Rule .1708 of this Section.

Statutory Authority G.S. 130A-294.

Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 18A .0301, .0420, .0425, .0427, and repeal rules cited as 18A .0201 - .0230.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Archdale Building, Groundfloor Hearing Room, 512 N. Salisbury Street, Raleigh, NC.

Reason for Proposed Action: The proposed changes in the shellfish and scallop rules will bring these rules into conformity with the National Shellfish Sanitation Program (NSSP) Manual of Operations.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND

COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 18 - ENVIRONMENTAL HEALTH

SUBCHAPTER 18A - SANITATION

SECTION .0200 - SANITATION OF SCALLOPS

.0201 DEFINITIONS

The following definitions shall apply throughout 15A NCAC 18A .0200:

- (1) ~~"Division" means the Division of Environmental Health or its authorized agents.~~
- (2) ~~"Scallops" means all varieties of bivalve mollusks of the family PECTINIDAE.~~
- (3) ~~"Sanitize" means the approved bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619.~~
- (4) ~~"Adulterated" means: they contain any poisonous or deleterious substance which may render them injurious to the health of the consumer; or that they have been shucked, packed, stored, or transported under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered unwholesome or injurious to health; or that they have been shucked or packed in a plant that does not comply with these Rules and which does not hold a valid permit from the Division; or that they are contaminated, filthy, decomposed, or otherwise unfit for food; or that they are otherwise adulterated in accordance with the provisions of G.S. 106-129.~~
- (5) ~~"Misbranded" means: the labeling is false or misleading in any particular; or that the labeling includes an identification number which has not been duly awarded to the plant by the Division or which is not currently in effect; or that scallop meat is packed for sale in containers without labeling; or that they are otherwise misbranded in accordance with the~~

provisions of G.S. 106-130.

- (6) ~~"Person" means an individual, firm, association, organization, partnership, business trust, corporation or company.~~
- (7) ~~"Shucking and packing plant" means and includes any establishment or place in which scallops are shucked or packed for sale; provided that this definition shall not be construed to mean and include private residences whose occupants harvest and shuck scallops for their own home consumption, and who have in their possession not more than one gallon of fresh, unfrozen scallop meat that was not packed in a plant approved by the Division.~~

Statutory Authority G.S. 130A-230.

.0202 ADULTERATED OR MISBRANDED SCALLOPS

(a) ~~No person within the State of North Carolina shall sell, offer, or expose for sale, or have in possession with intent to sell any scallops which are adulterated or misbranded.~~

(b) ~~Whenever an authorized agent of the Division finds adulterated or misbranded scallops in the possession of any person, the agent is authorized to:~~

- (1) ~~give the person notice that he is in violation of a rule of the Division and that legal action will be commenced; or~~
- (2) ~~in lieu of such notice, allow the person to dispose of the scallops voluntarily in such a manner as to preclude the sale of adulterated or misbranded scallops.~~

Statutory Authority G.S. 130A-230.

.0203 GROWING AND GATHERING: SCALLOPS SHUCKED AT SEA

(a) ~~Scallops shall be harvested only from those areas which have been approved by the state.~~

(b) ~~All boats and other conveyances used in the harvesting, handling, transportation, and storage of scallops shall be so constructed and maintained in a state of cleanliness and repair that the scallops transported or stored therein shall not be subject to contamination by bilge water, filth, dust or vermin.~~

(c) ~~Shell scallops shall be kept cool during harvesting, transportation, and holding.~~

(d) ~~Storage of scallops in fresh water is prohibited.~~

(e) ~~Scallops shucked at sea are not required to~~

comply with Section .0200 of this Subchapter.

(f) ~~Scallops shucked at sea must be packed in containers approved by the Division.~~

(g) ~~Containers of scallops, which are shucked at sea, must be labeled as required by the Division.~~

Statutory Authority G.S. 130A-230.

.0204 SEVERABILITY

~~If any provision of the rules in 15A NCAC 18A .0200 or the application thereof and any person or circumstance, is held invalid, the remainder of the rules in these sections or the application of such provisions to other persons or circumstances shall not be affected thereby.~~

Statutory Authority G.S. 130A-230.

.0205 INSPECTION AND APPROVAL

~~No person shall operate a shucking or packing plant for the shucking or packing of scallops within the State of North Carolina until the facility complies with this Section and until such plant shall have been inspected and approved by the Division.~~

Statutory Authority G.S. 130A-230.

.0206 PERMITS

(a) ~~No scallop shucking or packing plant shall be operated in North Carolina until a permit to operate shall have been issued by the Division.~~

(b) ~~A permit to operate shall be issued only after a sanitary inspection or reinspection by the Division shows that the plant complies with this Section.~~

(c) ~~Permits issued to one person are not transferable to others. All permits shall expire annually on June 30.~~

Statutory Authority G.S. 130A-230.

.0207 APPLICATION

~~Application for such inspection shall be made in writing by the person requesting a permit to operate. All certificates of inspection and permits shall be posted in a conspicuous place in the packing room.~~

Statutory Authority G.S. 130A-230.

.0208 REVOCATIONS

~~Violation of any of the rules of this Section shall constitute sufficient cause for revocation of the permit to operate.~~

Statutory Authority G.S. 130A-230.

.0209 SEPARATION OF OPERATIONS

~~There shall be provided a shucking and packing plant with a satisfactory shellstock storage room, shucking room, and a packing room for the storage, shucking, and packing of scallops.~~

Statutory Authority G.S. 130A-230.

.0210 LIGHTING AND VENTILATION

(a) ~~Natural or artificial lighting shall be provided in all parts of the plant. Light bulbs, fixtures, or other glass suspended within the plant shall be of safety type or otherwise protected to prevent contamination in case of breakage. Lighting intensities shall be a minimum of 25 foot candles on working surfaces in packing and shucking rooms.~~

(b) ~~Ventilation shall be provided to eliminate odors and condensation.~~

Statutory Authority G.S. 130A-230.

.0211 FLOORS

~~Floors shall be of concrete or other equally impervious materials, so constructed that they may be easily and thoroughly cleaned and shall be sloped so that drainage of all water therefrom shall be complete and rapid.~~

Statutory Authority G.S. 130A-230.

.0212 WALLS AND CEILINGS

~~Walls and ceilings of rooms in which scallops are stored, shucked, or packed, shall be smooth, washable, light colored, and kept in good repair.~~

Statutory Authority G.S. 130A-230.

.0213 INSECT AND RODENT CONTROL

~~The plant shall be so constructed as to prevent ready entrance of flies, rodents, and domestic animals. Screens shall be effective and kept in good repair.~~

Statutory Authority G.S. 130A-230.

.0214 SHUCKING BENCHES

~~Shucking benches and the walls immediately adjacent shall be constructed of smooth concrete or equally impervious materials to a height of at least two feet above the benches, and shall be provided with adequate and proper drainage.~~

Statutory Authority G.S. 130A-230.

.0215 REFRIGERATION

~~Refrigerators, ice boxes, or cold storage rooms shall maintain a temperature of 50 degrees F (10 degrees C) or below, and shall be constructed to permit easy and thorough cleaning and proper drainage and shall be kept clean.~~

Statutory Authority G.S. 130A-230.

.0216 TOILET FACILITIES

~~Separate and convenient toilet facilities shall be provided for each sex employed and shall comply with the N.C. State Building Code, Volume 2, Plumbing. Floors, walls, and ceilings shall be smooth, easily cleanable and kept clean. Fixtures shall be kept clean. All toilet wastes and other sewage shall be disposed of in a public sewer system or in the absence of a public sewer system, by an on-site sewage disposal system approved by the Department in accordance with G.S. 130A-335.~~

Statutory Authority G.S. 130A-230.

.0217 WATER SUPPLY

~~(a) The plants shall be provided with an adequate supply of water under pressure from a source approved by the Division.~~

~~(b) An automatically regulated hot water system shall be provided.~~

Statutory Authority G.S. 130A-230.

.0218 HAND WASHING FACILITIES

~~Hand washing facilities including lavatories, hot and cold running water, soap, and individual towels shall be provided in a convenient place in the shucking room.~~

Statutory Authority G.S. 130A-230.

.0219 WASHING AND SANITIZING FACILITIES

~~Washing and sanitizing facilities including a two compartment sink of sufficient size to wash and sanitize all utensils shall be provided. Permanent hot and cold water connections shall be installed so that both vats may receive hot and cold water service. Hot water of 170 degrees F. or above, or a standard chlorine solution shall be provided for the sanitization of utensils and equipment.~~

Statutory Authority G.S. 130A-230.

.0220 CONSTRUCTION OF EQUIPMENT

~~Shucking pails, skimmers, tubs, knives, and other equipment which may come in direct contact with shucked scallops shall be made of non-corrosive, non-rusting, smooth, impervious material and constructed so as to be easily cleanable.~~

Statutory Authority G.S. 130A-230.

.0221 PERSONAL HEALTH

~~No person shall work in the handling, shucking or packing of scallops, who has any communicable disease or has any open lesions or sores.~~

Statutory Authority G.S. 130A-230.

.0222 PERSONAL HYGIENE

~~All employees shall wash their hands thoroughly with warm water and soap before beginning work and after each visit to the toilet.~~

Statutory Authority G.S. 130A-230.

.0223 WASHING OF SCALLOPS

~~Scallops shall be shucked only in the shucking room and in such a manner that they are not subject to contamination or adulteration. Shucked scallop meats shall be washed on a skimmer with cold running water only, for but not more than three minutes. The washing of shucked scallop meats in non-perforated vessels is prohibited. Shucked scallops shall be free of grass, shell, and other extraneous material.~~

Statutory Authority G.S. 130A-230.

.0224 CONTAINERS

~~Shucked scallops shall be packed and shipped in approved single service containers sealed in such a manner that tampering may be easily discernible, and marked with the name and address of the packer, and the packer's certificate number impressed or embossed on the side of such container. Use of containers bearing the certificate number of another packer shall not be permitted.~~

Statutory Authority G.S. 130A-230.

.0225 PACKING

~~Shucked scallop meats shall be packed within one hour of shucking. Packed scallop meats shall be cooled to 50 degrees F. or less within three hours~~

~~after packing, and stored and shipped under similar temperature conditions.~~

Statutory Authority G.S. 130A-230.

.0226 CLEANSING OF EQUIPMENT

~~All utensils and tools which come in contact with scallop meats shall be thoroughly washed after use and subjected to an approved bactericidal process:~~

- ~~(1) by immersing in hot water at a temperature of 170 degrees F. or more for at least two minutes, or~~
- ~~(2) by immersing in a solution containing no less than 50 parts per million of available chlorine for two minutes.~~

Statutory Authority G.S. 130A-230.

.0227 INTERIOR OF PLANTS

~~The interior of all shucking and packing plants shall be kept clean. None of the operations shall be conducted in any room used for domestic purposes.~~

Statutory Authority G.S. 130A-230.

.0228 WASTE DISPOSAL

~~Scallop shells, unused parts of scallop bodies, washings, and other wastes shall be disposed of in a sanitary manner, as approved by the Division.~~

Statutory Authority G.S. 130A-230.

.0229 REPACKING

~~(a) Shucked scallops to be repacked shall be received at the repacking plant in approved shipping containers at a temperature of 50 degrees F. or less.~~

~~(b) During the repacking process, shucked scallops shall be held at a temperature sufficient to prevent deterioration and shall be stored at a temperature of 50 degrees F. or less.~~

~~(c) During the repacking process, handling and storage of scallops shall be done in a sanitary manner as prescribed in these Rules.~~

~~(d) Repacked scallops shall be repacked and shipped in approved single service containers sealed in such a manner that tampering may be easily discernible, and marked with the name and address of the repacker and the repacker's certificate number. Use of containers bearing the certificate number of another packer or repacker shall not be permitted.~~

Statutory Authority G.S. 130A-230.

.0230 APPEALS PROCEDURE

~~Appeals shall be conducted in accordance with G.S. 150B.~~

Statutory Authority G.S. 130A-230.

SECTION .0300 - SANITATION OF SHELLFISH - GENERAL

.0301 DEFINITIONS

The following definitions shall apply throughout this Subchapter:

- (1) "Adulterated" means the following:
 - (a) Any shellfish that have been harvested from prohibited areas;
 - (b) Any shellfish that have been shucked, packed, or otherwise processed in a plant which has not been permitted by the Division in accordance with these Rules;
 - (c) Any shellfish which exceed the bacteriological standards in Rule .0430 of this Subchapter;
 - (d) Any shellfish which are putrid or unfit for human consumption;
 - (e) Any shellfish which have been exposed to any unsanitary conditions; or
 - (f) Any shellfish which contain any added substance, unless the substance is approved by the Division or the United States Food and Drug Administration.
- (2) "Approved area" means an area determined suitable for the harvest of shellfish for direct market purposes.
- (3) "Bulk shipment" means a shipment of loose shellstock.
- (4) "Buy boat or buy truck" means any approved boat or truck that is used by a person permitted under these Rules to transport shellstock from one or more harvesters to a facility permitted under these Rules.
- (5) "Depuration" means mechanical purification or the removal of adulteration from live shellstock by any artificially controlled means.
- (6) "Depuration facility" means the physical structure wherein depuration is accomplished, including all the appurtenances necessary to the effective operation thereof.
- (7) "Division" means the Division of Environmental Health or its authorized agent.
- (8) "Heat shock process" means the practice

of heating shellstock to facilitate removal of the shellfish meat from the shell.

- (9) "Misbranded" means the following:
 - (a) Any shellfish which are not labeled with a valid identification number awarded by regulatory authority of the state or territory of origin of the shellfish; or
 - (b) Any shellfish which are not labeled as required by these Rules.
- (10) "Operating season" means the season of the year during which a shellfish product is processed.
- (11) "Person" means an individual, corporation, company, association, partnership, unit of government or other legal entity.
- (12) "Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.
- (13) "Relaying or transplanting" means the act of removing shellfish from one growing area or shellfish grounds to another area or ground for any purpose.
- (14) "Repacking plant" means a shipper, other than the original shucker-packer, who repacks shucked shellfish into containers for delivery to the consumer.
- (15) "Reshipper" means a shipper who ships shucked shellfish in original containers, or shellstock, from permitted shellstock dealers to other dealers or to consumers.
- (16) "Sanitary survey" means the evaluation of factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides and currents in the distribution and dilution of polluting materials, and the bacteriological quality of water.
- (17) "Sanitize" means the approved bactericidal treatment by a process which provides sufficient accumulative heat or concentration of chemicals for sufficient time to reduce the bacterial count, including pathogens, to a safe level on utensils and equipment.
- (18) "SELL BY date" means a date conspicuously placed on a container or tag by which a consumer is informed of the latest date the product will remain suitable for sale.
- (19) "Shellfish" means oysters, mussels, scallops and all varieties of clams. Scallops are to be excluded when the

final product is the shucked adductor muscle only.

- (20) "Shellstock" means any shellfish which remain in their shells.
- (21) "Shellstock conveyance" means all trucks, trailers, or other conveyances used to transport shellstock.
- (22) "Shellstock dealer" means a person who buys, sells, stores, or transports or causes to be transported shellstock which was not obtained from a person permitted under these Rules.
- (23) "Shellstock plant" means any establishment where shellstock are washed, packed, or otherwise prepared for sale.
- (24) "Shucking and packing plant" means any establishment or place where shellfish are shucked and packed for sale.
- (25) "Wet storage" means the temporary placement of shellstock from approved sources, in approved natural sea water.

Statutory Authority G.S. 130A-230.

SECTION .0400 - SANITATION OF SHELLFISH - GENERAL OPERATION STANDARDS

.0420 TRANSPORTING SHELLSTOCK

(a) All shellstock storage areas in trucks, buy boats, buy trucks, trailers, and other conveyances used for transporting shellstock shall be enclosed, tightly constructed, painted with a light color washable paint, kept clean, and shall be subject to inspection by the Division.

(b) Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which will keep them alive and clean and will prevent adulteration or deterioration. ~~During the months of April through October, inclusive, a~~ All shellstock shall be kept under mechanical refrigeration at a temperature of 50°F (10°C) or below. All conveyances used to transport shellstock shall be equipped with an operating thermometer.

(c) Buy boats and buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413 of this Subchapter. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification tags, and records.

Statutory Authority G.S. 130A-230.

.0425 TAGGING

(a) In order that information may be available to the Division with reference to the origin of shellstock, containers holding shellstock shall be identified with a uniform tag or label. ~~If shellstock is sold directly to the final consumer, the permitted dealer must display its name, address, and permit number in full view of the buying public, in lieu of individual shipping tags. If shellstock is to be resold or sold to a commercial establishment, each individual package shall be labeled or tagged with the required information.~~ The tag shall be durable, waterproof and measure at least 2-5/8 by 5-1/4 inches (6.7 by 13.3 centimeters). The tag shall contain legible information arranged in specific order as follows:

- (1) the dealer's name, address and certification number assigned by the appropriate shellfish control agency;
- (2) the original shipper's certification number, including the country or state abbreviation;
- (3) the harvest date;
- (4) the harvest location;
- (5) the type and quantity of shellfish; and
- (6) the following statement shall appear in bold capitalized type "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(b) ~~The information upon the tag or label shall include the name and address of shipper, permit number issued by the Division, together with the state abbreviation, date of harvesting, date of shipment or of reshipment, and name of the waters from which the shellfish were harvested.~~ The uniform tag or label shall remain attached to the shellstock container until the container is empty and thereafter shall be kept on file for 90 days.

~~(e) The stub of the tag shall not be removed from any package of shellstock until all of the contents of the package have been removed. Tags shall be durable, waterproof, and legible.~~

~~(d)(c)~~ All shellstock from a depuration facility must be identified as having been cleansed by a depuration facility identified by a name and permit number on the tag.

Statutory Authority G.S. 130A-230.

.0427 SHELLSTOCK STORAGE

Shellstock held in wet or dry storage must be kept so that they will not become adulterated. All shellstock held in dry storage ~~during the months of~~

~~April through October, inclusive,~~ shall be kept under mechanical refrigeration at a temperature of 50°F (10°C) or below. All refrigerated shellstock storage areas shall be equipped with an operating thermometer.

Statutory Authority G.S. 130A-230.

Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNHR - Commission for Health Services intends to amend rules cited as 15A NCAC 18A .2601, .2638 - .2639, and .2810.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Archdale Building, Groundfloor Hearing Room, 512 N. Salisbury Street, Raleigh, NC.

Reason for Proposed Action:

15A NCAC 18A .2601; .2638; .2639 - To allow new uses for pushcarts. To change food preparations to more controlled environments.

15A NCAC 18A .2810 - To amend Day Care food equipment rules to allow domestic stoves in all but large day care facilities or facilities engaged in catering.

Comment Procedures: *All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or*

proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 18 - ENVIRONMENTAL HEALTH

SUBCHAPTER 18A - SANITATION

SECTION .2600 - SANITATION OF RESTAURANTS AND OTHER FOODHANDLING ESTABLISHMENTS

.2601 DEFINITIONS

The following definitions shall apply in the interpretation and enforcement of this Section:

- (1) "Approved" means determined by the Department to be in compliance with this Section. Food service equipment which meets National Sanitation Foundation standards or equal shall be considered as approved. The National Sanitation Foundation Commercial Food Service Equipment Standards are hereby incorporated by reference including any subsequent amendments and editions. This material is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Environmental Health, 1330 St. Mary's Street, Raleigh, North Carolina. Copies may be obtained from NSF International, P.O. Box 13014, Ann Arbor, Michigan 48113-0140, at a cost of three hundred and twenty five dollars (\$325.00). Food which complies with requirements of the North Carolina Department of Agriculture or United States Department of Agriculture and the requirements of this Section shall be considered as approved.

- (2) "Catered elderly nutrition site" means an establishment or operation where food is served, but not prepared on premises, operated under the guidelines of the N.C. Department of Human Resources, Division of Aging.
- (3) "Department of Environment, Health, and Natural Resources" or "Department" means the North Carolina Department of Environment, Health, and Natural Resources. The term also means the authorized representative of the Department.
- (4) "Drink stand" means those establishments in which only beverages are prepared on the premises and are served in multi-use containers, such as glasses or mugs.
- (5) "Eating and cooking utensils" means any kitchenware, tableware, glassware, cutlery, utensils, containers, or other equipment with which food or drink comes in contact during storage, preparation, or serving.
- (6) "Employee" means any person who handles food or drink during preparation or serving, or who comes in contact with any eating or cooking utensils, or who is employed at any time in a room in which food or drink is prepared or served.
- (7) "Food" means any raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption.
- (8) "Food stand" means those food service establishments which prepare or serve foods and which do not provide seating facilities for customers to use while eating or drinking. Establishments which only serve such items as dip ice cream, popcorn, candied apples, or cotton candy are not included.
- (9) "Hermetically sealed container" means a container designed and intended to be secure against the entry of micro-organisms and to maintain the commercial sterility of its contents after processing.
- (10) "Local Health Director" means the administrative head of a local health department or his authorized representative.
- (11) "Mobile food unit" means a vehicle-mounted food service establishment designed to be readily

- moved.
- (12) "Person" means any individual, firm, association, organization, partnership, business trust, corporation, or company.
 - (13) "Potentially hazardous food" means any food or ingredient, natural or synthetic, in a form capable of supporting the growth of infectious or toxigenic microorganisms, including *Clostridium botulinum*. This term includes raw or heat treated foods of animal origin, raw seed sprouts, and treated foods of plant origin. The term does not include foods which have a pH level of 4.6 or below or a water activity (Aw) value of 0.85 or less.
 - (14) "Private club" means a private club as defined in G.S. 130A-247(2).
 - (15) "Pushcart" means a mobile piece of equipment or vehicle which serves ~~only hot dogs~~ foods which have been prepared, pre-portioned, and individually wrapped at a restaurant. The term also includes pushcarts permitted prior to January 1, 1994 which prepare, handle, or serve only hot dogs.
 - (16) "Responsible person" means the individual present in a food service establishment who is the apparent supervisor of the food service establishment at the time of inspection. If no individual is the apparent supervisor, then any employee is the responsible person.
 - (17) "Restaurant" means all establishments and operations where food is prepared or served at wholesale or retail for pay, or any other establishment or operation where food is prepared or served that is subject to the provisions of G.S. 130A-248. The term does not include establishments which only serve such items as dip ice cream, popcorn, candied apples, or cotton candy.
 - (18) "Sanitarian" means a person authorized to represent the Department on the local or state level in making inspections pursuant to state laws and rules.
 - (19) "Sanitize" means the approved bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619.
 - (20) "Sewage" means the liquid and solid human body waste and liquid waste generated by water-using fixtures and

appliances, including those associated with foodhandling. The term does not include industrial process wastewater or sewage that is combined with industrial process wastewater.

- (21) "Single service" means cups, containers, lids, closures, plates, knives, forks, spoons, stirrers, paddles, straws, napkins, wrapping materials, toothpicks, and similar articles intended for one-time, one person use and then discarded.
- (22) "Temporary food stand" means those food or drink stands which operate for a period of 15 days or less, in connection with a fair, carnival, circus, public exhibition, or other similar gathering.
- (23) "Temporary restaurant" means a restaurant, as defined in Item (17) of this Rule, that operates for a period of 15 days or less, in connection with a fair, carnival, circus, public exhibition, or other similar gathering.

Statutory Authority G.S. 130A-248.

.2638 GENERAL REQUIREMENTS FOR PUSHCARTS AND MOBILE FOOD UNITS

(a) ~~Approval~~ A permit shall be ~~granted~~ issued by the local health department which provides sanitation surveillance for the restaurant from which the pushcart or mobile food unit is to operate, if the local health department determines that the pushcart or mobile food unit complies with these Rules.

(b) ~~The written approval permit shall be in the possession of the person operating~~ posted on the pushcart or mobile food unit. Grade cards shall not be posted.

(c) The local health department which issues ~~approval~~ the permit shall be provided by individuals receiving approval a list of counties and locations where each pushcart or mobile food unit will operate.

(d) Individuals receiving ~~approval~~ a permit to operate a pushcart or mobile food unit shall provide the local health department in each county in which food service operations are proposed a list of locations where they will operate. Such lists must be kept current.

(e) Prior to initiating food service operations in a particular jurisdiction, the operator of the pushcart or mobile food unit shall submit to that particular jurisdiction such carts or units for inspection or reinspection to determine compliance with this

Section.

(f) Such carts or units shall operate in conjunction with a permitted restaurant and shall report at least daily to the restaurant for supplies, cleaning, and servicing. Sanitary storage facilities shall be provided at the restaurant for storage of all supplies. The pushcart shall also be stored in a sanitary area. Water faucets used to supply water for pushcarts and mobile food units shall be protected to prevent contact with chemicals, splash and other sources of contamination. Solid waste storage and liquid waste disposal facilities must also be provided on the restaurant premises.

(g) All foods shall be obtained from approved sources and shall be handled in a manner so as to be clean, wholesome, and free from adulteration.

(h) All potentially hazardous foods shall be maintained at 45° F (7° C) or below or 140° F (60° C) or above, or as required in Rule .2609 of this Section. A metal stem-type thermometer accurate to ± 2° F. (± 1° C.) shall be available to check food temperatures.

(i) Only single-service eating and drinking utensils shall be used in serving customers. Single-service items must be properly stored and handled.

(j) All garbage and other solid waste shall be stored and disposed of in an approved manner.

(k) Employees shall be clean as to their person and foodhandling practices. Clean outer clothing and hair restraints are required.

(l) No person who has a communicable or infectious disease that can be transmitted by foods, or who is a carrier of organisms that cause such a disease, or who has a boil, infected wound, or an acute respiratory infection with cough and nasal discharge, shall work with a pushcart or mobile food unit in any capacity in which there is a likelihood of such person contaminating food or food-contact surfaces, with disease-causing organisms or transmitting the illness to other persons.

(m) All equipment and utensils shall be easily cleanable and kept clean and in good repair.

(n) The pushcart or mobile food unit shall be kept in a clean and sanitary condition and be free of flies, roaches, rodents, and other vermin.

Statutory Authority G.S. 130A-248.

.2639 SPECIFIC REQUIREMENTS FOR PUSHCARTS

(a) Only hot dogs shall be prepared, handled, or served from a pushcart granted approval prior to January 1, 1994. All pushcarts permitted after January 1, 1994 shall serve only foods which have

been prepared, pre-portioned and individually pre-wrapped at a restaurant.

(b) Food and utensils on the cart exposed to the public or to dust or insects shall be protected by glass, or otherwise, on the front, top, and ends, and exposed only as much as may be necessary to permit the handling and serving of hot dogs.

(c) Toilet facilities, lavatory facilities, and running water are not required. Single-service towels are required.

(d) The permit applicant shall provide third party documentation to the Department which demonstrates the ability of all pre-portioned, individually pre-wrapped foods placed on the pushcart to hold temperatures under conditions approximating actual use, for the time periods specified by the permit applicant.

(e) Each pre-wrapped food item shall bear the name of the restaurant at which it was prepared, the name of the food item and the time and date of preparation. The wrapper shall cover the food at all times but sealing is not required.

(f) Pre-portioned, individually pre-wrapped food that remains after the specified time period has elapsed shall not be sold for human consumption.

(g) Pushcarts shall not be provided with seating facilities.

(h) Pushcarts shall not be used for consumer self-service.

Statutory Authority G.S. 130A-248.

SECTION .2800 - SANITATION OF CHILD DAY CARE FACILITIES

.2810 SPECIFICATIONS FOR KITCHENS, BASED ON NUMBER OF CHILDREN

(a) Day Care Facilities Licensed for 6-24 Children:

- (1) Domestic kitchen equipment may be used. Domestic kitchen equipment shall include at least a two-compartment sink, dishwasher, refrigeration equipment, and cooking equipment. In lieu of a dishwasher and two-compartment sink, a three-compartment sink may be used. Day care facilities using only single-service articles shall provide at least a two-compartment sink;
- (2) A separate lavatory for handwashing is required in the kitchen. This handwashing lavatory shall be used only by foodservice personnel;
- (3) After each use, all multi-use tableware and food-contact surfaces of equipment

and utensils shall be washed and rinsed in a dishwasher or three-compartment sink. Sanitization shall then take place in the sink by immersion for at least one minute in clean, hot water at least 170°F or at least two minutes in a clean solution containing:

- (A) At least 50 parts per million of available chlorine at a temperature of at least 75°F (24°C);
- (B) At least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75°F (24°C); or
- (C) At least 200 parts per million of quaternary ammonium products and having a temperature of at least 75°F (24°C), provided that the product is labeled to show that it is effective in water having a hardness value at least equal to that of the water being used.

(b) Day Care Facilities Licensed for 25 or More Children:

- (1) Kitchen equipment requirements shall include the following:
 - (A) Commercial kitchen equipment meeting NSF (National Sanitation Foundation) standards or equivalent shall be required in day care facilities licensed for 25 or more children; however, domestic stoves may be used in day cares licensed for or serving food to 79 or fewer people.
 - (B) Commercial kitchen equipment shall include at least a three-compartment sink with drainboards, refrigeration equipment, and cooking equipment.
- (2) A separate food preparation sink with drainboard shall be provided for the washing and processing of foods except where plan review shows that volume and preparation frequency do not require separate facilities.
- (3) A separate lavatory for handwashing is required in the kitchen. This handwashing lavatory shall be used only by food service personnel.
- (4) Day care facilities using single-service utensils and not preparing food other than simple snacks, shall provide at least a two-compartment sink with drainboards, refrigeration equipment, and a separate handwashing lavatory.

(c) Equipment that was installed in a day care facility prior to the effective date of these Rules

and that does not meet all the design and fabrication requirements of this Section shall be deemed acceptable if it is in good repair, capable of being maintained in a sanitary condition, and the food-contact surfaces are nontoxic. Replacement equipment and new equipment acquired after the effective date of these Rules shall meet the requirements of this Section. Upon change of ownership, or the closing of the operation and the issuance of a new license, the day care facility shall comply with all the rules of this Section.

Statutory Authority G.S. 110-91.

Notice is hereby given in accordance with G.S. 150B-21.2 that EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 18C .0102, .0201 - .0203, .0301 - .0303, .0305, .0307 - .0308, .0401 - .0405, .0407, .0501 - .0502, .0703, .0708, .0802 - .0805, .1002, .1004, .1207, .1209, .1211, .1301 - .1303, .1406; and adopt rules cited as 15A NCAC 18C .0409, .0710 - .0715, .1537.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N.C.

Reason for Proposed Action:

15A NCAC 18C .0102 - to clarify the applicability of these Rules by adding new definitions.

15A NCAC 18C .0201 - to allow non-transient, non-community water systems to use surface water supply without filtration subject to appropriate rules.

15A NCAC 18C .0202 - to incorporate the expanded water supply watershed classification categories adopted by the Environmental Management Commission as applicable to treatment of surface water by all public water systems.

15A NCAC 18C .0203 - to increase the protection of well water supplies and include non-transient, non-community wells.

15A NCAC 18C .0301 - .0308 - to expand the applicability of the requirements for submitting

plans, specifications, and reports to include non-transient, non-community water systems.

15A NCAC 18C .0401 - to expand the applicability of the minimum design requirements for approval of plans and specifications to include non-transient, non-community water systems.

15A NCAC 18C .0402 - to increase the protection of well water supplies and clarify the yield and laboratory certification requirements.

15A NCAC 18C .0403 - to allow flexibility in the maximum daily draft of a water treatment plant from unimpounded streams and allow for existing impoundments to be approved as raw water sources.

15A NCAC 18C .0404 - to increase the protection of water treatment facilities.

15A NCAC 18C .0405 - to modify the design criteria for hydropneumatic water storage tanks.

15A NCAC 18C .0407 - to increase the protection of electrical systems.

15A NCAC 18C .0409 - to establish and clarify the limitations on service connections to public water supply systems with and without a local water supply plan.

15A NCAC 18C .0501 - to retitle the Section.

15A NCAC 18C .0502 - to expand the applicability of the supplemental design criteria to include non-transient, non-community water systems and to provide for the approval of alternate designs.

15A NCAC 18C .0703 - to delineate the design requirements for flocculator paddles.

15A NCAC 18C .0708 - to provide more detailed design requirements for gravity filters.

15A NCAC 18C .0710 - to establish the requirements for use of direct filtration.

15A NCAC 18C .0711 - to establish the requirements for use of package water treatment plants.

15A NCAC 18C .0712 - to establish the limitations and requirements for use of pressure filters.

15A NCAC 18C .0713 - to establish the requirements for use of alternative filtration technologies.

15A NCAC 18C .0714 - to establish the requirements for pilot plant studies.

15A NCAC 18C .0715 - to establish the standards for evaluation of water system design features not otherwise specifically addressed.

15A NCAC 18C .0802 - to expand the requirement for water systems to use peak demand charts to include campgrounds and non-transient, non-community systems.

15A NCAC 18C .0803 - to expand the pressure tank volume requirement to include campgrounds.

15A NCAC 18C .0804 - to remove unnecessary reference.

15A NCAC 18C .0805 - to expand the elevated storage capacity requirement to include community and non-transient, non-community water systems.

15A NCAC 18C .1002 - to clarify the requirements for disinfection of wells.

15A NCAC 18C .1004 - to provide for the disinfection of filters using an alternative to chlorine.

15A NCAC 18C .1207 - to ease the restrictions on animals in the margins of reservoirs.

15A NCAC 18C .1209 - to incorporate the expanded water supply watershed classification categories adopted by the Environmental Management Commission as applicable to protection of reservoirs.

15A NCAC 18C .1211 - to incorporate the expanded water supply watershed classification categories adopted by the Environmental Management Commission as applicable to ground absorption sewage systems.

15A NCAC 18C .1301 - to broaden the applicability of the requirements for the operator in charge from just community to all public surface water systems requiring disinfection only and to clarify information required on monthly reports.

15A NCAC 18C .1302 - to broaden the applicability of the requirements for the operator in charge from just community to all filtered public water systems, to incorporate the expanded water supply watershed classification categories adopted by the Environmental Management Commission, and to clarify information required on monthly reports.

15A NCAC 18C .1303 - to broaden the applicability of the requirements for the operator in charge to include non-transient, non-community well systems and to clarify information required on monthly reports.

15A NCAC 18C .1406 - to increase the fluoride reporting frequency from monthly to weekly.

15A NCAC 18C .1537 - to establish the standards for drinking water additives.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only

persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

Fiscal Note: 15A NCAC 18C .0203 affects the expenditures or revenues of local funds. A fiscal note was submitted to the Fiscal Research Division on August 24, 1993, OSBM on August 24, 1993, N. C. League of Municipalities on August 27, 1993, and N. C. Association of County Commissioners on August 27, 1993.

CHAPTER 18 ENVIRONMENTAL HEALTH

SUBCHAPTER 18C - WATER SUPPLIES

SECTION .0100 - PROTECTION OF PUBLIC WATER SUPPLIES

.0102 DEFINITIONS

(a) The definitions contained in G.S. 130A-2 and G.S. 130A-313 are hereby ~~adopted~~ incorporated by reference ~~in accordance with G.S. 150B-14(e)~~ including any subsequent amendments and editions. Copies of this material may be obtained from the Department of Environment, Health, and Natural Resources, Division of Environmental Health, Public Water Supply Section, P.O. Box 29536, Raleigh, North Carolina 27626-0536 at no charge.

(b) The definitions contained in 40 C.F.R. 141.2 are hereby ~~adopted~~ incorporated by reference ~~in accordance with G.S. 150B-14(e)~~ including any subsequent amendments and editions except the following definitions are not adopted:

- (1) "Disinfection",
- (2) "Maximum containment level",
- (3) "Person",
- (4) "Public Water System", and
- (5) "Supplier of water".

This material is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Environmental Health, 1330 Saint Mary's Street, Raleigh, North Carolina. Non-members may obtain copies from the American Water Works Association, Information Services, 6666 West Quincy Avenue, Denver, Colorado 80235 at a cost of fifteen dollars (\$15.00) up to 20 pages and thirty cents (\$0.30) per page for each additional page.

(c) In addition to the definitions adopted by reference, the following definitions shall apply to this Subchapter:

- (1) "Act" means the North Carolina Drinking Water Act.
- (2) "Class I reservoir" shall mean a reservoir from which water flows by gravity or is pumped directly to a treatment plant or to a small intervening storage basin and thence to a treatment plant.
- (3) "Class II reservoir" shall mean a reservoir from which the water flows by gravity or is pumped to a Class I reservoir prior to final entrance to a water treatment plant.
- (4) "Class III reservoir" is a large impoundment used for electric power generation, flood control, and similar purposes, and which also serves as a source of raw water for a community water system.
- (5) "Cross-connection" shall mean:
 - (A) any physical connection between a potable water supply system and any other piping system, sewer fixture, container, or device, whereby water or other liquids, mixtures, or substances may flow into or enter the potable water supply system;
 - (B) any potable water supply outlet which is submerged or is designed or intended to be submerged in non-potable water or in any source of contamination or;
 - (C) an air gap, providing a space between the potable water pipe outlet and the flood level rim of a receiving vessel of less than twice the diameter of the potable water pipe.
- (6) "Community Water System intake"

shall mean the structure at the head of a conduit into which water is diverted from a stream or reservoir for transmission to water treatment facilities.

- (7) "Disinfection" means a process which inactivates pathogenic organisms in water.
- (8) "Fecal Coliform" means bacteria consistently found in the intestine of man and other warm blooded animals which are not normally disease producing but serve as indicators of recent fecal contamination. They are members of the Family Enterobacteriaceae, Genus Escherichia, Species Coli.
- (9) "Mobile Home Park" means a site or tract of land where spaces are provided for lease or rental only to mobile home occupants.
- (10) "Mobile home subdivision" means a subdivided site or tract of land in which lots are sold for use by mobile home occupants.
- (9) (11) "Non-potable water supply" shall mean waters not approved for drinking or other household uses.
- (+0) (12) "Potable water supply" shall mean water which is approved for drinking or other household uses.
- (+1) (13) "Raw water" ~~means shall mean~~ surface water or groundwater which because of bacteriological quality, chemical quality, turbidity, color, or mineral content makes it unsatisfactory as a source for a community water system without treatment.
- (+2) (14) "Raw water reservoir" ~~means shall mean~~ a natural or artificial impoundment used for the primary purpose of storing raw water to be subsequently treated for use as a source for a community water system.
- (15) "Service connection" shall mean a piped connection from a water main for the purpose of conveying water to a building or onto a premise for human use. A piped connection from a water main to a travel trailer space, camping space or marina slip is not a service connection.
- (16) "Water supply product" means any chemical or substance added to a public water system in conjunction with a treatment technique or material used in construction of a public water system.

The term includes any material used in the manufacture of public water system components, appurtenances, any pipe, storage tank, valve or fixture which comes in contact with water intended for use in a public water system.

Authority G.S. 130A-311 through 130A-327; P.L. 93-523; 40 C.F.R. 141.2.

SECTION .0200 - LOCATION OF SOURCES OF PUBLIC WATER SUPPLIES

.0201 SURFACE SUPPLIES FOR PUBLIC WATER SYSTEMS

(a) A surface supply may be used for a community or a non-transient, non-community water system with disinfection and without filtration if it complies with the provisions of this Section and Rule .2005 of this Subchapter.

(b) Such water supply shall be derived from uninhabited wooded areas.

(c) The entire watershed shall be either owned or controlled by the person supplying the water or be under the control of the federal or state government; however, no such new water supply shall be created except where the water system owner shall own in its entirety the watershed from which the water will be obtained.

(d) The water after disinfection shall be of potable quality as determined by bacteriological and chemical tests performed by a certified laboratory. The presence of contaminants shall not exceed the limits set forth in Section .1500 of this Subchapter.

(e) The water source shall have an WS-I classification as established by the Environmental Management Commission and shall meet the quality standards for that classification.

Statutory Authority G.S. 130A-315; 130A-318; P.L. 93-523.

.0202 REMOVAL OF DISSOLVED MATTER AND SUSPENDED MATTER

Any surface water which is to receive treatment for removal of dissolved matter or suspended matter in order to be used for a community public water system shall be obtained from a source which meets the WS-I, WS-II, ~~or~~ WS-III, WS-IV or WS-V stream classification standards established by the Environmental Management Commission and shall be properly protected from objectionable sources of pollution as determined by a sanitary survey of the watershed made by an authorized

representative of the Department. The source supply shall be sufficient in capacity to satisfy the anticipated needs of the users for the period of design.

Statutory Authority G.S. 130A-315; 130A-318; P.L. 93-523.

.0203 PUBLIC WELL WATER SUPPLIES

Any site or sites for any water supply well to be used as a community or non-transient, non-community water system shall be investigated by an authorized representative of the Division of Environmental Health. Approval by the Division is required in addition to any approval or permit issued by any other state agency. The site shall meet the following requirements for approval:

- (1) The well shall be located on a lot so that the area within 100 feet of the well shall be owned or controlled by the person supplying the water. The supplier of water shall be able to protect the well site from potential sources of pollution and to construct landscape features for drainage and diversion of pollution. When the supplier of water is unable to locate water from any other approved source or when an existing well is temporarily out of operation, a representative of the Division may approve a smaller well lot area.
- (2) The well shall be located at least 100 feet from any sewer or other potential sources of pollution unless the sewer is constructed of materials and joints that are equivalent to water main standards, in which case the sewer shall be at least 50 feet from the well. so the movement of contaminants from potential sources of pollution shall not interfere with the quality of the drinking water source. The minimum horizontal separation between the well and potential sources of pollution shall be as follows:
 - (a) 100 feet from any sanitary sewage disposal system, sewer, or a sewer pipe unless the sewer is constructed of material and joints that are equivalent to water main standards, in which case the sewer pipe shall be at least 50 feet from the well;
 - (b) 200 feet from a subsurface sanitary sewage treatment and disposal system designed for 3000 or more gallons of wastewater a day flows, unless it is

determined that the well water source utilizes a confined aquifer;

- (c) 500 feet from a seepage disposal site;
- (d) 100 feet from buildings, mobile homes, permanent structures, animal houses or lots, or cultivated areas to which chemicals are applied;
- (e) 100 feet from surface water;
- (f) 100 feet from a chemical or petroleum fuel underground storage tank with secondary containment;
- (g) 500 feet from a chemical or petroleum fuel underground storage tank without secondary containment;
- (h) 500 feet from the boundary of a ground water contamination area;
- (i) 500 feet from a sanitary landfill or non-permitted non-hazardous solid waste disposal site;
- (j) 1000 feet from a hazardous waste disposal site or otherwise in a location which conflicts with the North Carolina Hazardous Waste Management Rules;
- (k) 300 feet from a cemetery or burial ground; and
- (l) 100 feet from any other potential source of pollution.
- (3) The Department may require greater separation distances or impose other protective measures when necessary to protect the well from pollution; the Department shall consider as follows:
 - (a) The hazard or health risk associated with the source of pollution;
 - (b) The proximity of the potential source to the well;
 - (c) The type of material, facility or circumstance that poses the source or potential source of pollution;
 - (d) The volume or size of the source or potential source of pollution;
 - (e) Hydrogeological features of the site which could affect the movement of contaminants to the source water;
 - (f) The effect which well operation might have on the movement of contamination; and
 - (g) The feasibility of providing additional separation distances or protective measures.
- (4) The site shall be graded or sloped so that surface water is diverted away from the wellhead. The site shall not be subject to flooding. Groundwater under the direct influence of surface water shall

not be approved as a source unless there is no other approvable site available.

Statutory Authority G.S. 130A-315; 130A-318; P.L. 93-523.

SECTION .0300 - SUBMISSION OF PLANS: SPECIFICATIONS: AND REPORTS

.0301 APPLICABILITY: PRIOR NOTICE

(a) All persons, including units of local government, intending to construct, alter, or expand a community or non-transient, non-community water system shall give written notice thereof, including submission of applicable plans, specifications and engineering reports, to the Division of Environmental Health, as required by the rules of this Section. A non-community water system using surface water or ground water under the direct influence of surface water shall be subject to the provisions of this Rule. An adjacent water system shall not be subject to the provisions of this Rule unless the adjacent water system is constructed, altered or expanded on or after July 31, 1987.

(b) All reports, plans and specifications shall be submitted to the Division at least 30 days prior to the date upon which action by the Division is desired.

(c) If revisions to the plans or specifications are necessary, the engineer who prepared them will be notified. Revised plans and specifications will constitute a resubmittal and additional time will be required for review.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0302 PLANS

(a) Procedure Applicable to all Projects, Extensions, or Changes. All plans, specifications or other data intended for submission to the Division of Environmental Health, ~~in compliance with the statutes covering community water systems,~~ shall be submitted in triplicate for review by the Public Water Supply Section, Division of Environmental Health, P.O. Box 29536, Raleigh, North Carolina 27626-0536.

(b) ~~Plans for Community Water Systems.~~ Plans should consist of legible prints having black, blue, or brown lines on a white background suitable for microfilming. The plans shall not be more than 36 inches wide and 48 inches long.

Statutory Authority G.S. 130A-315; 130A-317;

P.L. 93-523.

.0303 SUBMISSIONS REQUIRED BY ENGINEER AND WATER SUPPLIER

Detailed plans and specifications ~~for community water systems~~ shall be prepared by a professional engineer licensed to practice in the State of North Carolina. The plans shall bear an imprint of the registration seal of the engineer. Upon completion of the construction or modification ~~of the community water system,~~ the water supplier shall submit a statement signed by a registered professional engineer and affixed with his professional engineering seal stating that construction was completed in accordance with approved plans and specifications and revised only in accordance with the provisions of Rule .0306 of this Section. The statement shall be based upon adequate observations during and upon completion of construction by the engineer or a representative of the engineer's office who is under the engineer's supervision.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0305 APPROVAL OF PLANS NECESSARY BEFORE CONTRACTING

(a) No construction ~~of community water systems~~ shall be undertaken, and no contract for construction, alteration, or installation ~~of community water systems~~ shall be entered into prior to approval of plans and specifications by the Department.

(b) Units of local government which have an adopted water system extension policy, upon submission to and approval of a copy of their policy by the Department, may be excluded from the requirements of submitting plans and specifications for water main extensions, and that would not have adverse effect upon the existing system supply or pressure, provided the following requirements are met:

- (1) Plans and specifications for all such extensions shall be prepared by or under the direct supervision of an engineer licensed to practice in the State of North Carolina.
- (2) All plans shall be approved by the units of local government engineering department or its consulting engineers prior to the commencement of construction.
- (3) The Department shall have approved the extension policy submitted by the

unit of local government prior to construction commencing.

- (4) The extension policy submitted for review and approval by the Department shall provide for establishing ownership, operation and maintenance of water system extensions, and shall constitute prior notice of proposed construction.
- (5) Where design is to be based on a local government's standard specifications in lieu of written separate specifications for each extension project, the standard specifications shall have been previously approved by the Department.
- (6) The local government shall have obtained from the Department a letter stating they have met the aforementioned requirement and are excluded from the requirement for submitting detailed plans and specifications for each minor extension in keeping with the intent of this Rule.
- (7) Where such minor additions or extensions have been made an annual up-to-date plan of the entire system shall be submitted for review and approval by the Division.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0307 ENGINEER'S REPORT

(a) The owner, when required, shall submit to the Division, an engineering report in duplicate covering the basic factors and principles considered in planning of the project.

(b) Such engineering reports shall be required for projects involving new ~~community~~ water systems, modification of existing ~~community~~ water ~~system~~ systems, development or modification of surface water sources and other ~~community~~ water system projects requiring significant engineering.

(c) Before preparation of the engineering report, the consulting engineer may wish to consult with the office or field staff of the Division of Environmental Health concerning the proposed source of supply, treatment methods, and alternatives.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0308 TYPE AND FORM OF EXHIBITS

(a) Engineer's Report. The engineer's report

(including any preliminary plans) shall contain the following information where applicable:

- (1) description of any existing water system related to the project;
 - (2) identification of the municipality, community, ~~or~~ area, or facility to be served by the proposed water system;
 - (3) the name and address of the owner;
 - (4) a description of the nature of the establishments and of the area to be served by the proposed water system;
 - (5) provisions for future extension or expansion of the water system;
 - (6) a projection of future water demand or requirements for service;
 - (7) any alternate plans for meeting the water supply requirements of the area;
 - (8) financial considerations of the project including:
 - (A) any alternate plans;
 - (B) costs of integral units;
 - (C) total costs;
 - (D) operating expenses; and
 - (E) methods of financing costs of construction, operation and maintenance;
 - (9) population records and trends, present and anticipated future water demands, present and future yield of source or sources of water supply;
 - (10) character of source or sources of water supply, including:
 - (A) hydrological data;
 - (B) stream flow rates;
 - (C) chemical, mineral, bacteriological, and physical qualities; and
 - (D) location and nature of sources of pollution; and
 - (11) proposed water treatment processes including:
 - (A) criteria and basis of design of units,
 - (B) methods or procedures used in arriving at recommendations, and
 - (C) reasons or justifications for any deviations from conventional or indicated process or method.
- (b) Plans. Plans for water supply systems shall consist of the following:
- (1) title information including the following:
 - (A) name of the city, town, board, commission or other owner for whom the plans were prepared;
 - (B) the locality of the project;
 - (C) the general title of the set of drawings

- and prints;
- (D) the specific title of each sheet;
- (E) the date; and
- (F) the scales used;
- (2) a preliminary plat plan or map showing the location of proposed sources of water supply;
- (3) a general map of the entire water system showing layout and all pertinent topographic features;
- (4) detail map of source or sources of water supply;
- (5) layout and detail plans for intakes, dams, reservoirs, elevated storage tanks, standpipes, pumping stations, treatment plants, transmission pipelines, distribution mains, valves, and appurtenances and their relation to any existing water system, and the location of all known existing structures or installations and natural barriers that might interfere with the proposed construction; and
- (6) the north point.
- (c) Specifications. Complete detailed specifications for materials, equipment, workmanship, test procedures and specified test results shall accompany the plans. The specifications shall include, where applicable:
 - (1) the design and number of chemical feeders, mixing devices, flocculators, pumps, motors, pipes, valves, filter media, filter controls, laboratory facilities and equipment, and water quality control equipment and devices;
 - (2) provision for continuing with minimum interruption the operation of existing water supply facilities during construction of additional facilities;
 - (3) safety devices and equipment; and
 - (4) procedure for disinfection of tanks, basins, filters, wells and pipes.
- (d) A supplier of water which has submitted a local water supply plan in accordance with G.S. 143-355(1) shall also provide a copy to the Division of Environmental Health.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

SECTION .0400 - WATER SUPPLY DESIGN CRITERIA

.0401 MINIMUM REQUIREMENTS

The design criteria given in this Section are the

minimum requirements for approval of plans and specifications of ~~community water systems~~ by the Division of Environmental Health, Department of Environment, Health, and Natural Resources. The Department provides additional guidelines supplementing criteria for design of water systems in 15A NCAC 18C .0500 - .1000.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0402 WATER SUPPLY WELLS

(a) Well Construction. The construction of water supply wells shall conform to well construction regulations and standards of the Division of Environmental Management, N.C. Department of Environment, Health, and Natural Resources.

(b) Upper Terminal of Well. The well casing shall neither terminate below ground nor in a pit. The pump pedestal for above ground pumps of every water supply well shall project not less than six inches above the concrete floor of the well house, or the concrete slab surrounding the well. The well casing shall project at least one inch above the pump pedestal. For submersible pumps the casing shall project at least six inches above the concrete floor or slab surrounding the well head.

(c) Sanitary Seal. The upper terminal of the well casing shall be sealed watertight with the exception of a vent pipe or vent tube having a downward-directed, screened opening.

(d) Concrete Slab or Well House Floor. Every water supply well shall have a continuous bond concrete slab or well house concrete floor extending at least three feet horizontally around the outside of the well casing. Minimum thickness for the concrete slab or floor shall be four inches.

(e) Sample Tap and Waste Discharge Pipe. Faucets or spigots shall be provided for sampling both raw water prior to treatment and treated water prior to delivery to the first customer. Sample spigots shall not be threaded for hose connection. Threaded hose bibs shall be equipped with anti-siphon devices. A water sample tap and piping arrangement for discharge of water to waste shall be provided.

(f) Physical Security and Well Protection. A water supply well shall be secured against unauthorized access and protected from the weather. One of the following structures shall be provided:

(1) Well house. A well house shall be constructed as follows:

(A) Structures shall comply with applicable provisions of state and local build-

ing codes;

- (B) Drainage shall be provided by floor drain, wall drain, or slope to door;
- (C) Access into the structure shall be a doorway with minimum dimensions of 36 inches wide and 80 inches high; and
- (D) The structure shall have adequate space for the use and maintenance of the piping and appurtenances. If treatment is provided at the well, the provisions of Rule .0404(a) of this Section shall apply.

(2) Prefabricated structures. A prefabricated structure shall be constructed as follows:

- (A) A well-head cover shall be hinged and constructed so that it can be lifted by one person;
- (B) A locking mechanism shall be provided; and
- (C) Permanent fastening to the slab (such as with bolts) shall not be permitted.

(3) Fencing and temperature protection. Fencing and temperature protection shall be constructed as follows:

- (A) The fence height shall be a minimum of six feet;
- (B) The fence shall be constructed of chain link with locked access;
- (C) The fence shall enclose the well; hydropneumatic tank, and associated equipment;
- (D) Access shall be provided for adequate maintenance and operation; and
- (E) The well, piping, treatment equipment, and electrical controls shall be protected against freezing. Wrapping with insulation is acceptable for appurtenances such as the air vent, meter, valves, and sample taps provided they are visible and accessible. Insulation shall be jacketed.

(f) (g) Yield:

- (1) Wells shall be tested for yield and drawdown. A report or log of at least a 24-hour drawdown test to determine yield shall be submitted to the Division of Environmental Health for each well.
- (2) Wells shall be located so that the drawdown of any well will not interfere with the required yield of another well.
- (3) The combined yield of all wells of a water system shall provide in 12 hours pumping time the average daily demand

as determined in ~~Subparagraph (f)(7)~~ Rule .0409 of this Section.

(4) The capacity of the permanent pump to be installed in each well shall not exceed the yield of the well as determined by the drawdown test.

(5) A residential community water system using well water as its source of supply and designed to serve 50 or more residences or connections shall provide at least two wells. A travel trailer park or campground designed to serve 100 or more connections shall provide at least two wells. In lieu of a second well, another approved water supply source may be accepted.

(6) A totalizing meter shall be installed in the piping system from each well.

~~(7) The well or wells serving a mobile home park shall be capable of supplying an average daily demand of 250 gallons per day per connection. The well or wells serving residences shall be capable of supplying an average daily demand of 400 gallons per day per connection.~~

(g) (h) Initial Disinfection of Water Supply Well. All new wells, and wells that have been repaired or reconditioned shall be cleaned of foreign substances such as soil, grease, and oil, and then shall be disinfected. A representative sample or samples of the water (free of chlorine) shall be collected and submitted to ~~an approved~~ a certified laboratory for bacteriological analyses. After disinfection the water supply shall not be placed into service until bacteriological test results of representative water samples analyzed in ~~an approved~~ a certified laboratory are found to be satisfactory.

~~(h)~~ (i) Initial Chemical Analyses. A representative sample of water from every new water supply well shall be collected and submitted for chemical analyses to the Division of Laboratory Services or to a certified laboratory ~~approved by the Division~~. The results of the analysis must be satisfactory before the well is placed into service.

(f) (j) Continuous Disinfection. Equipment designed for continuous application of chlorine or hypochlorite solution or some other approved and equally efficient disinfectant shall be provided for all well water supplies introduced on or after January 1, 1972. Equipment for determining residual chlorine concentration in the water shall be specified.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0403 SURFACE WATER FACILITIES

(a) Unimpounded Stream. Both the minimum daily flow of record of the stream and the estimated minimum flow calculated from rainfall and run-off shall exceed the maximum daily draft for which the water treatment plant is designed with due consideration given to requirements for future expansion of the treatment plant. The Department may approve a water plant capacity greater than the minimum daily flow of record of the stream when rules of other government agencies will not be violated. The maximum allowable system expansion shall be based on the minimum daily flow of record of the stream.

(b) Pre-settling Reservoirs. Construction of a pre-settling or pre-treatment reservoir shall be required where excessive bacterial concentrations or wide and rapid variations in turbidity or chemical qualities occur.

(c) Impoundments. Raw water storage capacity shall be sufficient to reasonably satisfy the designed water supply demand during periods of drought.

(d) Clearing of Land for Impoundment. The area in and around the proposed impoundment of class I and class II reservoirs shall be cleared as follows:

- (1) The area from normal full level to five feet below the normal full level of the impoundment shall be cleared and grubbed of all vegetation and shall be kept cleared until the reservoir is filled. Secondary growth shall be removed prior to flooding. ~~A margin of at least 50 feet around the impoundment shall be owned or controlled by the water supplier.~~
- (2) The entire area below the five foot water depth shall be cleared and shall be kept cleared of all growth of less than six inches in diameter until the reservoir is filled. Stumps greater than six inches in diameter may be cut off at ground level.
- (3) All brush, trees, and stumps shall be burned or removed from the proposed reservoir.

(e) Existing Impoundments. Existing impoundments may be approved as raw water sources as follows:

- (1) The requirements of Paragraph (c) of this Rule, and Section .0200 of this

Subchapter shall be met;

- (2) A class I or class II reservoir shall meet the requirements of Section .1200 of this Subchapter; and
- (3) The supplier of water shall have an engineer and other qualified consultants as needed conduct a study of the impoundment and provide the Department information to determine whether the requirements of this Subchapter are met. The study shall include as follows:
 - (A) Plans and specifications of the impounding structure;
 - (B) Information concerning clearing of the land for impoundment as provided in Paragraph (d) of this Rule;
 - (C) Information concerning sources of pollution on the watershed;
 - (D) Documentation of control by the supplier of water of the impoundment and 50 foot margin around the impoundment;
 - (E) Information concerning the quality of the water and sediments which could cause water quality fluctuations such as lake stratification, turnover and algae bloom; and
 - (F) Other information necessary to show the proposed source will meet the requirements of this Subchapter.

(f) A margin of at least 50 feet around the impoundment shall be owned or controlled by the water supplier.

~~(e)~~ (g) Intakes, Pumps, Treatment Units, and Equipment. Raw water intakes, pumps, treatment units and equipment shall be designed to provide water of potable quality meeting the water quality requirements stated in Section .1500 of this Subchapter.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0404 WATER TREATMENT FACILITIES

(a) Physical Security and Facility Protection. Treatment equipment and chemicals shall be secured against unauthorized access and shall be protected against the weather as follows:

- (1) Structures shall comply with provisions of state and local building codes;
- (2) Drainage shall be provided by floor drain, wall drain, or slope to door;
- (3) Access to the structure shall be a doorway with minimum dimensions of 36

inches wide and 80 inches high or larger. The doorway shall be large enough to accommodate installation or removal of equipment; and

- (4) The structure shall have space to facilitate operation and maintenance of treatment equipment, storage of chemicals, required piping and appurtenances, electrical controls, and laboratory testing. Space shall be provided for anticipated future equipment.

(b) Mixing and Dispersion of Chemicals. Provisions shall be made for ~~adequate~~ mixing and dispersion of chlorine and other chemicals applied to the water. There shall be provided a minimum of 20 minutes chlorine contact time prior to pumping the water to the distribution system. All facilities treating surface water or ground water influenced by surface water shall comply with the disinfection requirements in Section .2002 of this Subchapter.

~~(b)~~ (c) Chemical Feed Machines

- (1) Durable chemical feed machines designed for adjustable accurate control of feed rates shall be installed for application of all chemicals necessary for appropriate treatment of the water. Chemical pretreatment using coagulant chemicals is required prior to filtration by granular filter media. Sufficient stand-by units to assure uninterrupted operation of the treatment processes shall be provided. Continuous chemical application must be protected from electrical circuit interruption which could result in overfeed.

- (2) Chemical feed lines from the feeders to the points of application shall be of durable material, adequate in size, corrosion resistant, easily accessible for cleaning and protected against freezing. Excessive length shall be avoided and the number of bends reduced to a minimum.

- (3) Piping and appurtenances shall be constructed of suitable material for the chemical being added and the specific application.

~~(e)~~ (d) Disinfection Equipment

- (1) Equipment designed for application of chlorine, or some other approved, equally efficient disinfectant shall be provided. Stand-by units shall be provided. The plans and specifications shall describe the equipment in detail.

- (2) Chlorinators shall be installed in tightly constructed, above ground rooms with adequate mechanical ventilation to the outside air. The capacity of exhaust fans shall be sufficient to discharge all air in the rooms every 30 seconds to 1 minute. The fans or their suction ducts shall be located not more than eight inches above floor level. Provisions for entrance of fresh air shall be made. The point of discharge shall be so located as not to contaminate the air in any building or inhabited areas. Electrical switches for operation of fans shall be located outside the chlorinator rooms. Rooms used for storage of chlorine cylinders shall be designed as described above.

~~(d)~~ (e) Safety Breathing Apparatus. ~~Emergency~~ Self-contained emergency breathing equipment for operators shall be stored outside rooms where chlorine is used or stored.

~~(e)~~ (f) Meters and Gauges. Meters and gauges, including raw and finished water meters, shall be installed to indicate and record water flow entering the treatment plant and water pumped or conducted to the distribution system.

~~(f)~~ (g) Prevention of Backflow and Back-Siphonage. Submerged inlets and interconnections whereby non-potable water, or water of questionable quality, or other liquids may be siphoned or forced into or otherwise allowed to enter the finished water supply shall not be permitted.

~~(g)~~ (h) Chemical Storage. Separate space for storing at least 30 days supply of chemicals shall be provided. A separate room or partitioned space shall be provided for storage of dry fluoride chemicals or liquid fluoride chemicals in portable containers.

~~(h)~~ (i) Laboratory. Adequate space, equipment, and supplies shall be provided for daily, routine chemical and bacteriological tests. A layout of laboratory furniture and equipment shall be included in the plans.

~~(i)~~ (j) Toilet Facilities. Adequate toilet facilities shall be provided for the plant personnel.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0405 STORAGE OF FINISHED WATER

(a) Ground Level Storage

- (1) Water Ground Storage Tank. Finished water ground storage tanks shall be provided with a light-proof and

insect-proof cover of concrete, steel or other material approved by the Division. The construction joints between side walls and the covers of concrete tanks or reservoirs shall be above ground level and above flood level; except that clearwells constructed below filters may be excepted from this requirement when total design, including waterproof joints, gives equal protection.

- (2) **Access Manholes.** The access manholes for finished water storage tanks or reservoirs shall be framed at least four inches above the tank or reservoir covers at the opening and shall be fitted with solid covers of durable materials that overlap the framed openings and extend down around the frames at least two inches. The covers for the openings shall be hinged at one side and fitted with a locking device.
- (3) **Tanks or Reservoirs.** The tanks or reservoirs shall have vents with screened, downward directed openings. The vent and screen shall be of corrosion resistant, durable material.
- (4) **Overflow.** The overflow pipes for storage tanks or reservoirs shall not be connected directly to sewers or storm drains. Screens or other devices to prevent access by rodents, insects, etc. should be provided in the overflow pipe.
- (5) **Inlets and Outlets.** Water supply inlets and outlets of storage tanks and reservoirs shall be located and designed to provide adequate circulation of the water. Baffles shall be constructed where necessary to provide thorough circulation of the water.
- (6) **Drain Valves.** All tanks and reservoirs shall be equipped with drain valves.
- (b) **Elevated Storage Tanks**
 - (1) **Standards.** The specifications for elevated tanks, stand-pipes, towers, paints, coatings and other appurtenances shall meet the appropriate ANSI/AWWA Standards D 100-73, 84 and D 101-53(R86), and D 102-64 of the American Water Works Association, Inc., which is adopted are hereby incorporated by reference including any subsequent amendments and editions.

This material is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Environmental Health, 1330 Saint Mary's Street, Raleigh, North Carolina, in accordance with G.S. 150B-14(e) or approved equal standards. Copies of AWWA standards are available from Non-members may obtain copies from the American Water Works Association, 6666 W. Quincy Avenue, Denver, Colorado 80235 at a cost of eighteen dollars and fifty cents (\$18.50) for D 100-84 and nine dollars (\$9.00) for D 101-53(R86). Copies are available for public inspection at the principal address of the Division.

- (2) **Elevation of Storage Tanks.** The elevation of storage tanks shall be sufficient to produce a designed minimum distribution system pressure of 20 pounds per square inch at peak flow.
- (3) **Drain.** Elevated storage tanks shall be equipped with drain valves.
- (c) **Hydropneumatic Storage Tanks (Pressure Tanks)**
 - (1) **Use of Pressure Tanks.** Where well yields and pumping capacities are sufficient, hydropneumatic (pressure) tanks may be used to control pumps, stabilize pressures and provide a minimum of storage. Pressure tanks shall have the capacity to maintain a minimum pressure of 30 pounds per square inch throughout periods of peak flow. Pressure tanks shall not be considered acceptable for meeting total storage requirements for water systems of over 300 connections, except as provided in Rule .0405(d) of this Section.
 - (2) **Corrosion Control.** Pressure tanks shall be galvanized after fabrication, provided with an approved liner or coated in accordance with ~~AWWA Standard D 102-64 of the American Water Works Association, Inc., which is adopted by reference in accordance with G.S. 150B-14(e) or approved equal standard.~~ Copies of AWWA standards are available from the American Water Works Association, 6666 W. Quincy Avenue, Denver, Colorado 80235. Copies are available for public inspection at the principal address of the Division Rule .1537 of this

Subchapter.

- (3) Required Parts. Pressure tanks shall have access manholes, bottom drains, pressure gauges, and properly sized safety and vacuum relief valves.
- (4) Controls. Automatic pressure, start-stop controls for operation of pumps shall be provided.
- (5) Hydropneumatic Storage Tanks. Hydropneumatic storage tanks shall conform to the construction requirements for pressure vessels adopted by the North Carolina Department of Labor and codified in 13 NCAC 13 which is adopted by reference in accordance with G.S. 150B-14(c). Copies of the rules are available from the Boiler and Pressure Vessel Division, North Carolina Department of Labor, 214 West Jones Street, Raleigh, N.C. 27603.
- (6) Appurtenances to hydropneumatic storage tanks such as valves, drains, gauges, sight tubes, safety devices, air-water volume controls, and chemical feed lines shall be protected against freezing.

(d) High Yield Aquifers

- (1) Equipment. In lieu of providing elevated storage for systems over 300 connections in areas where aquifers are known to produce high yields, i.e., 400-500 gpm from an eight-inch well, a system of extra well pumping capacity, auxiliary power generating equipment, hydropneumatic tanks, controls, alarms and monitoring systems may be provided. The design and installation of such system shall assure that reliable, continuous service is provided.
- (2) Auxiliary Power. Such a system shall have an adequate number of wells equipped with sufficient pumping capacity so that the required flow rate can be maintained with the single largest capacity well and pump out of operation. Auxiliary power generating equipment shall be provided for each well sufficient to operate the pump, lights, controls, chemical feeders, alarms and other electrical equipment as may be necessary.
- (3) Pump Control. Hydropneumatic tanks designed in accordance with Paragraph

(c) of this Rule and Section .0800 of this Subchapter shall be provided to maintain pressure and control the pump operation.

- (4) Alarm System. An alarm system shall be provided which will send a visual or audible signal to a constantly monitored location so that the water system operator will be advised of a primary power failure.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0407 ELECTRICAL SYSTEMS

Electrical wiring and equipment shall comply with applicable provisions of the national, state, and local electrical codes. Protection against moisture and overheating shall be provided.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0409 SERVICE CONNECTIONS

(a) Local Water Supply Plan. Units of local government which are operating under a local water supply plan in accordance with G.S. 143-355(1) shall not be limited in the number of service connections.

(b) No local water supply plan. A public water system which does not have a local water supply plan as stated in Paragraph (a) of this Rule shall limit its number of service connections as follows:

- (1) A public water system serving one type of service connection shall meet the minimum daily flow requirements specified in Table 1:

Table 1: Minimum Daily Flow Requirements

<u>Type of Service Connection</u>	<u>Daily Flow for Design</u>
<u>Residential</u>	<u>400 gallon/connection</u>
<u>Mobile Home Parks</u>	<u>250 gallon/connection</u>
<u>Campgrounds and Travel Trailer Parks</u>	<u>120 gallon/space</u>
<u>Marina</u>	<u>10 gallon/boat slip</u>
<u>Marina with bathhouse</u>	<u>30 gallon/boat slip</u>
<u>Rest Homes and Nursing Homes</u>	
<u>with laundry</u>	<u>120 gallon/bed</u>
<u>without laundry</u>	<u>60 gallon/bed</u>
<u>Schools</u>	<u>15 gallon/student</u>
<u>Day Care Facilities</u>	<u>15 gallon/student</u>
<u>Construction, work, or summer camps</u>	<u>60 gallon/person</u>
<u>Business, office, factory (exclusive of industrial use)</u>	
<u>without showers</u>	<u>25 gallons/person/shift</u>
<u>with showers</u>	<u>35 gallon/person/shift</u>
<u>Hospitals</u>	<u>300 gallon/bed</u>

- (2) A public water system serving different types of service connections shall meet the maximum daily demand calculated as follows:
- (A) Where records of the previous year are available that reflect daily usage, the average of the two highest consecutive days of record of the water treated shall be the value used to determine if there is capacity to serve additional service connections (unusual events such as massive line breaks or line flushings shall not be considered).
- (B) Where complete daily records of water treated are not available, the public water system shall multiply the daily average use based on the amount of water treated during the previous year of record by the appropriate factor to determine maximum daily demand, as follows:
- (i) A system serving a population of 10,000 or less shall multiply the daily average use by 2.5;
or
(ii) A system serving a population greater than 10,000 shall multiply the daily average use by 2.0.

Statutory Authority G.S. 130A-315; 103A-317; P.L. 93-523.

SECTION .0500 - SUPPLEMENTAL DESIGN CRITERIA

.0501 PURPOSE

For the protection of the public health, and pursuant to authority granted by Article 10 of Chapter 130A of the General Statutes of North Carolina, the Commission for Health Services hereby adopts the following rules (15A NCAC 18C .0500 through .1000) governing the location of sources of supply of community water systems, the design and construction of community water systems, the operation of community water sys-

~~tems, and the protection of community water systems as supplemental design criteria for approval of plans and specifications.~~

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0502 DESIGN GUIDELINES

~~These design guidelines are intended to supplement the mandatory criteria established in the rules providing for the protection of community water systems (15A NCAC 18C) as adopted by the Commission for Health Services, and are to be~~

used as recommended guidelines in the preparation of plans and specifications for community water systems.

Community and non-transient, non-community water systems and non-community water systems using surface water or ground water under the influence of surface water shall comply with these supplemental design criteria unless alternate design proposals are approved by the Department. The Department shall consider the following factors in approving an alternate design:

- (1) The potential health risk of using the alternate design;
- (2) The need for deviation from the supplemental design criteria;
- (3) The degree of deviation from the supplemental design criteria; and
- (4) The capability of the alternate design to meet the maximum contaminant levels, treatment techniques and other requirements of this Subchapter.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

SECTION .0700 - SURFACE WATER TREATMENT FACILITIES

.0703 MECHANICAL FLOCCULATION

(a) Basin Inlet and Outlet. The design of inlets and outlets of flocculation basins shall prevent short circuiting of the water and destruction or deterioration of the floc.

(b) Detention Period. The flocculation basins should have a theoretical detention period of not less than 20 minutes.

(c) Agitator Control. The agitators of flocculation basins shall be equipped with variable speed controls.

(d) Paddles. Peripheral speed and paddle configuration shall be designed to obtain optimum velocity gradient.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0708 GRAVITY FILTERS

(a) Filtration Rates. The standard rate of filtration for a single media filter shall be two gallons per minute per square foot. Higher filtration rates up to four gallons per minute per square foot may be approved for dual media or multi-media filters. Filtration rates in excess of four gallons per minute per square foot may be approved subject to pilot plant or plant scale demonstrations conducted in

accordance with Rule .0714 of this Section.

(b) Wash Water Rate. The backwash rate of flow shall be designed to theoretically expand the filter media 50 percent.

(c) Rate Control Devices. Rate control equipment shall be provided to control or regulate the filtration rate and the backwash rate. If declining rate filtration is to be utilized, orifice plates shall be installed on each filter effluent pipe to control maximum filtration rates.

(d) Surface Washers. Filter beds shall be equipped with a revolving or fixed system of nozzles designed for ~~uniform waterjet~~ agitation of the entire beds.

(e) Gauges and Flow Indicators. Gauges or meters shall be installed to indicate the rate of filtration, the loss of head, and backwash rate for every filter.

(f) Filter Media:

- (1) Filter Sand. Filter sand shall be clean silica sand having:
 - (+) (A) an effective size of 0.35 mm to 0.55 mm,
 - (2) (B) a uniformity coefficient of not more than 1.70,
 - (3) (C) a dust content (passing 150 mesh Tyler) less than 0.5 percent, and
 - (4) (D) a depth of at least 24 inches and generally not more than 30 inches.
- (g) (2) Anthracite Filter Media. If anthracite coal is used as a single filter media, it shall have an effective size of 0.35 mm to 0.55 mm and a uniformity coefficient of 1.70 or less. Minimum depth of the media shall be 24 inches.
- (h) (3) Dual Media or Multi-media Filters. Dual media and mixed media filter beds may have a wider range of gradation than single media beds. Particle sizes may range from 0.15 mm to 1.2 mm within the beds. Influent water quality shall be considered in specifying particle sizes of mixed media beds. The minimum depth of the filter media ~~should shall~~ be 24 inches.

(i) (g) Supporting Media and Underdrain System. The underdrain system and layers of gravel or other media supporting the filter media shall be designed to provide uniform filtration and uniform backwash throughout the filter media.

(j) (h) Wash Water Troughs Elevation. The elevation of the bottom of the wash water troughs for new installations shall be above the maximum level of the expanded media during washing at the normal design wash water rate. The elevation of

the top of the wash water troughs shall provide a two-inch freeboard above the expanded media at the maximum rate of wash.

(*) (i) Turbidity Monitoring. Turbidimeters employing the nephelometric method, or measurement of the intensity of scattered light, ~~should~~ shall be provided for the continuous determination of the turbidities of filtered water from each filter unit.

(*) (j) Sampling Tap. A tap shall be installed for convenient sampling of the effluent from each filter.

(k) Multiple Filter Units. Two or more filter units shall be provided such that the average daily demand can be satisfied at the approved filtration rate with one filter removed from service.

(l) Structural Design. Filters shall have vertical walls with no protrusions or curvature. Floors of filter rooms shall be designed to prevent flooding or spillage into filters through provisions of over-flow drainage and a minimum of four inch curbs around the filters.

(m) Filter to Waste. All filters shall have provisions for filtering to waste with backflow prevention.

(n) Backwash Pump. Backwash capacity to ensure thorough cleaning of the filters shall be provided.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0710 DIRECT FILTRATION

Treatment plants which use direct filtration may be approved to treat high quality source water. An engineering report shall be submitted to the Department and shall include data and information to substantiate source water quality characteristics as follows:

- (1) The source water shall have constant low levels of microbiological organisms, turbidity, suspended matter and other contaminants, based on maximum contaminant levels set in this Subchapter;
- (2) The source water shall be derived from WS-I or WS-II watersheds; and
- (3) A pilot plant study shall be conducted in accordance with Rule .0714 of this Section.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0711 PACKAGE PLANTS

- (a) Package plants which use conventional

filtration treatment may be approved to treat high quality source waters. An engineering report shall be submitted to the Department and shall include data to substantiate the water quality characteristics as follows:

- (1) The source waters shall have low levels of microorganisms, turbidity, suspended matter and other contaminants, based on the maximum contaminant levels set in this Subchapter;
- (2) Raw water quality parameters shall not fluctuate;
- (3) The watershed shall be free of pollution sources and potential for contaminant spills;
- (4) The flocculation process shall have a minimum of 20 minutes theoretical detention time;
- (5) The sedimentation compartment shall utilize tube, settlers, plates or equivalent settling enhancement mechanisms and have a minimum 30 minutes detention time; and
- (6) The filter media shall be a minimum of 24 inches in depth and consist of dual or multi-media.

(b) Where a package plant incorporates flocculation and sedimentation into one process and complies with Subparagraph (a)(1), (2), and (6) of this Rule, a pilot plant study shall be conducted on the proposed raw water supply in accordance with Rule .0714 of this Section.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

.0712 PRESSURE FILTERS

Pressure filters shall not be used in treatment of surface waters. Pressure filters may be approved for treatment of groundwater under the influence of surface water under the following conditions:

- (1) Design standards for gravity filters in Rule .0708 of this Section shall apply;
- (2) Overall plant design shall comply with Rule .0404 of this Subchapter;
- (3) Special design or operational features or modifications shall be provided when needed due to water quality or design of the proposed filter; and
- (4) When necessary to demonstrate effective treatment of the water source by the proposed filter, a pilot plant study shall be conducted in accordance with Rule .0714 of this Section.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0713 OTHER FILTRATION TECHNOLOGIES

A public water system may propose an alternative filtration technology as provided in Rule .2003 of this Subchapter. If the Department determines that the proposed plant employs treatment techniques that are consistent with this Subchapter, a pilot study shall be conducted in accordance with Rule .0714 of this Section. If the pilot study demonstrates to the Department that the proposed plant can consistently produce water which complies with all requirements of this Subchapter, detailed engineering plans and specifications for the proposed plant and appurtenances shall be presented to the Department for review and approval prior to construction.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0714 PILOT PLANT STUDIES

(a) A pilot plant study proposal shall be submitted to the Department for approval before the study is conducted. The following conditions shall apply:

- (1) An engineering report shall describe the proposed study and shall include the information and data to justify use of the particular plant to treat the source water;
- (2) The proposed plant shall employ treatment techniques that are consistent with this Subchapter;
- (3) The pilot plant shall be of the same design and operation as the proposed plant;
- (4) A protocol for conducting the study shall be submitted which includes the duration, testing procedures, reporting procedures, plant scale and other factors which affect the proposed plant operation; and
- (5) The study shall be conducted over a time sufficient to treat all worst case source water conditions expected through the year.

(b) Pilot plant finished water shall not be introduced to a public water system.

(c) When the proposed plant or pilot plant has been tested extensively under worst case conditions on similar water and achieved 2.0 log removal of *Giardia* cysts and a maximum of 0.5 NTU turbidity

levels 95 percent of the time in filtered effluent, the particular model plant may be proposed without on-site testing.

(d) The pilot plant shall comply with the provisions of Section .0200 of this Subchapter.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0715 OTHER DESIGN STANDARDS

In evaluation of water systems or water system design features not addressed in this Rule, the Department shall apply standards from the American Water Works Association or Recommended Standards for Water Works of 10 states and Ontario. A copy is available for inspection at the Public Water Supply Section, 1330 St. Mary's Street, Raleigh, North Carolina.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

SECTION .0800 - HYDROPNEUMATIC STORAGE TANKS

.0802 CAPACITIES: DETERMINING PEAK DEMAND

There are charts available from the Plan Review Branch, Public Water Supply Section, Division of Environmental Health, which shall be used to determine the peak demand for residential communities, and mobile home parks, campgrounds, and non-transient, non-community water systems.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0803 CAPACITIES: DETERMINING TOTAL VOLUME

The total volume of the pressure tank shall be calculated by using the principle of Boyle's Law or by using the curves indicating air-water volume relationships available from the Plan Review Branch, Public Water Supply Section, Division of Environmental Health. The total volume (gallons) shall be not less than 25 times the number of connections or 500 gallons, whichever is greater for a mobile home park. In the case of a residential community (community water system) the total volume shall not be less than 40 times the number of connections or 500 gallons, whichever is greater. In the case of campgrounds, the total volume shall not be less than 10 times the number of connections or 500 gallons, whichever is greater.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

**.0804 CAPACITIES: GROUND STORAGE
PLUS HYDROPNEUMATIC TANKS**

When ground level storage tanks and high-service pumps are to be used, hydropneumatic tanks shall be sized in relation to peak demand and the high-service pump capacity ~~in accordance with the procedures outlined in .0801 to .0803 of this Section.~~

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.0805 CAPACITIES: ELEVATED STORAGE

(a) Where feasible, elevated storage capacity should meet the requirements of Fire Insurance Rating Bureau.

(b) The minimum capacity of elevated storage in a small municipality ~~should~~ shall be 75,000 gallons or a one-day supply, whichever is greater.

(c) The elevated storage for a large municipality ~~should~~ shall be sufficient to minimize the effect of fluctuating demand plus provide a reasonable reserve for fire protection. The combined elevated and ground storage of finished water ~~should~~ shall be at least one day's supply.

(d) In the case of community and non-transient, non-community water systems, the combined elevated and ground storage of the finished water shall be at least one-half days supply except that the provisions of Paragraphs (a), (b), and (c) of this Rule shall apply when these storage requirements are greater.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

**SECTION .1000 - DISINFECTION OF
WATER SUPPLY SYSTEMS**

.1002 DISINFECTION OF WELLS

(a) After water supply wells have been cleaned of foreign substances, including sediment, grease and oil, the wells shall be disinfected by the addition of chlorine solution in concentrations sufficient to produce a chlorine residual of at least 50 milligrams per liter (or ppm) in the entire water column within the well casing.

(b) The chlorine solution shall remain in the well for a period of 24 hours. ~~Then the~~ The well shall then be pumped until the water is free of chlorine.

(c) A representative sample or samples of the

water shall be collected and analyzed by a certified laboratory. If bacteriological tests indicate that the water is satisfactory, the well may be placed in service.

Statutory Authority G.S. 130A-315; 130A-317;
P.L. 93-523.

.1004 DISINFECTION OF FILTERS

(a) After filters have been thoroughly backwashed to remove dust, silt and other foreign matter the entire filter (including filter media, supporting material and underdrain system) shall be disinfected by application of a chlorine solution having a concentration of at least 50 milligrams per liter (or ppm).

(b) The solution shall be dispersed throughout the filter bed and remain in contact for a period of at least 24 hours.

(c) For treatment equipment that cannot tolerate chlorine, alternate disinfection procedures as recommended by the equipment manufacturer shall be reviewed by the Department.

Statutory Authority G.S. 130A-315; 130A-317; P.L. 93-523.

**SECTION .1200 - PROTECTION OF
FILTERED WATER SUPPLIES**

.1207 ANIMALS IN RESERVOIR

The watering, washing or wallowing of any horses, mules, cattle, or domestic animals shall not be permitted in or along the margin of any class I or class II reservoir. Domestic or farm animals shall be restrained from access to an area within 50 feet of the reservoir at normal full level unless each animal is under direct supervision and each activity involving animals is under the control and supervision of the supplier of water. The supplier of water shall ensure such activities do not adversely affect the drinking water supply.

Statutory Authority G.S. 130A-315; 130A-320;
P.L. 93-523.

**.1209 UNTREATED DOMESTIC SEWAGE
OR INDUSTRIAL WASTES**

No treated or untreated domestic sewage, treated or untreated industrial waste or by-products shall be stored on the watershed of or discharged into any public water supply reservoir or stream tributary to that reservoir whose waters are classified as WS-I. No untreated domestic sewage or industrial waste by-products shall be discharged

into any public water supply reservoir or stream classified as WS-II, ~~or~~ WS-III, WS-IV, or WS-V. No hazardous waste, industrial by-products, treated or untreated domestic sewage shall be stored in the watershed of a Class I or Class II water supply reservoir, without the approval of the Division. No hazardous waste or industrial by-products shall be stored in the watershed of a ~~Class WS-II, or Class WS-III, WS-IV, or WS-V~~ stream unless precautions are taken to prevent its being spilled into or otherwise entering the raw water supply. No wastewater treatment plant effluent shall be discharged into any public water supply reservoir or stream classified as WS-II, ~~or~~ WS-III, WS-IV, or WS-V without the approval of the Division.

Statutory Authority G.S. 130A-315; 130A-320; P.L. 93-523.

.1211 GROUND ABSORPTION SEWAGE COLLECTION: TREATMENT/DISP SYSTEMS

(a) No facility, including but not limited to a residence, mobile home, mobile home park, multi-unit building or dwelling, place of business or place of public assembly on a lot located on a watershed of a class I or class II reservoir or on the watershed of the portion of a stream classified as WS-I, WS-II, ~~or~~ WS-III, WS-IV, or WS-V extending from a class I reservoir to a downstream intake of a water purification plant shall use a ground absorption sewage disposal system unless all of the following criteria are met:

- (1) The lot includes at least 40,000 square feet, except as provided in Subparagraphs (a)(2) and (a)(3);
- (2) The lot shall include enough total area to equal an average of 40,000 square feet per residential dwelling unit for a multiple unit residential building or mobile home park;
- (3) The lot shall include enough total area to equal an average of 40,000 square feet for each business within a multiple unit place of business or place of public assembly;
- (4) The lot for any business or place of public assembly for which the anticipated wastewater generated exceeds 1250 gallons per day will require an additional 40,000 square feet of area ~~for~~ per each additional 1250 gallons per day or portion thereof. The anticipated wastewater generated shall

be determined in accordance with 15A NCAC 18A .1949;

- (5) The lot size requirement shall be determined by excluding streets; and
- (6) Compliance with all other applicable state and local rules and laws is achieved.

(b) The Director of the Division or his authorized representative, shall have authority, when special local factors permit or require it in order to protect the public health adequately and to ensure proper health and sanitary conditions, to increase the lot size requirements in particular cases upon a determination based on any of the following factors:

- (1) size of the reservoirs;
- (2) quantities and characteristics of the wastes;
- (3) type of business, use, or activity;
- (4) coverage of lot area by structures, parking lots and other improvements; and
- (5) type and location of the water supply.

(c) The requirements of this Rule do not apply to those portions of a water supply reservoir watershed which are drained by class B or class C streams. These requirements become effective whenever funds have been appropriated either for purchase of land or for construction of a class I or class II reservoir.

(d) The requirements of this Rule do not apply to water supply reservoir watersheds which are protected by the Water Supply Watershed Protection Act G.S. 143-214.5.

Statutory Authority G.S. 130A-315; 130A-320; P.L. 93-523.

SECTION .1300 - VARIANCES AND EXEMPTIONS

.1301 OPERATION REQUIRING DISINFECTION ONLY

(a) Operator in Charge. The operator in charge of a ~~community~~ public surface water system requiring disinfection shall be capable of computing chlorine dosages and other chemical dosages that may be applied to the water. The operator shall be familiar with the entire water system, including pipelines, chlorinators and other appurtenances pertaining to the operation of the entire system. The operator shall hold a valid certificate issued by the North Carolina Water Treatment Facility Operators Certification Board.

(b) Tests; Reports. The operator shall make

adequate residual chlorine tests and other applicable tests at least daily and shall report the results of the tests to the Public Water Supply Section in a monthly report ~~which shall include pertinent information required on forms provided~~ by the Department. Copies of this report form indicating the required information may be obtained from the Public Water Supply Section. A copy of each monthly report shall be submitted by the tenth day of the following month to the Public Water Supply Section.

Statutory Authority G.S. 130A-315; 90A-29; P.L. 93-523.

.1302 OPERATION OF FILTERED PUBLIC WATER SYSTEMS

(a) Operator in Charge. The person in responsible charge of operation of a ~~community public~~ water system filtration plant where raw water is obtained from a class WS-I, WS-II, ~~or~~ WS-III, WS-IV, or WS-V stream as classified by the Division of ~~environmental management~~ Environmental Management and removal of dissolved matter or suspended matter is required shall hold an appropriate valid certificate issued by the North Carolina Water Treatment Facility Operators Certification Board.

(b) Tests; Forms. Adequate bacteriological and chemical tests and analysis of the water shall be made at least daily when the plant is operating and shall be reported to the Public Water Supply Section, in a monthly report ~~which shall include pertinent information required on forms provided~~ by the Department. Copies of report forms indicating the required information may be obtained from the Public Water Supply Section. A copy of each monthly report shall be submitted by the tenth day of the following month to the Public Water Supply Section.

(c) Operation. An operator shall be on duty at the treatment facility whenever the treatment facility is in operation.

Statutory Authority G.S. 130A-315; 90A-29; P.L. 93-523.

.1303 OPERATION OF PUBLIC WATER SYSTEM WELLS

(a) Operator in Charge. The operator of a community and non-transient, non-community water system well shall be capable of computing chlorine dosages and other chemical dosages which are applied to the water when such treatment is required. The operator shall be familiar with the

entire water system, including pipelines, pumps, chlorinators, and other appurtenances pertaining to the operation of the entire water system. The operator shall hold a valid certificate issued by the North Carolina Water Treatment Facility Operators Certification Board.

(b) Tests; Forms. When application of chlorine and other chemicals are required, the operator shall make required residual chlorine tests and other tests at least daily and shall report his results to the Public Water Supply Section, in a monthly report ~~which shall include pertinent information required on forms provided~~ by the ~~Division De-~~ partment. Copies of this report form indicating the required information may be obtained from the Public Water Supply Section. A copy of each monthly report shall be submitted by the tenth day of the following month to the Public Water Supply Section.

Statutory Authority G.S. 130A-315; 90A-29; P.L. 93-523.

SECTION .1400 - FLUORIDATION OF PUBLIC WATER SUPPLIES

.1406 CONTROL OF TREATMENT PROCESS

(a) The treatment process shall result in the adjustment of fluoride ion (F) in the treated water to 1.0 mg/liter.

(b) A water treatment plant operator, having qualifications acceptable to the controlling health agencies, shall conduct the necessary chemical analyses and supervise application of the fluoride.

(c) An adequate number of samples shall be collected and analyzed from points before and after fluoridation and from one or more points in the distribution system. The minimum number of control tests and the number of check samples to be collected and submitted to the Division of Laboratory Services will be determined by the controlling health agencies in each instance.

(d) The fluoride content of the water shall be determined in accordance with either the procedure given in the latest edition of "Standard Methods for the Examination of Water and Wastewater" which is adopted by reference in accordance with G.S. 150B-14(c) or other procedures approved by the Secretary.

(e) Accurate records of the amount of fluoride applied to the water and the results of all fluoride analyses shall be recorded on forms approved by the Department and submitted to the Department ~~on or before the 15th day of the following month~~

weekly.

(f) The quality of the fluoride chemical applied to the water shall be approved by the Department. The manufacturer shall submit a certified copy of the chemical analysis of the product offered for sale. Test for the purity of the chemical shall include the U.S. Pharmacopoeia tests for heavy metals which is adopted in accordance with G.S. 150B-14(c).

Statutory Authority G.S. 130A-316.

SECTION .1500 - WATER QUALITY STANDARDS

.1537 DRINKING WATER ADDITIVES

(a) The standards set forth in American National Standards Institute/NSF International, codified at ANSI/NSF Standard 60 and ANSI/NSF Standard 61, are hereby incorporated by reference including any subsequent amendments and editions. This material is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Environmental Health, 1330 Saint Mary's Street, Raleigh, North Carolina. Copies of ANSI/NSF 60: Drinking Water Treatment Chemicals - Health Effects or ANSI/NSF 61: Drinking Water System Components - Health Effects may be obtained at a cost of forty-five dollars (\$45.00) each from NSF International, P.O. Box 130140, Ann Arbor, Michigan 48113-0140.

(b) A water supply product used in a public water system shall meet the standards incorporated by reference in Paragraph (a) of this Rule. A product certified by an organization having a third-party certification program accredited by the American National Standards Institute to test and certify such products is acceptable for use in a public water system.

(c) A supplier of water shall maintain a list of all water supply products used in a public water system for inspection by the department. Prior to using a product not previously listed, a supplier of water shall either determine the product is certified as required by Paragraph (b) of this Rule or notify the department of the type, name and manufacturer of a product.

(d) A supplier of water shall not willfully introduce or permit the introduction of a water supply product into a public water system which does not meet the requirements of this Rule.

Statutory Authority G.S. 103A-315; P.L. 93-523.

Notice is hereby given in accordance with G.S. 150B-21.2 that EHNR - Commission for Health Services intends to amend rule cited as 15A NCAC 19A .0206.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N. C.

Reason for Proposed Action: To extend the deadline by which the designated staff member in each organization shall have successfully completed a course in infection control approved by the Department.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE

COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

**CHAPTER 19
HEALTH: EPIDEMIOLOGY**

**SUBCHAPTER 19A - COMMUNICABLE
DISEASE CONTROL**

**SECTION .0200 - CONTROL MEASURES
FOR COMMUNICABLE DISEASES**

**.0206 INFECTION CONTROL - HEALTH
CARE SETTINGS**

(a) The following definitions shall apply throughout this Rule:

- (1) "Health care organization" means hospital; clinic; physician, dentist, podiatrist, or chiropractic office; home health agency; nursing home; local health department; community health center; mental health agency; hospice; ambulatory surgical center; urgent care center; emergency room; or any other health care organization that provides clinical care.
- (2) "Invasive procedure" means entry into tissues, cavities, or organs or repair of traumatic injuries. The term includes but is not limited to the use of needles to puncture skin, vaginal and cesarean deliveries, surgery, and dental procedures during which bleeding occurs or the potential for bleeding exists.

(b) Health care workers, emergency responders, and funeral service personnel shall follow blood and body fluid precautions with all patients.

(c) Health care workers who have exudative lesions or weeping dermatitis shall refrain from handling patient care equipment and devices used in performing invasive procedures and from all direct patient care that involves the potential for contact of the patient, equipment, or devices with the lesion or dermatitis until the condition resolves.

(d) All equipment used to puncture skin, mucous membranes, or other tissues in medical, dental, or other settings must be disposed of in accordance with 15A NCAC 13B after use or sterilized prior to reuse.

(e) In order to prevent transmission of HIV and hepatitis B from health care workers to patients, each health care organization that performs

invasive procedures shall implement a written infection control policy by July 1, 1993. The health care organization shall ensure that health care workers in its employ or who have staff privileges are trained in the principles of infection control and the practices required by the policy; require and monitor compliance with the policy; and update the policy as needed to prevent transmission of HIV and hepatitis B from health care workers to patients. The health care organization shall designate a staff member to direct these activities. By ~~January 1, 1994~~, September 1, 1994 the designated staff member in each health care organization shall have successfully completed a course in infection control approved by the Department. The course shall address:

- (1) Epidemiologic principles of infectious disease;
- (2) Principles and practice of asepsis;
- (3) Sterilization, disinfection, and sanitation;
- (4) Universal blood and body fluid precautions;
- (5) Engineering controls to reduce the risk of sharp injuries;
- (6) Disposal of sharps; and
- (7) Techniques which reduce the risk of sharp injuries to health care workers.

(f) The infection control policy required by this Rule shall address the following components that are necessary to prevent transmission of HIV and hepatitis B from infected health care workers to patients:

- (1) Sterilization and disinfection, including a schedule for maintenance and microbiologic monitoring of equipment; the policy shall require documentation of maintenance and monitoring;
- (2) Sanitation of rooms and equipment, including cleaning procedures, agents, and schedules;
- (3) Accessibility of infection control devices and supplies;
- (4) Procedures to be followed in implementing 15A NCAC 19A .0202(4) and .0203(b)(3) when a health care provider or a patient has an exposure to blood or other body fluids of another person in a manner that poses a significant risk of transmission of HIV or hepatitis B.

Statutory Authority G.S. 130A-144; 130A-145.

Notice is hereby given in accordance with G.S. 150B-21.2 that EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 19A .0401, .0406, .0502.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N.C.

Reason for Proposed Action:

15A NCAC 19A.0401 - This amendment adds three requirements to the current immunization schedule:

1. a second dose of measles vaccine before entering school (K-1),
2. a second dose of measles vaccine before entering college, and
3. a three dose series of hepatitis B vaccine for all infants.

It removes one restriction by allowing children over three years of age to receive a dose of *Hemophilus influenzae, b* (Hib) vaccine.

All three changes are current recommendations of the Centers for Disease Control and Prevention (CDC), Immunizations Practices Advisory Committee (ACIP). The Immunization Branch has been requested to make these changes by the NC Pediatric and Medical Societies, but until now the resources have not been available.

The requirement of these immunizations will compliment the Immunization Branch's implementation of universal distribution of vaccine (to all providers for all children) since G.S. 130A-433 allows only the distribution of "covered vaccine" (a vaccine administered pursuant to the requirements of G.S. 130A-152).

The addition of MMR2 and hepatitis B vaccine and the inclusion of 3-5 year olds in the Hib vaccine schedule were included in calculations presented to Fiscal Management for expansion budget considerations. They represent vaccines that legislators expect will be distributed to private physicians for administration to children seen in their offices.

15A NCAC 19A .0406 - Prior to the ratification of HB 452 (G.S. 130A-153), many attorneys, health care providers and facilities have used G.S. 130A-143, that strictly regulates the confidentiality of medical records to dictate policies regarding the sharing of immunization records. This strict interpretation has created a major barrier for providers and parents, who see or present a child for his/her shots but do not know the child's immunization status, even though an immunization certificate was issued when the immunization was administered. Frequently such information would not be released via telephone. Rather the previous provider of immunizations would require a written request or a parent's in-person request for records.

To remove the strict confidentiality constraints on sharing immunization records among providers (physicians, local health departments, etc.), G.S. 130A-153 was passed, and the Commission has been directed to define other person(s) who may need access to immunization information, in part, such as name, date and dosage administered matched with child identifiers, or in whole. Schools (K-12); day-care facilities; colleges; universities; residential and day camps; hospitals, for patients; and employers are institutions that need to know immunization information.

G.S. 130A-152 requires every child to be immunized against diphtheria, tetanus, whooping cough, poliomyelitis, red measles, mumps, rubella and a type of influenza that causes meningitis. G.S. 130A-155 requires a certificate of immunization, indicating that a child has received the required immunizations, be presented to a school (K-12), day care center, college and university prior to entry. If a child is not properly immunized and does not obtain the required vaccines, suspension is required.

15A NCAC 19A .0502 - To comply with G.S. 130A - 152 and G.S. 130A - 433 and the legislative intent of the 1993 General Assembly for the purchase of vaccines for all North Carolina providers for all North Carolina children, 15A NCAC 19A .0502 is proposed for amendment. The changes to the rule include:

1. the elimination of an income qualifier, thus allowing the distribution of required vaccines to all providers for all children (universal vaccine distribution), as funds

2. permit;
removal of the requirement for local health departments to redistribute vaccines to private providers, thus placing the responsibility for distribution of state-supplied vaccine, to the expanded provider community, on the Immunization Branch;
3. setting the "reasonable fee" that a provider can charge for an immunization visit;
4. the provider's agreement to waive the administration fee if a patient is unable to pay thus further ensuring that an opportunity to immunize a child is not missed because of referral to the health department or delay until the family can raise the money; and
5. expanding the flexibility regarding signing of separate vaccine Important Information Statements, thus eliminating some paper required for filing in the patients's chart.

North Carolina's preschool age-appropriate immunization rates are abysmally low, at 58.7 percent. A partial explanation for the underimmunization of preschoolers has to do with the decrease of private providers' participation in the immunization effort, over the past decade. Private providers have multiple opportunities to immunize many of the children in the state. However, over 90 percent of North Carolina physicians who participated in a fall of 1992 study of North Carolina Private Physician's Immunization Practices indicate that they refer, at least some, of their patients to the local health department for their shots. A large percentage of the responding physicians responded that their reason for referral was because "the parent said they could not afford "or" the physician was concerned that the family could not afford the immunization." The referred child may never make it to the health department, thus remaining susceptible to vaccine-preventable diseases.

More families will be able to get their children's shots at physicians' offices when the vaccine cost barrier is removed as it will be when vaccine is supplied free by the State. By setting a standard administration fee, physicians will charge all parents the same amount and will have to forfeit

the fee if a parent cannot afford it.

The fee \$16.48/per visit (same amount whether one or four injections) is the same fee reimbursed to local health departments by Medicaid. It is based on a cost study performed by UNC-CH, School of Public Health. It is higher than a 1992 CDC vaccine administration cost study that indicated \$10.34/visit, but this study is 18 months old and leaves the physicians no room for price mark-up.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

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CHAPTER 19 HEALTH: EPIDEMIOLOGY

SUBCHAPTER 19A - COMMUNICABLE DISEASE CONTROL

SECTION .0400 - IMMUNIZATION

.0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

(a) Every individual in North Carolina required to be immunized pursuant to G.S. 130A-152 through 130A-157 shall be immunized against the following diseases by receiving the specified minimum doses of vaccines by the specified ages:

- (1) diphtheria, tetanus, and whooping cough -- five doses: three doses by age one year and two booster doses, one in the second year of life and the second on or after the fourth birthday and before enrolling in school (K-1) for the first time;
- (2) oral poliomyelitis vaccine--three doses of trivalent type by age two years and a booster dose of trivalent type on or after the fourth birthday and before enrolling in school (K-1) for the first time; two doses of enhanced-potency inactivated poliomyelitis vaccine may be substituted for two doses of oral poliomyelitis vaccine;
- (3) measles (rubeola) vaccine -- ~~one dose~~ two doses of live, attenuated vaccine; one dose by age two years and a second dose before enrolling in school (K-1) for the first time;
- (4) rubella vaccine -- ~~one dose~~ two doses of live, attenuated vaccine; one dose by age two years and a second dose before enrolling in school (K-1) for the first time;
- (5) mumps vaccine -- ~~one dose~~ two doses of live, attenuated vaccine; one dose by age two years and a second dose before enrolling in school (K-1) for the first time;
- (6) Hemophilus influenzae, b, conjugate vaccine -- three doses of HbOC or two doses of PRP-OMP by age one year and a booster dose of any type by the second birthday; and
- (7) hepatitis B vaccine -- three doses by age one year.

(b) Notwithstanding the requirements of Paragraph (a) of this Rule:

- (1) An individual who has attained his or her seventh birthday without having been immunized against whooping cough shall not be required to be immunized with a vaccine preparation containing whooping cough antigen.
- (2) An individual who has been documented by serologic testing to have a protec-

tive antibody titer against rubella shall not be required to receive rubella vaccine.

- (3) An individual who has been diagnosed prior to January 1, 1994, by a physician licensed to practice medicine as having measles (rubeola) disease shall not be required to receive measles vaccine.
- (4) An individual attending school who has attained his or her 18th birthday shall not be required to receive oral polio vaccine.
- (5) An individual born prior to 1957 shall not be required to receive measles vaccine. An individual who has attained his or her fiftieth birthday shall not be required to receive rubella vaccine. An individual who entered a college or university after his or her thirtieth birthday and before February 1, 1989 shall not be required to meet the requirement for rubella vaccine.
- (6) Except as provided in Subparagraph (b)(8) of this Rule, the requirements for mumps vaccine, and for booster doses of diphtheria, tetanus, and whooping cough vaccine and oral poliomyelitis vaccine, shall not apply to individuals who enrolled for the first time in the first grade before July 1, 1987.
- (7) Individuals who receive the first booster dose of diphtheria, tetanus, and whooping cough vaccine on or after the fourth birthday shall not be required to have a second booster dose. Individuals who receive the third dose of oral poliomyelitis vaccine on or after the fourth birthday shall not be required to receive a fourth dose.
- (8) Individuals attending a college or university shall be required to have three doses of diphtheria/tetanus toxoid of which one must have been within the last ten years.
- (9) Individuals born before October 1, ~~1991~~ 1988 shall not be required to be vaccinated against Hemophilus influenzae, b. Individuals who receive the first dose of Hemophilus influenzae, b, vaccine on or after 12 months of age and before 15 months of age shall be required to have only two doses of HbOC or PRP-OMP. Individuals who receive the first dose of Hemophilus

influenzae, b, vaccine on or after 15 months of age shall be required to have only one dose of any of the hemophilus influenzae conjugate vaccines, including PRP-D.

- (10) Individuals born on or after July 1, 1994 shall not be required to be vaccinated against hepatitis B.
- (11) Except as provided in Subparagraph (b) (12) of this Rule, the requirement for a second dose of measles, mumps and rubella vaccine shall not apply to individuals who enroll in school (K-1) for the first time on or before July 1, 1994.
- (12) Individuals who enroll in a college or university for the first time after July 1, 1994 shall be required to have a second dose of measles, mumps and rubella vaccine.

Statutory Authority G.S. 130A-152(c); 130A-155.1.

.0406 ACCESS TO IMMUNIZATION INFORMATION

(a) Immunization information may be released in whole or in part to anyone not specified in G.S. 130A-153 and this Rule with the written consent of the person identified or their parent, guardian, or person standing in loco parentis.

(b) Immunization information specified in Paragraph (c) of this Rule may also be obtained without consent from a physician or local health department upon request by:

- (1) schools K-12, whether public, private or religious;
- (2) licensed and registered daycare facilities as defined in G.S. 110-86(3) and G.S. ~~110-102~~ 110-101;
- (3) Head Start; and
- (4) colleges and universities, whether public, private or religious.

(c) Upon request, persons specified in Paragraph (b) of this Rule may obtain the following information without consent about each individual for whom the person is required to receive a certificate of immunization ~~is required~~ by G.S. 130A-155 and 155.1;

- (1) name and address;
- (2) name of the parent, guardian, or person standing in loco parentis;
- (3) date of birth;
- (4) gender;
- (5) race;
- (6) vaccine type, date and dose

- administered;
- (7) the name and address of the physician or health department that administered each dose; and
- (8) the existence of a medical or religious exemption determined by the Immunization Branch to meet the requirements of G.S. 130A-156 and 15A NCAC 19A .0404 or G.S. 130A-157. If such a determination has not been made by the Immunization Branch, the person shall have access to the certification of medical and religious exemptions pursuant required to by G.S. 130A-156 and or G.S. 130A-157 and 15A NCAC 19A .0404.

Statutory Authority G.S. 130A-153.

SECTION .0500 - PURCHASE AND DISTRIBUTION OF VACCINE

.0502 VACCINE FOR PROVIDERS OTHER THAN LOCAL HEALTH DEPARTMENTS

(a) The Department of Environment, Health, and Natural Resources provides vaccines required by law free of charge to the following providers for administration to individuals who need vaccines to meet the requirement of G.S. 130A-152, 130-155.1 and 15A NCAC 19A .0401:

- (1) Community, migrant, and rural health centers;
- (2) Colleges and universities for students; and
- (3) Physicians and other health care providers, ~~to administer to patients whose gross family income is less than or equal to 185 percent of the federal poverty level.~~

(b) Upon request of the Department, required vaccines ~~shall may~~ be distributed by local health departments operating as agents of the State to providers listed in Subparagraphs (a)(1), (2) and (3) of this Rule.

(c) Providers authorized in Paragraph (a) of this Rule shall be eligible to receive free vaccines from the Department only if they sign an agreement with the Department. This agreement will be prepared by the Immunization Branch and will require the provider ~~to administer such vaccines only to eligible patients~~ to;

- (1) Charge no more than sixteen dollars and forty eight cents (\$16.48) as a only a reasonable administration fee for

administration of all vaccines given at a single visit;

- (2) provide all vaccines needed during a visit unless a specific contraindication exists to one or more of the vaccines;
- (3) Charge no additional office fee for an immunization-only visit;
- (4) Agree to waive the administration fee if a patient is unable to pay;
- (5) Impose no condition as a prerequisite to receiving vaccine;
- (6) ~~to submit monthly vaccine reports on a form prepared by the Immunization Branch~~ Report in writing or electronically the name and social security number of the person to whom vaccine was administered, the date of administration, the type and dose of vaccine(s) administered and the provider number of the physician or clinic administering the vaccine to the Immunization Branch, at least monthly by the fifth day of each month;
- (7) ~~to Report adverse vaccine reactions through the Vaccine Adverse Event Reporting System (VAERS);~~
- (8) ~~to Obtain a signed Parent Patient Notification (PPN)~~ Important Information Statement (IIS), Vaccine Information Pamphlet (VIP), or a separate signature card or log sheet that contains a declarative statement specified by the Branch for each dose of vaccine administered; and to retain the signed portion for a period of 10 years following the end of the calendar year in which the form was signed, or for 10 years following the recipient's age of majority, whichever is longer; and upon request, furnish copies of the signed portion to the local health department or the Department; to Keep a record of the vaccine manufacturer, lot number, and date of administration for each dose of vaccine administered;
- (9) ~~to Allow periodic inspection of their vaccine supplies and records by the Immunization Branch; and~~
- (10) ~~to Comply with the rules of this Section.~~

(d) A provider who fails to submit timely and accurate reports, as required in Paragraph (c) of this Rule, twice in any 12 month period shall have their eligibility to receive state vaccine suspended for a period of one year. A provider who fails to

comply with any of the other requirements of this Rule may have their eligibility suspended by the Department for a period determined by the Department and may be subject to an action brought pursuant to G.S. 130A-27. All suspensions of eligibility shall be in accordance with G.S. 130A-23.

Authority S.L. 1986, c. 1008, s. 2; S.L. 1987, c. 215, s. 7; G.S. 130A-152; 130A-155.1.

* * * * *

Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 19B .0101 and .0503.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Archdale Building, Groundfloor Hearing Room, 512 N. Salisbury Street, Raleigh, NC.

Reason for Proposed Action: This allows the transition for checking calibration of instruments from 0.10 to 0.08 pursuant to Ratified House Bill 385 which changes the 0.10 DWI Law to 0.08.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

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CHAPTER 19 - HEALTH: EPIDEMIOLOGY

SUBCHAPTER 19B - INJURY CONTROL

SECTION .0100 - GENERAL POLICIES

.0101 DEFINITIONS

The definitions in G.S. 18B-101, G.S. 20-4.01, G.S. 130A-3 and the following shall apply throughout this Subchapter:

- (1) "Alcoholic Breath Simulator" shall mean a specially designed constant temperature water-alcohol solution bath instrument devised for the purpose of providing a standard alcohol-air mixture;
- (2) "Ampul" means a small bulbous glass vessel hermetically sealed containing an alcohol-sensitive reagent consisting of at least 3 ml. of a solution containing, within plus or minus 10 percent, 0.025 percent weight per volume (w/v) potassium dichromate plus 0.025 percent w/v silver nitrate in 50 percent volume per volume (v/v) sulfuric acid and distilled water;
- (3) "Breath-testing Instrument" shall mean an instrument for making a chemical analysis of breath and giving the resultant alcohol concentration in grams of alcohol per 210 liters of breath or an instrument that reports an alcohol concentration as percent blood alcohol, which shall mean grams of alcohol per 210 liters of breath;
- (4) "Controlled Drinking Program" shall mean a bona fide scientific, experimental, educational, or demonstration program in which tests of a person's breath or blood are made for the purpose of determining his alcohol concentration when such person has consumed controlled amounts of alcohol;
- (5) "Director" shall mean the Director of the Division of Epidemiology of the Department;
- (6) "Handling Alcoholic Beverages" shall mean the acquisition, transportation, keeping in possession or custody, storage, administration, and disposition of alcoholic beverages done in connection with a controlled-drinking program;
- (7) "Observation Period" means a period during which a chemical analyst observes the person to be tested to determine that he has not ingested alcohol or other fluids, regurgitated, vomited, eaten, or smoked in the 15 minutes immediately prior to the collection of a breath specimen; the chemical analyst may observe while conducting the operational procedures in using a breath-testing instrument, and if a chemical analyst other than the one conducting the analysis is the observer, both chemical analysts must sign the operational checklist;
- (8) "Permittee" shall mean a chemical analyst currently possessing a valid permit from the Department to perform chemical analyses, of the type set forth within the permit;
- (9) "Simulator Solution" shall mean a water-alcohol solution made by preparing a stock solution of 60.5 grams of alcohol per liter of solution (77.0 ml. of absolute alcohol diluted to one liter with distilled water, or equivalent ratio) and then preparing the solution for simulator use as a control sample by using either 10 ml. or 8 ml. of stock solution and further diluting the solution to 500 ml. with distilled water, which then corresponds to the equivalent alcohol concentration of 0.10; 0.10 or 0.08 respectively.
- (10) "Verification of Instrumental Calibration" shall mean verification of instrumental accuracy by employment of a control sample from an alcoholic breath simulator using solution as specified in ~~Paragraph Item~~ (9) of this Rule and obtaining a result of 0.10 or 0.09 alcohol concentration, ~~with an allowable instrumental deviation not to exceed 10 percent under 0.10 alcohol concentration. Deviations on the high side are not permitted. when using 10 ml. of stock solution or a result of 0.08 or 0.07 when using 8 ml. of stock solution.~~ When the

procedures set forth for instruments in Section .0300 of these Rules this Subchapter are followed and the result specified herein is obtained, the instrument shall be deemed properly calibrated.

Statutory Authority G.S. 20-139.1(b); 20-139.1(g).

SECTION .0500 - ALCOHOL SCREENING TEST DEVICES

.0503 APPROVED ALCOHOL SCREENING TEST DEVICES: CALIBRATION

(a) The following breath alcohol screening test devices are approved as to type and make:

- (1) ALCO-SENSOR (with two-digit display), made by Intoximeters, Inc.
- (2) ALCO-SENSOR III (with three-digit display), made by Intoximeters, Inc.
- (3) BREATH-ALCOHOL TESTER MODEL BT-3, made by RepCo., Ltd.
- (4) ALCOTEC BREATH-TESTER, made by RepCo., Ltd.
- (5) ALCO-SENSOR IV, manufactured by Intoximeters, Inc.
- (6) PBA 3000, manufactured by Life Loc, Inc.
- (7) SD-2, manufactured by CMI, Inc.

(b) Calibration of alcohol screening test devices shall be verified at least once during each 30 day period of use by employment of a control sample from an alcoholic breath simulator or an ethanol gas standard. The device shall be deemed properly calibrated when ~~the~~ a result of ~~0.09 or 0.10~~ 0.09 is obtained using 10 ml. of stock solution or when a result of 0.08 or 0.07 is obtained using 8 ml. of stock solution.

- (1) Alcoholic breath simulators used exclusively for calibration of alcohol screening test devices shall have the solution changed every 30 days or after 25 calibration tests, whichever occurs first.
- (2) Requirements of Paragraph (b) and Subparagraph (b)(1) of this Rule shall be recorded on an alcoholic breath simulator log designed by the Injury Control Section and maintained by the user agency.

Statutory Authority G.S. 20-16.3.

Notice is hereby given in accordance with G.S.

150B-21.2 that EHNR - Commission for Health Services intends to amend rule cited as 15A NCAC 19C .0102 and adopt rules cited as 15A NCAC 19C .0701 - .0703.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N.C.

Reason for Proposed Action: On July 23, 1993, the General Assembly ratified Senate Bill 533 mandating statewide reporting of occupational diseases, illnesses, and injuries. This action is proposed to implement this legislation.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE

CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 19 HEALTH: EPIDEMIOLOGY

SUBCHAPTER 19C - OCCUPATIONAL HEALTH

SECTION .0100 - GENERAL

.0102 ACTIVITIES

(a) The Occupational Health Section shall conduct programs to help obtain a safe and healthy workplace. The activities shall include at least the following:

- (1) support the North Carolina Industrial Commission in meeting the legislative mandate assigned to evaluate and control incidences of asbestosis and silicosis in dusty trades;
- (2) supply program consultation services to North Carolina employers to evaluate hazardous conditions and recommend solutions and improvements;
- (3) provide occupational health nursing consultation to industries, academia, health care and related agencies and affiliated professions;
- (4) evaluate health conditions in places of employment;
- (5) implement the Asbestos Hazard Management Program in Section .0600 of these Rules;
- (6) implement the Occupational Health Surveillance Section .0700 of these Rules.

(b) The Occupational Health Section shall also offer technical assistance to other state and federal agencies.

Statutory Authority G.S. 130A-5(3).

SECTION .0700 - OCCUPATIONAL HEALTH SURVEILLANCE

.0701 DEFINITIONS

"Elevated blood lead toxicity" means a blood lead of 25 ug/dL or greater.

Statutory Authority G.S. 130A-455.

.0702 REPORTABLE DISEASES, ILLNESSES, AND INJURIES

The following named diseases, illnesses, and injuries are declared to be dangerous to the public

health and are hereby made reportable within the time period specified after the disease, illness, and injury is diagnosed:

- (1) asbestosis - five working days;
- (2) silicosis - five working days;
- (3) elevated adult blood lead toxicity - five working days;
- (4) injuries caused by tractors, farm equipment, or farm machinery that occur while working on a farm - five working days.

Statutory Authority G.S. 130A-455; 130A-456; 130A-457; 130A-458.

.0703 METHOD OF REPORTING

(a) When a physician makes a report of a disease, illness, or injury pursuant to G.S. 130-456 or a medical facility makes such a report pursuant to G.S. 130-457, the report shall be made to the Occupational Health Section as follows:

- (1) The report shall be made on the surveillance forms provided by the Occupational Health Section and shall include the following information:
 - (A) The name, address, telephone number, date of birth, social security number, race, gender, and job title of the person;
 - (B) The name, address, telephone number, and type of business of the person's employer;
 - (C) The name of the disease, illness, or injury being reported and date of onset; and
 - (D) The name, address, and telephone number of the physician, laboratory, or medical facility.
- (2) Surveillance forms are available from the SENSOR Program, Occupational Health Section, N.C. Division of Epidemiology, P.O. Box 27687, Raleigh, N.C. 27611-7687.

(b) All laboratories that perform blood lead tests shall report to the Occupational Health Section elevated blood lead levels for adults aged 18 years of age and above. The reports of the blood lead results shall include the specimen collection date, the person's name, age, gender, race, the submitting physician's name, address, and telephone number.

Statutory Authority G.S. 130A-455; 130A-458.

Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 21A .0816 - .0818.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Archdale Building, Groundfloor Hearing Room, 512 N. Salisbury Street, Raleigh, NC.

Reason for Proposed Action: This amendment reflects legislative changes and intent and increases the maximum first year funding for projects receiving grants from the Adolescent Pregnancy Prevention Program. These changes do not require the appropriation of additional state and local funds.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

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COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 21 - HEALTH: PERSONAL HEALTH

SUBCHAPTER 21A - WOMEN'S PREVENTIVE HEALTH

SECTION .0800 - ADOLESCENT PREGNANCY PREVENTION PROJECTS

.0816 DEFINITIONS

The following definitions shall apply throughout this Subchapter:

- (1) "APPP" means the Adolescent Pregnancy Prevention Program administered by the Division of Maternal and Child Health.
- (2) "Division of MCH" means the Division of Maternal and Child Health, Department of Environment, Health, and Natural Resources.
- (3) "Contractor" means a county or district health department or other public or private agency receiving APPP Project funds.
- (4) "Adolescent" means any individual 19 years of age and under.
- (5) "Major Equipment" means any fixed asset that has a unit cost of two thousand dollars (\$2,000) or more.
- (6) "Minor Remodeling" means any building or facility reconstruction project having a total cost of two thousand dollars (\$2,000) or less.
- (7) "Primary pregnancy prevention" means prevention of first pregnancy.

Statutory Authority G.S. 130A-124; S.L. 1989, c. 752, s. 136.

.0817 GRANT PROPOSALS

(a) Grants shall be awarded through a request for proposal (RFP) process that includes notification of potential applicant agencies of the eligibility criteria and requirements for funding.

(b) Grant proposals shall include information specified in Chapter 752, Section 136, 1989 Session Laws, and other information required by the Division of MCH in the RFP.

~~(c) Grant proposals shall include the following:~~

- ~~(1) evidence of public notice and a public hearing on the proposal, held by the appropriate board or council as follows:~~

~~(A) the board of county commissioners or its designee, or~~

~~(B) the city council or its designee, if the area in which the project will operate is solely within the boundaries of a municipality; and~~

~~(2) a statement of community support for the proposal, as submitted, from the board or council that conducted the public hearing on the proposal.~~

(c) The Division of MCH, in reviewing proposals of equal merit, shall give priority to those proposals focusing on male responsibility.

(d) The Division of MCH must allocate at least 75 percent of APPP funds for projects whose main focus is primary pregnancy prevention.

Statutory Authority G.S. 130A-124; S.L. 1989, c. 752, s. 136.

.0818 MAXIMUM FUNDING LEVEL

The maximum level of funding for any one project in the first year shall be ~~sixty~~ seventy-five thousand dollars ~~(\$60,000)~~ (\$75,000).

Statutory Authority G.S. 130A-124; S.L. 1989, c. 752, s. 136.

Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNHR - Commission for Health Services intends to amend rule cited as 15A NCAC 21B .0304.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Archdale Building, Groundfloor Hearing Room, 512 N. Salisbury Street, Raleigh, NC.

Reason for Proposed Action: This amendment reflects legislative changes as per the 1993 Session of the General Assembly, Chapter 321, Senate Bill 27, Section 283, Page 211. These changes do not require the appropriation of any additional state and local funds.

Comment Procedures: All persons interested in

these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

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CHAPTER 21 - HEALTH: PERSONAL HEALTH

SUBCHAPTER 21B - MATERNAL HEALTH

SECTION .0300 - RURAL OBSTETRICAL CARE INCENTIVE FUNDS

.0304 DISBURSEMENT OF FUNDS

(a) Subject to the availability of funds, the Maternal Health Branch shall disburse rural obstetrical care incentive funds to local health departments that have submitted an approved application as follows:

- (1) first priority shall be given to those counties that meet the criteria in Rule .0302(b)(1), second priority shall be given to those counties that meet the criteria in Rule .0302(b)(2), third priority shall be given to those counties that meet the criteria in Rule

.0302(b)(3), and fourth priority shall be given to those counties that meet one or more of the criteria in Rule .0302(b)(4);

- (2) the Maternal Health Branch shall rank and disburse funds to underserved counties within each priority group according to the anticipated improvement in obstetrical coverage that will result from funding; and
- (3) Counties funded shall receive ongoing funding based upon a renewal application that has been reviewed and approved by the Maternal Health Branch.

(b) For each eligible physician with whom the local health department contracts, the health department will be paid either the difference between the physician's premiums with obstetrical care coverage and without obstetrical care coverage, or ~~six~~ seven thousand five hundred dollars (~~\$6,500~~) (\$7,500), whichever is less. Payment shall be based upon a maximum of one million / one million dollars (\$1,000,000/\$1,000,000) coverage. The local health department will then pay this amount to the physician to cover a portion of the physician's annual malpractice insurance premiums. The total payments to one physician cannot exceed the amount stated in this Paragraph.

(c) For each eligible nurse-midwife with whom the local health department contracts, the health department will be paid the total amount of the nurse-midwife's premium or ~~three~~ four thousand dollars (~~\$3,000~~) (\$4,000) or, whichever is less. The local health department will then pay this amount to the nurse-midwife to cover a portion of the nurse-midwife's annual malpractice insurance premiums. The total payments to one nurse-midwife cannot exceed the amount stated in this Paragraph.

(d) No more than ~~nineteen~~ thirty thousand ~~five hundred~~ dollars (~~\$19,500~~) (\$30,000) may be disbursed to any underserved county.

(e) No funds may be disbursed to a health department in the absence of a contract with an eligible physician or nurse-midwife.

Statutory Authority S.L. 1989, c. 1066, s. 49.

Notice is hereby given in accordance with G.S. 150B-21.2 that EHNHR - Commission for Health

Services intends to amend rule cited as 15A NCAC 24A .0302.

The proposed effective date of this action is January 4, 1994.

The public hearing will be conducted at 10:00 a.m. on October 15, 1993 at the Groundfloor Hearing Room, Archdale Building, 512 N. Salisbury Street, Raleigh, N.C.

Reason for Proposed Action: This amendment extends time frames for both Authorization Requests and claims to one year from date of service (currently 90 days for Authorization Requests and 180 days for claims). This insurance and other third party payers and still have time to bill DEHNR programs if that is needed. This will also reduce the number of appeals filed because of denials due to late Authorization Requests or late claims.

Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629. All written comments must be received by October 20, 1993. Persons who wish to speak at the hearing should contact John P. Barkley at (919)733-4618. Persons who call in advance of the hearing will be given priority on the speaker's list. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or proposed changes from staff pursuant to comments made during the public hearing process.

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OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

CHAPTER 24 - GENERAL PROCEDURES FOR PUBLIC HEALTH PROGRAMS

SUBCHAPTER 24A - PAYMENT PROGRAMS

SECTION .0300 - ELIGIBILITY PROCEDURES

.0302 AUTHORIZATIONS AND CLAIMS PROCESSING TIME FRAMES

The following time frames shall apply to all payment programs:

- (1) An Authorization Request must be received by the Department within ~~90 days~~ one year after the date of service or it will be denied.
- (2) The Department shall respond to an Authorization Request within 45 days after receipt.
- (3) If additional information is requested, this information must be received within ~~90 days~~ one year after the date of service or within 30 days after the date of the Department's request, whichever is later, or the Authorization Request will be denied.
- (4) The Department shall approve or deny an Authorization Request within 45 days after receipt of all necessary information.
- (5) A claim for payment must be received by the Department within ~~180 days~~ one year after the date of service or within 45 days after the date of authorization approval, whichever is later, or the claim will be denied. Corrections to claims and requests for payment adjustment must be received by the Department within one year after the date of service or within 45 days after the date the claim is paid or returned for additional information, whichever is later, or the claim will be denied.
- (6) ~~A claim shall show payments by other third party payors or it shall show that all other payors have denied payment or that there are no other payors. Once another payor has been billed, if no response has been received within 80 days after the date of service, the provider may bill the~~

~~Department, but the claim shall indicate that the other payor has been billed and no response has been received. If payment is received later from the other payor, the provider shall refund the Department. If there are other third party payors, a claim must show payments by those payors or it must include copies of the denials of payment from those payors. Providers must bill other payors and wait at least six months after the date of service to receive payment or denial of payment before billing the Department. If no response has been received within six months after the date of service, the provider may bill the Department, but the claim must state the date that the other payors were billed.~~ Providers of pharmacy outpatient services are required to bill Medicaid. However, they are not required to bill other third party payors and wait ~~80 days~~ six months before billing the Department but are required to refund the Department if other third party payments are received.

- (7) The Department shall pay or deny a claim within 45 days after receipt of a completed claim.
- (8) Authorization Requests and claims for payment shall be submitted on forms approved by the Department.

Statutory Authority G.S. 130A-5(3); 130A-124; 130A-127; 130A-129; 130A-205.

TITLE 19A - DEPARTMENT OF TRANSPORTATION

Notice is hereby given in accordance with G.S. 150B-21.2 that the Division of Motor Vehicles intends to amend rule cited as 19A NCAC 3D .0224.

The proposed effective date of this action is December 1, 1993.

Instructions on How to Demand a Public Hearing (must be requested in writing within 15 days of notice): The agency will schedule a public hearing on the proposed rule if it receives a written request for a hearing within 15 days from the date the proposed text is published. The request for hearing must be mailed to: Jerry Arrowood, Enforce-

ment Section, Division of Motor Vehicles, 1100 New Bern Avenue, Raleigh, NC 27697.

Reason for Proposed Action: To provide for revocation of a motor vehicle dealer's license for failure to pay the civil penalty assessed by the Division of Motor Vehicles pursuant to G.S. 20-79(e)(2).

Comment Procedures: Written comments on the proposed rule may be submitted by mailing the comments to the following address within 30 days after the proposed text is published or until a requested public hearing is held, whichever is longer: Jerry Arrowood, Enforcement Section, Division of Motor Vehicles, 1100 New Bern Ave., Raleigh, NC 27697.

CHAPTER 3 - DIVISION OF MOTOR VEHICLES

SUBCHAPTER 3D - ENFORCEMENT SECTION

SECTION .0200 - MOTOR VEHICLE DEALER, SALES, DISTRIBUTOR AND FACTORY REPRESENTATIVE LICENSE

.0224 ILLEGAL USE OF DEALER PLATES

(a) It is illegal to use dealer plates on vehicles operated for any other business that the dealer is engaged in. The sale of vehicles not required to be registered, excluding the sale of farm tractors which are part of the inventory of the dealer, is considered another business and delivery of such vehicles by motor transport is not permitted with dealer plates.

(b) Parts trucks used in delivering parts to other sales outlets may use dealer plates only if the sale of parts is incident to the dealer business. A parts business that is separate and apart from the dealership cannot use dealer plates.

(c) It is illegal to use dealer plates on vehicles that are not owned by the dealer.

(d) It is illegal for persons other than dealers, corporate officers, ~~full-time and designated part-time~~ or employees of a dealer who regularly work for the dealer at least 15 hours a week, to operate a dealership vehicle unless they are in possession of a 96-hour permit. The said permit must include license plate number, permittee's name, address, driver's license number, date and

hour of issue and must be signed by dealer or sales manager and person receiving vehicle. A duplicate copy of the permit must be retained by the dealer. The permit is void ~~Void~~ if erasures are made.

(e) It is illegal to use dealer plates on wreckers used for general wrecker service or on wreckers which move vehicles on a rotation basis at the request of state or local law enforcement authorities. It is permissible to use a dealer plate on wreckers which tow vehicles for the dealer's customers only.

(f) The civil penalty imposed upon a dealer pursuant to G.S. 20-79(e)(2) is due in full upon assessment by the Division. The license of a dealer who fails to pay the civil penalty within 30 days after notice of the assessment is delivered to the dealer or an employee of the dealer shall be revoked by the Division until the penalty is paid in full.

Statutory Authority G.S. 20-39; 20-79; 20-302.

TITLE 20 - STATE TREASURER

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Trustees of Firemen's and Rescue Squad Workers' Pension Fund intends to amend rules cited as 20 NCAC 2N .0209 and .0218.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on October 4, 1993 at the Department of State Treasurer, Room 100, Albemarle Building, 325 N. Salisbury Street, Raleigh, NC 27603.

Reason for Proposed Action:

20 NCAC 2N .0209 - To implement procedures for purchase of prior service credit with the Firemen's and Rescue Squad Workers' Pension Fund.

20 NCAC 2N .0218 - To clarify payment of benefits for volunteer firemen and rescue squad workers for the Firemen's and Rescue Squad Workers' Pension Fund.

Comment Procedures: Interested parties may comment either written or orally at the hearing. Written comments may be filed from September 15, 1993 through October 15, 1993. Such written

comments must be sent to Stephen F. Albright, APA Coordinator, Dept. of State Treasurer, 325 N. Salisbury Street, Raleigh, NC 27603.

CHAPTER 2 - RETIREMENT SYSTEMS

SUBCHAPTER 2N - NORTH CAROLINA FIREMEN'S PENSION FUND

SECTION .0200 - GENERAL PROVISIONS

.0209 PRIOR SERVICE CREDIT

~~At the time an eligible fireman or an eligible rescue squad worker applies for membership, he or she may purchase credit for prior service as either an eligible fireman or an eligible rescue squad worker, provided that he or she has not previously been a member. Prior service credit may be purchased in no less than monthly increments and up to a maximum of 12 months. The cost of each month of prior service credit shall be the same as the monthly payment required by G.S. 118-40 or 118-41 at the time of the application.~~

Eligible prior service not purchased under the provisions of G.S. 58-86-45(b) may be purchase under the provisions of G.S. 58-86-45(a1) by payment of a lump sum amount equal to the full liability of the service credits calculated on the basis of the assumptions used for purposes of the actuarial valuation of the Pension Fund's liabilities and shall take into account the retirement allowance arising on account of the additional service credit at the earliest age at which the applicant could retire on a retirement allowance.

- (1) Eligible applicants who desire to purchase credit for service under the provisions of G.S. 58-86-45(a1) shall make application and acquire certification (as necessary) from the eligible fire department or rescue squad on a form designated for this purpose.
- (2) The phrase "fireman or rescue squad worker" as used in G.S. 58-86-45(a1) shall mean any person who is or was an eligible fireman or eligible rescue squad worker as defined and provided by G.S. 58-86-25 and G.S. 58-86-30.
- (3) The phrase "periods of service" as used in G.S. 58-86-45(a1) shall mean eligible service as defined and provided by G.S. 58-86-25 and G.S. 58-86-30.
- (4) The phrase "not otherwise creditable" as used in G.S. 58-86-45(a1) shall refer to eligible service as defined and provided by G.S. 58-86-25 and G.S. 58-86-30 for

which retirement credit is not currently established in the Pension Fund.

(5) The cost to purchase creditable service hereunder shall be computed as follows:

- (a) determine amount of service to be purchased;
- (b) determine nearest age of applicant, which for the purposes of this Rule is the year and whole month of the age of the member;
- (c) determine if an applicant is currently a contributing member of the Pension Fund;
- (d) if applicant is currently a contributing member of the Pension Fund, multiply the cost per year of service (as provided by the Pension Fund's consulting actuary) at the applicant's nearest age times the amount of service to be purchased; however, the cost shall not exceed the cost as provided under Subitem (5)(e) of this Rule for an applicant the same age who is not currently a contributing member;
- (e) if applicant is not currently a contributing member of the Pension Fund, obtain the lump sum amount at the applicant's nearest age by referring to the present value cost as provided by the Pension Fund's consulting actuary;
- (f) the amount of service to be purchased in a single transaction shall be all eligible service, as defined and provided by G.S. 58-86-25 and G.S. 58-86-30, or such portion in full years as the applicant may elect;
- (g) a fee in the amount of twenty-five dollars (\$25.00) for each payment shall be assessed members at the time of purchase as provided by law.

Statutory Authority G.S. 58-86-10; 58-86-45.

.0218 RETIREMENT BENEFITS

(a) In order to receive retirement benefits under G.S. 418-42 58-86-55 a member must submit to the office of the director an application for service retirement and the certification of retirement form. The applications and certifications will be processed at the end of the month; therefore, the application and certification must be filed with the office of the director at least 30 days prior to the last day worked if the applicant is to receive retirement benefits by the first of the month following his retirement.

(b) The application for service retirement is used to determine when benefits commence and the amount of benefits. The signature of the applicant must be notarized. The application asks for personal identification information including the member's name, his register number, age and designated beneficiary.

(c) The certification of retirement form asks the retiring member's fire chief or rescue squad captain to certify the date of retirement. The form asks for personal identification information such as the retiree's name, last date of employment, and the chief's or captain's certification of retirement.

(d) A member who has met all the requirements for receipt of a pension as set out in G.S. 55-86-55, and whose 20 years of service as an "eligible fireman" or "eligible rescue squad worker" were rendered exclusively through volunteer service, shall be deemed to be terminated and retired and therefore eligible to receive the monthly pension provided by G.S. 58-86-55 regardless of any capacity in which he/she may be employed or reemployed, including salaried positions as firemen or rescue squad workers.

(4) (e) The forms described in Paragraphs (b) and (c) of this Rule may be obtained from the office of the director at the address shown in Rule .0106(a) of this Chapter Subchapter.

Statutory Authority G.S. 58-86-10; 58-86-55.

TITLE 21 - OCCUPATIONAL LICENSING BOARD

Notice is hereby given in accordance with G.S. 150B-21.2 that the State Board of Refrigeration Examiners intends to adopt 21 NCAC 60 .0209, .0312 - .0314 and amend rules cited as 21 NCAC 60 .0101 - .0102, .0207, .1102 - .1103.

The proposed effective date of this action is December 1, 1993.

The public hearing will be conducted at 10:00 a.m. on October 12, 1993 at 3716 National Drive, Suite 120, Raleigh, NC 27612.

Reason for Proposed Action:

21 NCAC 60 .0101 - clarifies duties of officers.
21 NCAC 60 .0102 - corrects address.
21 NCAC 60 .0207 - increases experience and/or education required to sit for refrigeration examina-

tion in order to ensure the protection of the public health, comfort and safety.

21 NCAC 60 .0210 - clarifies expenses for special examinations.

21 NCAC 60 .0312 - requires license be returned to Board Office prior to new license being issued.

21 NCAC 60 .0313 - requires processing fee for submittal of bad check.

21 NCAC 60 .0314 - clarifies use of license.

21 NCAC 60 .1102 - corrects address.

21 NCAC 60 .1103 - defines and clarifies disciplinary action that may be taken by the Board.

Comment Procedures: All persons interested in this matter are invited to attend the public hearing. The State Board of Refrigeration Examiners will receive mailed written comments postmarked no later than October 15, 1993. More information may be obtained by contacting the Board Office, P.O. Box 30693, Raleigh, NC 27622, (919) 781-1602.

CHAPTER 60 - BOARD OF REFRIGERATION EXAMINERS

SECTION .0100 - ORGANIZATION AND DEFINITIONS

.0101 STRUCTURE OF BOARD

The Board is structured according to G.S. 87-52. The Board employs executive director and an office secretary. The Chairman, Secretary and Treasurer shall be elected at the first regular meeting of each year and shall assume office at the April meeting following election. It shall be the duty of the Chairman to call and preside over all meetings of the Board and perform such other duties as may come within the jurisdiction of his/her office. It shall be the duty of the Secretary to function as Chairman in the event of his/her absence or inability. The Chair of the Board shall appoint regular committees to implement prescribed phases of the Board's functions. The Chair shall designate the membership of the committees.

Statutory Authority G.S. 87-52; 87-54.

.0102 OFFICE OF BOARD

The Board's office is located at ~~323 West Morgan Street,~~ 3716 National Drive, Suite 120, Raleigh, North Carolina. The Board's mailing address is P.O. Box ~~40553~~ 30693, Raleigh, North Carolina ~~27605~~ 27622. The Board's rules are available for

inspection at this office during regular office hours. The materials used in rule-making decisions will be available for inspection at said office.

Statutory Authority G.S. 87-54; 150B-11(2).

SECTION .0200 - EXAMINATIONS

.0207 REQUIREMENTS FOR EXAMINATION APPLICANTS

(a) An applicant shall be eligible to take the examination upon:

- (1) Filing with the Board an application, on a form provided by the Board, together with the combined examination-license fee.
- (2) Furnishing with his application information satisfactorily verifying that he has acquired at least ~~2000~~ 4000 hours of refrigeration experience gained while engaged actively and directly in the installation, maintenance, servicing or repairing of commercial, industrial or institutional refrigeration equipment. Prior to filing the application, qualifying experience must be acquired while working ~~a minimum of 2000 hours~~ under the supervision of a person who holds a valid refrigeration contractor's license, who is a registered professional engineer or who has equivalent industry experience. Up to one-half the experience may be in academic or technical training directly related to the field of endeavor for which examination is requested. Applicants who obtain a license will receive a certificate issued by the Board, bearing that license number. The license number shall not be assigned or transferred to another individual.

(b) The deadline for receipt of applications for a regular examination shall be six weeks prior to the examination date. If an application is received after the published deadline, it shall be returned to the applicant, and he shall be notified that he may apply for and take the next examination. The Board, at its discretion, may choose to waive this requirement in extenuating circumstances. The Board publishes the deadline for application receipt in selected newspapers, on posters mailed to all refrigeration wholesalers in North Carolina and in its quarterly newsletter.

(c) If a person files an application for examination which is accepted, and takes and fails the

examination, his verification of refrigeration experience is kept and is sufficient for taking any future examination, provided he files another application accompanied by the required fee.

Statutory Authority G.S. 87-54; 87-58.

.0210 SPECIAL EXAMINATION

The expense deposit for a special examination pursuant to G.S. 87-58 shall be in an amount determined by the Board. After the examination, the Board will determine the full cost of the examination and refund any balance remaining.

Statutory Authority G.S. 87-54; 87-58(d); 93B-8(c).

SECTION .0300 - LICENSES AND FEES

.0312 CHANGE OF TRADE NAME

The trade name under which a license is issued may be changed upon request to and approval by the Board. The last license issued to the licensee must be returned to the Executive Director along with the form provided by the Board.

Statutory Authority G.S. 87-54; 87-60.

.0313 PROCESSING FEE FOR SUBMITTAL OF BAD CHECK

Any person or firm submitting to the Board a check which is subsequently returned to the Board because of insufficient funds in or no account at a bank will be charged the maximum processing fee allowed by G.S. 25-3-512. Until such time as the payer of such a bad check has made the check good and paid the prescribed processing fee, the payer will not be eligible to take an examination, obtain a license or have a license renewed.

Statutory Authority G.S. 87-54; 87-63.

.0314 USE OF LICENSE

The licensed contractor shall not permit the use of his license by any other person.

Statutory Authority G.S. 87-54; 87-57.

SECTION .1100 - DISCIPLINARY ACTION

.1102 PREFERRING CHARGES

Any person who believes that any refrigeration contractor is in violation of the provisions of G.S. 87-59 may prefer charges against such contractor by setting forth the charges in writing with particu-

larity including, but not limited to, the date and place of the alleged violation. Such charges shall be signed and sworn to by the party preferring such charges and filed with the Executive Director of the State Board of Refrigeration Examiners at the office of the Board, ~~323 West Morgan Street, P.O. Box 10553, 3716 National Drive, P.O. Box 30693, Raleigh, North Carolina 27605 27622.~~

Statutory Authority G.S. 87-59; 150B-11(1).

.1103 PRELIMINARY DETERMINATION

(a) A charge, filed under Rule .1102 of this Section, shall be referred initially to a review committee.

(b) The review committee shall be made up of the following individuals:

- (1) one officer, other than the Chairman, of the State Board of Refrigeration Examiners,
- (2) the legal counsel of the Board,
- (3) the Executive Director of the State Board of Refrigeration Examiners.

(c) The review committee shall have the authority to determine prior to a full Board hearing whether or not charges as may be filed against a refrigeration contractor are unfounded, frivolous or trivial. The determination of the review committee shall be final in this respect.

(d) Once a charge is referred to the review committee a written notice of said charge shall be forwarded to the licensee against whom the charge is made. Notice of the charge and of the alleged facts and circumstances surrounding the charge shall be given personally or by registered or certified mail, return receipt requested. A response to said charges shall be requested of the licensee so charged and shall be made within twenty days from the date shown on the return mail certificate or date of personal notice.

(e) If the licensee denies the charges brought against him, then in the sole discretion of the review committee, additional investigative personnel may be retained by the Board for the purpose of obtaining evidence relating to such charges. The reasonable expenses of any such additional personnel shall be borne by the Board.

(f) After all preliminary evidence has been received by the review committee it shall make a preliminary determination of the charges filed against the refrigeration contractor. From the evidence it may recommend to the Board that:

- (1) the charges be dismissed as unfounded, frivolous, trivial; or
- (2) when the charge is admitted by the

licensee or the evidence warrants, the Board ~~issue a reprimand and order the licensee not to commit in the future the specific act or acts admitted by him to have been in violation of any of the provisions of G.S. 87-59, 87-57, or 87-61; or be presented with the charge for its decision.~~ If the charge is of such gravity as to make the imposition of punitive sanctions likely, the Board may administer one or more of the following penalties if the licensee is found to be guilty as prescribed by law:

- (A) Reprimand;
- (B) Suspension from practice for a period not to exceed 12 months;
- (C) Probationary revocation of license upon conditions set by the Board as the case shall warrant with revocation upon failure to comply with the conditions; or
- (D) Revocation of license.

- (3) if the charge is denied and evidence warrants, or if the charge, while admitted, is of such gravity as to make the imposition of punitive sanctions likely, the charge be presented to the Board for its decision on the merits of the charge in accordance with the statutes governing contested cases.

In connection with any such reprimand and subsequent order the Board may also provide that in the event the licensee is determined to have violated in the future any of the aforementioned statutes the Board may suspend or revoke his license as prescribed by law.

Statutory Authority G.S. 87-57; 87-59; 150B-11(1).

The Rules Review Commission (RRC) objected to the following rules in accordance with G.S. 143B-30.2(c). State agencies are required to respond to RRC as provided in G.S. 143B-30.2(d).

ADMINISTRATION

Department of Administration's Minimum Criteria

1 NCAC 39 .0101 - Purpose	RRC Objection	06/17/93
No Response from Agency	Obj. Cont'd	07/15/93
Agency Responded	Obj. Cont'd	08/20/93
1 NCAC 39 .0301 - Exceptions to Minimum Criteria	RRC Objection	06/17/93
No Response from Agency	Obj. Cont'd	07/15/93
Agency Responded	Obj. Cont'd	08/20/93

Low-Level Radioactive Waste Management Authority

1 NCAC 37 .0306 - Preferred Site	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

COMMERCE

Banking Commission

4 NCAC 3J .0204 - Application for Renewal of Certificate of Registration	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
4 NCAC 3J .0302 - Record and Bookkeeping Requirements	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

COMMUNITY COLLEGES

Community Colleges

23 NCAC 2C .0105 - Establishing Colleges	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0202 - Curriculum	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0203 - Extension Programs	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0304 - Expenditures/State Funds: Accreditation Expenses & Dues		08/20/93
Agency Withdrew Rule		
23 NCAC 2D .0305 - Expenditure of State Funds: Postage Machines	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0307 - Expenditure of State Funds: Certificate Costs		08/20/93
Agency Withdrew Rule		
23 NCAC 2D .0309 - Expenditure of State Funds: Travel and Allowances		08/20/93
Agency Withdrew Rule		
23 NCAC 2D .0310 - Live Projects	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0311 - Handling Overhead Receipts and Allowances		08/20/93
Agency Withdrew Rule		

RRC OBJECTIONS

23 NCAC 2D .0312 - Bookstore: Vending Machine	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0313 - Acquisition of Automated Data Processing Resources		
Agency Withdrew Rule		08/20/93
23 NCAC 2D .0318 - Equipment Budget Requests: Distribution of Funds	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0319 - Allotment Procedures for Human Resources Development		
Agency Withdrew Rule		08/20/93
23 NCAC 2D .0320 - Library Book Funding System & Budgetary Application	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0321 - Payroll Deduction		
Agency Withdrew Rule		08/20/93
23 NCAC 2D .0323 - Reporting of Student Hrs/Membership/Curriculum Classes	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0324 - Rept/Stu Hrs/Membership/Extension (Non-Credit) Classes	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0601 - Appropriation Requests and Allocation Policy	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2D .0602 - Capital Project Approval and Obtaining Capital Funds	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2E .0101 - Program Classification	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2E .0102 - Curriculum Programs: Degrees, Diplomas, Certificates	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2E .0201 - Establishing or Terminating Curriculums	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 2E .0203 - Standards for Technical-Vocational Curriculums		
Agency Withdrew Rule		08/20/93

General Provisions

23 NCAC 1A .0001 - Definitions	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
23 NCAC 1A .0003 - Authority	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

ENVIRONMENT, HEALTH, AND NATURAL RESOURCES

Environmental Management

15A NCAC 2H .1110 - Implementation	RRC Objection	02/18/93
Agency Responded	Obj. Cont'd	03/18/93
Agency Responded	Obj. Cont'd	05/19/93
Agency Responded	Obj. Cont'd	06/17/93
Agency Responded	Obj. Cont'd	07/15/93
No Response from Agency	Obj. Cont'd	08/20/93

Solid Waste Management

15A NCAC 13B .1604 - General Requirements for MSWLF Facilities	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
15A NCAC 13B .1618 - Site Study for MSWLF Facilities	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
15A NCAC 13B .1622 - Location Restrictions for MSWLF Facility Siting	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

RRC OBJECTIONS

15A NCAC 13B .1624 - Construction Requirements for MSWLF Facilities	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
15A NCAC 13B .1626 - Operational Requirements for MSWLF Facilities	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
15A NCAC 13B .1635 - Assessment of Corrective Measures	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

HUMAN RESOURCES

Children's Services

10 NCAC 41R .0002 - Administration and Organization	RRC Objection	07/15/93
Agency Responded	Obj. Cont'd	08/20/93

LICENSING BOARDS AND COMMISSIONS

Landscape Architects

21 NCAC 26 .0203 - General Obligations of Practice: Mandatory Standards	RRC Objection	06/17/93
Agency Repealed Rule	Obj. Removed	06/17/93
21 NCAC 26 .0205 - Forms of Practice	RRC Objection	06/17/93
Rule Returned to Agency		07/15/93
21 NCAC 26 .0207 - Application of Professional Seal	RRC Objection	06/17/93
Rule Returned to Agency		07/15/93
21 NCAC 26 .0208 - Improper Conduct	RRC Objection	06/17/93
Rule Returned to Agency		07/15/93
21 NCAC 26 .0209 - Unprofessional Conduct	RRC Objection	06/17/93
Agency Revised Rule	Obj. Removed	07/15/93
21 NCAC 26 .0210 - Dishonest Practice	RRC Objection	06/17/93
Agency Revised Rule	Obj. Removed	07/15/93
21 NCAC 26 .0211 - Incompetence	RRC Objection	06/17/93
Agency Revised Rule	Obj. Removed	07/15/93
21 NCAC 26 .0301 - Examination	RRC Objection	06/17/93
Agency Revised Rule	Obj. Removed	07/15/93

Pharmacy

21 NCAC 46 .1809 - Emergency Prescription Refills	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

Social Work

21 NCAC 63 .0201 - Definitions	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93
21 NCAC 63 .0210 - Provisional Certificates	RRC Objection	08/20/93
Agency Revised Rule	RRC Objection	08/20/93
21 NCAC 63 .0501 - Introduction		
Agency Withdrew Rule		08/20/93

REVENUE

Sales and Use Tax

17 NCAC 7B .0902 - Advertising Artists: Paste-Ups and Mechanicals	RRC Objection	08/20/93
Agency Revised Rule	Obj. Removed	08/20/93

RRC OBJECTIONS

17 NCAC 7B .0904 - Public Relation Firms
Agency Revised Rule

RRC Objection 08/20/93
Obj. Removed 08/20/93

This Section of the Register lists the recent decisions issued by the North Carolina Supreme Court, Court of Appeals, Superior Court (when available), and the Office of Administrative Hearings which invalidate a rule in the North Carolina Administrative Code.

1 NCAC 5A .0010 - ADMINISTRATIVE PROCEDURES

Thomas R. West, Administrative Law Judge with the Office of Administrative Hearings, declared two portions of Rule 1 NCAC 5A .0010 void as applied in *Stauffer Information Systems, Petitioner v. The North Carolina Department of Community Colleges and The North Carolina Department of Administration, Respondent and The University of Southern California, Intervenor-Respondent* (92 DOA 0666).

10 NCAC 3H .0315(b) - NURSING HOME PATIENT OR RESIDENT RIGHTS

Dolores O. Nesnow, Administrative Law Judge with the Office of Administrative Hearings, declared Rule 10 NCAC 3H .0315(b) void as applied in *Barbara Jones, Petitioner v. North Carolina Department of Human Resources, Division of Facility Services, Licensure Section, Respondent* (92 DHR 1192).

10 NCAC 3R .1124(f) - ACCESSIBILITY TO SERVICES

Beecher R. Gray, Administrative Law Judge with the Office of Administrative Hearings, declared Rule 10 NCAC 3R .1124(f) void as applied in *Britthaven, Inc. d/b/a Britthaven of Morganton, Petitioner v. N.C. Department of Human Resources, Division of Facility Services, Certificate of Need Section, Respondent and Valdese Nursing Home, Inc., Respondent-Intervenor* (92 DHR 1785).

15A NCAC 3O .0201(a)(1)(A) - STDS FOR SHELLFISH BOTTOM & WATER COLUMN LEASES

Julian Mann III, Chief Administrative Law Judge with the Office of Administrative Hearings, declared Rule 15A NCAC 3O .0201(a)(1)(A) void as applied in *William R. Willis, Petitioner v. North Carolina Division of Marine Fisheries, Respondent* (92 EHR 0820).

15A NCAC 19A .0202(d)(10) - CONTROL MEASURES - HIV

Brenda B. Becton, Administrative Law Judge with the Office of Administrative Hearings, declared Rule 15A NCAC 19A .0202(d)(10) void as applied in *ACT-UP TRIANGLE (AIDS Coalition to Unleash Power Triangle), Steven Harris, and John Doe, Petitioners v. Commission for Health Services of the State of North Carolina, Ron Levine, as Assistant Secretary of Health and State Health Director for the Department of Environment, Health, and Natural Resources of the State of North Carolina, William Cobey, as Secretary of the Department of Environment, Health, and Natural Resources of the State of North Carolina, Dr. Rebecca Meriwether, as Chief, Communicable Disease Control Section of the North Carolina Department of Environment, Health, and Natural Resources, Wayne Bobbitt Jr., as Chief of the HIV/STD Control Branch of the North Carolina Department of Environment, Health, and Natural Resources, Respondents* (91 EHR 0818).

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.

<u>AGENCY</u>	<u>CASE NUMBER</u>	<u>ALJ</u>	<u>DATE OF DECISION</u>	<u>PUBLISHED DECISION REGISTER CITATION</u>
ADMINISTRATION				
LMS Express, Inc. v. Administration, Div of Purchase & Contract	92 DOA 0735	Morgan	06/04/93	
Stauffer Information Systems v. Community Colleges & Administration	92 DOA 0803	West	06/10/93	8:7 NCR 613
McLaurin Parking Co. v. Administration	92 DOA 1662	Morrison	04/02/93	8:3 NCR 320
Warren H. Arrington Jr. v. Division of Purchase & Contract	93 DOA 0132	West	07/21/93	
ALCOHOLIC BEVERAGE CONTROL COMMISSION				
Alcoholic Beverage Control Comm. v. Ann Oldham McDowell	92 ABC 0260	Morgan	04/01/93	
Curtis Ray Lynch v. Alcoholic Beverage Control Comm.	92 ABC 0288	Gray	05/18/93	
Alcoholic Beverage Control Comm. v. Ezra Everett Rigsbee	92 ABC 0702	West	07/30/93	
Alcoholic Beverage Control Comm. v. Partnership, Phillip Owen Edward	92 ABC 0978	Gray	05/28/93	
Alcoholic Beverage Control Comm. v. Gary Morgan Neugent	92 ABC 1086	Becton	03/22/93	
Alcoholic Beverage Control Comm. v. Kirby Ronald Eldridge	92 ABC 1153	Chess	04/26/93	
Alcoholic Beverage Control Comm. v. Gloria Black McDuffie	92 ABC 1476	West	05/26/93	
Alcoholic Beverage Control Comm. v. Larry Isaac Hailstock	92 ABC 1483	Reilly	04/07/93	
Alcoholic Beverage Control Comm. v. Anthony Ralph Cecchini Jr.	92 ABC 1690	Morgan	06/29/93	
Johannie L. Baker v. Alcoholic Beverage Control Commission	92 ABC 1735	Chess	05/07/93	
RAMSAC Enterprises, Inc. v. Alcoholic Beverage Control Comm.	93 ABC 0002	Morrison	07/02/93	
Alcoholic Beverage Control Comm. v. Aubrey Rudolph Wallace	93 ABC 0047	Gray	05/28/93	
Alcoholic Beverage Control Comm. v. Mermaid, Inc.	93 ABC 0076	Gray	08/04/93	
Alcoholic Beverage Control Comm. v. Majdi Khalid Wahdan	93 ABC 0087	Becton	07/06/93	8:9 NCR 785
Cornelius Hines T/A Ebony Lounge v. Alcoholic Beverage Ctl. Comm.	93 ABC 0118	Morrison	08/04/93	
Alcoholic Beverage Control Comm. v. Homer Patrick Godwin Jr.	93 ABC 0125	Reilly	05/13/93	
Alcoholic Beverage Control Comm. v. Wanda Lou Ball	93 ABC 0182	Nesnow	07/29/93	
Charles Anthonious Morant v. Alcoholic Beverage Control Comm.	93 ABC 0232	Chess	07/20/93	
Alcoholic Beverage Control Comm. v. Billy Fincher McSwain Jr.	93 ABC 0239	Gray	08/26/93	
ABC Comm. v. Partnership/T/A Corrothers Comty Ctr & Private Club	93 ABC 0318	Reilly	07/22/93	
Alcoholic Beverage Control Comm. v. James Elwood Alphin	93 ABC 0326	Gray	08/26/93	
Alcoholic Beverage Control Comm. v. James William Campbell	93 ABC 0327	Gray	08/09/93	
Alcoholic Beverage Control Comm. v. Richard Donald James Jr.	93 ABC 0431	Nesnow	09/01/93	
Charles Edward Hare, Club Paradise v. Alcoholic Beverage Ctl. Comm.	93 ABC 0644	Gray	08/10/93	
Alcoholic Bev. Control Comm. v. Mild & Wild, Inc., Sheila Scholz	93 ABC 1475	Nesnow	03/23/93	
COMMERCE				
Lester Moore v. Weatherization Assistance Program	93 COM 0105	Gray	03/08/93	
CRIME CONTROL AND PUBLIC SAFETY				
George W. Paylor v. Crime Victims Compensation Comm.	91 CPS 1286	Morgan	04/27/93	
Steven A. Barner v. Crime Victims Compensation Comm.	92 CPS 0453	Nesnow	06/01/93	
Anthony L. Hart v. Victims Compensation Comm.	92 CPS 0937	Chess	03/01/93	
Jennifer Ayers v. Crime Victims Compensation Comm.	92 CPS 1195	Reilly	03/19/93	
Janie L. Howard v. Crime Victims Compensation Comm.	92 CPS 1787	Reilly	03/26/93	
Isabelle Hyman v. Crime Victims Compensation Comm.	92 CPS 1807	Morrison	05/24/93	
James G. Pellom v. Crime Control & Public Safety	93 CPS 0034	Gray	05/05/93	
Norman E. Brown v. Victims Compensation Commission	93 CPS 0141	West	07/07/93	
Moses H. Cone Mem Hosp v. Victims Compensation Comm.	93 CPS 0152	Nesnow	04/02/93	8:3 NCR 327
David & Jane Spano v. Crime Control & Public Safety	93 CPS 0160	Nesnow	07/30/93	8:10 NCR 862
Phillip Edward Moore v. Crime Control & Public Safety	93 CPS 0169	Nesnow	05/20/93	
Norma Jean Purkett v. Crime Victims Compensation Comm.	93 CPS 0205	West	08/27/93	8:12 NCR 1171
Sheila Carter v. Crime Control and Public Safety	93 CPS 0249	Morgan	08/25/93	
John Willie Leach v. Crime Victims Compensation Comm.	93 CPS 0263	Morrison	05/20/93	
Nellie R. Mangum v. Crime Victims Compensation Comm.	93 CPS 0303	Morrison	06/08/93	
Constance Brown v. Crime Victims Compensation Comm.	93 CPS 0351	Reilly	05/24/93	

CONTESTED CASE DECISIONS

AGENCY	CASE NUMBER	ALJ	DATE OF DECISION	PUBLISHED DECISION REGISTER CITATION
ENVIRONMENT, HEALTH, AND NATURAL RESOURCES				
Charles L. Wilson v. Environment, Health, & Natural Resources	91 EHR 0664	Morgan	03/23/93	
J. Bruce Mulligan v. Environment, Health, & Natrual Resources	91 EHR 0773	West	07/13/93	
Michael D. Barnes v. Onslow Cty Hlth & Environment and EHR	91 EHR 0825	Morgan	06/21/93	
William E. Finck v. Environment, Health, & Natural Resources	92 EHR 0040	Gray	06/14/93	
Utley C. Stallings v. Environment, Health, & Natural Resources	92 EHR 0062	Gray	03/15/93	
A.J. Ballard Jr., Tire & Oil Co., Inc. v. Env., Health, & Nat. Res.	92 EHR 0754	Nesnow	08/30/93	
Safeway Removal, Inc. v. Environment, Health, & Natural Res.	92 EHR 0826	West	03/12/93	8:1 NCR 83
Elizabeth City/Pasquotank Cty Mun Airport Auth v. EHNR	92 EHR 1140	Gray	04/13/93	
Interstate Brands Corp & Donald Leflew v. Env., Health, & Nat. Res.	92 EHR 1201 ^{*1}	Reilly	08/12/93	
Service Oil Company v. Environment, Health, & Natural Resources	92 EHR 1205	Reilly	05/27/93	
Interstate Brands Corp & Donald Leflew v. Env., Health, & Nat. Res.	92 EHR 1224 ^{*1}	Reilly	08/12/93	
Residents of Camm & Shell v. Health Environmental - Septic Tank Div.	92 EHR 1462	Morrison	08/25/93	
City of Salisbury v. Environment, Health, & Natural Resources	92 EHR 1472	Morrison	04/22/93	
Willie M. Watford v. Hertford Gates District Health Department	92 EHR 1600	Chess	03/24/93	
Standard Speciality Contractors, Inc. v. EHNR	92 EHR 1660	Reilly	05/21/93	
Shawqi A. Jaber v. Environment, Health, & Natural Resources	92 EHR 1784	Becton	07/07/93	
Angela Power, Albert Power v. Children's Special Health Svcs.	93 EHR 0008	Becton	03/24/93	
Erby Lamar Grainger v. Environment, Health, & Natural Resources	93 EHR 0071	Reilly	06/21/93	
Mustafa E. Essa v. Environment, Health, & Natural Resources	93 EHR 0146	Gray	03/29/93	
Charlie Garfield McPherson Swine Farm v. Env., Health, & Nat. Res.	93 EHR 0181	Reilly	07/23/93	8:10 NCR 870
Rosetta Brimage, Vanessa Pack v. Env. Health of Craven County	93 EHR 0206	Nesnow	05/20/93	
R.L. Stowe Mills, Inc. v. Environment, Health, & Natural Resources	93 EHR 0219	Morrison	08/11/93	8:11 NCR 996
O.C. Stafford/Larry Haney v. Montgomery Cty. Health Dept.	93 EHR 0224	Gray	06/07/93	
Fred M. Grooms v. Environment, Health, & Natural Resources	93 EHR 0276	West	08/27/93	8:12 NCR 1176
Bobby Anderson v. Environment, Health, & Natural Resources	93 EHR 0299	Reilly	06/07/93	
Shell Bros. Dist., Inc. v. Environment, Health, & Natural Resources	93 EHR 0308	Becton	05/18/93	
Fred C. Gosnell & wife, Patricia T. Gosnell v. Env., Health, & Nat. Res.	93 EHR 0340	Becton	08/11/93	
Holding Bros., Inc. v. Environment, Health, & Natural Resources	93 EHR 0380	Nesnow	08/03/93	8:11 NCR 1001
Hamilton Beach/Proctor-Silex, Inc. v. Environment, Health, & Natrl Res	93 EHR 0477	Reilly	06/29/93	

HUMAN RELATIONS COMMISSION

Human Relations Comm. on behalf of Marsha Crisco v. Hayden Morrison	93 HRC 0167	Reilly	08/18/93	8:12 NCR 1168
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HUMAN RESOURCES

O.C. Williams v. Human Resources	91 CSE 0036 ^{*2}	Morgan	03/30/93	
Ronald Terry Brown v. Human Resources	91 CSE 0249	Morgan	05/17/93	
Dennis K. King v. Human Resources	91 CSE 1122	Morgan	07/28/93	
Cathy Harris, A/K/A Cathy D. Grubb v. Human Resources	91 CSE 1131	Morgan	08/24/93	
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Michael L. Ray v. Human Resources	91 CSE 1173	Morgan	05/17/93	
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John Henry Byrd v. Human Resources	92 CSE 1250	Reilly	06/04/93	

* Consolidated cases.

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Robert E. Watson v. Human Resources	92 CSE 1265	Reilly	05/06/93	
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Larry L. Crowder v. Human Resources	92 CSE 1396	Reilly	04/15/93	
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Ocie C. Williams v. Human Resources	92 CSE 1405	Mann	06/25/93	
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Floyd Excell Stafford v. Human Resources	92 CSE 1412	Reilly	08/31/93	
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Harold R. Pledger v. Human Resources	92 CSE 1455	Morrison	05/20/93	
Henry Alston Jr. v. Human Resources	92 CSE 1460	Becton	06/29/93	
Michael W. Bentley v. Human Resources	92 CSE 1512	Nesnow	06/09/93	
Dale Robert Stuhre v. Human Resources	92 CSE 1516	Reilly	05/11/93	
James T. Carter Jr. v. Human Resources	92 CSE 1517	Mann	08/31/93	
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James C. Dixon Jr. v. Human Resources	92 CSE 1522	Becton	05/11/93	
Wallace M. Cooper v. Human Resources	92 CSE 1527	Reilly	05/11/93	
Jarvis N. Price v. Human Resources	92 CSE 1531	Morrison	05/12/93	
Thomas L. Yates v. Human Resources	92 CSE 1535	Gray	05/10/93	
Robert E. Tarlton Sr. v. Human Resources	92 CSE 1536	Gray	05/17/93	
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James A. Coleman v. Human Resources	92 CSE 1540	Reilly	05/11/93	
Romeo F. Skapple v. Human Resources	92 CSE 1545	Gray	04/26/93	
Jeffrey L. Garrett v. Human Resources	92 CSE 1557	Gray	04/22/93	
Edward Kirk v. Human Resources	92 CSE 1560	Gray	06/29/93	
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John G. Williams v. Human Resources	92 CSE 1632	Mann	08/10/93	
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Dialysis Care of North Carolina, Inc., d/b/a Dialysis Care of Cumberland County v. Human Resources, Division of Facility Services, Certificate of Need Section, and Bio-Medical Applications of Fayetteville d/b/a Fayetteville Kidney Center, Webb-Lohavichan-Melton Rentals, Bio-Medical Applications of North Carolina, Inc., d/b/a BMA of Raeford and Webb- Lohavichan Rentals	92 DHR 1109*	Morgan	06/22/93	8:8 NCR 687
Dialysis Care of North Carolina, Inc., d/b/a Dialysis Care of Cumberland County v. Human Resources, Division of Facility Services, Certificate of Need Section, and Bio-Medical Applications of Fayetteville d/b/a Fayetteville Kidney Center, Webb-Lohavichan-Melton Rentals, Bio-Medical Applications of North Carolina, Inc., d/b/a BMA of Raeford and Webb- Lohavichan Rentals	92 DHR 1110*	Morgan	06/22/93	8:8 NCR 687
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Barbara Jones v. Human Resources	92 DHR 1192	Nesnow	04/02/93	8:3 NCR 313
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Katie Kelly v. Human Resources	93 DHR 0441	Chess	07/26/93	
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Carolyn M. Hair v. St Employees Comprehensive Major Medical	92 INS 1464	Chess	03/10/93	
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Lawrence D. Wilkie, Jerry R. Evans, Jules R. Hancart, James H. Johnson, James D. Fishel v. Justice	90 OSP 1065*4	Mann	05/04/93	
Lawrence D. Wilkie, Jerry R. Evans, Jules R. Hancart, James H. Johnson, James D. Fishel v. Justice	90 OSP 1066*4	Mann	05/04/93	
Lawrence D. Wilkie, Jerry R. Evans, Jules R. Hancart, James H. Johnson, James D. Fishel v. Justice	90 OSP 1067*4	Mann	05/04/93	
Lawrence D. Wilkie, Jerry R. Evans, Jules R. Hancart, James H. Johnson, James D. Fishel v. Justice	90 OSP 1068*4	Mann	05/04/93	
Bernie B. Kelly v. Correction	91 OSP 0344	Morrison	05/27/93	
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William Marshall Boyd Jr. v. County Commissioners of Hyde & Certain Board of Health Members	92 OSP 0090	Gray	08/25/93	
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Laverne B. Hill v. Transportation	92 OSP 0431*	West	03/08/93	8:1 NCR 88
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Anna L. Spencer v. Mecklenburg County Area Mental Health	92 OSP 0584	Becton	08/16/93	8:1 NCR 88
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David Scales v. Correction	92 OSP 0989	Chess	06/24/93	
Suzanne Ransley Hill v. Environment, Health, & Nat. Res.	92 OSP 0992	Reilly	03/18/93	8:1 NCR 88
Herman James Goldstein v. UNC-Chapel Hill et al.	92 OSP 1047	Morrison	05/04/93	
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John B. Sauls v. Wake County Health Department	92 OSP 1142	Reilly	03/08/93	
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Brenda K. Campbell v. Employment Security Commission	92 OSP 1505	Morrison	03/17/93	8:1 NCR 88
Christie L. Guthrie v. Environment, Health, & Natural Resources	92 OSP 1555	Becton	05/31/93	
Sharon Reavis v. Crime Control & Public Safety	92 OSP 1606	Morrison	08/19/93	8:12 NCR 1163
James B. Price v. Transportation	92 OSP 1657	Mann	03/19/93	
Jerry L. Jones v. N.C.S.U. Physical Plant	92 OSP 1661	Chess	07/06/93	8:1 NCR 88
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Terry Steve Brown v. Iredell County Health Department	93 OSP 0101	Morgan	08/06/93	8:1 NCR 88
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Michael L. Pegram v. Correction	93 OSP 0275*	Reilly	06/28/93	8:1 NCR 88
Jerry D. Doss Sr. v. Correction	93 OSP 0287	Gray	05/17/93	
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<u>AGENCY</u>	<u>CASE NUMBER</u>	<u>ALJ</u>	<u>DATE OF DECISION</u>	<u>PUBLISHED DECISION REGISTER CITATION</u>
STATE TREASURER				
Herman D. Brooks v. Bd of Trustees /Teachers' & St Emp Ret Sys	91 DST 0566	Gray	04/13/93	
Henrietta Sandlin v. Teachers' & State Emp Comp Major Medical Plan	92 DST 0305	Morgan	04/12/93	
Mary Alyce Carmichael v. Bd/Trustees/Teachers' & St Emp Ret Sys	92 DST 1506	Chess	04/08/93	
W. Rex Perry v. Bd/Trustees/Teachers' & St Emp Ret Sys	93 DST 0133	West	08/12/93	8:11 NCR 992
TRANSPORTATION				
Yates Construction Co., Inc. v. Transportation	92 DOT 1800	Morgan	03/25/93	
UNIVERSITY OF NORTH CAROLINA HOSPITALS				
Constance V. Graham v. UNC Hospital	93 UNC 0269	Morgan	07/20/93	
Jacqueline Florence v. UNC Hospitals	93 UNC 0355	Becton	06/16/93	

STATE OF NORTH CAROLINA
COUNTY OF FORSYTH

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
92 OSP 1606

SHARON REAVIS,
Petitioner,

v.

N.C. DEPARTMENT OF CRIME CONTROL AND
PUBLIC SAFETY, DIVISION OF VICTIM AND
JUSTICE SERVICES,
Respondent.

RECOMMENDED DECISION

The appeal of Sharon Reavis, a former employee of the North Carolina Department of Crime Control and Public Safety, Division of Victim and Justice Services, was heard by Fred G. Morrison Jr., Senior Administrative Law Judge, Office of Administrative Hearings, on July 14 and 15, 1993, in Raleigh, North Carolina. Following the hearing, the parties filed proposed decisions.

APPEARANCES

FOR THE PETITIONER: Marvin Schiller
Attorney at Law
Raleigh, North Carolina

FOR THE RESPONDENT: Linda M. Fox
Assistant Attorney General
N.C. Department of Justice
Raleigh, North Carolina

ISSUE

Whether the Respondent had just cause (procedurally and substantively) to terminate Petitioner's employment.

OPINION OF THE ADMINISTRATIVE LAW JUDGE

FINDINGS OF FACT

1. Petitioner Sharon Reavis was a program manager responsible for the Community Service Work Program in Forsyth County. Her duties included maintaining her own community service clients and supervising four Community Service Coordinators. She had been continually employed by the Respondent from October 1, 1984, until she was dismissed on September 30, 1992. She was in pay grade 66 when terminated.
2. In September of 1990, Larry F. Habegger pled guilty in Forsyth County Superior Court to five counts of embezzling trust funds. Judge Coy E. Brewer, Jr. sentenced him to three years in prison, but suspended it and placed him on supervised probation for five years. Special conditions of Habegger's probation were that he serve 5 consecutive days in the Davie County jail once each year for 5 years; that he make restitution in the amount of \$48,253.04 to the Young Trust of Thomasville, NC; and, that he complete 600 hours of community or reparation service during the period of probation, as

directed by the community service coordinator. The judge intended that Habegger complete at least 120 hours of community service during each of the five years of his probationary sentence. He did not specify the county where Habegger was to perform community service.

3. Prior to his trial, Habegger had been referred for community-based punishment and therefore community service because he had no prior record and appeared to be an excellent risk. On January 22, 1990, Petitioner by memo told the referral source that a tentative placement site had been located for Habegger.
4. The Petitioner and most of the members of her staff knew Mr. Habegger because he had either performed legal services for them or because he was a local attorney. The Petitioner knew Mr. Habegger for both reasons. Mr. Habegger was competent and well-liked.
5. It was a common practice in Area D, which included Forsyth County and was supervised by Becky Mullins, to transfer cases to the county where the probation officer supervising a defendant was located. In Mr. Habegger's case, that county was Davie. The Petitioner chose not to transfer Mr. Habegger's case, but retained it in Forsyth. Judicial Notice is taken of the fact that Forsyth and Davie counties adjoin and Advance is only a few miles from Winston-Salem.
6. Larry Habegger lived in Advance, Davie County, NC, where he was supervised by a local probation officer. He had graduated from Wake Forest University Law School and practiced law in Winston-Salem, Forsyth County, NC, prior to his sentence.
7. Habegger went to Petitioner's office for an official interview on October 23, 1990. Ms. Reavis assigned his case to coordinator Jean Guterrez because the latter was new and had no prior relationship with Habegger. Ms. Guterrez had been with the office for nine months. The other coordinators had five and nine years experience. Mr. Habegger's case was the highest profile case Ms. Guterrez was assigned in 1990.
8. On March 10, 1992, the Petitioner, in a random case review, selected Mr. Habegger's case file which was maintained by Ms. Guterrez. Mr. Habegger was to have completed 120 hours of community service in each year and by 3/10/92, should have completed more than 120 hours. The file reviewed by the Petitioner indicated Mr. Habegger was told in October 1990 to report to the Forsyth County Clerk's Office and perform community service, and he failed to show up. Mr. Habegger was not reported for noncompliance nor did the file contain any explanation for his failure to appear. From December 1990 until March 1991, there was no direct contact between Mr. Habegger and Ms. Guterrez.
9. According to the file, in March 1991, Mr. Habegger was reassigned to the Salvation Army Boys Club by Ms. Guterrez to do his community service. He did not report there. Mr. Habegger was not reported for noncompliance nor was there any explanation for his failure to appear.
10. In October 1991, Mr. Habegger submitted hours he claimed to have performed in Davie County with a little league ball team and at Brenner Children's Hospital in Forsyth County raising funds and organizing a golf tournament. He had placed himself with both agencies in violation of Respondent's policy
11. These hours were not approved by Petitioner as legitimate community service work because no proper assignment had been made prior to the service. Also, the Davie team was never an approved agency and Brenner's not until mid-1991 after most of Habegger's claimed hours. Mr. Habegger was approved for service with Brenner when it executed and returned an agreement on July 15, 1991. In July of 1992, Ms. Guterrez incorrectly advised Habegger's attorney that his client had complied with community service requirements through work at Brenner Children's Hospital.
12. Pursuant to V&J Policy, a coordinator must first find an approved agency and then assign a client to

that agency. Every thirty days, the coordinator is to monitor the progress of a client. The file reviewed by the Petitioner showed Ms. Guterrez had talked to Mr. Habegger five times in 17 months. She had made several other attempts, as had he, without connecting.

13. If a client fails to appear or does not perform his assigned community service hours without justification, he is to be reported back to court for failure to comply with conditions of probation either through the probation officer or by the coordinator when it is unsupervised probation.
14. The Petitioner, after reviewing all the improprieties in Mr. Habegger's file on March 10, 1992, concluded that he had approximately 17 hours of valid community service of the more than 120 hours needed.
15. The Petitioner did not require that Mr. Habegger be reported to his probation officer for being in noncompliance on March 10, 1992, when she became aware of it; instead, the Petitioner instructed Ms. Guterrez to transfer the case to Davie County.
16. The case was not transferred on March 10, 1992; had not been transferred when the Petitioner went out on sick leave on March 23, 1992; and, still was not transferred when she returned from leave on April 27, 1992.
17. In September 1992, Mr. James Coman of the Attorney General's Office called the Director of Victim and Justice Services, Art Zeidman, inquiring about the number of hours of community service performed by Mr. Habegger. Efforts were being made to defeat an attempt by Habegger's attorney to get his client's probation terminated. Coman had prosecuted the cases in Superior Court and was concerned that the community service and jail time were not being completed as ordered.
18. An investigation was conducted by Mr. Zeidman and his staff, and the Petitioner and Ms. Guterrez were questioned about the case in September. As of September of 1992, the case had not been transferred to Davie County. Ms. Guterrez testified that Habegger's attorney and probation officer asked her to delay any transfer until a decision was reached on the request for termination of probation.
19. The Petitioner first told Mr. Zeidman her last involvement with the case was when she told Ms. Guterrez to clean up the file and transfer the case to Davie County on March 10, 1992.
20. Ms. Guterrez, on the other hand, told Mr. Zeidman the Petitioner was aware of the lack of hours performed by Mr. Habegger and when the Petitioner returned from sick leave, was aware of the delay in transferring the case.
When informed of this contradiction, Petitioner told Zeidman that perhaps she did mention the transfer to Guterrez following her return to work.
21. On September 28, 1992, Becky Mullins, Area Manager, conducted a predissmissal conference with the Petitioner advising her that Mr. Zeidman was considering terminating her on September 30, 1992.
22. During the conference, the Petitioner was advised her action was considered personal misconduct. The misconduct was stated to be showing favoritism to Habegger and not having him reported to his probation officer in March of 1992 for failure to do community service from October of 1990 through March of 1992 as ordered by the court.
23. The Petitioner was also advised that she was believed to have been untruthful to Mr. Zeidman when he first inquired about her knowledge of and involvement with the Habegger case following her return from surgery.
24. The Petitioner was given the opportunity to present additional information to Mr. Zeidman before the final decision was made, but did not do so.

25. Mr. Zeidman discharged Petitioner from employment by letter to her dated September 30, 1992. The termination letter states, in essence, that the "specific incidents" of alleged personal misconduct are:
 1. That in October 1990, you showed favoritism toward a criminal defendant, Larry Habegger, by failing to transfer his case to Davie County, and in March of 1992, by failing to require Jean Guterrez to close his case, and instead asking her to transfer it, in violation of policy.
 2. That on September 23, 1992, when asked about the Habegger case, you changed your story as to your knowledge and involvement.
 3. That you knew or should have known that Habegger was seeking credit for hours not worked or not approved, and failed to take immediate action.
26. Mr. Zeidman also dismissed Jean Guterrez for her conduct in this matter. Following her appeal of this termination, Ms. Guterrez reached a settlement with the agency and has been reinstated. Also, Zeidman informed Coman of these disciplinary actions.
27. On December 7, 1992, Mr. Habegger appeared in court before Judge Coy E. Brewer, Jr. to request that his probation be terminated. Through his attorney, Mr. Habegger claimed to have paid the \$48,253.04 in restitution and completed the required hours of community service due to that date. The Attorney General's Office did not oppose termination on the grounds of failure to pay restitution or perform required community service, but objected because Habegger had only completed five days of the 25 days in jail. James Coman argued that justice required that Habegger serve 20 more days in jail before termination. Judge Brewer ordered that Habegger's probation be terminated as of January 31, 1993, provided that by that date he had served an additional ten days in jail.

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

CONCLUSIONS

1. Sharon Reavis, Petitioner, was a permanent State employee at the time of her dismissal. Because she has alleged that Respondent lacked just cause for her dismissal, the Office of Administrative Hearings has jurisdiction to hear her appeal and issue a recommendation to the State Personnel Commission which shall make the final decision in this matter. G.S. 126-35, 126-37, 126-39, 150B-23 and 150B-36.
2. G.S. 126-35 provides, in part, "that no permanent employee subject to the State Personnel Act shall be dismissed, except for just cause." Where just cause is an issue, Respondent bears the ultimate burden of persuasion. A just cause issue carries both substantive and procedural questions. Causes for dismissal fall into two categories: (1) causes relating to performance of duties; and (2) causes relating to personal conduct detrimental to State services -- no prior warnings are required under (2).
3. In Jones v. Department of Human Resources, 300 NC 690, 691 (1980), the Supreme Court of North Carolina held that "prior to dismissal for causes relating to performance of duties, a permanent State employee is entitled to three separate warnings that his performance is unsatisfactory. He must receive: (1) an oral warning explaining how he is not meeting the job's requirements; (2) a second oral warning outlining his unsatisfactory performance with a follow-up letter reviewing the points covered by the oral warning; (3) a final written warning setting forth in numerical order the specific acts or omissions that are the reasons for the disciplinary action."
4. Respondent has not met its burden of showing just cause for terminating Petitioner's employment. While it is concluded that Ms. Reavis failed to exert effective control over and properly manage the Habegger case, such behavior falls in the area of improper job performance rather than personal conduct. Since there was no evidence that she had received prior warnings, dismissal was not in order. A warning was appropriate.

As to charges of favoritism, Petitioner did no favors in approving a convicted attorney for community service work in the Clerk of Court's Office in the county of his conviction. It would have been difficult for him to look those people in the eye each day, which could be why he failed to report. Furthermore, the Salvation Army Boys Club assignment was appropriate for an attorney who had embezzled funds from clients who trusted him. One goal of community service is hopefully a change in values on the part of offenders. The Salvation Army certainly offers that possibility.

This was a case of supervised probation with three special conditions. Ms. Reavis did not abuse her discretion by not seeking immediate revocation only 17 months into a 60 month probationary period, which the sentencing judge ordered terminated at the completion of 28 months on January 31, 1993.

Respondent's second reason in the letter of dismissal was not specific enough to satisfy statutory requirements, nor did the evidence show a change significant enough to warrant dismissal.

Based on the foregoing Findings of Fact and Conclusions, the Administrative Law Judge makes the following:

RECOMMENDED DECISION

That the Petitioner be reinstated with full benefits, including back pay and attorney's fees, with an appropriate warning being given her for inadequate job performance.

ORDER

It is hereby ordered that the agency serve a copy of the final decision on the Office of Administrative Hearings, P.O. Drawer 27447, Raleigh, N.C. 27611-7447, in accordance with North Carolina General Statute 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 recommended decision and to present written arguments to those in the agency who will make the final decision. G.S. 150B-36(a).

The agency is required by G.S. 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 State Personnel Commission.

This the 19th day of August, 1993.

Fred G. Morrison Jr.
Senior Administrative Law Judge

V.

HAYDEN MORRISON,
Respondent.

PROPOSAL FOR DECISION

ISSUE

STIPULATIONS

- ## FINDINGS OF FACT

1. In March - April, 1991, Marsha Crisco and her son, Scott, who was one year old, were searching for a place to live. Ms. Crisco was recently separated from her husband. She and her husband were selling their house in Charlotte. Ms. Crisco hoped to move near Mooreville where her parents lived so that they might assist her in caring for her handicapped son.
2. The respondent is the owner and manager of Leisurewood Mobile Home Estates (hereinafter "Leisurewood") in Iredell County. Leisurewood has no facilities and services specially designed for older persons. There was no evidence that Leisurewood provided housing under any State or federal program for elderly persons. Leisurewood was not occupied solely by persons 62 years of age or older.
3. Ms. Crisco's father knew the respondent and asked him if his daughter could rent a lot in Leisurewood. The respondent stated that he did not rent to adults with children. Her father had given

the respondent a news article stating that discrimination in housing against families with children was prohibited.

4. Her father told Ms. Crisco about his conversation with the respondent. Nevertheless, Ms. Crisco and her mother decided to stop at Leisurewood and speak to the respondent. Ms. Crisco asked the respondent if she could rent a lot at Leisurewood. The respondent said no and made a statement that he did not rent to individuals who were under 40 years of age, single, or had children. Ms. Crisco felt humiliated and embarrassed at being denied a place to live. Several tenants at Leisurewood were under 40 years of age.
5. Although Ms. Crisco had hoped, with her father's assistance, to purchase a mobile home in order to have more space than an apartment and to make an investment, she decided to rent an apartment because no other mobile home park was as well kept as Leisurewood. She spent \$30 and, on and after February 1, 1993, \$35 per month for renting storage space for furniture that could not fit into her apartment. There was no evidence whether the apartment rent plus the storage rent was greater than what she would have had to pay for the lot rent and monthly payments on the mobile home.
6. At the hearing, the respondent contended that the mobile home park was full (either mobile homes were on the lots or individuals had reserved the lots), but he did not offer, in March - April, 1991, to place Ms. Crisco's name on his waiting list. It was the respondent's practice to offer individuals the opportunity to place their names on the waiting list. Furthermore, contrary to the respondent's contention, the mobile home park had three vacancies during March - April, 1991, when Ms. Crisco asked to rent a lot. The records of Duke Power Company showed that on Lot #3, service was disconnected on 10/24/90 and reconnected on 9/25/91; on Lot #25, service was disconnected on 2/26/91 and reconnected on 6/14/91; and on Lot #35, service was disconnected on 8/14/90 and reconnected on 5/13/91. The respondent's rental and deposit receipt book (more trustworthy than a hand-made rent payment chart) may have indicated that there were deposits on the lots, but the respondent failed to produce the book at the hearing. (The respondent had answered an interrogatory on June 16, 1993, that he would produce the book. T p 186) The respondent's contention that he took the rental and deposit receipt book to a copier less than three weeks before the hearing and subsequently lost the book and the copy lacks any credibility. ("I got it back but its been lost or misplaced since." Morrison, T p 188) Furthermore, this complete lack of credibility supports a finding that there were no deposits on the three lots. Therefore, the undersigned finds that three lots in Leisurewood were vacant with no deposits on them in March - April, 1991, when Ms. Crisco asked to rent a lot.
7. Animus against Ms. Crisco's son living with her was the motivation for the respondent's failure to rent a lot to Ms. Crisco in Leisurewood.

CONCLUSIONS OF LAW

1. The respondent intentionally violated G.S. 41A-4(a)(1) in March - April, 1991, by refusing to rent a mobile home lot to Ms. Crisco because of familial status.
2. The respondent intentionally violated G.S. 41A-4(a)(6) in March - April, 1991, by making verbal and written statements indicating his intent to discriminate in a real estate transaction because of Ms. Crisco's familial status.
3. The exemption in G.S. 41A-6(e) with respect to housing for older persons is inapplicable to Leisurewood.
4. Ms. Crisco, pursuant to G.S. 41A-7, is entitled to compensatory damages of two thousand dollars (\$2,000.00) from the respondent for her humiliation and embarrassment as a result of the respondent's failure to rent a mobile home lot to her because of familial status.

5. The petitioner, pursuant to G.S. 41A-7, is authorized to assess a civil penalty against the respondent.
6. The petitioner, pursuant to G.S. 41A-7, is authorized to enjoin future violations.

PROPOSAL FOR DECISION

It is proposed that (i) the respondent compensate Ms. Crisco in the amount of two thousand dollars (\$2,000.00), (ii) the respondent pay a civil penalty of two thousand dollars (\$2,000.00), and (iii) the respondent be ordered to cease his discriminatory policies and practices.

NOTICE

The final decision in this contested case shall be made by the Human Relations Commission. Each party has the right to file exceptions and proposed findings of fact and to present oral and written arguments on the decision to this agency.

This the 18th day of August, 1993.

Robert Roosevelt Reilly, Jr.
Administrative Law Judge

STATE OF NORTH CAROLINA
COUNTY OF WASHINGTON

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
93 CPS 0205

NORMA JEAN PURKETT

Petitioner,

v.

CRIME VICTIMS COMPENSATION COMMISSION,

Respondent.

RECOMMENDED DECISION

This contested case was heard on July 19, 1993 in Williamston, North Carolina, by Administrative Law Judge Thomas R. West.

APPEARANCES

Petitioner, Norma Jean Purkett, appeared on her own behalf.

Respondent was represented by Assistant Attorney General, Joseph P. Dugdale.

ISSUE

Did the North Carolina Crime Victims Compensation Commission err in one of the five ways described in G.S. 150B-23 when it denied Petitioner's claim for victim's compensation for expenses incurred as the result of the criminal homicide of Petitioner's father?

BURDEN OF PROOF

The burden is on Petitioner to prove by the greater weight of the substantial evidence that Respondent erred by denying compensation.

OFFICIAL NOTICE

Official notice is taken of Chapter 15B of the General Statutes of North Carolina. G.S. 15B-11(b) is the basis of the action taken by Respondent Commission.

WITNESSES

The following persons testified on behalf of Respondent:

Joyce Hyman
Emanuel Lee Hyman
Eric A. Hooks - SBI Special Agent

The following persons testified on behalf of Petitioner:

Sgt. Leo C. Ussery - Plymouth, N.C. Police Department
Sheila Kendall
Rebecca Barrett
Robin L. McNair

STATEMENT OF THE CASE

On the night of September 3, 1991, Robert McNair walked out of the church he served as pastor. Emanuel Lee Hyman struck and killed Rev. McNair. Hyman was charged with McNair's murder. In March 1992, Hyman was tried for murder, convicted of voluntary manslaughter, and sentenced to serve 120 days in jail.

The McNair family incurred medical expenses of \$7,000.00 (Seven Thousand Dollars) and funeral expenses of over \$2,000.00 (Two Thousand Dollars) as the result of the criminal homicide of Rev. McNair.

Norma J. Purkett, Rev. McNair's daughter, filed a claim with the Crime Victims Compensation Commission for reimbursement of the expenses.

On November 18, 1992, the Director of the Commission recommended to the Commission that the claim be denied. The Director found that "he offender discovered the victim with the offender's wife at the location and became angered." From this finding, the Director concluded that McNair's misconduct contributed to his death, so that pursuant to G.S. 15B-11(b), the claim for victim's compensation must be denied.

The Commission considered the Director's recommendation, and on January 8, 1993, ordered that Purkett's claim be denied. Purkett filed the petition commencing this contested case and challenging the Commission's decision on February 22, 1993.

FINDINGS OF FACT

1. Norma Jean Purkett is the daughter of Robert L. McNair, Sr. Purkett qualifies as a "claimant" under the North Carolina Crime Victims Compensation Act (Chapter 15B of the North Carolina General Statutes). Charges for medical service rendered to Robert L. McNair at the time of his death and his funeral expenses, up to \$2,000.00 (Two Thousand Dollars), are "allowable expenses" payable to Purkett from the Crime Victims Compensation Fund.
2. Claims for compensation exceeding \$5,000.00 (Five Thousand Dollars) are decided by the Crime Victims Compensation Commission on a review of written evidence submitted to the Commission by the Director of the Commission. Purkett's claim exceeded \$5,000 (Five Thousand Dollars) and was denied by the Commission.
3. The Commission denied Purkett's claim pursuant to G.S. 15B-11(b). The Commission took the position in denying Purkett's claim that because Rev. McNair was " ... with the offender's wife ... " at the time he was killed, his misconduct contributed to his death so that the claim should be denied. The Commission's meaning is not apparent unless one uses his imagination and presupposes that it is not misconduct to be in the presence of another man's wife.
4. The Plymouth police and the SBI investigated Rev. McNair's homicide. In addition, the criminal trial and conviction of Emanuel Hyman preceded the Commission's determination. The Commission reviewed information from all of these sources in making its determination that Purkett's claim should be denied.
5. Robert L. McNair, Sr. was the pastor of a church in Plymouth. McNair was at least 50 years of age at the time of his death and had been a widower for approximately ten (10) years.
6. Emanuel Lee Hyman and Joyce Hyman have been married for approximately 19 (nineteen) years. The two have three (3) children. The Hymans joined Rev. McNair's church in 1978, but left the church in the early 1980s because Rev. McNair and Joyce Hyman were having an affair. The Hymans separated for approximately one (1) year at the time they left Rev. McNair's church.

7. Emanuel Lee Hyman became the pastor of Temple Christian Church.
8. Joyce Hyman resumed attending Rev. McNair's church one (1) year after she and Emanuel had left the church. Rev. Hyman accepted his wife's return to Rev. McNair's church but did not bless it. Joyce Hyman became the Associate Minister of McNair's church.
9. Rebecca Barrett has known Robert McNair ever since she was fifteen (15) years old. Barrett and McNair were engaged to be married in their youth. McNair is the father of Barrett's daughter Sheila Kendall. Barrett did not marry McNair and moved to New York City. Barrett and McNair both subsequently married other people and the two families remained close. Barrett's family visited Plymouth once or twice a year for a week. Sheila Kendall spent most of the summers during her youth in Plymouth in Rev. McNair's home.
10. Approximately ten (10) years ago, Rev. McNair's wife died. Approximately five (5) to six (6) years ago, Barrett's husband died. Rev. McNair asked Barrett to marry him and confessed he was having an affair with Joyce Hyman, but wanted it to be over.

Barrett and Rev. McNair became engaged, but through the intervention of Barrett's minister, she did not marry McNair.
11. Sometime during 1989 or 1990, Rev. McNair told his daughter, Sheila Kendall, of his affair with Joyce Hyman. Kendall understood that the affair was ending then, and understood that her father had approached Emanuel Hyman several times to make peace.
12. In September 1991, Rev. McNair told Rebecca Barrett that he wanted to resume their engagement and get married. Rev. McNair admitted his affair with Joyce Hyman. McNair was depressed about the relationship. Many people had left Rev. McNair's church by this time because of the affair.
13. Robin McNair is Rev. McNair's youngest daughter. Her father sought her forgiveness in 1990 for his having an affair with Joyce Hyman. Robin McNair believed the affair was over in 1991 when Rev. McNair resumed his engagement with Rebecca Barrett.
14. Joyce Hyman had an affair with Rev. McNair in the early 1980's and resumed the affair after she resumed living with her husband and returned to Rev. McNair's church. Joyce Hyman and her husband, Emanuel, often had words about the relationship. Rev. Hyman had words with Rev. McNair about the affair on occasion. At times the confrontations became heated.
15. At some date right before September 3, 1991, Joyce Hyman told Emanuel Hyman that her affair with McNair was over.
16. On the night of September 3, 1991 (Tuesday), Joyce Hyman went to a prayer service at Rev. McNair's church. She left the church after the service ended, but then returned. Hyman was in a room with McNair with all the lights out. All the doors to the church were locked. Joyce Hyman and Rev. McNair talked about ending their affair and Joyce Hyman kissed Rev. McNair. Joyce Hyman testified that nothing unseemly happened that night between her and Rev. McNair, but testified that she couldn't say something wouldn't have happened if her husband hadn't come to the church.
17. Rev. Hyman knew his wife been having an affair with Rev. McNair for several years and believed she was having an affair with McNair in September 1991.
18. Emanuel Hyman testified that he came to Rev. McNair's church on the night of September 1991 because he had a doctor's appointment the next day and needed to get some X-Rays out of Joyce's car.

19. Emanuel Hyman testified at the hearing as follows:

When Rev. Hyman got to the church, all the lights were off. All the doors of the church were locked. Rev. Hyman knocked at the front door and at a side door. No one answered. Rev. McNair came out of the church and came at Rev. Hyman with his fists raised. Hyman backed up, picked up a stick and started swinging it. Rev. Hyman knocked Rev. McNair down, threw the stick away and ran away.

20. The autopsy performed on Rev. McNair showed that his skull was indented on the left side, his left collarbone was broken, two ribs were broken on his left side, and one of his arms was bruised.
21. Rev. Hyman testified on cross-examination by Purkett that he did not go to the church with the idea of catching his wife with Rev. McNair. Hyman observed that if he had wanted to catch his wife and McNair in an affair, he could have done so many times. Purkett questioned the credibility of Rev. Hyman's testimony that McNair charged him. Hyman responded that you never know what a man is thinking that is doing something wrong.
22. On September 4, Hyman turned himself in to the Plymouth police and confessed to killing Rev. McNair.
23. The SBI investigated the homicide at the request of the Plymouth Police. Special Agent Eric A. Hooks interviewed Emanuel Hyman several times. Hyman's testimony at this contested case hearing is consistent with the story he consistently told to Hooks of the events which led to the death of Rev. McNair. Hyman's testimony at this contested case hearing is consistent with his testimony at his criminal trial.
24. Sgt. Leo C. Ussery also interviewed Emanuel Hyman after Hyman turned himself in to the police. The statement Hyman gave to Ussery on September 5, 1991 is consistent with Hyman's testimony at this contested case.
25. Emanuel Hyman was charged and tried in Superior Court for the murder of Robert L. McNair, Sr. Hyman was found not guilty of murder. Hyman was found guilty of voluntary manslaughter and sentenced to a jail term of 120 (One Hundred Twenty) days. Hyman has served that term.

Based on the foregoing, the undersigned makes the following:

CONCLUSIONS OF LAW

1. The Commission's written denial of Purkett's claim for compensation from the Crime Victims Compensation Fund is vague and ambiguous.
2. McNair placed himself in a position on the night of his homicide in which Hyman could reasonably conclude that his wife and McNair were engaged in an extra-marital affair.
3. Emanuel Hyman's acquittal of murder and conviction of voluntary manslaughter by a jury negates the element of malice in Hyman's killing of McNair.
4. Emanuel Hyman killed Rev. McNair because either he acted in self defense to McNair's attack and used excessive force or he acted in the heat of passion and killed McNair because of McNair's long term affair with Joyce Hyman.
5. Either scenario results in a conclusion that Rev. McNair was engaged in misconduct, and a conclusion that the misconduct contributed to his death.
6. The Commission's denial of compensation benefits to Purkett, although vague and ambiguous, is not

erroneous in one of the ways described in G.S. 150B-23.

Based on the foregoing, the undersigned makes the following:

RECOMMENDED DECISION

The request for relief in the petition for contested case hearing should be DENIED.

ORDER

It is hereby ordered that the agency serve a copy of the final decision on the Office of Administrative Hearings, P.O. Drawer 27447, Raleigh, N.C. 27611-7447, in accordance with North Carolina General Statute 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 recommended decision and to present written arguments to those in the agency who will make the final decision. G.S. 150B-36(a).

The agency is required by G.S. 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 Crime Victims Compensation Commission.

This the 27th day of August, 1993.

Thomas R. West
Administrative Law Judge

**N. C. DEPARTMENT OF ENVIRONMENT,
HEALTH, AND NATURAL RESOURCES**
Respondent.

September 15, 1993

EXHIBITS

Listing of exhibits was omitted from this publication. If you would like a copy of the listing of exhibits, please contact the Office of Administrative Hearings.

ISSUES

The parties stipulated at the hearing that the issue to be resolved in this contested case is as follows:

1. Whether the Petitioner erred in installing a bed type wastewater field on his property without first obtaining an improvement permit from the Halifax County Health Department.

Respondent sought a stipulation that another issue was to be resolved. The issue is as follows:

2. Whether the improvement permit issued to the Petitioner by the Halifax County Health Department on December 11, 1992 is correct as to the additional amount of drainfield required to be installed.

Petitioner did not stipulate that Issue #2 was appropriate to be resolved. Over Mr. Grooms' objection, the Administrative Law Judge ruled that Issue #2 would be decided.

BURDEN OF PROOF

The burden is on Respondent to show by the greater weight of the substantial evidence that it should prevail on both issues.

OFFICIAL NOTICE

Official notice is taken of the following:

1. Article 11, Chapter 130A of the General Statutes of North Carolina.
2. 15A NCAC 18A .1900 et. seq.

STIPULATED FACTS

The parties stipulated to the following undisputed facts:

1. There is a two bedroom residence existing on the Petitioner's property which property is the subject of this contested case.
2. On or about October 14, 1992, the Petitioner caused to be installed on his property a bed type wastewater field which measures approximately 8 feet by 50 feet.
3. The Petitioner did not obtain an improvement permit from the Halifax County Health Department prior to installing the bed type field.

Based on the substantial evidence admitted, the undersigned finds the following to be the facts:

FINDINGS OF FACT

1. On October 14, 1992, a resident of Halifax County complained to the Halifax County Health Department that Fred Grooms was illegally repairing a septic tank system at a mobile home owned

by him. The citizen who complained is in the business of repairing septic tank systems.

2. Moulton Bailey is an Environmental Health Specialist employed by the Halifax County Health Department (hereafter "Halifax"). Over the objection of Petitioner, Bailey was found to be an expert in soil science. Bailey inspected Grooms' property on October 14, 1992, and saw Floyd Baugham placing gravel in a pit with a backhoe. The pit was approximately three feet deep and located at the outlet end of a septic tank. Bailey saw broken terra cotta tile lying broken and scattered in the area of the work and saw excavated dirt containing gravel.
3. Terra cotta tile was, in times past, used to construct nitrification lines leading from septic tanks. For several years, and in the present, plastic pipe with holes in it has been used to construct the lines.
4. Bailey told Baugham he was repairing a septic tank system without a permit and directed Baugham to stop work.
5. On October 15, 1992, Bailey went back to Fred Grooms' property and saw that the pit had been covered with dirt. No final inspection had been done or Certificate of Completion issued.
6. On October 16, 1992, Halifax wrote Petitioner Fred Grooms (hereafter "Grooms") a letter advising him that before repairing his septic system, Grooms was required to have a permit. Halifax issued a Sewage Violation Notice to Grooms because the work on his septic system had rendered the sewage system inoperable. The letter informed Grooms he had fifteen days to secure a permit and repair his system or vacate the property.
7. On October 26, 1992, Grooms applied for an Improvement Permit to repair the septic system at his house.
8. Bailey, Jeff Dillard, and Rebecca Edwards met with Grooms on his property on November 12, 1992. Dillard was another Environmental Health Specialist and Edwards was Bailey's and Dillard's supervisor. The Halifax employees probed the bed system installed by Grooms and augured two holes on his property to a depth of forty eight inches. Bailey and Dillard completed a Site/Soil Evaluation form with the results of their visit.
9. The Halifax employees concluded from the existence of broken terra cotta pipe, excavated dirt containing gravel and presence of fecal material and toilet tissue on the ground that the previous system had failed and had been repaired by Baugham on October 14, 1992.
10. The failure of the septic tank system which caused fecal material and toilet tissue to be on the ground occurred after Baugham's work on October 14, 1992 and before October 26, 1992. The failure was the result of plumbing defects between the fixtures in the mobile home and the septic tank.
11. The Halifax employees concluded from the visit that Grooms had installed a "bed system" for treatment of effluent from his house; the dimensions of the system are 8' by 50' (400 sq.ft.); and the "bed system" is 3' deep with the bottom foot being filled with gravel. Dillard was received, without objection, as an expert in soil science and installation of septic tank systems pursuant to the General Statutes and administrative rules covering those systems.
12. Bailey and Dillard found that Type II soils were present in the hole shown as #1 on Exhibit R7 to a depth of 48". Type II soils were present in hole #2 between 24" and 36" below the surface. Type III soils were present below 36". Bailey and Dillard concluded from the soils observed in the two auger holes that the structure of the soil below 36" was weak and of Type III.
13. Bed systems such as that installed by Grooms can be permitted if the soil texture can be classified into Soil Group I, II, or III. See 15A NCAC 18A .1955(d). The soil texture that is relevant in this case is the texture of soil one foot below the bottom of the nitrification trench or bed. See 15A NCAC 18A

.1955(b).

14. The mobile home on Grooms' property has two bedrooms. In determining the size a septic tank system needs to be to effectively treat sewage, dwelling units have been determined to have a minimum volume of 240 gallons per day. 15A NCAC 18A .1949(a).
15. Type III soils have a long term acceptance rate of sewage of 0.6 - 0.3. 0.3 is the acceptance rate for Type III soils with good structure. 0.6 is the acceptance rate for Type III soils with weak structures. Bailey and Dillard determined from their observation of soils augured from Grooms' property that the structure was weak and that the soil had a long term acceptance rate of 0.5.
16. Applying these two values Dillard determined that a conventional trench system would need to be 480 sq. ft. to effectively treat effluent from Grooms' mobile home. (240 gpd divided by 0.5 gpd/sq.ft. = 480 sq.ft.).
17. Therefore, the bed system installed by Grooms would need to be 720 sq. ft. to effectively treat effluent. The bed system installed by Grooms is 400 sq. ft.
18. Halifax wrote Grooms on November 16, 1992 setting forth its conclusions and offering to issue Grooms a permit for one of two options:
 - a. Increase the existing bed system by 320 sq. ft.; or
 - b. Install 213 sq. ft. of trench system (71' long x 3' wide).

Halifax asked Grooms to notify it by November 24, 1992 which option he chose.

19. The option of installing the trench system is significantly cheaper than expanding the bed system.
20. Grooms wrote Halifax a letter dated November 23, 1992 in which he stated his opinion that he had not repaired the septic tank system at his property, but had performed maintenance. A permit is not required for maintenance of a septic tank system.
21. Halifax wrote Grooms on December 11, 1992 taking the position that he had repaired his septic tank system without a permit, as a result he had violated the laws and administrative rules governing septic tank systems, and that the repair was inadequate to effectively treat sewage from the mobile home on his property.
22. Halifax enclosed a permit allowing Grooms to add a 3' x 71' trench to the existing bed system. The system is illustrated on exhibit R11. Grooms has declined to modify the bed system on his property.
23. Halifax enclosed in its letter of December 11, 1992, a "Second + Final Sewage Violation Notice" requiring Grooms to increase the size of the drainfield on the property, pursuant to one of the two options by January 15, 1993.
24. By letter dated January 28, 1993, Halifax forwarded to Grooms the forms to file this contested case. Halifax extended to March 31, 1993, the date by which Grooms was required to comply with the Second and Final Violation Notice. The letter states, " As of March 31, 1993, if a contested case has not been started or if your sewage system has not been properly repaired, we will proceed with legal action by swearing out a warrant"
25. On March 11, 1993, Grooms filed the petition commencing this contested case. Halifax has not sworn out a warrant against Grooms.

Based on the foregoing, the undersigned makes the following:

CONCLUSIONS OF LAW

1. On or about October 14, 1992, Grooms repaired the septic tank system on his property without a permit.
2. The repaired septic tank system cannot be operated in compliance with Article 11 of Chapter 130A of the North Carolina General Statutes or 15A NCAC 18A .1900 et. seq.
3. The repair of the septic tank system on Grooms property on or about October 14, 1992 is in violation of G.S. 130A-336.
4. Halifax has correctly applied the laws and rules governing the installation of septic tank systems in concluding that an addition of 213 sq. ft. of trench or 320 sq. ft. of bed system would render the repaired septic tank system permissible under the laws and rules governing the installation of septic tank systems.

Based on the foregoing, the undersigned makes the following:

RECOMMENDED DECISION

It is recommended that no relief requested by Grooms in his Petition be granted.

ORDER

It is hereby ordered that the agency serve a copy of the final decision on the Office of Administrative Hearings, P.O. Drawer 27447, Raleigh, N.C. 27611-7447, in accordance with North Carolina General Statute 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 recommended decision and to present written arguments to those in the agency who will make the final decision. G.S. 150B-36(a).

The agency is required by G.S. 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 Secretary of Environment, Health and Natural Resources, or his designee.

This the 26th day of August, 1993.

Thomas R. West
Administrative Law Judge

The North Carolina Administrative Code (NCAC) has four major subdivisions of rules. Two of these, titles and chapters, are mandatory. The major subdivision 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. The other two, subchapters and sections are optional subdivisions to be used by agencies when appropriate.

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