# NORTH CAROLINA REGISTER

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# Contact List for Rulemaking Questions or Concerns

For questions or concerns regarding the Administrative Procedure Act or any of its components, consult with the agencies below. The bolded headings are typical issues which the given agency can address, but are not inclusive.

## Rule Notices, Filings, Register, Deadlines, Copies of Proposed Rules, etc.

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## Fiscal Notes & Economic Analysis and Governor's Review

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Raleigh, North Carolina 27603-8005 (919) 733-0640 FAX
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Raleigh, North Carolina 27603
contact: Amy Bason amy.bason@ncacc.org

NC League of Municipalities (919) 715-4000
215 North Dawson Street
Raleigh, North Carolina 27603
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## Legislative Process Concerning Rule-making

Joint Legislative Administrative Procedure Oversight Committee
545 Legislative Office Building
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| | | |
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**NORTH CAROLINA REGISTER**
Publication Schedule for January 2013 – December 2013

| FILING DEADLINES | | | NOTICE OF TEXT | | PERMANENT RULE | | | TEMPORARY RULES |
|---|---|---|---|---|---|---|---|---|
| Volume & issue number | Issue date | Last day for filing | Earliest date for public hearing | End of required comment period | Deadline to submit to RRC for review at next meeting | Earliest Eff. Date of Permanent Rule | Delayed Eff. Date of Permanent Rule<br>31st legislative day of the session beginning: | 270th day from publication in the Register |
| 27:13 | 01/02/13 | 12/06/12 | 01/17/13 | 03/04/13 | 03/20/13 | 05/01/13 | 05/2014 | 09/29/13 |
| 27:14 | 01/15/13 | 12/19/12 | 01/30/13 | 03/18/13 | 03/20/13 | 05/01/13 | 05/2014 | 10/12/13 |
| 27:15 | 02/01/13 | 01/10/13 | 02/16/13 | 04/02/13 | 04/22/13 | 06/01/13 | 05/2014 | 10/29/13 |
| 27:16 | 02/15/13 | 01/25/13 | 03/02/13 | 04/16/13 | 04/22/13 | 06/01/13 | 05/2014 | 11/12/13 |
| 27:17 | 03/01/13 | 02/08/13 | 03/16/13 | 04/30/13 | 05/20/13 | 07/01/13 | 05/2014 | 11/26/13 |
| 27:18 | 03/15/13 | 02/22/13 | 03/30/13 | 05/14/13 | 05/20/13 | 07/01/13 | 05/2014 | 12/10/13 |
| 27:19 | 04/01/13 | 03/08/13 | 04/16/13 | 05/31/13 | 06/20/13 | 08/01/13 | 05/2014 | 12/27/13 |
| 27:20 | 04/15/13 | 03/22/13 | 04/30/13 | 06/14/13 | 06/20/13 | 08/01/13 | 05/2014 | 01/10/14 |
| 27:21 | 05/01/13 | 04/10/13 | 05/16/13 | 07/01/13 | 07/22/13 | 09/01/13 | 05/2014 | 01/26/14 |
| 27:22 | 05/15/13 | 04/24/13 | 05/30/13 | 07/15/13 | 07/22/13 | 09/01/13 | 05/2014 | 02/09/14 |
| 27:23 | 06/03/13 | 05/10/13 | 06/18/13 | 08/02/13 | 08/20/13 | 10/01/13 | 05/2014 | 02/28/14 |
| 27:24 | 06/17/13 | 05/24/13 | 07/02/13 | 08/16/13 | 08/20/13 | 10/01/13 | 05/2014 | 03/14/14 |
| 28:01 | 07/01/13 | 06/10/13 | 07/16/13 | 08/30/13 | 09/20/13 | 11/01/13 | 05/2014 | 03/28/14 |
| 28:02 | 07/15/13 | 06/21/13 | 07/30/13 | 09/13/13 | 09/20/13 | 11/01/13 | 05/2014 | 04/11/14 |
| 28:03 | 08/01/13 | 07/11/13 | 08/16/13 | 09/30/13 | 10/21/13 | 12/01/13 | 05/2014 | 04/28/14 |
| 28:04 | 08/15/13 | 07/25/13 | 08/30/13 | 10/14/13 | 10/21/13 | 12/01/13 | 05/2014 | 05/12/14 |
| 28:05 | 09/03/13 | 08/12/13 | 09/18/13 | 11/04/13 | 11/20/13 | 01/01/14 | 05/2014 | 05/31/14 |
| 28:06 | 09/16/13 | 08/23/13 | 10/01/13 | 11/15/13 | 11/20/13 | 01/01/14 | 05/2014 | 06/13/14 |
| 28:07 | 10/01/13 | 09/10/13 | 10/16/13 | 12/02/13 | 12/20/13 | 02/01/14 | 05/2014 | 06/28/14 |
| 28:08 | 10/15/13 | 09/24/13 | 10/30/13 | 12/16/13 | 12/20/13 | 02/01/14 | 05/2014 | 07/12/14 |
| 28:09 | 11/01/13 | 10/11/13 | 11/16/13 | 12/31/13 | 01/21/14 | 03/01/14 | 05/2014 | 07/29/14 |
| 28:10 | 11/15/13 | 10/24/13 | 11/30/13 | 01/14/14 | 01/21/14 | 03/01/14 | 05/2014 | 08/12/14 |
| 28:11 | 12/02/13 | 11/06/13 | 12/17/13 | 01/31/14 | 02/20/14 | 04/01/14 | 05/2014 | 08/29/14 |
| 28:12 | 12/16/13 | 11/21/13 | 12/31/13 | 02/14/14 | 02/20/14 | 04/01/14 | 05/2014 | 09/12/14 |

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## EXPLANATION OF THE PUBLICATION SCHEDULE

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

### GENERAL

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

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

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

### FILING DEADLINES

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

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

### NOTICE OF TEXT

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

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

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

**FIRST LEGISLATIVE DAY OF THE NEXT REGULAR SESSION OF THE GENERAL ASSEMBLY**: This date is the first legislative day of the next regular session of the General Assembly following approval of the rule by the Rules Review Commission. See G.S. 150B-21.3, Effective date of rules.

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**NOTICE OF RULE MAKING PROCEEDINGS AND PUBLIC HEARING**

**NORTH CAROLINA BUILDING CODE COUNCIL**

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

**Citation to Existing Rule Affected by this Rule-Making:** *North Carolina Building, Energy Conservation, Fire, Plumbing, and Residential Codes.*

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

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

**Public Hearing: Tuesday,** *June 11, 2013, 9:00AM, NCSU McKimmon Center, 1101 Gorman Street, Raleigh, NC 27606. Comments on both the proposed rule and any fiscal impact will be accepted.*

**Comment Procedures:** *Written comments may be sent to Chris Noles, Secretary, NC Building Code Council, NC Department of Insurance, 322 Chapanoke Road, Suite 200, Raleigh, NC 27603. Comments on both the proposed rule and any fiscal impact will be accepted. Comment period expires on July 15, 2013.*

**Statement of Subject Matter:**

**1. Request by Bobby W. Patterson, representing Architectural Design Associates, PLLC, to amend the 2012 NC Building Code, Sections 3404 and 3408. The proposed amendment is as follows:**

**SECTION 3404**
**ALTERATIONS**
**3404.4.2 Seismic upgrades.** Seismic upgrades shall not be required in alterations to an existing building (Building A) where all of the following conditions exist:
1. The alterations in Building A are being undertaken to allow an existing Building B to be vacated for seismic upgrades.
2. The Occupancy Categories (Table 1604.5) of the two buildings are the same or higher for Building A.
3. Building A will be temporarily used to facilitate the seismic upgrades to Building B, and occupied as such for a period of no more than 5 years after issuance of a Certificate of Occupancy for Building A.
4. Building A is located in a Seismic Design Category (SDC) area A or B as defined by FEMA.

**SECTION 3408**
**CHANGE OF OCCUPANCY**
**3408.4 EXCEPTIONS**
3. Seismic upgrades shall not be required in a change of use to an existing building (Building A) where all of the following conditions exist:
3.1. The alterations in Building A are being undertaken to allow an existing Building B to be vacated for seismic upgrades.
3.2. The Occupancy Categories (Table 1604.5) of the two buildings are the same or higher for Building A.
3.3. Building A will be temporarily used to facilitate the seismic upgrades to Building B, and occupied as such for a period of no more than 5 years after issuance of a Certificate of Occupancy for Building A.
3.4. Building A is located in a Seismic Design Category (SDC) area A or B as defined by FEMA.

Motion/Second – Bob Ruffner/Approved – The request was granted unanimously. The proposed effective date of this rule is January 1, 2015.
Reason Given – Adding these exceptions to the Code will allow a process of renovating an existing building for short-term occupancy during the full renovation of the currently occupied facility to upgraded seismic resistance.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with either a small decrease or no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or increase local and state funds. A fiscal note has not been prepared.

**2. Request by Kent P. Misegades, representing U-Fuel, Inc., to amend the 2012 NC Fire Code, Section 2206.2.3. The proposed amendment is as follows:**

**2206.2.3 Above-ground tanks located outside, above grade.** Above-ground tanks shall not be used for the storage of Class I, II or IIIA liquid motor fuels except as provided by this section.

1. ~~Above-ground tanks used for outside, above-grade storage of Class I liquids shall be *listed* and *labeled* as protected above-ground tanks and be in accordance with Chapter 34. Such tanks shall be located in accordance with Table 2206.2.3.~~ Deleted.
2. Above-ground tanks used for above-grade storage of Class I, II or IIIA liquids are allowed to be protected above-ground tanks or, when *approved* by the *fire code official*, other above-ground tanks that comply with Chapter 34. Tank locations shall be in accordance with Table 2206.2.3.
3. Tanks containing fuels shall not exceed 12,000 gallons (45 420 L) in individual capacity or 48,000 gallons (181 680 L) in aggregate capacity. Installations with the maximum allowable aggregate capacity shall be separated from other such installations by not less than 100 feet (30 480 mm).
4. Tanks located at farms, construction projects, or rural areas shall comply with Section 3406.2.

Motion – Alan Perdue/Second – Lon McSwain/Denied – The request was denied as presented.
Reason Given – This petition potentially benefits a proprietary product and also affects other liquids. This petition will cause a substantial economic impact. No further action will be taken on this item.

**3. Request by Patrick Holzer, representing Certified Foam, to amend the 2012 NC Fire Code, Section 404.3.3. The proposed amendment will add allowances and requirements for lockdown devices for classroom doors.**

**403.3.3 Lockdown plans.** Where facilities develop a lockdown plan, the lockdown plan shall be in accordance with Section 404.3.3.1 through 404.3.3.3.
**404.3.3.1 Lockdown plan contents.** Lockdown plans shall be *approved* by the *fire code official* and shall include the following:
1. Initiation. The plan shall include instructions for reporting an emergency that requires a lockdown.
2. Accountability. The plan shall include accountability procedures for staff to report the presence or absence of occupants.
3. Recall. The plan shall include a prearranged signal for returning to normal activity.
4. Secured areas. The plan shall include an identified means of establishing each secured area, including the use of an emergency lockdown safety mechanism as described in Section 1008.1.11.
5. Communication and coordination. The plan shall include an *approved* means of two-way communication between a central location and each secured area.

**404.3.3.2 Training frequency.** The training frequency shall be included in the lockdown plan. The lockdown drills shall not substitute for any of the fire and evacuation drills required in Section 405.2.
**404.3.3.3 Lockdown notification.** The method of notifying building occupants of a lockdown shall be included in the plan. The method of notification shall be separate and distinct from the fire alarm signal.

Motion – Al Bass/Second – Kim Reitterer/Approved – The request was granted unanimously and was sent to the Building and Fire Committees for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – No provisions exist in the current code to identify a means of establishing a secured area in the event of a lockdown situation.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**4. Request by Patrick Holzer, representing Certified Foam, to amend the 2012 NC Building (and Fire) Code, Section 1008. The proposed amendment is as follows:**

**1008.1.11 Emergency lockdown safety mechanisms.** *Approved* emergency lockdown safety mechanisms shall be permitted in schools for the purposes of establishing a secured area in accordance with lockdown plans in Section 404.3.3 and Items 1-7 below:
1. The emergency lockdown safety mechanism shall be readily distinguishable as engaged or disengaged.
2. Clearly identifiable operating procedures shall be posted on or within close proximity of the installed mechanism.
3. The emergency lockdown safety mechanism shall be readily engaged from the egress side without the use of a key or special knowledge or effort.
4. The emergency lockdown safety mechanism shall have a built-in mechanical feature to prevent unintended engagement.
5. The emergency lockdown safety mechanism shall be readily disengaged from the ingress side with proper tools and instruction.
6. The mechanism shall be installed 6 inches (152 mm) minimum and 48 inches (1219 mm) maximum above the finished floor. However, the maximum installed height shall be limited such that the emergency lockdown safety mechanism is as least 30 inches (762 mm) from any glass openings within the door.
7. A building occupant shall not be required to pass through more than one door equipped with an emergency lockdown safety mechanism before entering an exit.

Motion – Kim Reitterer/Second – Lon McSwain/Approved – The request was granted unanimously and was sent to the Building and Fire Committees for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – No provisions exist in the current code that identifies how to establish a secure area as defined in the Fire Code, Section 402, Emergency Planning and Preparedness, for a lockdown situation in a school.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with a net increase in cost. This rule is not expected to either have a substantial economic impact or affect state funds. This rule is expected to increase local funds. A fiscal note has not been prepared.

**5. Request by Joseph Vetter, representing 4-J Design, Inc., to amend the 2012 NC Plumbing Code, Section 504.6, #2. The proposed amendment is as follows:**

**504.6 Requirements for discharge piping.**

2. Discharge through an air gap or air gap fitting located in the same room as the water heater, either on the floor, into an indirect waste receptor or outdoors.

Motion – Al Bass/Second – Ralph Euchner/Approved – The request was granted unanimously and was sent to the Mechanical Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – This amendment will aid in the efficiency of installation in water heater discharge piping, when an air gap is required, by allowing a connection to the T&P valve.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**6. Request by Wayne Hamilton, representing the NC Fire Service Code Revision Committee, to amend the 2012 NC Fire Code, Section 909.20.6. The proposed amendment is as follows:**

Add New Section:

**909.20.6 Manual smoke removal.** Where manually operated panels or windows are required by section 403.4.6 of the Building Code, they shall be maintained in an operable condition and identified in an *approved* manner.

Motion – Alan Perdue/Second – Mack Nixon/Approved – The request was granted unanimously and was sent to the Fire Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – The Building Code, Section 403.4.6 is an option that allows operable panels or windows as a manual smoke control method in high-rise buildings. There are no companion Fire Code, Section 909.20 maintenance requirements as there are for mechanical systems.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**7. Request by Wayne Hamilton, representing the NC Fire Service Code Revision Committee, to amend the 2012 NC Fire Code, Section 316.5.3. The proposed amendment is as follows:**

Add new section to:

**316.5 Structures and outdoor storage underneath high-voltage transmission lines.**

**316.5.3 Parking.** Transient parking of passenger vehicles is allowed as follows:
1. The utility provider grants permission to park within their easement or right of way.
2. Each vehicle shall be 10,000lb GVW or less.
3. The lowest conductor of the transmission line shall be 25ft. above parking lot surface.
4. The transmission line voltage shall be 230kv or less.
5. Transient parking is a time period of no more than twelve consecutive hours.

Motion – Kim Reitterer/Second – Alan Perdue/Approved – The request was granted unanimously and was sent to the Fire Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – Combustible storage under high power transmission lines is an infrastructure damage risk from a hostile fire and smoke increases the arcing potential between the conductors. This section was drafted in response to a request from the NC Department of Commerce in regards to a major industry recruited into the state and a subsequent draft OSFM interpretation regarding their site plan. Our research indicates that transient vehicle parking is an acceptable risk based on some limiting factors. The NEC

allows parking based on the voltage involved and a separation distance. Rather than reproduce the table with varying voltages and distances, the maximum separation distance is used. If a situation arises where a site requests less than 25-feet, then the NEC table could be used as an alternate method. This code change has been vetted with Duke/Progress Energy, as this is a deviation from the model 2009 IFC.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**8. Request by Wayne Hamilton, representing the NC Fire Service Code Revision Committee, to amend the 2012 NC Fire (and Building) Code, Section 903.2.8. The proposed amendment is as follows:**

Revise section by adding exceptions:

**[F] 903.2.8 Group R.** An automatic sprinkler system shall be installed in accordance with Section 903.3 throughout all buildings with a Group R fire area.
**Exceptions:**
1. An *automatic sprinkler system* is not required in new adult and child care facilities located in existing Group R-3 and R-4 occupancies.
2. An automatic sprinkler system is not required in ~~Group R-1~~ temporary overflow shelters.
3. Group R2 buildings for housing farm workers and/or their families on a farm may install a 13D multipurpose sprinkler system, when all of the following conditions are met:
3.1. The Group R building cannot exceed a single story,
3.2. 2500 square feet in area, and
3.3. Two remote means of egress are provided.
4. Group R-2 *fire areas* in fire stations may install a 13D sprinkler system in accordance with 903.3.5.1 when separated from other occupancies by a *fire wall.*
4.1. The Group R building cannot exceed a single story,
4.2. 2500 square feet in area, and
4.3. Two remote means of egress are provided.
5. An *automatic sprinkler system* is not required in camping units located within a campground when one story, less than 400 square feet, and without a kitchen.

Motion – Mack Nixon/Second – Lon McSwain/Approved – The request was granted unanimously and was sent to the Building and Fire Committees for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – Item 2 is an editorial correction. Items 3 and 4 are proposed to allow limited commercial use of a NFPA 13D sprinkler system with a domestic water supply. Item 5 is proposed to exempt small commercial camping cabins from sprinkler requirements.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with either a small decrease or no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**9. Request by Duke Geraghty, representing Starco Realty and Construction, to amend the 2012 NC Residential Code, Section R301.2.1.2. The proposed amendment is as follows:**

**R301.2.1.2 Protection of openings.** Windows in buildings located in windborne debris regions shall have glazed openings protected from windborne debris. Glazed opening protection for windborne debris shall meet the requirements of the Large Missile Test of ASTM E 1996 and ASTM E 1886 referenced therein. Garage door glazed opening protection for windborne debris shall meet the requirements of an *approved* impact resisting standard or ANSI/DASMA 115.
**Exception:** Wood structural panels with a minimum thickness of 7/16 inch (11 mm) and a maximum span of 8 feet (2438 mm) shall be permitted for opening protection in one- and two-story buildings. Panels shall be precut and attached to the framing surrounding the opening containing the product with the glazed opening. Panels ~~shall be predrilled as required for the anchorage method and~~ shall be secured with the attachment hardware provided. Attachments shall be designed to resist the component and cladding loads determined in accordance with either Table R301.2(2) or ASCE 7, ~~with the permanent corrosion resistant attachment hardware provided and anchors permanently installed on the building~~. Attachment in accordance with Table R301.2.1.2 is permitted for buildings with a mean roof height of 33 feet (10 058 mm) or less where wind speeds do not exceed 130 miles per hour (58 m/s).

**TABLE R301.2.1.2**
**WINDBORNE DEBRIS PROTECTION FASTENING SCHEDULE**
**FOR WOOD STRUCTURAL PANELS[a,b,c,d]**

| FASTENER TYPE | FASTENER SPACING (inches)[a,b] | | |
|---|---|---|---|
| | Panel span ≤ 4 feet | 4 feet < panel span ≤ 6 feet | 6 feet < panel span ≤ 8 feet |
| No. 8 wood screw ~~based anchor with 2-inch embedment length~~ | 16 | 10 | 8 |
| No. 10 wood screw ~~based anchor with 2-inch embedment length~~ | 16 | 12 | 9 |
| ¼-inch lag screw ~~based anchor with 2-inch embedment length~~ | 16 | 16 | 16 |

For SI: 1 inch = 25.4 mm, 1 foot = 304.8 mm, 1 pound = 4.448 N, 1 mile per hour = 0.447 m/s.

a. This table is based on 130mph wind speeds and a 33-foot mean roof height.
b. Fasteners shall be installed at opposing ends of the wood structural panel. Fasteners shall be located a minimum of 1 inch from the edge of the panel.
c. ~~Anchors~~ Fasteners shall be long enough to penetrate through the exterior wall covering ~~with an embedment length of 2 inches minimum into the building frame.~~ and a minimum of 1¼ inches into wood wall framing and a minimum of 1¼ inches into concrete block or concrete, and into steel framing a minimum of 3 exposed threads. Fasteners shall be located a minimum of 2½ inches from the edge of concrete block or concrete.
d. Where panels are attached to masonry or masonry/stucco, they shall be attached using vibration-resistant anchors having a minimum ultimate withdrawal capacity of 1500 pounds.

Motion – David Smith/Second – Mack Nixon/Approved – The request was granted unanimously and was sent to the Residential Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – This proposal eliminates the requirement for permanent anchors to be installed. Fasteners will be provided to install the panels.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**10. Request by R. Christopher Mathis, representing Mathis Consulting Company, to amend the 2012 NC Energy Conservation Code, Table 502.1.2 & Tables 502.1.2(1). The proposed amendment is as follows:**

**Modify Table 502.1.2 as follows:**

**TABLE 502.1.2**
**BUILDING ENVELOPE REQUIREMENTS OPAQUE ELEMENT, MAXIMUM U-FACTORS**

| CLIMATE ZONE | 3 | | 4 | | 5 | |
|---|---|---|---|---|---|---|
| | ALL OTHER | GROUP R | ALL OTHER | GROUP R | ALL OTHER | GROUP R |
| **Roofs** | | | | | | |
| Metal buildings ~~(with R-5 thermal blocks)~~[a] | U-0.041 | U-0.041 | ~~U-0.035~~ U-0.037 | ~~U-0.035~~ U-0.037 | ~~U-0.035~~ U-0.037 | ~~U-0.035~~ U-0.037 |
| **Walls, Above Grade** | | | | | | |
| Metal building | ~~U-0.072~~ U-0.094 | U-0.050 | U-0.060 | U-0.050 | U-0.050 | U-0.050 |

**Modify Table 502.1.2(1) as follows:**

**TABLE 502.1.2(1)**
**BUILDING ENVELOPE REQUIREMENTS – OPAQUE ASSEMBLIES**

| CLIMATE ZONE | 3 | | 4 | | 5 | |
|---|---|---|---|---|---|---|
| | ALL | GROUP R | ALL | GROUP R | ALL | GROUP R |

| | OTHER | | OTHER | | OTHER | |
|---|---|---|---|---|---|---|
| **Roofs** | | | | | | |
| Metal buildings (with R-5 thermal blocks)[a, b] | R-10 + R-19 FC | R-10 + R-19 FC | R-19 + R-11 LS Or R-25 + R-8 LS | R-19 + R-11 LS Or R-25 + R-8 LS | R-19 + R-11 LS Or R-25 + R-8 LS | R-19 + R-11 LS Or R-25 + R-8 LS |
| **Walls, Above Grade** | | | | | | |
| Metal building[b] | ~~R-0 + R-13 ci~~ R-0 + R-9.8 ci | R-0 + R-19 ci | R-0 + R-15.8 ci | R-0 + R-19 ci | R-0 + R-19 ci | R-0 + R-19 ci |

LS = Liner System – Liner systems shall have a minimum R-5 thermal spacer block between the purlins and the metal roof panels as required, unless compliance is shown by the overall assembly U-factor
FC = Filled Cavity – Filled Cavity assemblies shall have a minimum R-5 thermal spacer block between the purlins and the metal roof panels as required, unless compliance is shown by the overall assembly U-factor

Motion – David Smith/Second – Mack Nixon/Approved – The request was granted unanimously and was sent to the Energy Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – These slight decreases in energy efficiency coordinate with the recently revised values in ASHRAE 90.1 negotiated by the metal building industry. This proposal also offers additional prescriptive compliance options.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with either a small decrease or no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**11. Request by Lon McSwain, representing the NC BCC Building Standing Committee, to amend the 2012 NC Building Code, Section 101.2. The proposed amendment is as follows:**

**Exceptions:** If any of the following apply the building or structure is exempt from the provisions of this code:
1. Detached one- and two-family dwellings and multiple single-family dwellings (townhouses) not more than three stories above grade plane in height with a separate means of egress and their accessory structures shall comply with the *International Residential Code*.
2. Farm Buildings as described by G.S. 143-138(b4) that are not used for sleeping purposes and located outside the buildings rules jurisdiction of any municipality.
~~**Exception:** All buildings used for sleeping purposes shall confirm to the provisions of the technical codes.~~
3. Greenhouses as described by G.S. 143-138(b4) for farm building use located outside or inside the building rules jurisdiction of a municipality or a county.
4. Farm buildings for equine activities as described by G.S. 143-138(b4) and located outside the building rules jurisdiction of a municipality.
5. The design, construction, location, installation or operation of equipment for storing, handling and transporting liquefied petroleum gases for fuel purposes up to the outlet of the first stage pressure regulator, and anhydrous ammonia or other liquid fertilizers.
6. The design, construction, location, installation or operation of equipment or facilities of a public utility, as defined in G.S. 62-3, or an electric or telephone membership corporation, including without limitation poles, towers and other structures supporting electric or communication lines from the distribution network up to the meter location.
**Note:** All *buildings* owned and operated by a public utility or an electric or telephone membership corporation shall meet the provisions of the code.
7. The Storage and Handling of Hazardous Chemicals Right to Know Act, Article 18 of Chapter 95 of the North Carolina General Statutes.

Motion – Kim Reitterer/Second – Alan Perdue/Approved – The request was granted unanimously and was sent to the Building Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – This proposal is to add recently enacted farm building exceptions to the code.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**12. Request by Lon McSwain, representing the NC BCC Building Standing Committee, to amend the 2012 NC Building & Fire Codes, Section 1018.6. The proposed amendment is as follows:**

**1018.6 Corridor continuity.** Fire-resistant-rated corridors shall be continuous from the point of entry to an exit, and shall not be interrupted by intervening rooms.

**Exceptions:**

1. Foyers, lobbies or reception rooms constructed as corridors shall not be constructed as intervening rooms.
2. A toilet room as defined by the NC Plumbing Code that meets all of the following requirements may be included as part of the rated corridor enclosure:
2.1. The toilet room shall be separated from the remainder of the building by fire-resistant-rated construction meeting the same requirements as the corridor construction;
2.2. No other rooms open off of the toilet room;
2.3. No gas or electric appliances other than electric hand dryers are located in the toilet room; and
2.4. The toilet room is not used for any other purpose.

Motion – Kim Reitterer/Second – Cindy Browning/Approved – The request was granted unanimously and was sent to the Building Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – This is proposal to coordinate with the Building Code, Table 715.4. Toilet rooms that have little to no fuel load pose no significant hazard to the rated exit access corridor.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**13. Request by Chris Noles, representing NCDOI on behalf of the NC BCC, to amend the 2012 NC Building Code, Appendix *NEW*, Sections 101.1, 102, & 103. The proposed amendment is as follows:**

The purpose of this section is to address structures such as camping cabins or primitive structures that are used on a temporary basis.

**101.1 Scope.** The purpose of this section is to address buildings that are subject to limited portions of the building code.

**102 Terms.**
**102.1 Primitive structure** – Buildings not used as a primary residence intended for the primary purpose of rustic living. These structures are not equipped with water or electricity and are used on a temporary basis.
**102.2 Roof-only structures** – Buildings without walls such as pavilions or gazebos that do not exceed 750 square feet.

**103 Design**

**103.1 Applicability.** Primitive and roof-only structures shall only be applicable to code sections identified in the following;
**103.1.1 Structural stability.** The structures shall be evaluated to meet the interior and exterior loading requirements contained in Chapter 16 of the Building Code.
**103.1.2 Clearance to Combustibles.** Ignition sources such as fireplaces or stoves shall be separated from combustibles in accordance with Chapter 7 of the Building Code.
**103.1.3 Fires.** Recreational fires shall be separated from the buildings in accordance with the Fire Code.
**103.1.4 Egress.** A clear means of egress shall be maintained from each sleeping room.
**103.2 Issues not addressed**. Life safety issues not covered by this section shall be mitigated by code official.

Motion – Al Bass/Second – Mack Nixon/Approved – The request was granted unanimously and sent to the Building Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – The purpose of this section is to address structures, such as camping cabins or primitive structures, that are used on a temporary basis.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**14. Request by Barry Gupton, representing NCDOI, to amend the 2012 NC Plumbing Code, Section 403.6.3. The proposed amendment is as follows:**

**403.6.3 Picnic shelters.** Where picnic shelters that are less than 750-square feet (70-square meters) in aggregate area are installed in a community recreation area, and parking is not either provided or required, public toilet facilities are not required. The travel distance to the dwellings served shall be limited to 1640-feet (500-meters).

Motion – Al Bass/Second – Mack Nixon/Approved – The request was granted unanimously and sent to the Mechanical Committee for review. The proposed effective date of this rule is January 1, 2015.

Reason Given – The Code requires public toilet facilities at all structures used by the public. This proposal provides an allowance for residents to use private toilet facilities within their own dwellings for small picnic shelters within walking distance.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with either a small decrease or no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.

**15. Request by David Smith, NC BCC, to amend the 2012 NC Residential Code, Sections R322.2.1 and R322.3.2. The proposed amendment is as follows:**

**R322.2.1 Elevation requirements.**
1. Buildings and structures shall have the lowest floors elevated to or above the base flood elevation ~~plus one foot (305 mm),~~ or the design flood elevation, whichever is higher.
2. In areas of shallow flooding (AO Zones), buildings and structures shall have the lowest floor (including basement) elevated at least as high above the highest adjacent grade as the depth number specified in feet (mm) on the FIRM ~~plus one foot (305 mm),~~ or at least 3 feet (915 mm) if a depth number is not specified.
3. Basement floors that are below grade on all sides shall be elevated to or above the base flood elevation ~~plus one foot (305 mm),~~ or the design flood elevation, whichever is higher.

**Exception:** Enclosed areas below the design flood elevation, including basements whose floors are not below grade on all sides, shall meet the requirements of Section R322.2.2.

**R322.3.2 Elevation requirements.**
1. All buildings and structures erected within coastal high hazard areas shall be elevated so that the lowest portion of all structural members supporting the lowest floor, with the exception of mat or raft foundations, piling, pile caps, columns, grade beams and bracing, is:
1.1. Located at or above the design flood elevation, if the lowest horizontal structural member is oriented parallel to the direction of wave approach, where parallel shall mean less than or equal to 20 degrees (0.35 rad) from the direction of approach, or
1.2. Located at the base flood elevation ~~plus 1 foot (305 mm),~~ or the design flood elevation, whichever is higher, if the lowest horizontal structural member is oriented perpendicular to the direction of wave approach, where perpendicular shall mean greater than 20 degrees (0.35 rad) from the direction of approach.
2. Basement floors that are below grade on all sides are prohibited.
3. The use of fill for structural support is prohibited
4. Minor grading, and the placement of minor quantities of fill, shall be permitted for landscaping and for drainage purposes under and around buildings and for support of parking slabs, pool decks, patios and walkways.

**Exception:** Walls and partitions enclosing areas below the design flood elevation shall meet the requirements of Sections R322.3.4 and R322.3.5.

Motion – David Smith /Second – Mack Nixon/Granted – The request was granted unanimously and sent to the Residential Committee for review. The proposed effective date of this rule is January 1, 2015.
Reason Given – The proposal allows for flood elevation design compatible with local flood ordinances and FIRMs. This is coordination between construction and insurance regulations. The proposed effective date of this rule is January 1, 2015.
Fiscal Statement – This rule is anticipated to provide equivalent compliance with no net decrease/increase in cost. This rule is not expected to either have a substantial economic impact or affect local and state funds. A fiscal note has not been prepared.
Note – A hearing was previously held on this item on September 10, 2012.

***Note from the Codifier:*** *The notices published in this Section of the NC Register include the text of proposed rules. The agency must accept comments on the proposed rule(s) for at least 60 days from the publication date, or until the public hearing, or a later date if specified in the notice by the agency. If the agency adopts a rule that differs substantially from a prior published notice, the agency must publish the text of the proposed different rule and accept comment on the proposed different rule for 60 days.*
*Statutory reference: G.S. 150B-21.2.*

**TITLE 15A – DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

***Notice*** *is hereby given in accordance with G.S. 150B-21.2 that the NC Radiation Protection Commission intends to amend the rules cited as 15A NCAC 11 .0104, .0105, .0117, .0301, .0303-.0305, .0309, .0317, .0318, .0321, .0322, .0328, .0331, .0333, .0334, .0338, .0352, .0358, .0361, .0362, .1004, .1604, .1626, .1633, .1648 and repeal the rules cited as 15A NCAC 11 .0325, .0326.*

**Agency obtained G.S. 150B-19.1 certification:**
☒ **OSBM certified on:** *04/18/2013*
☐ **RRC certified on:**
☐ **Not Required**

**Link to agency website pursuant to G.S. 150B-19.1(c):** *http://www.ncdhhs.gov/dhsr/ruleactions.html*

**Proposed Effective Date:** *October 1, 2013*

**Public Hearing**:
**Date:** *July 10, 2013*
**Time:** *10:00 a.m.*
**Location:** *3825 Barrett Drive, Conference Room 101, Raleigh, NC 27609*

**Reason for Proposed Action:** *The Radiation Protection Commission is proposing to amend its rules in 15A NCAC 11 to comply with the federal requirements of the U.S. Nuclear Regulatory Commission (NRC). North Carolina entered into an agreement with the United States Atomic Energy Commission (now NRC) effective August 1, 1964. This agreement provided for the discontinuance of United States Atomic Energy Commission regulatory authority and responsibility within the state. For the agreement to be approved, the United States Atomic Energy Commission had to determine that the NC program for radiation protection was compatible with federal regulations, and that the program was adequate to protect public health and safety. NC became an Agreement State as a result of the agreement signed by the Governor. The agreement requires NC to continue to maintain compatibility with federal (NRC) radiation protection rules. The NC Radiation Protection Section is inspected by the NRC every four years to verify that the radiation protection program remains compatible and adequate to protect public health and safety. Part of the NRC inspection is to verify rules compatibility with federal rules. In most cases, the NC radiation protection program rules must be identical with the matching federal rule. Failure to maintain compatibility with appropriate federal rules could result in NC losing its Agreement State status with the NRC. In that event, the NRC would then resume regulatory authority over radioactive materials use in NC. Reverting back to federal control would result in substantial fee increases for NC business entities that require use of radioactive materials. In most cases, the NRC radioactive materials license fees are at least double the current NC fees.*

**Procedure by which a person can object to the agency on a proposed rule:** *An individual may object to the agency on the proposed rules by submitting written comments on the proposed rule to Megan Lamphere, NC Division of Health Service Regulation, 2719 Mail Service Center, Raleigh, NC 27699-2719. They may also object by attending the public hearing and personally voice their objections during that time.*

**Comments may be submitted to:** *Megan Lamphere, NC Division of Health Service Regulation, 2719 Mail Service Center, Raleigh, NC 27699-2719, fax 919-733-3207, or email dhsr.rulescoordinator@dhhs.nc.gov.*

**Comment period ends:** *July 15, 2013*

**Procedure for Subjecting a Proposed Rule to Legislative Review:** If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

**Fiscal impact (check all that apply).**
☐ **State funds affected**
☐ **Environmental permitting of DOT affected**
**Analysis submitted to Board of Transportation**
☐ **Local funds affected**
**Date submitted to OSBM:**
☐ **Substantial economic impact (≥$500,000)**
☒ **Approved by OSBM**
☐ **No fiscal note required by G.S. 150B-21.4**

## CHAPTER 11 – RADIATION PROTECTION

## SECTION .0100 – GENERAL PROVISIONS

### 15A NCAC 11 .0104 DEFINITIONS

As used in these Rules, the following definitions ~~shall~~ apply.

(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

(2) "Accelerator produced material" means any material made radioactive by use of a particle accelerator.

(3) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.

(4) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

(5) "Adult" means an individual 18 or more years of age.

(6) "Agency" means the~~ North Carolina Department of Environment and Natural Resources, Division of Environmental Health~~, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

(7) "Agreement state" has the meaning as defined in G.S. 104E-5(2).

(8) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(10) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:

(a) in excess of the derived air concentrations (DACs) specified in Appendix B to 10 CFR 20.1001 - 20.2401; or

(b) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(11) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

(12) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2401).

(13) "Annually" means either:

(a) at intervals not to exceed 12 consecutive months; or

(b) once per year at the same time each year (completed during the same month each year over a period of multiple years).

(14) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. APF can be divided into the ambient airborne concentrations to estimate inhaled air concentrations.

(15) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(16) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is ~~specifically~~ so designated by the agency under Rule .0112 of this Section.

(17) "Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.

(18) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that ~~contribute to background radiation and~~ are not under the control of the licensee or registrant.

"Background radiation" does not include sources of radiation regulated by the agency.

(19) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s-1).

(20) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Byproduct material" has the meaning as defined in ~~G.S. 104E-5(4).~~G.S. 104E-5(4), and in addition includes:

(a) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(b) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(c) Any discrete source of Radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity, or any material that:

(i) has been made radioactive by use of a particle accelerator; and

(ii) is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and

(d) Any discrete source of naturally occurring radioactive material, other than source material, that

(i) the US Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection, the Secretary of Energy, the Secretary of Homeland Security, and the head of an other appropriate federal agency, determines would poses a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) is extracted or converted after extraction for use in a commercial, medical, or research activity.

(22) "Class", "lung class" or "inhalation class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times as follows:

CLASSIFICATION OF INHALED MATERIAL

| Class | Clearance half-time |
|---|---|
| Class D (Day) | less than 10 days |
| Class W (Weeks) | 10 days to 100 days |
| Class Y (Years) | greater than 100 days |

(23) "Clinical procedures manual" means a collection of procedures governing the medical use of radioactive material not requiring a written directive that describes each method by which the licensee performs clinical procedures and includes other instructions and precautions. Each clinical procedure including the radiopharmaceutical, dosage and route of administration, shall be approved in writing by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

~~(23)~~(24) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

~~(24)~~(25) "Commission" has the meaning as defined in G.S. 104E-5(5).

~~(25)~~(26) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

~~(26)~~(27) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma\, w_T H_{T,50}$).

(28) "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET

radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

~~(27)~~(29) "Constraint (dose constraint)" means a value above which specified licensee actions are required.

~~(28)~~(30) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

~~(29)~~(31) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

~~(30)~~(32) "Curie" is the special unit of radioactivity. One curie is equal to $3.7 \times 10^{10}$ disintegrations per second = $3.7 \times 10^{10}$ becquerels = $2.22 \times 10^{12}$ disintegrations per minute.

~~(31)~~(33) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

~~(32)~~(34) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for either unrestricted use and termination of the license or for restricted use and termination of the license.

~~(33)~~(35) "Deep-dose equivalent" ($H_d$), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of one cm (1000 $mg/cm^2$).

~~(34)~~(36) "Demand respirator" means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

~~(35)~~(37) "Department" has the meaning as defined in G.S. 104E-5(6).

~~(36)~~(38) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

~~(37)~~(39) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of ALI. DAC values are given in Table 1, Column 3, of Appendix B to 10 CFR 20.1001 - 20.2401).

~~(38)~~(40) "Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 Sv).

~~(39) "Diagnostic clinical procedures manual" means a collection of written procedures governing the use of radioactive material that describes each method by which the licensee performs diagnostic clinical procedures and includes other instructions and precautions. Each diagnostic clinical procedure including the radiopharmaceutical, dosage and route of administration, shall be approved by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved written procedure for all diagnostic clinical procedures performed at the facility.~~

(41) "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

~~(40)~~(42) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

~~(41)~~(43) "Distinguishable from Background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using measurement technology, survey and statistical techniques as defined in 10 CFR 20.1003.

~~(42)~~(44) "Dose" (or radiation dose) is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

~~(43)~~(45) "Dose equivalent" ($H_T$) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the

location of interest. The units of dose equivalent are the rem and sievert (Sv).

~~(44)~~(46) "Dose limits" (see "Limits" defined in this Rule).

~~(45)~~(47) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

~~(46)~~(48) "Effective dose equivalent" ($H_E$) is the sum of the products of the dose equivalent to the organ or tissue ($H_T$) and the weighting factors ($w_T$) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

~~(47)~~(49) "Embryo/fetus" means the developing human organism from conception until the time of birth.

~~(48)~~(50) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

~~(49)~~(51) "Equipment services" means the selling, installation, rebuilding, conversion, repair, inspection, testing, survey or calibration of equipment which can affect compliance with these Rules by a licensee or registrant.

~~(50)~~(52) "Exposure" means being exposed to ionizing radiation or to radioactive material.

~~(51)~~(53) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

~~(52)~~(54) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

~~(53)~~(55) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

~~(54)~~(56) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

~~(55)~~(57) "Filtering facepiece (dust mask)" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

~~(56)~~(58) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

~~(57)~~(59) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

~~(58)~~(60) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2D11 et seq;), as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using sources of radiation.

~~(59)~~(61) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).

~~(60)~~(62) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

~~(61)~~(63) "High radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~(62)~~(64) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

~~(63)~~(65) "Hospital" means a facility that provides as its primary functions diagnostic services and intensive medical and nursing care in the treatment of acute stages of illness.

~~(64)~~(66) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

~~(65)~~(67) "Individual" means any human being.

~~(66)~~(68) "Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) the assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(c) the assessment of dose equivalent by the use of survey data.

~~(67)~~(69) "Individual monitoring devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

~~(68)~~(70) "Inhalation class" (see "Class" defined in this Rule).

~~(69)~~(71) "Inspection" means an ~~official~~ examination or observation to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.

~~(70)~~(72) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

~~(71)~~(73) "Lens dose equivalent" or "LDE" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm$^2$).

~~(72)~~(74) "License", except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

~~(73)~~(75) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.

~~(74)~~(76) "Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context indicates otherwise, use of the term Agreement State in this Chapter ~~shall be deemed to include~~ includes licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

~~(75)~~(77) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

~~(76)~~(78) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

~~(77)~~(79) "Lost or missing licensed radioactive material" means licensed radioactive material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

~~(78)~~(80) "Lung class" (see "Class" as defined in this Rule).

~~(79)~~(81) "Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.

~~(80)~~(82) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

~~(81)~~(83) "Member of the public" means any individual except when that individual is receiving an occupational dose.

~~(82)~~(84) "Minor" means an individual less than 18 years of age.

~~(83)~~(85) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

~~(84)~~ (86)"Monitoring", "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

~~(85)~~(87) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

~~(86)~~(88) "Negative pressure respirator" means a tight-fitting respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside of the respirator.

~~(87)~~(89) "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

~~(88)~~(90) "NRC" means the United States Nuclear Regulatory Commission or its authorized representatives.

~~(89)~~(91) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or registrant or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, from voluntary participation in medical research programs, or as a member of the general public.

~~(90)~~(92) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged ~~particles.~~ particles, in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

~~(91)~~(93) "Person" has the meaning as defined in G.S. 104E-5(11).

~~(92)~~(94) "Personnel monitoring equipment" means devices, such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

~~(93)~~(95) "Pharmacist" means a person licensed by ~~this state~~ North Carolina to practice ~~pharmacy.~~ pharmacy (21 NCAC 46 .1500).

~~(94)~~(96) "Physician" means an individual licensed to practice medicine in ~~this state.~~North Carolina (G.S. Chapter 90, Article 1).

~~(95)~~(97) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose ~~limits.~~ limits as defined in Rule .1608 of this Chapter.

~~(96)~~(98) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(99) "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating an accelerator or a cyclotron for the purpose of producing PET radionuclides.

~~(97)~~(100) "Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

~~(98)~~(101) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive; or

(b) In accordance with the directions of an authorized user.

~~(99)~~(102) "Prescribed dose" means:

(a) for teletherapy or accelerator radiation:

(i) the total dose; and

(ii) the dose per fraction as documented in the written directive;

(b) for brachytherapy:

(i) the total source strength and exposure time; or

(ii) the total dose, as documented in the written directive;

(c) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(d) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in a written directive.

~~(100)~~(103) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

~~(101)~~(104) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or ~~to~~ another source of radiation within a licensee's or registrant's control. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, or from voluntary participation in medical research programs.

~~(102)~~(105) "Qualitative fit test (QLFT)" means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

~~(103)~~(106) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem in this Rule.

~~(104)~~(107) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

~~(105)~~(108) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

~~(106)~~(109) Quarterly" means either:

(a) at intervals not to exceed 13 weeks; or

(b) once per 13 weeks at about the same time during each 13 week period (completed during the same month of the quarter (first month, second month or third month) each quarter over a time period of several quarters.

~~(107)~~(110) "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

~~(108)~~(111) "Radiation" ~~(ionizing radiation)~~, except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).

~~(109)~~(112) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

~~(110)~~(113) "Radiation dose" means dose.

~~(111)~~(114) "Radiation machine" has the meaning as defined in G.S. 104E-5(13).

~~(112)~~(115) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.

~~(113)~~(116) "Radioactive material" has the meaning as defined in G.S. 104E-5(14).

~~(114)~~(117) "Radioactive waste disposal facility" means any low-level radioactive waste disposal facility, as defined in G.S. 104E-5(9c), established for the purpose of receiving low-level radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee for the purpose of disposal.

~~(115)~~(118)"Radioactive waste processing facility" means any low-level radioactive waste facility, as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.

~~(116)~~(119) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

~~(117)~~(120) "Radiobioassay" means bioassay.

~~(118)~~(121) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as published by the International Commission on Radiological Protection. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

~~(119)~~(122) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

~~(120)~~(123) "Registration" means registration with the agency in accordance with these Rules.

~~(121)~~(124) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

~~(122)~~(125) "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

| TYPE OF RADIATION | Quality Factor (Q) | Absorbed Dose Equal to a Unit Dose Equivalent[a] |
|---|---|---|
| X-, gamma, or beta radiation | 1 | 1 |
| Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge | 20 | 0.05 |
| Neutrons of unknown energy | 10 | 0.1 |
| High-energy protons | 10 | 0.1 |

[a] Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body.

If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

| | Neutron Energy (MeV) | Quality Factor[a] (Q) | Fluence per Unit Dose Equivalent[b] (neutrons $cm^{-2}$ $rem^{-1}$) |
|---|---|---|---|
| (thermal) | $2.5 \times 10^{-8}$ | 2 | $980 \times 10^{6}$ |
| | $1 \times 10^{-7}$ | 2 | $980 \times 10^{6}$ |
| | $1 \times 10^{-6}$ | 2 | $810 \times 10^{6}$ |
| | $1 \times 10^{-5}$ | 2 | $810 \times 10^{6}$ |
| | $1 \times 10^{-4}$ | 2 | $840 \times 10^{6}$ |
| | $1 \times 10^{-3}$ | 2 | $980 \times 10^{6}$ |
| | $1 \times 10^{-2}$ | 2.5 | $1010 \times 10^{6}$ |
| | $1 \times 10^{-1}$ | 7.5 | $170 \times 10^{6}$ |
| | $5 \times 10^{-1}$ | 11 | $39 \times 10^{6}$ |
| | 1 | 11 | $27 \times 10^{6}$ |
| | 2.5 | 9 | $29 \times 10^{6}$ |
| | 5 | 8 | $23 \times 10^{6}$ |

| | | |
|---|---|---|
| 7 | 7 | $24 \times 10^6$ |
| 10 | 6.5 | $24 \times 10^6$ |
| 14 | 7.5 | $17 \times 10^6$ |
| 20 | 8 | $16 \times 10^6$ |
| 40 | 7 | $14 \times 10^6$ |
| 60 | 5.5 | $16 \times 10^6$ |
| $1 \times 10^2$ | 4 | $20 \times 10^6$ |
| $2 \times 10^2$ | 3.5 | $19 \times 10^6$ |
| $3 \times 10^2$ | 3.5 | $16 \times 10^6$ |
| $4 \times 10^2$ | 3.5 | $14 \times 10^6$ |

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

~~(123)~~(126) Research and development" means:

(a) theoretical analysis, exploration, or experimentation; or

(b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

~~(124)~~(127)"Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

~~(125)~~(128)"Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

~~(126)~~(129)"Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

~~(127)~~(130)"Roentgen" (R) means the special unit of exposure. One roentgen equals $2.58 \times 10^{-4}$ coulombs/kilogram of air.

~~(128)~~(131)"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

~~(129)~~(132)"Sealed source" means radioactive material that is ~~permanently bonded, fixed or encapsulated so as to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.~~ encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~(130)~~(133)"Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

~~(131)~~(134)"Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

~~(132)~~(135)"Semiannually" means either:

(a) at intervals not to exceed six months; or

(b) once per six months at about the same time during each six month period (completed during the sixth month of each six month period over multiple six month periods).

~~(133)~~(136)"Shallow-dose equivalent" ($H_s$), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm$^2$).

~~(134)~~(137)"SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

~~(135)~~(138)"Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the

absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

~~(136)~~(139)"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

~~(137)~~(140)"Source material" has the meaning as defined in G.S. 104E-5(15).

~~(138)~~(141)"Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~(139)~~(142)"Special form radioactive material" means radioactive material which satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission, Subpart F of 10 CFR Part 71, and the tests prescribed in Rule .0114 of this Section. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements, Subpart F of 10 CFR Part 71, in effect on June 30, 1984, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

~~(140)~~(143)"Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

~~(141)~~(144)"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of uranium-235, uranium enriched in uranium-235 and plutonium in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified in this Rule for the same kind of special nuclear material. The sum of these ratios for all the kinds of special nuclear material in combination shall not exceed unity. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

$$\frac{\text{175 (gram contained U-235)}}{350} + \frac{\text{50 (grams U-233)}}{200} + \frac{\text{50 (grams Pu)}}{200} \text{ is } < \text{or} = 1$$

~~(142)~~(145)"State" means the State of North Carolina.

~~(143)~~(146)"Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

~~(144)~~(147)"Supplied-air respirator (SAR or airline respirator)" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

~~(145)~~(148)"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

~~(146)~~(149)"These Rules" means Chapter 11 of this Title.

~~(147)~~(150)"Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

~~(148)~~(151)"To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable ~~effort.~~ effort, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

~~(149)~~(152)"Total effective dose equivalent" (TEDE) means the sum of the ~~deep-dose~~ effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

~~(150)~~(153)"Toxic or hazardous constituent of the waste" means the nonradioactive content of waste which, notwithstanding the radioactive content, would be classified as "hazardous waste" as defined in G.S. 130A-290(8).

~~(151)~~(154)"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed $A_1$ for

special form radioactive material or $A_2$ for normal form radioactive material, where $A_1$ and $A_2$ are given in Rule .0113 of this Section or may be determined by procedures described in Rule .0113 of this Section. All quantities of radioactive material greater than a Type A quantity are Type B.

~~(152)~~(155)"Unit dosage" means a dosage intended for medical use in an individual that has been obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements.

~~(153)~~(156)"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

~~(154)~~(157)"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

~~(155)~~(158)"User seal check (fit check)" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

~~(156)~~(159)"Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

~~(157)~~(160)"Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes those low-level radioactive wastes containing source, special nuclear, or radioactive material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low-level waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in Sub-items (21)(b), (c), and (d) of the definition of "Byproduct Material" set forth in this Rule, and licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

~~(158)~~(161)"Waste, Class A" is defined in Rule .1650 of this Chapter.

~~(159)~~(162)"Waste, Class B" is defined in Rule .1650 of this Chapter.

~~(160)~~(163)"Waste, Class C" is defined in Rule .1650 of this Chapter.

~~(161)~~(164)"Week" means seven consecutive days starting on Sunday.

~~(162)~~(165)"Weighting factor", $w_T$, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of $w_T$ are:

ORGAN DOSE WEIGHTING FACTORS

| Organ or Tissue | $w_T$ |
|---|---|
| Gonads | 0.25 |
| Breast | 0.15 |
| Red bone marrow | 0.12 |
| Lung | 0.12 |
| Thyroid | 0.03 |
| Bone surfaces | 0.03 |
| Remainder | 0.30[a] |
| Whole body | 1.00[b] |

[a] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[b] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T$ = 1.0, has been specified.

~~(163)~~(166)"Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

~~(164)~~(167)"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

~~(165)~~(168)"Working level" (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of $1.3 \times 10^5$ MeV of potential alpha particle energy.

~~(166)~~(169)"Working level month" (WLM) means an exposure to one working level for 170 hours.

~~(167)~~(170)"Written directive" means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the patient or human research subject's name and the following information:

(a) for the administration of greater than 30 microcuries (1.11 Megabecquerels (MBq)) of sodium iodide I-131, the dosage;
(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:
  (i) radionuclide;
  (ii) dosage; and
  (iii) route of administration;
(c) for teletherapy or accelerator radiation therapy:
  (i) total dose;
  (ii) dose per fraction;
  (iii) treatment site; and
  (iv) number of fractions;
(d) for high-dose-rate remote afterloading brachytherapy:
  (i) radionuclide;
  (ii) treatment site;
  (iii) dose per fraction
  (iv) number of fractions; and
  (v) total dose;
(e) for all other brachytherapy:
  (i) prior to implantation:
    (A) radionuclide;
    (B) treatment site; and
    (C) dose; and
  (ii) after implantation:
    (A) radionuclide;
    (B) treatment site;
    (C) number of sources;
    (D) total source strength and exposure time; and
    (E) total dose; and
(f) for gamma stereotactic radiosurgery:
  (i) the total dose;
  (ii) treatment site; and
  (iii) values for the target coordinate settings per treatment for each anatomically distinct treatment site.

~~(168)~~(171)"Year" means the period of time beginning in January used to determine compliance with the provisions of Section .1600 of this Chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

*Authority G.S. 104E-7(a)(2).*

**15A NCAC 11 .0105 OTHER DEFINITIONS**

Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter.

*Authority G.S. 104E-7.*

**15A NCAC 11 .0117 INCORPORATION BY REFERENCE**

(a) For the purpose of the rules in this Chapter, the following rules, standards and other requirements are hereby incorporated by reference including any subsequent amendments and editions:
(1) Appendix A, Appendix B, Appendix C, and Appendix G to 10 CFR Parts 20.1001 - 20.2401;
(2) 10 CFR Part 21, 10 CFR Part 30.1, 30.4, 30.10, 10 CFR ~~Part 31,~~ Part 31 except 31.5, 10 CFR Part 32.2, 32.13, 32.24, 32.110, 32.201, 32.210, ~~10 CFR Part 32,~~ Subpart J of 10 CFR Part 35, 10 CFR 35.50, 35.51, 35.55, 35.57, 35.59, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, Subpart H of 10 CFR Part 35, 35.1000, 10 CFR Part 36, 10 CFR Part 40 except 40.12(b), 40.23, 40.27, 40.28, 40.31(j-m), 40.32(d), and parts of (e) pertaining to uranium enrichment, and (g), 40.33, 40.38, 40.41(d), (e)(1), (e)(3), (g), (h), 40.51(b)(6), 40.64, 40.66-67; ~~and 10 CFR Part 50;~~
~~(3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;~~
(3) 10 CFR Part 61 except 61.16, 61.23(i),(j), 10 CFR Part 70 except 70.1 (c), (d), (e), 70.13-14, 70.20(a), (b), 70.21(a)(1), (c), (f-h), 70.22(b), (c), (f-n), 70.23 (a)(6-12), (b), 70.23a, 70.24, 70.25(a)(1), 70.31(c-e), 70.32(a)(1), (a)(4-7), (b)(1), (b)(3), (b)(4)(c-k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.52, 70.55(c), 70.59-62, 70.64-66, 70.72-74, 70.76, 70.82, 10 CFR Part 71.0, 71.1, 71.2, 71.3, 71.13, 71.4, 71.5, 71.8, 71.14(a), 71.15, 71.17(a) – (e), 71.20, 71.21, 71.22, 71.23, 71.47, Subpart G of 10 CFR Part 71, 10 CFR 71.101(a) – (c)(1), 71.101(f), 71.101(g), 71.103, 71.105, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, Appendix A to 10 CFR Part 71, and 10 CFR Part 150 except 150.3 Definition: Foreign Obligations, 150.7, 150.10, 150.14, 150.15, 150.15a, 150.16-17, 150.17a, 150.19, 150.21;
(4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;
(5) 39 CFR Part 14 and 39 CFR Part 15;
(6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];
(7) 40 CFR Part 261;
(8) 49 CFR Parts 100-189;

(9) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended", signed July 21, 1964;

(10) "Standards and Specifications for Geodetic Control Networks (September 1984);

(11) "Geometric Geodetic Survey Accuracy Standards and Specifications for Geodetic Surveys Using GPS Relative Positioning Techniques";

(12) "Reference Man: Anatomical, Physiological and Metabolic Characteristics" (ICRP Publication No. 23) of the International Commission on Radiological Protection;

(13) "10 CFR, Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 FR 7540"; and

(14) American National Standard ~~N432-1980~~ N43.9"Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography".

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available for inspection at the ~~Department of Environment and Natural Resources, Division of Radiation Protection~~ Agency at the address listed in Rule .0111 of this Section. Except as noted in the Subparagraphs of this Paragraph, copies of the rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

(1) Three dollars ($3.00) for the appendixes listed in Subparagraph (a)(1) of this Rule, available from the ~~Division of Radiation Protection;~~ Agency;

(2 ~~Twenty-five~~ Sixty-Seven dollars ~~($25.00)~~ ($67.00)for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts ~~0-50~~1-50;

(3) ~~Eighteen dollars~~ Sixty-Four~~($18.00)~~ ($64.00) for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;

(4) ~~Eighteen dollars~~ Sixty-Six~~($18.00)~~ ($66.00) for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;

(5) ~~Sixteen dollars~~ Forty-Seven~~($16.00)~~ ($47.00) for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;

(6) Thirty-six dollars ($36.00) for the manual listed in Subparagraph (a)(6) of this Rule; http://pe.usps.gov/text/dmm300/dmm300_landing.htm

(7) ~~Thirty one~~ Fifty-Six dollars ~~($31.00)~~ ($56.00) for the regulations listed in Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299;

(8) For the regulations listed in Subparagraph (a)(8) of this Rule:

(A) ~~Twenty three~~ Seventy dollars ~~($23.00)~~ ($70.00) for a volume containing 49 CFR Parts 100-177; and

(B) ~~Seventeen~~ Seventy dollars ~~($17.00)~~ ($70.00) for a volume containing 49 CFR Parts 178-199;

(9) One dollar ($1.00) for the agreement in Subparagraph (a)(9) of this Rule, available from the ~~Division of Radiation Protection;~~ Agency;

(10) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(10) of this Rule, available from the National Geodetic Information Center, N/CG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(11) Two dollars and eighty-five cents ($2.85) for the standards and specifications in Subparagraph (a)(11) of this Rule, available from the National Geodetic Information Center, NCG174, Rockwall Building, Room 24, National Geodetic Survey, NOAA, Rockville, MD 20852;

(12) ~~One hundred and five~~ Two Hundred Eighteen dollars ~~($105.00)~~ ($218.00) for the ICRP Publication No. 23 in Subparagraph (a)(12) of this Rule, available from Pergamon Press, Inc., Maxwell House, Fairview Park, Elmsford, NY 10523;

(13) Two dollars ($2.00) for the document in Subparagraph (a)(13) of this Rule, available from the ~~Division of Radiation Protection;~~ Agency;

(14) ~~Thirty eight dollars~~ Twenty-Five plus five dollars shipping and handling ~~($43.00)~~ ($30.00) for the American National Standard ~~N432-1980~~ N43.9in Subparagraph (a)(14) of this Rule, available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone number (212) 642-4900.

(c) Nothing in this incorporation by reference of 10 CFR Part 61 in Subparagraph (a)(3) of this Rule shall limit or affect the continued applicability of G.S. 104E-25(a) and (b).

*Authority G.S. 104E-7; 104E-15(a); 150B-21.6.*

**SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL**

**15A NCAC 11 .0301 PURPOSE AND SCOPE**

(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, ~~own~~ own, manufacture and produce, or acquire radioactive material except as authorized in a specific or general license issued pursuant to, or as otherwise provided in, this Section.

(b) In addition to the requirements of this Section,

(1) All licensees are subject to the requirements of Sections .1000 and .1600 of this Chapter, except as otherwise provided in the rules of this Section;

(2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter;

(3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700 of this Chapter;

(4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the requirements of Section .1200 of this Chapter;

(5) Licensees engaged in well-logging operations are subject to the requirements of Section .1300 of this Chapter; and

(6) Licensees engaged in the operation of panoramic and underwater irradiators are subject to the requirements of Section .0100 of this Chapter.

(c) In addition to the requirements of this Section, all licensees are subject to the annual fee provisions contained in Section .1100 of this Chapter.

(d) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter except as specifically provided otherwise in Section .1200.

*Authority G.S. 104E-7; 104E-9(8); 104E-10(b); 104E-19.*

**15A NCAC 11 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL**

(a) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Paragraph ~~(b)~~(d) of this Rule or equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued pursuant to ~~Rule .0325 of this Section.~~ 10 CFR 32.11.

(b) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in these rules to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Paragraph (d) of this Rule, and introduced into the product or material by a licensee holding a specific license issued by the US Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.

(c) This Rule shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

~~(b)~~(d) Except as provided in Paragraph (a) and (b) of this Rule, any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in the following table:

EXEMPT CONCENTRATIONS

| Element (atomic number) | Isotope | Column I Gas concentration microcurie/ml | Column II Liquid and solid concentration microcurie/ml |
|---|---|---|---|
| Antimony (51) | Sb 122 | | 3X10-4 |
| | Sb 124 | | 2X10-4 |
| | Sb 125 | | 1X10-3 |
| Argon (18) | Ar 37 | 1X10-3 | |
| | Ar 41 | 4X10-7 | |
| Arsenic (33) | As 73 | | 5X10-3 |
| | As 74 | | 5X10-4 |
| | As 76 | | 2X10-4 |
| | As 77 | | 8X10-4 |
| Barium (56) | Ba 131 | | 2X10-3 |
| | Ba 140 | | 3X10-4 |
| Beryllium (4) | Be 7 | | 2X10-2 |
| Bismuth (83) | Bi 206 | | 4X10-4 |
| Bromine (35) | Br 82 | 4X10-7 | 3X10-3 |
| Cadmium (48) | Cd 109 | | 2X10-3 |
| | Cd 115m | | 3X10-4 |
| | Cd 115 | | 3X10-4 |
| Calcium (20) | Ca 45 | | 9X10-5 |

| | | | | |
|---|---|---|---|---|
| | Ca 47 | | 5X10-4 | |
| Carbon (6) | C 14 | 1X10-6 | 8X10-3 | |
| Cerium (58 | Ce 141 | | 9X10-4 | |
| | Ce 143 | | 4X10-4 | |
| | Ce 144 | | 1X10-4 | |
| Cesium (55) | Cs 131 | | 2X10-2 | |
| | Cs 134m | | 6X10-2 | |
| | Cs 134 | | 9X10-5 | |
| Chlorine (17) | Cl 38 | 9X10-7 | 4X10-3 | |
| Chromium (24) | Cr 51 | | 2X10-2 | |
| Cobalt (27) | Co 57 | | 5X10-3 | |
| | Co 58 | | 1X10-3 | |
| | Co 60 | | 5X10-4 | |
| Copper (29) | Cu 64 | | 3X10-3 | |
| Dysprosium (66) | Dy 165 | | 4X10-3 | |
| | Dy 166 | | 4X10-4 | |
| Erbium (68) | Er 169 | | 9X10-4 | |
| | Er 171 | | 1X10-3 | |
| Europium (63) | Eu 152 | | 6X10-4 | |
| | (T1/2 =9.2 Hrs.) | | | |
| | Eu 155 | | 2X10-3 | |
| Fluorine (9) | F 18 | 2X10-6 | 8X10-3 | |
| Gadolinium (64) | Gd 153 | | 2X10-3 | |
| | Gd 159 | | 8X10-4 | |
| Gallium (31) | Ga 72 | | 4X10-4 | |
| Germanium (32) | Ge 71 | | 2X10-2 | |
| Gold (79) | Au 196 | | 2X10-3 | |
| | Au 198 | | 5X10-4 | |
| | Au 199 | | 2X10-3 | |
| Hafnium (72) | Hf 181 | | 7X10-4 | |
| Hydrogen (1) | H 3 | 5X10-6 | 3X10-2 | |
| Indium (49) | In 113m | | 1X10-2 | |
| | In 114m | | 2X10-4 | |
| Iodine (53) | I 126 | 3X10-9 | 2X10-5 | |
| | I 131 | 3X10-9 | 2X10-5 | |
| | I 132 | 8X10-8 | 6X10-4 | |
| | I 133 | 1X10-8 | 7X10-5 | |
| | I 134 | 2X10-7 | 1X10-3 | |
| Iridium (77) | Ir 190 | | 2X10-3 | |
| | Ir 192 | | 4X10-4 | |
| | Ir 194 | | 3X10-4 | |
| Iron (26) | Fe 55 | | 8X10-3 | |
| | Fe 59 | | 6X10-4 | |
| Krypton (36) | Kr 85m | 1X10-6 | ~~1X10-6~~ | |
| | Kr 85 | 3X10-6 | ~~3X10-6~~ | |
| Lanthanum (57) | La 140 | | 2X10-4 | |
| Lead (82) | Pb 203 | | 4X10-3 | |
| Lutetium (71) | Lu 177 | | 1X10-3 | |
| Manganese (25) | Mn 52 | | 3X10-4 | |
| | Mn 54 | | 1X10-3 | |
| | Mn 56 | | 1X10-3 | |
| Mercury (80) | Hg 197m | | 2X10-3 | |
| | Hg 197 | | 3X10-3 | |
| | Hg 203 | | 2X10-4 | |
| Molybdenum (42) | Mo 99 | | 2X10-3 | |
| Neodymium (60) | Nd 147 | | ~~6X10-3~~ | 6X10-4 |
| | Nd 149 | | ~~3X10-4~~ | 3X10-3 |
| Nickel (28) | Ni 65 | | 1X10-3 | |
| Niobium(Columbium)(41) | Nb 95 | | 1X10-3 | |

| | | | |
|---|---|---|---|
| | Nb 97 | | 9X10-3 |
| Osmium (76) | Os 185 | | 7X10-4 |
| | Os 191m | | 3X10-2 |
| | Os 191 | | 2X10-3 |
| | Os 193 | | 6X10-4 |
| Palladium (46) | Pd 103 | | 3X10-3 |
| | Pd 109 | | 9X10-4 |
| Phosphorus (15) | P 32 | | 2X10-4 |
| Platinum (78) | Pt 191 | | 1X10-3 |
| | Pt 193m | | 1X10-2 |
| | Pt 197m | | 1X10-2 |
| | Pt 197 | | 1X10-3 |
| ~~Polonium (84)~~ | ~~Po 210~~ | | ~~7X10-6~~ |
| Potassium (19) | K 42 | | 3X10-3 |
| Praseodymium (59) | Pr 142 | | 3X10-4 |
| | Pr 143 | | 5X10-4 |
| Promethium (61) | Pm 147 | | 2X10-3 |
| Pm 149 | | 4X10-4 | |
| ~~Radium (88)~~ | ~~Ra 226~~ | | ~~1X10-7~~ |
| | ~~Ra 228~~ | | ~~3X10-7~~ |
| Rhenium (75) | Re 183 | | 6X10-3 |
| | Re 186 | | 9X10-4 |
| | Re 188 | | 6X10-4 |
| Rhodium (45) | Rh 103m | | 1X10-1 |
| | Rh 105 | | 1X10-3 |
| Rubidium (37) | Rb 86 | | 7X10-4 |
| Ruthenium (44) | Ru 97 | | ~~4X10-3~~ 4X10-4 |
| | Ru 103 | | 8X10-4 |
| | Ru 105 | | 1X10-3 |
| | Ru 106 | | 1X10-4 |
| Samarium (62) | Sm 153 | | 8X10-4 |
| Scandium (21) | Sc 46 | | 4X10-4 |
| | Sc 47 | | 9X10-4 |
| | Sc 48 | | 3X10-4 |
| Selenium (34) | Se 75 | | 3X10-3 |
| Silicon (14) | Si 31 | | 9X10-3 |
| Silver (47) | Ag 105 | | 1X10-3 |
| | Ag 110m | | 3X10-4 |
| | Ag 111 | | 4X10-4 |
| Sodium (11) | Na 24 | | 2X10-3 |
| Strontium (38) | Sr 85 | | ~~1X10-3~~ 1X10-4 |
| | Sr 89 | | 1X10-4 |
| | Sr 91 | | 7X10-4 |
| | Sr 92 | | 7X10-4 |
| Sulfur (16) | S 35 | 9X10-8 | 6X10-4 |
| Tantalum (73) | Ta 182 | | 4X10-4 |
| Technetium (43) | Tc 96m | | 1X10-1 |
| | Tc 96 | | 1X10-3 |
| Tellurium (52) | Te 125m | | 2X10-3 |
| | Te 127m | | 6X10-4 |
| | Te 127 | | 3X10-3 |
| | Te 129m | | 3X10-4 |
| | Te 131m | | 6X10-4 |
| | Te 132 | | 3X10-4 |
| Terbium (65) | Tb 160 | | 4X10-4 |
| Thallium (81) | Tl 200 | | 4X10-3 |
| | Tl 201 | | 3X10-3 |
| | Tl 202 | | 1X10-3 |
| | Tl 204 | | 1X10-3 |

| | | | |
|---|---|---|---|
| Thulium (69) | Tm 170 | | 5X10-4 |
| | Tm 171 | | 5X10-3 |
| Tin (50) | Sn 113 | | 9X10-4 |
| | Sn 125 | | 2X10-4 |
| Tungsten(Wolfram) (74) | W 181 | | 4X10-3 |
| | W 187 | | 7X10-4 |
| Vanadium (23) | V 48 | | 3X10-4 |
| Xenon (54) | Xe 131m | | 4X10-6 |
| | Xe 133 | | 3X10-6 |
| | Xe 135 | | 1X10-6 |
| Ytterbium (70) | Yb 175 | | 1X10-3 |
| Yttrium (39) | Y 90 | | 2X10-4 |
| | Y 91m | | 3X10-2 |
| | Y 91 | | 3X10-4 |
| | Y 92 | | 6X10-4 |
| | Y 93 | | 3X10-4 |
| Zinc (30) | Zn 65 | | 1X10-3 |
| | Zn 69m | | 7X10-4 |
| | Zn 69 | | 2X10-2 |
| Zirconium (40) | Zr 95 | | 6X10-4 |
| | Zr 97 | | 2X10-4 |
| Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years | | 1X10-10 | 1X10-6 |

~~(e)~~(e) In Column I of the table, in Paragraph (b) of this Rule, values are given only for those materials normally used as gases.
~~(d)~~(f) In Column II of the table, in Paragraph (b) of this Rule, the units, microcuries per gram, are used for solids.
~~(e)~~(g) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Paragraph (b) of this Rule, the activity stated is that of the parent isotope and takes into account the daughters.
~~(f)~~(h) For purposes of this Rule, where a combination of isotopes is involved, the limit for the combination shall be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Paragraph (b) of this Rule for the specific isotope when not in combination. The sum of the ratios shall not exceed unity. An example of this is:

Concentration of Isotope A in Product
Exempt concentration of Isotope A +

Concentration of Isotope B in Product
Exempt concentration of Isotope B less than or equal to 1

*Authority G.S. 104E-7; 104E-10; 104E-20.*

**15A NCAC 11 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL**

(a) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.
(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued ~~by:~~ by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material.

~~(1) the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material;~~
~~(2) the agency pursuant to Rule .0326 for radioactive material other than source, byproduct and special nuclear material; or~~
~~(3) any agreement state pursuant to equivalent regulation for radioactive material other than source, byproduct and special nuclear material.~~

(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph ~~(e)~~(f) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph ~~(e)~~(f) of this Rule.
(e) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits in Paragraph (f) of this Rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this Section.
~~(e)~~(f) Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of

which does not exceed the applicable quantity set forth in the following table:

EXEMPT QUANTITIES

| Radioactive Material | Microcuries |
|---|---|
| Antimony-122 (Sb 122) | 100 |
| Antimony-124 (Sb 124) | 10 |
| Antimony-125 (Sb 125 | 10 |
| Arsenic-73 (As 73) | 100 |
| Arsenic-74 (As 74) | 10 |
| Arsenic-76 (As 76) | 10 |
| Arsenic-77 (As 77) | 100 |
| Barium-131 (Ba 131) | 10 |
| Barium-133 (Ba 133) | 10 |
| Barium-140 (Ba 140) | 10 |
| Bismuth-210 (Bi 210) | 1 |
| Bromine-82 (Br 82) | 10 |
| Cadmium-109 (Cd 109) | 10 |
| Cadmium-115m (Cd 115m) | 10 |
| Cadmium-115 (Cd 115) | 100 |
| Calcium-45 (Ca 45) | 10 |
| Calcium-47 (Ca 47) | 10 |
| Carbon-14 (C 14) | 100 |
| Cerium-141 (Ce 141) | 100 |
| Cerium-143 (Ce 143) | 100 |
| Cerium-144 (Ce 144) | 1 |
| Cesium-129 (Cs 129) | 100 |
| Cesium-131 (Cs 131) | 1,000 |
| Cesium-134m (Cs 134m) | 100 |
| Cesium-134 (Cs 134) | 1 |
| Cesium-135 (Cs 135) | 10 |
| Cesium-136 (Cs 136) | 10 |
| Cesium-137 (Cs 137) | 10 |
| Chlorine-36 (Cl 36) | 10 |
| Chlorine-38 (Cl 38) | 10 |
| Chromium-51 (Cr 51) | 1,000 |
| Cobalt-57 (Co 57) | 100 |
| Cobalt-58m (Co 58m) | 10 |
| Cobalt-58 (Co 58) | 10 |
| Cobalt-60 (Co 60) | 1 |
| Copper-64 (Cu 64) | 100 |
| Dysprosium-165 (Dy 165) | 10 |
| Dysprosium-166 (Dy 166) | 100 |
| Erbium-169 (Er 169) | 100 |
| Erbium-171 (Er 171) | 100 |
| Europium-152 (Eu 152) 9.2h | 100 |
| Europium-152 (Eu 152) 13 yr | 1 |
| Europium-154 (Eu 154) | 1 |
| Europium-155 (Eu 155) | 10 |
| Fluorine-18 (F 18) | 1,000 |
| Gadolinium-153 (Gd 153) | 10 |
| Gadolinium-159 (Gd 159) | 100 |
| Gallium-67 (Ga 67) | 100 |
| Gallium-72 (Ga 72) | 10 |
| Germanium-68 (Ge 68) | 10 |
| Germanium-71 (Ge 71) | 100 |
| Gold-195 (Au 195) | 10 |
| Gold-198 (Au 198) | 100 |
| Gold-199 (Au 199) | 100 |
| Hafnium-181 (Hf 181) | 10 |
| Holmium-166 (Ho 166) | 100 |
| Hydrogen-3 (H 3) | 1,000 |
| Indium-111 (In 111) | 100 |
| Indium-113m (In 113m) | 100 |
| Indium-114m (In 114m) | 10 |
| Indium-115m(In 115m) | 100 |
| Indium-115 (In 115) | 10 |
| Iodine-123 (I 123) | 100 |
| Iodine-125 (I 125) | 1 |
| Iodine-126 (I 126) | 1 |
| Iodine-129 (I 129) | 0.1 |
| Iodine-131 (I 131) | 1 |
| Iodine-132 (I 132) | 10 |
| Iodine-133 (I 133) | 1 |
| Iodine-134 (I 134) | 10 |
| Iodine-135 (I 135) | 10 |
| Iridium-192 (Ir 192) | 10 |
| Iridium-194 (Ir 194) | 100 |
| Iron-52 (Fe 52) | 10 |
| Iron-55 (Fe 55) | 100 |
| Iron-59 (Fe 59) | 10 |
| Krypton-85 (Kr 85) | 100 |
| Krypton-87 (Kr 87) | 10 |
| Lanthanum-140 (La 140) | 10 |
| Lutetium-177 (Lu 177) | 100 |
| Manganese-52 (Mn 52) | 10 |
| Manganese-54 (Mn 54) | 10 |
| Manganese-56 (Mn 56) | 10 |
| Mercury-197m (Hg 197m) | 100 |
| Mercury-197 (Hg 197) | 100 |
| Mercury-203 (Hg 203) | 10 |
| Molybdenum-99 (Mo 99) | 100 |
| Neodymium-147 (Nd 147) | 100 |
| Neodymium-149 (Nd 149) | 100 |
| Nickel-59 (Ni 59) | 100 |
| Nickel-63( Ni 63) | 10 |
| Nickel-65 (Ni 65) | 100 |
| Niobium-93m (Nb 93m) | 10 |
| Niobium-95 (Nb 95) | 10 |
| Niobium-97 (Nb 97) | 10 |
| Osmium-185 (Os 185) | 10 |
| Osmium-191m (Os 191m) | 100 |
| Osmium-191 (Os 191) | 100 |
| Osmium-193 (Os 193) | 100 |
| Palladium-103 (Pd 103) | 100 |
| Palladium-109 (Pd 109) | 100 |
| Phosphorus-32 (P 32) | 10 |
| Platinum-191 (Pt 191) | 100 |
| Platinum-193m (Pt 193m) | 100 |
| Platinum-193 (Pt 193) | 100 |
| Platinum-197m (Pt 197m) | 100 |
| Platinum-197 (Pt 197) | 100 |
| Polonium-210 (Po 210) | 0.1 |
| Potassium-42 (K 42) | 10 |
| Potassium-43 (K 43) | 10 |
| Praseodymium-142 (Pr 142) | 100 |

| | |
|---|---|
| Praseodymium-143 (Pr 143) | 100 |
| Promethium -147 (Pm 147) | 10 |
| Promethium-149 (Pm 149) | 10 |
| Rhenium-186 (Re 186) | 100 |
| Rhenium-188 (Re 188) | 100 |
| Rhodium-103m (Rh 103m) | 100 |
| Rhodium-105 (Rh 105) | 100 |
| Rubidium-81 (Rb 81) | 10 |
| Rubidium-86 (Rb 86) | 10 |
| Rubidium-87 (Rb 87) | 10 |
| Ruthenium-97 (Ru 97) | 100 |
| Ruthenium-103 (Ru 103) | 10 |
| Ruthenium-105 (Ru 105) | 10 |
| Ruthenium-106 (Ru 106) | 1 |
| Samarium-151 (Sm 151) | 10 |
| Samarium-153 (Sm 153) | 100 |
| Scandium-46 (Sc 46) | 10 |
| Scandium-47 (Sc 47) | 100 |
| Scandium-48 (Sc 48) | 10 |
| Selenium-75 (Se 75) | 10 |
| Silicon-31 (Si 31) | 100 |
| Silver-105 (Ag 105) | 10 |
| Silver-110m (Ag 110m) | 1 |
| Silver-111 (Ag 111) | 100 |
| Sodium-22 (Na 22) | 10 |
| Sodium-24 (Na 24) | 10 |
| Strontium-85 (Sr 85) | 10 |
| Strontium-89 (Sr 89) | 1 |
| Strontium-90 (Sr 90) | 0.1 |
| Strontium-91 (Sr 91) | 10 |
| Strontium-92 (Sr 92) | 10 |
| Sulfur-35 (S 35) | 100 |
| Tantalum-182 (Ta 182) | 10 |
| Technetium-96 (Tc 96) | 10 |
| Technetium-97m (Tc 97m) | 100 |
| Technetium-97 (Tc 97) | 100 |
| Technetium-99m (Tc 99m) | 100 |
| Technetium-99 (Tc 99) | 10 |
| Tellurium-125m (Te 125m) | 10 |
| Tellurium-127m (Te 127m) | 10 |
| Tellurium-127 (Te 127) | 100 |
| Tellurium-129m (Te 129m) | 10 |
| Tellurium-129 (Te 129) | 100 |
| Tellurium-131m (Te 131m) | 10 |
| Tellurium-132 (Te 132) | 10 |
| Terbium-160 (Tb 160) | 10 |
| Thallium-200 (Tl 200) | 100 |
| Thallium-201 (Tl 201) | 100 |
| Thallium-202 (Tl 202) | 100 |
| Thallium-204 (Tl 204) | 10 |
| Thulium-170 (Tm 170) | 10 |
| Thulium-171 (Tm 171) | 10 |
| Tin-113 (Sn 113) | 10 |
| Tin-125 (Sn 125) | 10 |
| Tungsten-181 (W 181) | 10 |
| Tungsten-185 (W 185) | 10 |
| Tungsten-187 (W 187) | 100 |
| Vanadium-48 (V 48) | 10 |
| Xenon-131m (Xe 131m) | 1,000 |
| Xenon-133 (Xe 133) | 100 |
| Xenon-135 (Xe 135) | 100 |
| Ytterbium-175 (Yb 175) | 100 |
| Yttrium-87 (Y 87) | 10 |
| Yttrium-88 (Y 88) | 10 |
| Yttrium-90 (Y 90) | 10 |
| Yttrium-91 (Y 91) | 10 |
| Yttrium-92 (Y 92) | 100 |
| Yttrium-93 (Y 93) | 100 |
| Zinc-65 (Zn 65) | 10 |
| Zinc-69m (Zn 69m) | 100 |
| Zinc-69 (Zn 69) | 1,000 |
| Zirconium-93 (Zr 93) | 10 |
| Zirconium-95 (Zr 95) | 10 |
| Zirconium-97 (Zr 97) | 10 |
| Any radioactive material not listed above other than alpha emitting radioactive material | 0.1 |

*Authority G.S. 104E-7; 104E-10(b); 104E-20.*

**15A NCAC 11 .0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL**

(a) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from the rules of this Chapter may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

~~(b) Certain items containing radioactive material are exempt as provided in this Paragraph.~~

~~(1)~~(b) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products, any person is exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

~~(A)~~(1) timepieces or hands or dials containing not more than the following ~~specified~~ quantities of radioactive material and not exceeding the following ~~specified~~ levels of radiation:

~~(i)~~(A) 25 millicuries of tritium per timepiece;

~~(ii)~~(B) five millicuries of tritium per hand;

~~(iii)~~(C) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

~~(iv)~~(D) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;

~~(v)~~(E) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

~~(vi)~~(E) 60 microcuries of promethium-147 per watch dial or 120 microcuries of

promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

~~(vii)~~(F) the levels of radiation from hands and dials containing promethium-147 ~~will not exceed~~, when measured through 50 milligrams per square centimeter of absorber:

~~(I)~~(i) for wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;

~~(II)~~(ii) for pocket watches, 0.1 millirad per hour at one centimeter from any surface; or

~~(III)~~(iii) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface or:

(iv) 1 microcurie of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

~~(B)~~(2) Reserved ~~lock illuminators containing not more than 15 millicuries of tritium or not more than two millicuries of promethium-147 installed in automobile locks (the levels of radiation from each lock illuminator containing promethium-147 shall not exceed one millirad per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber);~~

~~(C)~~(3) balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance ~~part;~~ part manufactured before December 17, 2007;

~~(D)~~(4) Reserved ~~automobile shift quadrants containing not more than 25 millicuries of tritium;~~

~~(E)~~(5) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium ~~gas; gas~~ manufactured before December 17, 2007;

~~(F)~~(6) Reserved ~~thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;~~

(7) Ionization chamber smoke detectors containing not more than 1 microcurie of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

~~(G)~~(8) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive ~~material~~ material and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents):

~~(i)~~(A) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

~~(ii)~~(B) one microcurie of cobalt-60;

~~(iii)~~(C) five microcuries of nickel-63;

~~(iv)~~(D) 30 microcuries of krypton-85;

~~(v)~~(E) five microcuries of cesium-137; and

~~(vi)~~(F) 30 microcuries of promethium-147; ~~and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents)~~; and

~~(H)~~(9) ionizing radiation measuring instruments containing for purposes of internal calibration or standardization, sources of radioactive material each not exceeding the applicable quantity set forth in Rule .0304~~(e)~~(f) of this ~~Section.~~ Section, and each instrument contains no more than 10 exemption quantities.

~~(I)~~(10) Reserved ~~spark gap irradiation containing not more than one microcurie f cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.~~

~~(2)~~(c) For purposes of ~~Part (b)(1)(H)~~ Subparagraph (b)(8) of this Rule, where there is involved a combination of radionuclides, the limit for the combination shall be derived as follows:

~~(A)~~(1) Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between the quantity present in the instrument and the exempt quantity established in Rule .0304~~(e)~~(f) of this Section for the specific radionuclide when not in combination;

~~(B)~~(2) No ratio shall exceed one and the sum of such ratios shall not exceed ~~10.~~ 10; and

~~(C)~~(3) For the purpose of ~~Part (b)(1)(H)~~ Subparagraph (b)(8), 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.

~~(c)~~(d) Self-luminous products are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the rules of this Chapter to the extent that ~~any~~ the person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

(2) The exemption in Subparagraph (c)(1) of this Rule does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

~~(d)~~(e) Gas and aerosol detectors are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, ~~or produce~~ produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the rules of this Chapter to the extent that ~~any~~ the person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall be manufactured, ~~imported,~~ processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or any agreement state, pursuant to Section 32.26 of 10 CFR 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(2) Gas and aerosol detectors previously manufactured and distributed to general licensees before November 30, 2007 in accordance with a specific license issued by an agreement state ~~shall be considered~~ are exempt ~~under Subparagraph (d)(1) of this Rule~~ from the rules in this Chapter, provided that the devices are labeled in accordance with the specific license authorizing distribution of the general licensed device, and providing further that the devices meet the requirements of Rule .0327 of this Section.

~~(e) Resins containing scandium-46 are exempt as provided in this Paragraph.~~

~~(1) Any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. These resins shall be manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall be manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.~~

~~(2) This exemption does not authorize the manufacture of any resins containing scandium-46.~~

~~(f) Capsules containing Carbon-14 urea for "in-vivo" diagnostic use for humans are exempt as provided in this Paragraph:~~

~~(1)~~(f) Except ~~as provided in Subparagraphs (2) and (3) of this Paragraph,~~ as follows, any person is exempt from the requirements for a license set forth in this Section provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing approximately one microcurie (37kBq) Carbon-14 urea each for "in-vivo" diagnostic use for ~~humans.~~ humans:

~~(2)~~(1) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license from the agency.

~~(3)~~(2) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license from the U.S. Nuclear Regulatory Commission.

~~(4)~~(g) Nothing in this Rule relieves persons from complying with applicable FDA and other federal regulations, and North Carolina requirements governing the receipt, administration, and use of drugs.

*Authority G.S. 104E-7; 104E-10(b); 104E-20.*

**15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES**

(a) A general license shall be issued to commercial and industrial firms; research, educational and medical institutions; individuals in the conduct of their business; and federal, state, or local government agencies to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location,

radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been:

(1) manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations; and

(2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this ~~Rule:~~ Rule shall:

(1) ~~shall~~ assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(2) ~~shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, except as follows:

(A) Devices containing only krypton need not be tested for leakage of radioactive material; and

(B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or ten microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) ~~shall~~ assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

(A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or

(B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement ~~state.~~ State;

(4) ~~shall~~ maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, ~~to include~~including:

(A) the name of the person(s) performing the test(s) and the date(s) of the test(s);

(B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;

Retention of leakage or contamination, on-off mechanism and on-off indicator test records shall be retained for three years after the next required test is performed or until the sealed source is disposed of or transferred. Retention of other records of tests required in Subparagraph (c)(3) of this Rule shall be retained for three years from the date of the recorded test or until the device is disposed of or transferred.

~~(C) retention of leakage or contamination, on-off mechanism and on-off indicator test records for one year after the next required test is performed or until the sealed source is disposed of or transferred, whichever is shorter;~~

~~(D) retention of other records of tests required in Subparagraph (c)(3) of this Rule for two years from the date of the recorded test or until the device is disposed of or transferred.~~

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been:

(A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or

(B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material

contained in the device; and within 30 days, furnish to the agency at the address in Rule .0111 of this Chapter a report containing a ~~brief~~ description of the event and the remedial action taken. ~~In the event that~~ If 0.005 microcurie or more of removable radioactive contamination is detected, or if the failure of or damage to a source of radiation is likely to result in the contamination of the facility or the environment, a plan for ensuring that the facility and the environment are acceptable for unrestricted use shall be submitted to the agency at the address in Rule .0111 of this Chapter.

(6) shall not abandon the device containing radioactive material;

(7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer to a person holding a specific license authorizing receipt of the device; and, ~~prior to the~~ within 30 days ~~of~~ after transfer of a device to a specific licensee or export ~~the transfer~~ of a device ~~to a specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report that contains:

(A) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(B) the name, address and specific license number of the person receiving the ~~device; and~~ device (license number not applicable if exported); and

(C) the date of the ~~transfer.~~ transfer; and

(8) shall obtain written approval by the Agency before transferring the device to any other specific licensee not identified in this Rule; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments (As defined in 10 CFR 31.5) the existing label otherwise required by Subparagraph (c)(1) of this Rule so that the device is labeled in compliance with Rule .0328(a)(3) of this Chapter; however, the manufacturer, model number, and serial number must be retained;

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under Subparagraph (c)(7) of this Rule.

~~(8)~~(9) shall transfer or dispose of the device only by export as provided by Subparagraph (c)(7) of this Rule, or by transfer to another general licensee only where the device:

(A) remains in use at a particular location. In this case the transferor shall give the transferee a copy of this Rule and any safety documents identified in the label of the device, and the transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(10) of this Rule as having knowledge of and authority to take actions to ensure compliance with the requirements contained in these Rules; or

~~(i) In this case the transferor shall give the transferee a copy of this Section and any safety documents identified in the label of the device;~~

~~(ii) The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(10) of this Rule as having knowledge of and authority to take actions to ensure compliance with the requirements contained in these Rules; or~~

(B) is held in storage by the licensee or an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

~~(9)~~(10) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but ~~shall be~~ is exempt from the other requirements of Section .1600 of this Chapter;

~~(10)~~(11) shall appoint an individual responsible for having knowledge of the requirements contained in these Rules and the authority for taking the actions required to comply with these Rules. The general licensee, through this individual, shall ensure the day-to-day compliance with these Rules. The appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard;

~~(11)~~(12) shall register, when required by the agency, any source of radiation subject to a general license in accordance with the rules in this Section. Each address for a location of use represents a separate general license and requires a separate registration action;

~~(12)~~(13) shall register, on an annual basis, all devices containing, based on the activity indicated on the label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37MBq) of cobalt-60, 1 mCi (37 MBq) of ~~americium-241~~ americium-241, 0.1 millicurie (3.7 MBq) of radium-226,or any other transuranic isotope. Each address for a location of use represents a separate general license and requires a separate registration action. Annual registration consists of verifying, correcting, or adding to the information provided in a request for annual registration within 30 days of a request from the agency. The general licensee shall furnish the following information for annual registration:

(A) the name and mailing address of the general licensee;

(B) ~~specific~~ information about each device to include the manufacturer or initial transferor, model number, serial number, the radioisotope, and the activity indicated on the label;

(C) the name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with Subparagraph (c)(10) of this Rule;

(D) the address or location at which the device(s) are to be used or stored. For portable devices that are granted a general license by the agency, the address of the primary place of storage;

(E) certification by the responsible person designated by the general licensee that the information concerning the device(s) has been verified through a physical inventory and a check of label information; and

(F) certification by the responsible person designated by the general licensee that they are aware of the requirements of the general ~~license.~~ license;

~~(13)~~(14) shall report changes to the mailing address to the agency within 30 days of the effective date of the change;

~~(14)~~(15) shall report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;

(16) shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency a written justification for the request. The request to extend the allotted time will be granted upon agency review of the licensee request and supporting information related to the need for extension;

~~(15)~~(17) shall not hold devices that are not in use for longer than two years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service or transferred to another person, the devices must be tested for leakage and shutter operation. Devices kept in standby for future use shall be excluded from the two year time limit if quarterly physical inventories of these devices are performed while in standby.

(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or ~~distribution~~ import of devices containing radioactive material.

(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT**

(a) Applications for specific licenses shall be filed on an agency form. Completed applications shall include the following

information and other information necessary for the Agency to determine if the applicant meets the requirements for a license:~~required by the agency form:~~

(1) name, address and use location of the applicant;

(2) training and experience of radioactive material users and of the person responsible for radiation protection;

(3) types, quantities and uses of radioactive materials;

(4) description of facilities, equipment and safety program;

(5) procedures for disposal of radioactive material; and

(6) how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of radioactive waste.

(b) The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must:

(1) Identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under10 CFR 32.210 , with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material, with a State under provisions comparable to 10 CFR 32.210;

(2) Contain the information identified in 10 CFR 32.210(c); or

(3) For sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the US Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:

(A) All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

(B) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

~~(e)~~(f) Applications and documents submitted to the agency may be made available for public inspection except as ~~may be~~ are determined otherwise by the agency pursuant to the provisions of G.S. 104E-9(4).

~~(f)~~(g) A license application shall be approved if the agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) the issuance of the license will not be inimical to the health and safety of the public; and

(4) the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.

~~(g)~~(h) ~~As provided~~ If required by Rule .0353 of this Section, certain applications for specific licenses filed under this Section must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. ~~In the case of renewal applications submitted before the effective date of this Rule, this submittal may follow the renewal application but must be submitted on or before the effective date of this Rule.~~

*Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18.*

**15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE**

(a) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or

Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this ~~Rule,~~ Rule and Rule .0117(a)(2) of this Chapter, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; ~~or~~

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Authorized user" means a ~~physician~~ physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a),35.490(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

(e) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(g) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

(h) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(i) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

(j) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(k) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Pulsed dose-rate afterloader" means a type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

(l) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Radiation safety officer" ~~as used in this Section,~~ means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule and Rule.0117 (a)(2) of this Chapter, "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a tissue volume.

(n) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(o) For the purposes of this Rule and Rule .0117(a)(2) of this Chapter, "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that ~~work.~~ work; and

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of ~~appropriate~~ instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:
(A) general characteristics of radiation and radioactive materials;
(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;
(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;
(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;
(E) principles and practices of radiation protection; and
(F) additional training in the above subjects, as appropriate, when new duties are ~~added.~~ added;

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the ~~activites;~~ activities; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be ~~immediately~~ accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1) In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

(z) A licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations

from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS**

(a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of unsealed radioactive material shall be approved if:

(1) the applicant satisfies the requirements in Rule .0319 or Rule .0320 of this Section;

(2) the applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic or therapeutic procedure(s) requested;

(3) the physicians designated in the application as individual users, have clinical experience as required by Rule .0117(a)(2) of this Chapter;

(4) the physicians and all other personnel who will be involved in the preparation and use of radioactive material have training and experience in the handling of unsealed radioactive material appropriate to their use of radioactive material and as required by Rule .0117(a)(2) of this Chapter;

(5) the applicant has radiation safety operating procedures for handling and disposal of the radioactive material that provide protection to the workers, the public and the environment from radiation exposure and radioactive ~~contamination.~~ contamination; and

(6) the applicant has a clinical procedures manual, as appropriate for licensed activities.

(b) Any person authorized by Rules .0318, .0319, .0320, .0322, or .0324 of this Section for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources net exceeding 30 millicuries (mCi)(1.11 Gigabecquerel (GBq)) each, manufactured and distributed by a person licensed under 10 CFR 32.74 or equivalent Agreement State regulations;

(2) Sealed sources, not exceeding 30 mCi (1.11 GBq) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under 10 CFR 32.74, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi (0.56 GBq);

(4) Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of 200 microcuries (μCi) (7.4 Megabecquerel (MBq)) or 1000 times the quantities in Appendix C of 10 CFR Part 20; and

(5) Technetium-99m in amounts as needed.

(c) Any licensee who possesses sealed sources as calibration and reference sources pursuant to Paragraph (b) of this Rule shall test each source for leakage and contamination prior to initial use and at intervals not to exceed six months or at other intervals approved by the U.S. Nuclear Regulatory Commission or an Agreement State in the Sealed Source and Device Registry. If there is reason for the licensee to suspect that a sealed source may have been damaged, or might be leaking, it shall be tested for leakage before further use.

(d) Leak test results shall be recorded in units of microcuries and maintained for inspection by the agency.

(e) Any licensee who possesses and uses calibration and reference sources pursuant to Paragraph (b) of this Rule shall:

(1) follow the radiation safety and handling instructions that are required by the licensing agency to be furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source;

(2) maintain such instructions in a legible and conveniently available form; and

(3 conduct a quarterly physical inventory to account for all sources received an possessed under the license. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of the sources and the date of the inventory.

(f) Any licensee who is licensed pursuant to Rules .0318, .0319, .0320, or .0324 of this Section for medical use of unsealed radioactive material also is authorized to use radioactive material under the general license in Rule .0314 of this Chapter for the specified IN VITRO uses without filing agency forms as required by Rule .0314(b) of the Chapter, provided that the licensee is subject to the other provisions of Rule .0314 of this Chapter.

(g) For each individual receiving radiopharmaceutical therapy and hospitalized because the individual cannot be released in accordance with Rule .0358 of this Section, a licensee shall:

(1) provide a private room with a private sanitary facility;

(2) post the individual's door with a "Radioactive Materials" sign and note on the door or the individual's chart, where and how long visitors may stay in the individual's room;

(3) either monitor material or items removed from the individual's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste; and

(4) Notify the Radiation Safety Officer and authorized user as soon as feasible if the individual has a medical emergency and immediately if the patient dies.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES**

(a) In addition to the requirements set forth in Rule .0318, .0319, or .0320 of this Section, a specific license for human use of sealed sources shall be issued only if the applicant, or if the application is made by an institution, the individual user:

(1) has training and experience as required by Rule .0117(a)(2) of this Chapter, and

(2) is a physician.

(b) The licensee shall comply with the provisions of Section .0700 of this Chapter and the requirements of Subpart H of 10 CFR Part 35.

(c) For medical use, a licensee may only use:

(1) Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 or equivalent requirements of an Agreement State;

(2) Sealed sources or devices noncommercially transferred from a licensee licensed pursuant to Section .0300 of this Chapter, 10 CFR Part 35, or ~~equivalent regulations of~~ an Agreement State medical use licensee;

(3) Teletherapy sources manufactured and distributed in accordance with 10 CFR Part 30 or the equivalent requirements of an Agreement State; or

(4) Brachytherapy sources, photon emitting remote ~~afterlaoder~~ afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses;~~use as approved in:~~

(A) As approved in the Sealed Sources and Device Registry; or

(B) ~~Research~~ In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the ~~FDA.~~ FDA provided the requirements of 10 CFR 35.49(a) are met.

(d) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released in accordance with Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions;

(3) Patient or human research subject control;

(4) Visitor control, including both:

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this ~~Chapter.~~ Chapter; and

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(e) The licensee shall retain records of the radiation safety instruction required in Paragraph (d) of this Rule for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS**

~~(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to~~

persons exempt under Rule .0303(b) of this Section will be issued if:

(1) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(2) the applicant provides a detailed analysis which demonstrates that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being, use of lower concentration is not feasible and that the concentrations of radioactive material at the time of transfer, or that reconcentration of the radioactive material, will not exceed the concentrations listed in the table in Rule .0303(b) of this Section.

(A) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in the table in Rule .0303(b) of this Section, the activity stated is that of the parent isotope and takes into account the daughters.

(B) Values are given in Column I of the table in Rule .0303(b) of this Section, only for those materials normally used as gases.

(C) For purposes of this Rule where there is involved a combination of isotopes, the limit for the combination shall be derived as follows:

(i) Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in the table in Rule .0303(b) of this Section for the specific isotope when not in combination.

(ii) The sum of these ratios shall not exceed unity.

Example:

Exempt concentration of Isotope A + Exempt concentration of Isotope B less than or equal to 1

(b) Each person licensed under Paragraph (a) of this Rule shall file with the agency an annual report which shall identify:

(1) the type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

(2) name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

(3) the type and quantity of radionuclide introduced into each such product or material; and

(4) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

If no transfers of radioactive material have been made pursuant to Paragraph (a) of this Rule during the reporting period, the report shall so indicate. The report shall cover the 12-month period ending June 30, and shall be filed within 30 days thereafter.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION**

(a) An application for a specific license to distribute radioactive material other than source, byproduct or special nuclear material to persons exempt from these Rules pursuant to Rule .0304(e) of this Section will be approved if:

(1) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) The applicant submits copies of prototype labels and brochures and the agency approves their labels and brochures.

(b) The license issued pursuant to this Rule is subject to the following conditions:

(1) No more than ten exempt quantities shall be sold or transferred in any single transaction. An exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fraction shall not exceed unity.

(2) Each exempt quantity shall be separately and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Rule .0304(e) of this Section. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(3) The immediate container of each quantity of separately packaged fractional quantity of radioactive material shall bear the words "Radioactive Material".

(4) In addition to the labeling information required by Subparagraph (b)(3) of this Rule, the label affixed to the immediate container, or an accompanying brochure, shall:

(A) state that the contents are exempt from U.S. Nuclear Regulatory Commission or agreement state requirements;

(B) contain the following statements:

(i) Radioactive material;

(ii) Not for human use;

(iii) Introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited;

(iv) Exempt quantities should not be combined.

(C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(c) Each person licensed under Paragraph (a) of this Rule shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under Rule .0304(e) of this Section or the equivalent regulations of an agreement state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the 12 month period ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this Rule during the reporting period, the report shall so indicate.

(d) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED**

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Rule .0309 of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state ~~will~~ shall be approved if:

(1) the applicant satisfies the general requirements of Rule .0317 of this Section;

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) the device can be safely operated by persons not having training in radiological protection;

(B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar ~~quarter~~ year a dose in excess of ten percent of the limits specified in the table of Rule .1604 of this Chapter; and

(C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(i) whole body, head and trunk, active blood-forming organs, gonads, or lens of eye: 15 rems;

(ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter: 200 rems; or

(iii) other organs: 50 rems. and

(3) each device bears a durable, legible, ~~clearly~~ visible label or labels approved by the agency, which contain in ~~a clearly~~ an identified and separate statement:

(A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(B) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) the information called for in the following statement in the same or substantially similar form: "The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

CAUTION - RADIOACTIVE MATERIAL
(name of manufacturer or distributor)

~~(4)~~ ~~the~~The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) ~~In the event~~If the applicant desires that the device ~~be required to~~ be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that ~~such~~ a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a ~~significant~~ bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency ~~will~~ shall consider information which includes:~~includes, but is not limited to:~~

(1) primary containment (source capsule);
(2) protection of primary containment;
(3) method of sealing containment;
(4) containment construction materials;
(5) form of contained radioactive material;
(6) maximum temperature withstood during prototype test;
(7) maximum pressure withstood during prototype tests;
(8) maximum quantity of contained radioactive material;
(9) radiotoxicity of contained radioactive material; and
(10) operating experience with identical devices or similarly designed and constructed devices.

(c) ~~In the event~~If the applicant desires that the general licensee under Rule .0309 of this Section, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, or an agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application:

(1) Written instructions to be followed by the general licensee;
(2) Estimated calendar quarter doses associated with ~~such~~ the activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license; and
(3) information to demonstrate that performance of such activity(ies) is unlikely to cause that individual to receive a calendar ~~quarter~~ year dose in excess of ten percent of the limits specified in Rule .1604 of this Chapter.

(d) Each person licensed under this Rule to distribute devices shall furnish a copy of the general license contained in Section 31.5 of 10 CFR Part 31 to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0309 of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 31.5 of 10 CFR Part 31 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 31.5 of 10 CFR Part 31. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state's equivalent regulations shall be furnished.

(e) Each person, licensed under this Rule to distribute devices, shall report to the agencies specified in Subparagraphs (e)(1), (2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. The reports shall be submitted to:

(1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;
(2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0309 of this Section; and

(3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 31.5 of 10 CFR Part 31.

(f) Each person, licensed under this Rule to distribute devices, shall maintain for agency inspection either copies of all reports required in Paragraph (e) of this Rule or a record containing substantially the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS**

An application for a specific license to manufacture or distribute radioactive material for use under the general license in Rule .0314 of this Section ~~will~~ shall be approved if the following requirements are satisfied:

(1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(a) iodine-125 in units not exceeding ten microcuries each;

(b) iodine-131 in units not exceeding ten microcuries each;

(c) carbon-14 in units not exceeding ten microcuries each;

(d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(e) iron-59 in units not to exceed 20 microcuries each;

(f) cobalt-57 in units not to exceed ten microcuries each;

(g) selenium-75 in units not exceeding 10 microcuries~~0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.~~ each; or

(h) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(3) Each prepackaged unit bears a durable, ~~clearly~~ visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this Rule, and

(b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the words, "CAUTION, RADIOACTIVE MATERIAL", and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS".

(4) The following statement, or a ~~substantially similar~~ statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for IN VITRO clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer)

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains ~~adequate~~ information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule .1628 of this Chapter.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS**

An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule .0318, .0319, or .0320 of this Section for ~~the radiopharmaceuticals and associated uses in Groups I, II or IV~~ medical use shall be approved subject to the following conditions:

(1) the applicant satisfies the requirements of Rule .0317 of this Section; and

(2) the applicant meets the applicable requirements in Section 32.72 of 10 CFR ~~Part 32.~~ Part 32, and Section 30.32(j) of 10 CFR Part 30.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS**

An application for a specific license to manufacture and distribute generators and reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Rule .0321 of this Section for the generators, reagent kits and associated medical uses ~~in Group III will~~ shall be approved subject to the following conditions:

(1) the applicant satisfies the general requirements of Rule .0317 of this Section, and

(2) the applicant satisfies the applicable requirements in Section 32.73 of 10 CFR Part 32 or their equivalent.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES**

~~(a) Each license issued pursuant to the rules in this Section shall be subject to all the provisions of the Act, now or hereafter in effect, to all rules adopted pursuant to provisions of the Act and to orders of the agency.~~

~~(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.~~

~~(c)~~(a) Each person licensed by the agency pursuant to this Section shall confine his use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

~~(d)~~(b) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) licensee;

(2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

~~(e)~~(c) The notification in Paragraph (d) of this Rule shall indicate:

(1) the bankruptcy court in which the petition for bankruptcy was filed; and

(2) the date of the filing of the petition.

~~(f)~~(d) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and prior approval by the agency.

(e) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule .0361 of this Section. The licensee shall record the results of each test and retain each record for three years after the record is made.

(f) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(g) Authorization under Rule .0333 of this Section to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(h) Each licensee authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(1) Satisfy the labeling requirements in Rule .1626 of this Chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. and

(2) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Rule .0333 of this Section.

(i) A licensee that is a pharmacy authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs be:

(1) an authorized nuclear pharmacist that meets the requirements in Rule .0318 of this Section, or

(2) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule .0318 of this Section.

(j) A pharmacy, authorized under Rule .0333 of this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Rule .0318 of this Section.

*Authority G.S. 104E-7; 104E-10(b).*

**15A NCAC 11 .0352 EMERGENCY PLANS**

(a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:

(1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or

(2) an emergency plan for responding to a release of radioactive material.

(b) ~~One or more of the~~ The following factors may be used to support an evaluation submitted under Subparagraph (a)(1) of this Rule:

(1) the radioactive material is physically separated so that only a portion could be involved in an accident;

(2) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(3) the release fraction in the respirable size range would be lower than the release fraction shown in Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;

(4) the solubility of the radioactive material would reduce the dose received;

(5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Subparagraph (e)(1) of this Rule; and

(6) operating restrictions or procedures would prevent a release fraction as large as that shown in Subparagraph (e)(1) of this Rule; or

(7) ~~other~~ factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of this Rule must include the following information:

(1) ~~brief~~ description of the licensee's facility and potentially impacted area near the site;

(2) identification of each type of radioactive materials accident for which protective actions may be needed;

(3) classification system for classifying accidents as alerts or site area emergencies;

(4) identification of the means of detecting each type of accident in a timely manner quickly enough to mitigate off-site consequences;

(5) ~~brief~~ description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment;

(6) ~~brief~~ description of the methods and equipment to assess releases of radioactive materials;

(7) ~~brief~~ description of the responsibilities of licensee personnel, should an accident occur, including identification of personnel responsible for ~~promptly~~ notifying off-site response organizations and the agency, and responsibilities for developing, maintaining, and updating the plan;

(8) ~~brief~~ description of notification and coordination, to include a commitment to and a brief description of the means to ~~promptly~~ notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate, provided that:

(A) a control point ~~shall be~~ is established;

(B) the notification and coordination ~~shall be~~ is planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination;

(C) the licensee ~~shall also commit~~ commits to notify the agency ~~immediately~~ after notification of the appropriate off-site response organizations, ~~not to exceed~~ within one hour after the licensee declares an emergency; and

(D) the reporting requirements in Subparagraph (c)(8) of this Rule do not substitute for or relieve the licensee from responsibility for complying with the requirements in the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements;

(9) ~~brief~~ description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the agency;

(10) ~~brief~~ description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any ~~special~~ instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel, where such training shall:

(A) familiarize personnel with site-specific emergency procedures; and

(B) ~~thoroughly~~ prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;

(11) ~~brief~~ description of the means of restoring the facility to a safe condition after an accident;

(12) ~~brief~~ description of provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies where such provisions ~~shall~~ meet the following ~~specific~~ requirements:

(A) quarterly communications checks with off-site response organizations

~~shall~~ include the check and update of all necessary telephone numbers;

(B) while participation of off-site response organizations in biennial exercises is ~~encouraged but~~ not required, ~~the licensee shall~~ invite off-site response organizations to participate in the biennial exercises;

(C) accident scenarios for biennial exercises ~~shall not be~~ are not known to most exercise participants;

(D) ~~the licensee shall~~ critique of each exercise using individuals who do not have direct implementation responsibility for the plan; ~~and~~

(E) critiques of exercises ~~shall~~ evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response; and

(F) deficiencies found by the critiques in Part (c)(12)(E) of this Rule ~~shall be~~ are corrected; and

(13) certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 day comment period to the agency with the emergency plan.

(e) Quantities of radioactive material requiring ~~consideration of the need for~~ an emergency plan for responding to a release as used in this Rule and ~~special~~ instructions for use are:

~~(1)~~ TABLE

| RADIOACTIVE MATERIAL | RELEASE FRACTION | QUANTITY (CURIES) |
|---|---|---|
| Actinium-228 | 0.001 | 4,000 |
| Americium-241 | .001 | 2 |
| Americium-242 | ~~001~~.001 | 2 |
| Americium-243 | .001 | 2 |
| Antimony-124 | .01 | 4,000 |
| Antimony-126 | .01 | 6,000 |
| Barium-133 | .01 | 10,000 |
| Barium-140 | .01 | 30,000 |
| Bismuth-207 | .01 | 5,000 |
| Bismuth-210 | .01 | 600 |
| Cadmium-109 | .01 | 1,000 |
| Cadmium-113 | .01 | 80 |
| Calcium-45 | .01 | 20,000 |
| Californium-252 | .001 | 9 (20 mg) |
| Carbon-14 ~~(NON CO)~~ (NON $CO_2$) | .01 | 50,000 |
| Cerium-141 | .01 | 10,000 |
| Cerium-144 | .01 | 300 |
| Cesium-134 | .01 | 2,000 |
| Cesium-137 | .01 | 3,000 |
| Chlorine-36 | .5 | 100 |
| Chromium-51 | .01 | 300,000 |
| Cobalt-60 | .001 | 5,000 |
| Copper-64 | .01 | 200,000 |
| Curium-242 | .001 | 60 |
| Curium-243 | .001 | 3 |
| Curium-244 | .001 | 4 |
| Curium-245 | .001 | 2 |
| Europium-152 | .01 | 500 |
| Europium-154 | .01 | 400 |
| Europium-155 | .01 | 3,000 |
| Germanium-68 | .01 | 2,000 |
| Gadolinium-153 | .01 | 5,000 |
| Gold-198 | .01 | 30,000 |
| Hafnium-172 | .01 | 400 |

| | | |
|---|---|---|
| Hafnium-181 | .01 | 7,000 |
| Holmium-166 m | .01 | 100 |
| Hydrogen-3 | .5 | 20,000 |
| Iodine-125 | .5 | 10 |
| Iodine-131 | .5 | 10 |
| Indium-114 m | .01 | 1,000 |
| Iridium-192 | .001 | 40,000 |
| Iron-55 | .01 | 40,000 |
| Iron-59 | .01 | 7,000 |
| Krypton-85 | 1.0 | 6,000,000 |
| Lead-210 | .01 | 8 |
| Manganese-56 | .01 | 60,000 |
| Mercury-203 | .01 | 10,000 |
| Molybdenum-99 | .01 | 30,000 |
| Neptunium-237 | .001 | 2 |
| Nickel-63 | .01 | 20,000 |
| Niobium-94 | .01 | 300 |
| Phosphorus-32 | .5 | 100 |
| Phosphorus-33 | .5 | 1,000 |
| Polonium-210 | .01 | 10 |
| Potassium-42 | .01 | 9,000 |
| Promethium-145 | .01 | 4,000 |
| Promethium-147 | .01 | 4,000 |
| Ruthenium-106 | .01 | 200 |
| Samarium-151 | .01 | 4,000 |
| Scandium-46 | .01 | 3,000 |
| Selenium-75 | .01 | 10,000 |
| Silver-110 m | .01 | 1,000 |
| Sodium-22 | .01 | 9,000 |
| Sodium-24 | .01 | 10,000 |
| Strontium-89 | .01 | 3,000 |
| Strontium-90 | .01 | 90 |
| Sulfur-35 | .5 | 900 |
| Technetium-99 | .01 | 10,000 |
| Technetium-99 m | .01 | 400,000 |
| Tellurium-127 m | .01 | 5,000 |
| Tellurium-129 m | .01 | 5,000 |
| Terbium-160 | .01 | 4,000 |
| Thulium-170 | .01 | 4,000 |
| Tin-113 | .01 | 10,000 |
| Tin-123 | .01 | 3,000 |
| Tin-126 | .01 | 1,000 |
| Titanium-44 | .01 | 100 |
| Vanadium-48 | .01 | 7,000 |
| Xenon-133 | 1.0 | 900,000 |
| Yttrium-91 | .01 | 2,000 |
| Zinc-65 | .01 | 5,000 |
| Zirconium-93 | .01 | 400 |
| Zirconium-95 | .01 | 5,000 |
| Any other beta-gamma emitter | .01 | 10,000 |
| Mixed fission products | .01 | 1,000 |
| Mixed corrosion products | .01 | 10,000 |
| Contaminated equipment beta-gamma | .001 | 10,000 |
| Irradiated material, any form other than solid noncombustible | .01 | 1,000 |
| Irradiated material, solid Noncombustible | .001 | 10,000 |
| Mixed radioactive waste beta-gamma | .01 | 1,000 |

| | | |
|---|---|---|
| Packaged mixed waste, beta-gamma | .001 | 10,000 |
| Any other alpha emitter | .001 | 2 |
| Contaminated equipment, alpha | .0001 | 20 |
| Packaged waste, alpha | .0001 | 20 |

~~(2)~~(f) For combinations of radioactive materials, ~~consideration of the need for~~ an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in the table in Subparagraph (e)(1) of this Rule exceeds one.
~~(3)~~(g) Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

*Authority G.S. 104E-7; 104E-18.*

**15A NCAC 11 .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS**

(a) A licensee may authorize the release from its control ~~of~~ any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 millirem (5 mSv).

(b) The licensee shall provide the released ~~individual~~ individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 100 millirem (1 mSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 mSv) ~~assuming~~ if there ~~were~~ is no interruption of breast-feeding, the instructions shall ~~also~~ include:

(1) Guidance on the interruption or discontinuation of breast-feeding; and
(2) Information on the consequences of failure to follow the guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an ~~individual,~~ individual for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered;
(2) Using an occupancy factor less than 0.25 at one meter;
(3) Using the biological or effective half-live; or
(4) Considering the shielding by tissue.

(d) The licensee shall maintain a ~~record,~~ record for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 millirem (5 mSv).

*Authority G.S. 104E-7(a)(8).*

**15A NCAC 11 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL**

(a) A licensee may use any unsealed radioactive material prepared for use for uptake, dilution, or excretion studies, imaging and localization ~~studies and radiopharmaceutical therapy that is:~~ studies, and use requiring a written directive in accordance with Rule .0104 of this Chapter that is:

(1) Obtained from a manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State ~~requirements;~~ requirements;
(2) ~~Prepared by:~~ Obtained from a positron emission tomography (PET) radioactive drug producer licensed under 10 CFR 30.32(j), 15A NCAC 11 .0333, or equivalent Agreement State requirements;
~~(A) An authorized nuclear pharmacist;~~
~~(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2);~~
~~(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;~~
(3) Excluding production of PET radionuclides, prepared by:
(A) An authorized nuclear pharmacist;
(B) A physician who is an authorized user identified on a North Carolina Radioactive Materials License, an Agreement State Radioactive Materials License, or a license issued by the U.S. Nuclear Regulatory Commission or who meets the requirements in 15A NCAC 11 .0117(a)(2); or
(C) An individual under the supervision, as specified in Rule .0318 of this Section, of the authorized nuclear pharmacist in Part (a)(2)(A) of this Rule or the physician who is an authorized user in Part (a)(2)(B) of this Rule;
~~(3)~~(4) Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research

Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA; or

~~(4)~~(5) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA.

(b) A licensee shall not administer to humans a radiopharmaceutical ~~containing~~ that contains:~~more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m.~~

(1) more than 0.15 microcurie (0.15 kilobecquerel) of molybdenum-99 per millicurie (megabecquerel) of technetium-99m; or

(2) more than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of rubidium-82 chloride, or 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie (megabecquerel) of rubidium-82 chloride.

~~(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.~~

(c) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99 radiopharmaceutical shall measure the molybdenum-99 concentration in the first eluate after receipt of a generator to demonstrate compliance with Paragraph (b) of this Rule.

(d) A licensee that uses strontium-82/rubidium-82 generators for preparing a rubidium-82 radiopharmaceutical shall measure the concentrations of strontium-82 and strontium-85 before the first patient use of the day to demonstrate compliance with Paragraph (b) of this Rule.

~~(d)~~(e) A licensee that must measure ~~molybdenum~~ molybdenum-99, or strontium-82 and strontium-85,concentration shall retain a record of each measurement for three years. The record shall ~~include for each measured elution of technetium-99m:~~ include:

(1) for each measured elution of technetium-99m:the ratio of the measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m (or kilobecquerels of molybdenum-99 per megabecquerel of technetium-99m);

(2) for each measured elution of rubidium-82: the ratio of the measures expressed as microcuries of strontium-82 and strontium-85 per millicurie of rubidium-82 (or kilobecquerel strontium-82 and strontium-85 per megabecquerel rubidium-82); and

~~(2)~~(3) the time and date of the measurement; and

~~(3)~~(4) the initials of the individual who made the measurement.

*Authority G.S. 104E-7(a)(2); 104E-10(b); 104E-12.*

**15A NCAC 11 .0362 DECAY-IN-STORAGE**

(a) A licensee may hold radioactive material with a physical half-life of less than ~~165~~ 275 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of Rule .1628 of this Chapter if the licensee:

(1) holds radioactive material for decay a minimum of 10 half-lives;

(2) monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter capable of detecting a dose rate of 0.1 millirem (1 microsievert) per hour and with no interposed shielding; and

(3) removes or obliterates all radiation labels.

(b) A licensee shall retain a record of each disposal permitted under Paragraph (a) of this Rule for three years. The record shall include:~~include the date of the disposal, the date on which radioactive material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate used, and the dose rate measured at the surface of each waste container.~~

(1) the date of the disposal;

(2) the date on which radioactive material was placed in storage;

(3) the radionuclides disposed;

(4) the survey instrument used;

(5) the background dose rate used; and

(6) the dose rate measured at the surface of each waste container.

*Authority G.S. 104E-7(a)(2); 104E-10(b).*

**15A NCAC 11 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS**

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified in this Rule. The information reported shall include data and results obtained pursuant to rules of this Chapter, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this Chapter. Each notification and report shall:

(1) be in writing;

(2) include identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) include the individual's exposure information; and

(4) contain the following statement: This report is furnished to you under the provisions of Section 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS, REPORTS AND INSPECTIONS. You should preserve this report for further reference.

~~be in writing; include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:~~

~~This report is furnished to you under the provisions of Section 15A NCAC 11 .1000; NOTICES, INSTRUCTIONS, REPORTS AND INSPECTIONS. You should preserve this report for further reference.~~

(b) ~~At the request of any worker, each licensee or registrant shall advise such worker annually of the worker's radiation dosage and exposure to radioactive materials as shown in records maintained by the licensee or registrant pursuant to Paragraphs (a) and (c) of this Rule.~~ Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of Rule .1640 of this Chapter. The licensee or registrant shall provide an annual report to each individual monitored under Rule .1614 of this Chapter of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials. ~~Such~~ The report shall:

(1) be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

(2) shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and

(3) shall include the dates and locations of work under the license or registration in which the worker participated during this period.

~~shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and shall include the dates and locations of work under the license or registration in which the worker participated during this period.~~

(d) When a licensee or registrant is required pursuant to Rule ~~.1647~~ .1646, .1647, or .1648 of this Chapter to report to the agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included ~~therein.~~in the report to the agency. ~~Such~~ The reports shall be transmitted at a time no later than the transmittal to the agency.

*Authority G.S. 104E-7; 104E-10; 104E-12.*

**15A NCAC 11 .1604 OCCUPATIONAL DOSE LIMITS FOR ADULTS**

(a) ~~The~~ A licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures as provided in Rule .1608 of this Section, to the following dose limits:

(1) an annual limit, which is the more limiting of:
   (A) the total effective dose equivalent being equal to five rems (0.05Sv); or
   (B) the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv); and

(2) the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:
   (A) an eye dose equivalent of 15 rems (0.15 Sv), and
   (B) a shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in Item (5) of Rule .1608 of this Section.

~~(c) The assigned deep-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, eye dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.~~

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent unless the effective dose equivalent is determined by a dosimetry method approved by the agency as consistent with this Chapter. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix B to 10 CFR §§ 20.1001 - 20.2401 and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.
(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. Requirements for annual limits on intake for uranium are provided in Appendix B to 10 CFR §§ 20.1001 - 20.2401.
(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Requirements for determining prior occupational exposure are provided in Rule .1638(e) of this Section.

*Authority G.S. 104E-7(a)(2).*

**15A NCAC 11 .1626 LABELING REQUIREMENTS AND EXEMPTIONS**

(a) The licensee shall ensure ~~that each container of licensed radioactive material bears a durable, clearly visible label bearing the radiation symbol and the words:~~ that:

(1) each container of licensed radioactive material bears a durable, visible label bearing the radiation symbol and the words:
CAUTION
RADIOACTIVE MATERIAL

or the words:

DANGER
RADIOACTIVE MATERIAL

The label shall also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize ~~exposures.~~ exposures; and

(2) each syringe and vial that contains unsealed radioactive material for medical use is labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise ~~clearly~~ indicate that the container no longer contains radioactive materials.
(c) Except as required in Subparagraph (a)(2) of this Rule, a~~A~~ licensee is not required to label:

(1) containers holding licensed radioactive material in quantities less than the quantities listed in Appendix C to 10 CFR §§ 20.1001 - 20.2401;
(2) containers holding licensed radioactive material in concentrations less than those specified in Table 3 of Appendix B to 10 CFR §§ 20.1001 - 20.2401;
(3) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Section;
(4) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation,
(5) containers that are accessible only to individuals authorized to handle or use ~~them,~~ them or to work in the vicinity of the ~~containers,~~ containers if the contents are identified to these individuals by a readily available written record, for example, (containers in locations such as water-filled canals, storage vaults, or hot cells, provided the record shall be retained as long as the containers are in use for the purpose indicated on the record; or
(6) installed manufacturing or process equipment, such as piping and tanks).

*Authority G.S. 104E-7(a)(2).*

**15A NCAC 11 .1633 TRANSFER FOR DISPOSAL AND MANIFESTS**

(a) The requirements of this Rule and Appendix G to 10 CFR 20, incorporated by reference in Rule .0117 of this Chapter, are designed to:

(1) control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in Appendix G to 10 CFR 20, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste disposal facility, as defined in Rule .1202 of this Chapter;
(2) establish a manifest tracking system; and
(3) supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this Rule and Appendix G to 10 CFR 20.
(c) Each shipment manifest shall include a certification by the waste generator as specified in Appendix G to 10 CFR 20.
(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in this Rule and Appendix G to 10 CFR 20.
(e) Reports and notifications required to be made to the nearest regional administrator by Appendix G to 10 CFR 20 shall, instead, be made to the agency.

(f) Any licensee shipping radioactive material as defined in Rule .0104 of this Chapter intended for ultimate disposal at a land disposal facility as defined in Rule .1202 of this Chapter must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this 10 CFR 20.
(g) Radioactive material as defined in Rule .0104 of this Chapter may be disposed of in accordance with Rule .1628 of this Section, even though it is not defined as low-level radioactive waste. Any licensed radioactive material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of this Rule.
(h) A licensee may dispose of radioactive material as defined in Rule .0104 of this Chapter, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

*Authority G.S. 104E-7(a)(2),(a)(3); 104E-12(a).*

**15A NCAC 11 .1648 REPORTS OF PLANNED SPECIAL EXPOSURES**
(a) The licensee or registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with Rule .1608 of this Section, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by Rule .1639 of this Section.
(b) When a licensee or registrant is required by this Rule to report to the agency any exposure of an identified occupationally exposed individual or an identified member of the public to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the agency. This report must be transmitted no later than the transmittal to the agency.

*Authority G.S. 104E-7(a)(2); 104E-12(a).*

## TITLE 21 – OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

## CHAPTER 22 - HEARING AID DEALERS AND FITTERS BOARD

***Notice** is hereby given in accordance with G.S. 150B-21.2 that the NC State Hearing Aid Dealers and Fitters Board intends to adopt the rule cited as 21 NCAC 22A .0401; amend the rules cited as 21 NCAC 22A .0501, .0503; 22F .0107; 22I .0103; and repeal the rules cited as 21 NCAC 22A .0301, .0303, .0307-.0312.*

**Agency obtained G.S. 150B-19.1 certification:**

☐ **OSBM certified on:**
☐ **RRC certified on:**
☒ **Not Required**

**Link to agency website pursuant to G.S. 150B-19.1(c):** *http://www.nchalb.org/regulatory/rulechange.php*

**Proposed Effective Date:** *September 1, 2013*

**Public Hearing**:
**Date:** *June 6, 2013*
**Time:** *12:45 p.m.*
**Location:** *Commission Room, Office of Administrative Hearings, 1711 New Hope Church Road, Raleigh, NC 27609*

**Reason for Proposed Action:** *The Board has done an annual review of rules, in consideration of changes in G.S. 93D. Rules are to clarify hearing testing requirements, and to provide definitions for new rules, as well as to address how applications are submitted and reviewed by the Board and to allow a registered sponsor access to apprentice exam results.*

**Procedure by which a person can object to the agency on a proposed rule:** *A person can object to the agency by speaking at the public hearing on June 6, 2013 or by submitting written comments to the following address no later than July 15, 2013: NC State Hearing Aid Dealers and Fitters Board, ATTN: Rulemaking, P. O. Box 97833, Raleigh, NC 27624.*

**Comments may be submitted to:** *Catherine Jorgensen, Rulemaking Coordinator, NC State Hearing Aid Dealers and Fitters Board, P. O. Box 97833, Raleigh, NC 27624*

**Comment period ends:** *July 15, 2013*

**Procedure for Subjecting a Proposed Rule to Legislative Review:** If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

**Fiscal impact (check all that apply).**
☐ **State funds affected**
☐ **Environmental permitting of DOT affected**
**Analysis submitted to Board of Transportation**
☐ **Local funds affected**
**Date submitted to OSBM:**
☐ **Substantial economic impact (≥$500,000)**

☐ **Approved by OSBM**
☒ **No fiscal note required by G.S. 150B-21.4**

**SUBCHAPTER 22A - BOARD RULES**

**SECTION .0300 – DEFINITIONS**

**21 NCAC 22A .0301 DEFINITIONS AND INTERPRETATIONS**

~~(a) The rules of statutory construction concerning number and gender as contained in G.S. 12-3(1) shall be applied in the construction of these Rules.~~

~~(b) The definitions cited in this Section shall serve as interpretations for terms appearing in Chapter 93D of the General Statutes of North Carolina and in these Rules. In addition, the definitions contained in the Food and Drug Administration Standards concerning Hearing Aid Devices, Title 21 of the Code of Federal Regulations Part 801, as published in the 42nd Volume of the Federal Register (February 15, 1977) page 9294 are adopted herein by reference, in accordance with G.S. 150B-14(b), with the following additions and amendments:~~

~~(1) "Reconditioned" shall mean that the condition of the hearing aid is the same as a used hearing aid.~~

~~(2) "Audiologist" shall mean any individual holding a valid non-temporary license as an audiologist issued by the North Carolina Board of Examiners for Speech and Language Pathologists and Audiologists. Such individual is not required to serve as an apprentice, as set forth in G.S. 93D-5, before applying for issuance of a license by examination, in accordance with the consent judgment entered in 80-CVS-8161 and filed in Wake County Superior Court Division, the case entitled Audiology Council of North Carolina, Inc., v. The North Carolina Hearing Aid Dealers and Fitters Board.~~

*Authority G.S. 93D-3(c); 150B-14.*

**21 NCAC 22A .0303 LICENSE**

~~"License" shall mean the printed certificate, issued by the Board, which an individual is required to obtain before engaging in the fitting and selling of hearing aids independent of a sponsor.~~

*Authority G.S. 93D-3(c); 93D-5.*

**21 NCAC 22A .0307 REGISTERED APPRENTICE**

~~"Registered Apprentice" shall mean any individual who has duly made application to the Board and has been issued an apprentice registration certificate which entitles such individual to fit and sell hearing aids under the supervision of a licensee approved by the Board.~~

*Authority G.S. 93D-3(c); 93D-9.*

**21 NCAC 22A .0308 REGISTERED APPLICANT**

~~"Registered Applicant" shall mean any individual, including a registered apprentice, who has duly made application to the Board for issuance of a license and for which one or more of the following conditions apply:~~

~~(1) The individual is seeking admission to the next scheduled qualifying examination given by the Board (license by examination);~~

~~(2) The individual is seeking reciprocity pursuant to G.S. 93D-6;~~

~~(3) The individual is seeking reinstatement of an expired license as set forth in G.S. 93D-11; or~~

~~(4) The individual is seeking reissuance of a suspended license in accordance with the provisions of G.S. 93D-13.~~

*Authority G.S. 93D-3(c).*

**21 NCAC 22A .0309 DULY MADE APPLICATION**

~~"Duly made application" shall mean that the completed application form, including all required documents, photographs, and fees, and any supplemental information requested by the Board pursuant to 21 NCAC 22F .0004(a), is physically received in the office of the Board.~~

*Authority G.S. 93D-3(c).*

**21 NCAC 22A .0310 ONE FULL YEAR OF APPRENTICESHIP**

~~"One full year of apprenticeship" shall mean that an individual, who is not an Audiologist and does not hold a masters degree in Audiology, has held a valid apprentice registration certificate for a period of 365 calendar days, has engaged in fitting and selling hearing aids for a minimum of 30 clock hours per week for a period of 50 weeks, and has received a minimum of 750 clock hours of direct supervision from a licensee approved by the Board. The maximum time span allowed for completing the 365 calendar day requirement shall not exceed 24 consecutive months from the date of issuance of the initial apprentice registration certificate.~~

*Authority G.S. 93D-3(c).*

**21 NCAC 22A .0311 DIRECT SUPERVISION**

~~"Direct supervision" shall mean the provision of general direction and control, including immediate personal on-site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the provision of consultation and instruction.~~

*Authority G.S. 93D-3(c).*

**21 NCAC 22A .0312 AUDIOMETER**

~~"Audiometer" shall mean an electronic device, used for air conduction testing, bone conduction testing, and for obtaining speech audiometry results, which contains a masking circuit, at least one VU meter, and capability of sound field output.~~

*Authority G.S. 93D-3(c).*

**SECTION .0400 - DEFINITIONS**

**21 NCAC 22A .0401 DEFINITIONS AND INTERPRETATIONS**

(a) The rules of statutory construction concerning number and gender as contained in G.S. 12-3(1) shall be applied in the construction of these Rules.

(b) The definitions contained in the Food and Drug Administration Standards concerning Hearing Aid Devices, Title 21 of the Code of Federal Regulations Part 801.420 are adopted herein by reference, in accordance with G.S. 150B-14(b), with the following additions and amendments:

(1) "Reconditioned" shall mean that the condition of the hearing aid is the same as a used hearing aid; and

(2) "Audiologist" shall mean any individual holding a valid non-temporary license as an audiologist issued by the North Carolina Board of Examiners for Speech and Language Pathologists and Audiologists.

(c) The definitions cited in this Section shall serve as interpretations for terms appearing in Chapter 93D of the General Statutes of North Carolina and in these Rules.

(1) "Advertising" means a written or oral communication that is published, disseminated, circulated, or placed before the public for the purpose of attracting public attention to a product, business, or service.

(2) "Apprentice" means an individual who holds a valid Board-issued apprentice registration certificate to fit and sell hearing aids under the supervision of a Registered Sponsor.

(3) "Audiometer" means an electronic device, used for air conduction testing, bone conduction testing, and for obtaining speech audiometry results, which contains a masking circuit, at least one VU meter, and capability of sound field output.

(4) "Direct supervision" means the provision of general direction and control by a Registered Sponsor, including regular on-site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the regular provision of consultation and instruction.

(5) "Duly made application" means a completed application received in the office of the Board, including all required documents, photographs, fees, and supplemental information requested in the application.

(6) "One full year of apprenticeship" means that an apprentice has satisfied each of the following requirements within 24 consecutive months from the date of issuance of the initial apprentice registration certificate:

(A) work under the supervision of a Registered Sponsor for a minimum of 30 clock hours per week for a period of 50 weeks;

(B) complete a minimum of 750 clock hours of fitting and selling hearing aids under the supervision of a Registered Sponsor; and

(C) hold a valid apprentice registration certificate for a period of 365 calendar days.

(7) "Personal supervision" means the provision of specific direction and control by the Registered Sponsor or a North Carolina licensed Hearing Aid Specialist approved by the Registered Sponsor, requiring immediate personal in-room supervision, including immediate personal on-site inspection and evaluation of work constituting the fitting and selling of hearing aids, as well as the provision of consultation and instruction.

(8) "Registered Applicant" means any individual, including an apprentice, approved and registered to sit for the next scheduled licensing exam.

(9) "Registered Sponsor" means a person with a permanent license as an audiologist under Article 22 of Chapter 90 of the General Statutes who is registered in accordance with G.S. 93D-3(c)(16), or a licensee of the Board who has been approved as a sponsor of an apprentice.

*Authority G.S. 93D-3(c); 93D-9; 150B-14.*

**SECTION .0500 – SUBMISSION OF APPLICATIONS AND FEES**

**21 NCAC 22A .0501 FEE SCHEDULE**

The Board hereby establishes the following fees:

~~(10)~~(1) Application for registration as an apprentice $100.00

~~(11)~~(2) Renewal of apprentice registration. $150.00

(3) Application for registration of a Registered Sponsor not otherwise licensed by the Board. $150.00

~~(7)~~(4) Application for a license by examination. $250.00

~~(6)~~(5) Examination fee. $300.00

~~(9)~~(6) Issuance of certificate of license after successfully passing examination. $ 25.00

~~(13)~~(7) To reissue a suspended license more than 90 days after but not more than two years after license suspended. $200.00

~~(12)~~(8) Annual license renewal. $250.00

(a) Late fee ~~to reinstate expired license~~ within 60 days after license

expiration (in addition to renewal fee). $ 25.00

(b) Late fee ~~to reinstate expired license~~ more than 60 days after license expiration (in addition to renewal fee). $ 50.00

~~(3)~~(9) For approval of a continuing education program provider. $ 40.00

~~(4)~~(10) Verifying and recording attendance at a continuing education program (per program, per person). $ 15.00

~~(1)~~(11) For a continuing education make-up class provided by the Board, not to exceed two days (per person, per day). $ 50.00

~~(5)~~(12) For a voluntary apprentice training workshop (per person, per day, not to exceed three days). $ 50.00

~~(2)~~(13) For a license examination preparation course provided by the Board, not to exceed three days (per person, per day). $ 50.00

(14) Processing fee for a check on which payment has been refused by the payor bank because of insufficient funds or because the drawer did not have an account at that bank. $ 25.00

~~(8) Application for a license to fit and sell hearing aids in this state by a licensee of another state or territory. $150.00~~

*Authority G.S. 12-3.1; 25-3-506; 93D-3; 93D-5; 93D-6; 93D-8; 93D-9; 93D-11; 93D-13.*

**21 NCAC 22A .0503 SUBMISSION OF APPLICATIONS AND FEES**

~~(a) An Application for Renewal or Replacement of Apprentice Certificate shall be submitted to the Board no later than ten working days after the date that any of the following conditions exist:~~

~~(1) a registered apprentice is separated from his sponsor for any reason and the individual wishes to obtain a new certificate to replace the invalidated certificate;~~

~~(2) a registered apprentice is notified by the Board that he or she failed to pass the qualifying examination and the individual wishes to renew his or her certificate; and~~

~~(3) the Board notifies an individual that his apprentice registration certificate has been invalidated for any reason and the individual wishes to obtain a new certificate to replace the invalidated certificate.~~

~~(b) No later than ten working days after a registered apprentice has held a valid apprentice registration certificate for 365 calendar days, the apprentice shall submit an Application for License and shall take the next scheduled licensing examination. All registered apprentices shall reapply for a license by examination, within the time prescribed in Paragraph (c) of this Rule, each time they take and fail to pass the licensing examination.~~

~~(c) When a registered applicant makes application to take an examination, the duly made application shall be considered by the Board to be timely if it is received by the Board no later than 45 consecutive days prior to the examination date. An untimely application is grounds for denying an applicant admission to an examination.~~

~~(d) All fees shall be made payable to the N.C. Hearing Aid Dealers and Fitters Board. When a company or personal check is received in payment of any fee, the Board shall wait until final credit on the check is received before providing the license or other document requested. A processing fee of twenty dollars ($20.00) (or any greater amount allowed by law) shall be charged for any check on which payment is refused by the payor bank because of insufficient funds or because the drawer did not have an account at that bank at the time the check was presented to the Board.~~

(a) The Board shall accept a digital image of a signed affidavit or other document required as part of an application as the original when submitted electronically in conjunction with the electronic application.

(b) If an applicant submits an incomplete application, the Board shall deny the application after 10 business days, unless the applicant provides supplemental information to make it a duly made application, as defined in 21 NCAC 22A .0401, by the 10th business day. After 10 business days, the Board will classify the application as "abandoned by the applicant" and shall not apply any fee paid or document submitted for the abandoned application to any other application. This Rule does not extend an application deadline set forth in any other rule of this Chapter.

(c) When an individual makes application to take an examination, the duly-made application shall be considered by the Board to be timely if it is received by the Board no later than 45 consecutive days prior to the examination date. An untimely application is grounds for denying an applicant admission to an examination.

(d) No later than 10 business days after an apprentice has held a valid apprentice registration certificate for 365 calendar days, the apprentice shall make application to take the next scheduled licensing examination. All apprentices shall reapply for a license by examination, within the time prescribed in Paragraph (c) of this Rule, each time they take and fail to pass the licensing examination.

(e) No later than 20 calendar days after the date printed on the Official Notice of Examination Results, a registered apprentice, who failed to pass the qualifying examination, shall make application to renew the apprentice certificate until the following examination, or the Sponsor shall submit written notice to the Board that the apprenticeship is being terminated by the current expiration date of the certificate.

(f) An applicant's failure to submit a duly made application by the application deadline is grounds for the Board to deny the application.

*Authority G.S. 93D-3(c); 93D-5; 93D-9.*

**SUBCHAPTER 22F - GENERAL EXAMINATION AND LICENSE PROVISIONS**

**21 NCAC 22F .0107 COMMUNICATION OF RESULTS OF EXAMINATIONS**

(a) The office of the Board shall issue written notification to each registered applicant by mailing exam results to the physical address provided by the applicant concerning the applicant's performance on the qualifying examination no later than 30 working days after the date of the examination.

(b) A copy of the applicant's exam results shall be mailed to the applicant's Registered Sponsor at the mailing address on file with the Board at the same time the results are mailed to the applicant.

*Authority G.S. 93B-8; 93D-3(c).*

**SUBCHAPTER 22I - PROFESSIONAL AFFAIRS**

**21 NCAC 22I .0103 VISUAL INSPECTION AND HEARING TEST**

(a) All licensees and registered apprentices shall make a visual inspection of the external auditory canal and the tympanic membrane, using a device having its own light source in order to fulfill the requirements of 21 CFR 801 (effective August 15, 1977), Subpart 801.420 concerning the warning to hearing aid dispensers.

(b) All licensees and registered apprentices shall conduct a hearing test using an audiometer, the calibration for which is on file at the Board office, or equivalent physiologic testing.

(c) A hearing test shall be conducted within 90 days prior to the dispensing of a hearing aid and a copy of the hearing test shall be maintained for a period of at least three years.

(d) The hearing test shall be conducted in an environment conducive to obtaining accurate results and shall include the following, unless physiologic testing is utilized:

~~(2)~~(1) live voice or recorded voice speech audiometry, including speech reception threshold testing and speech discrimination testing; and

~~(1)~~(2) pure tone audiometry, including air conduction testing and bone conduction ~~testing;~~ testing as follows:

(A) air conduction testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, 3000Hz, and 4000 Hz;

(B) mid-octave air conduction testing performed when there is a 20 dB or greater difference between any adjacent octaves; and

(C) bone conduction testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz;

(D) effective masking, if audiometric testing reveals a difference between the ears at any one frequency equal to or greater than 40 decibels or if there is audiometric air-bone gap of 15 dB or greater.

~~(3) effective masking, if audiometric testing reveals a difference between the ears at any one frequency equal to or greater than 40 decibels or if there is audiometric air bone gap of 15 dB or greater.~~

~~(4) testing at least at the following frequencies: 500 Hz, 1000 Hz, 2000 Hz, 3000Hz, and 4000 Hz;~~

~~(5) mid-octavetesting performed when there is a 20 dB or greater difference between any adjacent octaves.~~

(e) All licensees and registered apprentices shall evaluate dispensed products to determine ~~effectiveness.~~ effectiveness and shall maintain documentation of the verification for a period of at least three years. Measures of evaluation shall include at least one of the following:

(1) sound field measurements;
(2) real ear measurements; or
(3) client evaluation sheets.

*Authority G.S. 93D-3(c).*

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**CHAPTER 46 - BOARD OF PHARMACY**

***Notice** is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rules cited as 21 NCAC 46 .3401-.3402, .3404 and repeal the rules cited as 21 NCAC 46 .3403, .3405-.3408.*

**Agency obtained G.S. 150B-19.1 certification:**
☐ **OSBM certified on:**
☐ **RRC certified on:**
☒ **Not Required**

**Link to agency website pursuant to G.S. 150B-19.1(c):** *www.ncbop.org/lawandrules.htm*

**Proposed Effective Date:** *November 1, 2013*

**Public Hearing**:
**Date:** *September 10, 2013*
**Time:** *5:00 p.m.*
**Location:** *North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517*

**Reason for Proposed Action:** *Revisions simplify categorizations of automated medication systems and certain recordkeeping obligations, consolidate the rules and remove redundancies.*

**Procedure by which a person can object to the agency on a proposed rule:** *Any person may object to the proposed amendments by attending the public hearing on September 10, 2013 and/or by submitting a written objection by September 10, 2013 to Jay Campbell, Executive Director, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, fax (919)246-1056, email*

*jcampbell@ncbop.org. The North Carolina Board of Pharmacy is interested in all comments pertaining to the proposed rules. All persons interested and potentially affected by the proposal are strongly encouraged to read this entire notice and make comments on the proposed rules.*

**Comments may be submitted to:** *Jay Campbell, 6015 Farmington Road, Suite 201, Chapel Hill, NC 27517, fax (919)246-1056, email jcampbell@ncbop.org*

**Comment period ends:** *September 10, 2013*

**Procedure for Subjecting a Proposed Rule to Legislative Review:** If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

**Fiscal impact (check all that apply).**

☐ **State funds affected**
☐ **Environmental permitting of DOT affected**
**Analysis submitted to Board of Transportation**
☐ **Local funds affected**
**Date submitted to OSBM:**
☐ **Substantial economic impact (≥$500,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required by G.S. 150B-21.4**

**SECTION .3400 – AUTOMATED DISPENSING ON DRUG SUPPLY DEVICES**

**21 NCAC 46 .3401 DEFINITIONS**

For purposes of this Section, ~~these Rules,~~ the following terms are defined as follows:

(1) "Automated medication system" means a robotic, ~~mechanical~~ mechanical, or computerized device that is not used for ~~medication~~ drug compounding and is designed to:
(a) Distribute ~~medications~~ drugs in a licensed health care facility that holds a pharmacy permit; or
(b) Package ~~medications~~ drugs for final distribution by a pharmacist.

~~(2) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.~~

~~(3) "Decentralized automated medication system" means automated medication systems that are located outside of a pharmacy department but within the same institution.~~

~~(4)~~(2) "Distribution" means the process of providing a drug to an individual authorized to administer ~~medications~~ drugs and licensed as a health care provider in the state of North Carolina pursuant to an order issued by an authorized prescriber.

~~(5) "Medication" means a medicinal drug or proprietary preparation.~~

~~(6)~~(3) ~~"High risk override medication" means~~ "Override medication" means:
(a) ~~a single dose of medication~~ A drug that may be removed from ~~a decentralized~~ an automated medication system prior to pharmacist review because the Multidisciplinary Committee has determined that the clinical status of the patient would be compromised by ~~delay.~~ delay;

~~(7) "Low risk override medication" is a medication~~
(b) A drug determined by the Multidisciplinary Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, ~~and~~ which may be removed from ~~a decentralized~~ an automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

~~(8)~~(4) "Physician controlled medication" is a ~~medication~~ drug ordered, prepared ~~or~~ and administered by a ~~physician.~~ physician or under the physician's direct supervision.

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3402 GENERAL REQUIREMENTS FOR THE USE OF AUTOMATED MEDICATION SYSTEMS**

~~General Requirements for the Use of Automated Medication Systems include the following:~~

(a) The pharmacist-manager shall assure compliance with all requirements of the Pharmacy Practice Act and this Section.

~~(1)~~(b) The ~~consultant pharmacist of record or~~ pharmacist-manager shall be responsible for:

~~(a)~~(1) Maintaining a record of each transaction or operation;
~~(b)~~(2) Controlling access to the automated medication system;
~~(c)~~(3) Maintaining policies and procedures for:

~~(i)~~(A) Operating ~~of~~ the automated medication system;

~~(ii)~~(B) Training personnel who use the automated medication system;

~~(iii)~~(C) Maintaining patient services whenever the automated medication system is not operating; and

~~(iv)~~(D) Defining a procedure for a pharmacist to grant access to the ~~medication~~ drugs in the automated medication system or to deny access to the ~~medication~~ drugs in the automated medication system.

~~(d)~~(4) ~~Security of~~ Securing the automated medication system;

~~(e)~~(5) Assuring that a patient receives the pharmacy services necessary for ~~good~~ appropriate pharmaceutical care;~~care in a timely manner;~~

~~(f)~~(6) Assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;

~~(g) Establishing a comprehensive Quality Assurance program;~~

~~(h)~~(7) Establishing a procedure for stocking or restocking the automated medication system; and

~~(i)~~(8) Insuring compliance with all requirements for packaging and labeling.

~~(2)~~(c) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug~~medication~~ except ~~a high risk override medication, a low risk~~ an override medication or a physician controlled medication.

~~(3)~~(d) A pharmacist shall perform retrospective drug use review for ~~a high risk override medication and a low risk~~ an override medication.

(e) The pharmacist-manager shall convene or identify a Multidisciplinary Committee, which is charged with oversight of the automated medication system. The Multidisciplinary Committee shall:

(1) Include the pharmacist-manager or the pharmacist-manager's designee;

(2) Establish the criteria and process for determining which drug qualifies as an override medication; and

(3) Develop policies and procedures regarding the operation of the automated medication system.

(f) A pharmacy utilizing an automated medication system may distribute patient-specific drugs within the health care facility without verifying each individual drug selected or packaged by the system, if:

(1) The initial medication order has been reviewed and approved by a pharmacist; and

(2) The drug is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer drugs.

(g) The pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(1) Review of override medication utilization;

(2) Investigation of any medication error related to drugs distributed or packaged by the automated medication system;

(3) Review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated medication system;

(4) Review of the operation of the automated medication system;

(5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the pharmacy; and

(6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(h) The pharmacist-manager shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:

(1) Transaction records for all non-controlled drugs or devices distributed by the automated medication system;

(2) Transaction records from the automated medication system for all controlled substances dispensed or distributed; and

(3) Any report or analysis generated as part of the quality assurance program required by Paragraph (g) of this Rule.

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3403 MULTIDISCIPLINARY COMMITTEE FOR DECENTRALIZED AUTOMATED MEDICATION SYSTEMS**

~~(a) The consultant pharmacist of record or pharmacist manager shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.~~

~~(b) The Multidisciplinary Committee shall:~~

~~(1) Include at least one pharmacist;~~

~~(2) Establish the criteria and process for determining which medication qualifies as a high risk override medication or a low risk override medication in a decentralized automated medication system; and~~

~~(3) Develop policies and procedures regarding the decentralized automated medication system.~~

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3404 STOCKING OR RESTOCKING OF AN AUTOTMATED MEDICATION SYSTEM**

(a) ~~Medications in an Automated Medication System shall be stocked or restocked by a pharmacist or by a pharmacy technician supervised by a pharmacist as satisfied by Paragraph (d)(2)~~ Responsibility for accurate stocking and restocking of an automated medication system lies with the pharmacist-manager and with any pharmacist tasked with supervising such functions as specified in Subparagraph (b)(2) of this Rule.

(b) The stocking or restocking of an automated medication ~~system~~ system, where performed by someone other than a pharmacist, shall follow one of the following procedures to ensure correct ~~medication~~ drug selection:

(1) A pharmacist shall conduct and document a daily audit of ~~medications~~ drugs placed or to be placed into an automated medication system ~~that~~by a pharmacy technician, which audit may include random sampling.

(2) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of ~~medication~~ drugs placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification ~~technology~~ process shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist. When a bar code verification, electronic verification, or similar verification process is utilized as specified in this section, stocking and restocking functions may be performed by a pharmacy technician or by a registered nurse trained and authorized by the pharmacist-manager.

(c) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the ~~medication~~ drug stocking, restocking or verification process.

(d) Medication Reuse. ~~Medication~~ Any drug that has been removed from the automated medication system shall not be replaced into the system unless:

(1) ~~a pharmacist has examined the medication,~~ the drug's purity, packaging, and ~~the~~ labeling have been examined according to policies and procedures established by the pharmacist-manager to determine~~and determined~~ that reuse of the drug~~medication~~ is appropriate; or

(2) specific drugs,~~medications,~~ such as multi-dose vials, have been exempted by the Multidisciplinary Committee.

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3405 CENTRALIZED AUTOMATED MEDICATION SYSTEMS**

~~A pharmacist utilizing a centralized automated medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if :~~

~~(1) The initial medication order has been reviewed and approved by a pharmacist; and~~

~~(2) The medication is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer medication.~~

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3406 QUALITY ASSURANCE PROGRAM**

~~The consultant pharmacist of record or pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:~~

~~(1) Review of high risk override medication and low risk override medication utilization;~~

~~(2) Investigation of a medication error related to the automated medication system;~~

~~(3) Review of a discrepancy or transaction reports and identification of patterns of inappropriate use or access;~~

~~(4) Review of the operation of the system;~~

~~(5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the pharmacy; and~~

~~(6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.~~

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3407 RECORD KEEPING**

~~(a) The consultant pharmacist of record or pharmacist-manager shall maintain records related to the automated medication system for the system in a readily retrievable manner.~~

~~(b) The following records shall be maintained for at least three years.~~

~~(1) Daily audits of stocking or restocking, if applicable;~~

~~(2) Daily audits of the output of a centralized automated medication system, if applicable; and~~

~~(3) Transaction records for all non-controlled medications or devices distributed by the automated medication system.~~

~~(c) The following records shall be maintained for at least three years:~~

~~(1) Any report or analysis generated as part of the quality assurance program;~~

~~(2) A report or database related to access to the system or any change in the access to the system or access to medication in the system; and~~

~~(3) Transaction records from the automated medication system for all controlled substances dispensed or distributed.~~

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

**21 NCAC 46 .3408 COMPLIANCE**

~~The consultant pharmacist of record or pharmacist manager shall assure compliance with all requirements of the Pharmacy Practice Act and Board rules.~~

*Authority G.S. 90-85.6; 90-85.32; 90-85.33.*

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**CHAPTER 68 – SUBSTANCE ABUSE PROFESSIONAL PRACTICE BOARD**

***Notice*** *is hereby given in accordance with G.S. 150B-21.2 that the NC Substance Abuse Professional Practice Board intends to amend the rules cited as 21 NCAC 68 .0101, .0206, .0209, .0301, .0303-.0306, and .0512.*

**Agency obtained G.S. 150B-19.1 certification:**
- ☐ **OSBM certified on:**
- ☐ **RRC certified on:**
- ☒ **Not Required**

**Link to agency website pursuant to G.S. 150B-19.1(c):** *www.ncsappb.org*

**Proposed Effective Date:** *October 1, 2013*

**Public Hearing**:
**Date:** *June 18, 2013*
**Time:** *10:00 a.m.*
**Location:** *11 Glenwood Avenue, Raleigh, NC 27603*

**Reason for Proposed Action:** *Changes in policies by IC & RC/AODA, Inc. that statute directs Board to follow with attendant fee deletion; Feedback from credentialed professionals less burdensome if more continuing education hours selected from their specific field rather than same general requirements; Technical corrections resulting from enactment of Session Law 2005-431 and Session Law 2008-130 making rules unambiguous; Clarify existing rules.*

**Procedure by which a person can object to the agency on a proposed rule:** *Any person may submit comments to the Board either orally or in writing at the Public Hearing. Other written comments should be mailed (to be received by the end of the comment period) to: Ms. Anna Misenheimer, Executive Director, NC Substance Abuse Professional Practice Board, P. O. Box 10126, Raleigh, NC 27605.*

**Comments may be submitted to:** *Ms. Anna Misenheimer, Executive Director, NCSAPPB, P. O. Box 10126, Raleigh, NC 27605; email anna@recanc.com*

**Comment period ends:** *July 15, 2013*

**Procedure for Subjecting a Proposed Rule to Legislative Review:** If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

**Fiscal impact (check all that apply).**
- ☐ **State funds affected**
- ☐ **Environmental permitting of DOT affected**
  **Analysis submitted to Board of Transportation**
- ☐ **Local funds affected**
  **Date submitted to OSBM:**
- ☐ **Substantial economic impact (≥$500,000)**
- ☐ **Approved by OSBM**
- ☒ **No fiscal note required by G.S. 150B-21.4**

**SECTION .0100 - GENERAL**

**21 NCAC 68 .0101 DEFINITIONS**

As used in the General Statutes or this Chapter, the following terms have the following meaning:

(1) "Applicant" means a person who submits documentation seeking Board status for registration or certification.

(2) "Application packet" means a set of instructions and forms required by the Board for registration.

(3) "Approved Supervisor" means a supervisor as set out in G.S. 90-113.31. This is a person who fulfills or is in the process of fulfilling the requirements for this Board designation pursuant to Rule .0211 of this Chapter by completing its academic, didactic and experiential requirements.

(4) "Assessment" means identifying and evaluating an individual's strengths, weaknesses, problems and needs for the development of a treatment or service plan for alcohol, tobacco or drug abuse.

(5) "Clinical Supervision" means clinical oversight required for all credentials with a minimum of 50 percent clinical supervision that shall accrue in person, face-to-face, while in the proximity of the same room whereas the balance of this requirement may be fulfilled electronically via video, face-to-face, if performed in real time.

(6) "Clinical Supervision Specific Education" means training that directly covers the aspects of clinical supervision of a substance abuse professional or any of the 12 core functions in their clinical application.

(7) "Client" means an individual who is in receipt of substance abuse counseling.

(8) "Complainant" means a person who has filed a complaint pursuant to these Rules.

(9) "Consultation" means a meeting for discussion, decision-making and planning with other service providers for the purpose of providing substance abuse services.

(10) "Crisis" means a decisive, crucial event either directly or indirectly related to alcohol or drug use, in the course of treatment that threatens to compromise or destroy the rehabilitation effort.

(11) "Deemed Status Group" means those persons who are credentialed as a clinical addictions specialist because of their membership in a deemed status discipline.

(12) "Education" means a service which is designed to inform and teach various groups including clients, families, schools, businesses, churches, industries, civic and other community groups about the nature of substance abuse disorders and about available community resources. It also serves to improve the social functioning of recipients by increasing awareness of human behavior and providing alternative cognitive or behavioral responses to life's problems.

(13) "Full Time" means 2,000 hours per year.

(14) "General Professional Skill Building" means education provided to enhance general skills of a substance abuse professional.

(15) "Hearing panel" means a body composed of members of a committee designated by the chairperson of the committee to conduct an informal hearing to determine that the applicant meets the standards required to be maintained for or awarded a credential.

(16) "Impairment" means a mental illness, substance abuse or chemical dependency, physical illness, or aging problem.

(17) "Letter of Reference" means a letter that recommends a person for certification.

(18) "Membership In Good Standing" means a member's certification is not in a state of revocation, lapse, or suspension. However, an individual whose certification is suspended and the suspension is stayed is a member in good standing during the period of the stay.

(19) "Passing score" means the score set by the entity administering the exam.

(20) "Person served" means an individual who is not a client but is in receipt of substance abuse prevention counseling.

(21) "Personal service" means the actual delivery of a document into the hands of the person to whom it is addressed.

(22) "President" means the President of the Board.

(23) "Prevention Consultation" means a service provided to other mental health, human service, and community planning/development organizations or to individual practitioners in other organizations to assist in the development of insights and skills of the practitioner necessary for prevention.

(24) "Prevention performance domains" means areas of professional activities to include:

(a) planning and evaluations;

(b) education and skill development;

(c) community organization;

(d) public and organizational policy; and

(e) professional growth and responsibility.

(25) "Referral" means identifying the needs of an individual that cannot be met by the counselor or agency and assisting the individual in utilizing the support systems and community resources available.

(26) "Rehabilitation" means re-establishing the functioning needed for professional competency.

(27) "Reinstatement" means an action where the Board restores certification or registration to an applicant after the applicant completes the requirements imposed by the Board.

(28) "Relapse" means the return to the pattern of substance abuse as well as the process during which indicators appear prior to the person's resumption of substance abuse or a re-appearance or exacerbation of physical, psychological or emotional symptoms of impairment.

(29) "Renewal" means an action by the Board granting a substance abuse professional a consecutive certification or registration based upon the completion of requirements for renewal as prescribed by the Board.

(30) "Revival" means an action by the Board granting a substance abuse professional a certification or registration following a lapse of certification or registration wherein the professional must also meet the requirements for renewal as prescribed by the Board.

(31) "Reprimand" means a written warning from the Board to a person making application for certification by the Board or certified by the Board.

(32) "Respondent" means a person who is making application for certification by the Board or is certified by the Board against whom a complaint has been filed.

(33) "Sexual activity" means:

(a) Contact between the penis and the vulva or the penis and the anus;
(b) Contact between the mouth and the penis, the mouth and the vulva, or the mouth and the anus; or
(c) The penetration, however slight, of the anal or genital opening of another by a hand or finger or by any object with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person.

(34) "Sexual contact" means any of the following actions:
(a) Vaginal intercourse, cunnilingus, fellatio, or anal intercourse, if initiated, agreed to, or not resisted by the substance abuse professional; or
(b) Kissing or the intentional touching of the other's lips, genital area, groin, inner thigh, buttocks, breasts, or any other body parts, as well as the clothing covering any of these body parts for the purpose of sexual stimulation or gratification of either the substance abuse professional or the client if initiated, agreed to, or not resisted by the substance abuse professional.

(35) "Substance Abuse Counseling Experience" means approved supervised experience that may be full time or part-time, paid or voluntary, and must include all of the 12 core functions (Rule .0204 of this Chapter) as documented by a job description and supervisors evaluation.

(36) "Substance Abuse Prevention Consultant Experience" means approved supervised experience that may be full time or part-time, paid or voluntary, and must include all of the prevention domains referenced by Rule .0206 of this Chapter and as documented by a job description and supervisor's evaluation.

(37) "Substance Abuse Specific" means education focused upon alcohol and other drugs and the substance abusing population and is provided for a substance abuse professional by one whose education and experience is in the field of alcohol and other drugs.

(38) "Supervised Practice" means supervision of the applicant in the knowledge and skills related to substance abuse professionals.

(39) "Supervisor of Record" means the substance abuse professional primarily responsible for providing applicant or practice supervision to a supervisee.

~~(39)~~(40) "Suspension" means a loss of certification or the privilege of making application for certification.

*Authority G.S. 90-113.30; 90-113.33; 90-113.40; 90-113.41; 90-113.41A.*

## SECTION .0200 - CERTIFICATION

### 21 NCAC 68 .0206 PROCESS FOR PREVENTION CONSULTANT CERTIFICATION

(a) ~~Prevention consultant certification shall be offered to those persons whose~~ The Board shall certify an applicant as a Substance Abuse Prevention Consultant as set out in Article 5C of Chapter 90 of the North Carolina General Statutes. A Prevention Consultant's primary responsibilities are to provide substance abuse information and education, environmental approaches, alternative activities, community organization, networking, and referral.

(b) Requirements for certification shall be as follows:

(1) ~~10,000~~ 6,000 hours (~~five~~ three years) work experience in prevention consultation obtained in a minimum of ~~60~~ 36 months without a baccalaureate degree or 4,000 hours (two years) work experience in prevention consultation obtained in a minimum of 24 months with a baccalaureate degree in a human services field from a regionally accredited college or university;

(2) 270 hours of academic and didactic training divided in the following manner:
(A) 170 hours primary and secondary prevention and in the prevention performance domains; and
(B) 100 hours in substance abuse specific studies, which includes ~~12 hours in HIV/AIDS/STDS/TB/Bloodborne pathogens training and six hours in prevention specific ethics training;~~ six hours of HIV/AIDS/STDS/TB/Bloodborne pathogens training and education, six hours professional ethics education, and six hours of education to be selected from Subparagraph (3) of this Paragraph as set out below.

(3) The six hours of additional education that may be included in the 100 hours in substance abuse specific studies described in Part (2)(B) of this Paragraph shall be selected from the following:
(A) Nicotine Dependence;
(B) Psychopathology;
(C) Evidence-Based Treatment Approaches;
(D) Substance Abuse Issues in Older Adults; and
(E) Substance Abuse Issues Affecting Veterans.

~~(3)~~(4) A minimum of 300 hours of supervised practical training practice hours documented by a certified substance abuse professional;

~~(4)~~(5) Evaluations from a supervisor on this practice as well as two evaluations from colleagues or co-workers;

~~(5)~~(6) Successful completion of an IC&RC/AODA, Inc. or its successor organization written examination;

~~(6)~~(7) A form signed by the applicant attesting to the applicant's adherence to the Ethical Standards of the Board;

~~(7)~~(8) An application packet fee of twenty-five dollars ($25.00), a registration fee of one hundred twenty-five dollars ($125.00), and an examination fee of one hundred twenty-five dollars ($125.00).

*Authority G.S. 90-113.30; 90-113.31; 90-113.33; 90-113.34; 90-113.38; 90-113.40; 90-113.41.*

**21 NCAC 68 .0209 RECIPROCITY**

(a) If a Counselor, Prevention Consultant, Clinical Supervisor, or Clinical Addictions Specialist holds a ~~certification~~ credential issued by an IC&RC/AODA, Inc. member board or a successor organization as a certified substance abuse counselor (to include alcohol and other drugs), certified Prevention Consultant, certified Clinical Supervisor, or ~~certified~~ credentialed Clinical Addictions Specialist, the person may transfer this ~~certification~~ credential to North Carolina by applying a transfer fee as assessed by the IC&RC/AODA, Inc. or its successor organization.

(b) The reciprocal ~~certification~~ credential effective date shall remain the same as in the previous state.

(c) At the time when ~~recertification~~ re-credentialing is required, it will be the individual's responsibility to submit an application for ~~recertification.~~ re-credentialing. For the period of the first ~~recertification~~ re-credentialing in North Carolina, the Board shall accept the member's former State ~~recertification~~ re-credentialing requirements for the purpose of reciprocal ~~recertification.~~ re-credentialing. At the end of this ~~recertification~~ re-credentialing period, it shall be the individual's responsibility to conform to the ~~recertification~~ re-credentialing requirements of North Carolina in effect at the time of ~~recertification.~~ re-credentialing.

*Authority G.S. 90-113.30; 90-113.33; 90-113.38.*

**SECTION .0300 - CLINICAL ADDICTIONS SPECIALIST**

**21 NCAC 68 .0301 SCOPE**

The rules in this Section apply to a person seeking ~~certification~~ licensure as a clinical addictions specialist and a credentialing body of a professional discipline seeking deemed status.

*Authority G.S. 113.30; 90-113.40; 90-113.41A.*

**21 NCAC 68 .0303 APPLICATION FOR DEEMED STATUS BY PROFESSIONAL DISCIPLINE**

(a) Any credentialing body of a professional discipline seeking deemed status shall forward a letter of intent with a request for an application to become a deemed status organization to the Board.

(b) ~~As directed by the Board, the discipline~~ The credentialing body shall provide the following:

(1) Documentation that it meets the requirements of G.S. 90-113.41A;

(2) A copy of the ethical code and statement, if any, it requires its members to sign indicating that the member will comply with the discipline's code of ~~ethics; and,~~ ethics and any substantiating data that supports the ethical process of the professional discipline;

(3) ~~Documentation~~ If the examination is required by the credentialing body, documentation describing the exam process each applicant must pass in order to be awarded the professional group's substance abuse specialty ~~credential.~~ credential. If the examination for the specialty is not administered by the professional group, the applicant shall pass the Board's exam for licensure.

(c) A professional discipline granted deemed status shall provide the name of any member whose credential is revoked, suspended or denied within 60 days from the date of action.

(d) The professional discipline, to the extent allowed by its statutes and rules, shall provide any information requested by the Board that has been submitted to the professional discipline regarding the complaint against its member, subsequent to the disposition of the complaint.

(e) If no information has been received by the Board within six months, or the Board is not satisfied with the disposition of the complaint, the Board may initiate its own disciplinary action.

*Authority G.S. 90-113.32; 90-113.33; 90-113.41A; 90-113.43.*

**21 NCAC 68 .0304 THREE-YEAR STANDARDS REVIEW OF DEEMED STATUS STANDING**

(a) The Standards ~~and Credentialing~~ Committee of the Board shall review the standards of each professional discipline every third year as required in G.S. 90-113.41A.

(b) The Board shall send notice to the discipline 90 days in advance of the end of the three-year period following the date deemed status was granted or renewed.

(c) The discipline shall report current standards, including an update of all information originally required.

(d) The Board may require further substantiation and explanation of this data.

*Authority G.S. 90-113.32; 90-113.33; 90-113.41A; 90-113.43.*

**21 NCAC 68 .0305 LICENSURE REQUIREMENTS FOR INDIVIDUAL APPLICANT**

In addition to meeting the requirements of G.S. 90-113.40, an applicant seeking ~~certification~~ licensure as a clinical addictions specialist shall submit the following, if applicable:

(1) Documentation ~~evidencing that 12~~ of completion of:

(a) Six hours of HIV/AIDS/STDS/TB/Bloodborne pathogens training and ~~education and~~ education;

(b) Six hours of professional ethics ~~training~~ training; and

(c) Six hours of clinical supervision specific training. All hours listed in Sub-items (a), (b), and (c) of this Item may be included in the 180 hours completed for licensure in the core competencies by the applicant not in the deemed status group as well as six hours also included in this group and selected from the following list: ~~were included in the 180 hours completed for certification in the core competencies by the applicant not in the deemed status group;~~

(i) Nicotine Dependence;

(ii) Psychopathology;

(iii) Evidence-Based Treatment Approaches;

(iv) Substance Abuse Issues in Older Adults; and

(v) Substance Abuse Issues Affecting Veterans.

(2) Copy of a substance abuse specialty certificate or its equivalent;

(3) Copy of his or her masters' or doctorate degree diploma;

(4) Completed registration form; and

(5) Payment of the following fees:

(a) All applicants who are in the deemed status group shall make payment of a non-refundable application fee of ten dollars ($10.00) and payment of a non-refundable ~~certification~~ credentialing fee of forty dollars ($40.00).

(b) All other applicants shall make payment of an application packet fee of twenty-five dollars ($25.00) and payment of a non-refundable ~~certification~~ credentialing fee of one hundred twenty-five dollars ($125.00).

(c) All applicants seeking ~~certification~~ credentialing pursuant to Criteria ~~A~~ A, Criteria B, and Criteria C of G.S. 90-113.40(c) shall make payment of a non-refundable ~~written~~ examination fee of one hundred twenty-five dollars ~~($125.00)~~ ($125.00). ~~and payment of a non-refundable oral examination fee of one hundred dollars ($100.00).~~

~~(d) All applicants seeking certification pursuant to Criteria B of G.S. 90-113.40(c) shall make payment of a non-refundable written examination fee of one hundred twenty-five dollars ($125.00).~~

~~(e) All applicants seeking certification pursuant to Criteria C of G.S. 90-113.40(c) shall make payment of a non-refundable oral examination fee of one hundred dollars ($100.00).~~

*Authority G.S. 90-113.30; 90-113.33; 90-113.38; 90-113.40; 90-113.41; 90-113.43.*

**21 NCAC 68 .0306 RENEWAL OF INDIVIDUAL LICENSURE AS CLINICAL ADDICTIONS SPECIALIST**

(a) An applicant who is in the deemed status group shall submit the following every two years:

(1) A completed application form and a copy of the applicant's current substance abuse certification or its equivalent from the ~~applicant's~~ deemed status professional discipline.

(2) A non-refundable ~~recertification~~ re-licensing fee of thirty-five dollars ($35.00).

(b) All other individual applicants shall:

(1) Renew ~~certification~~ licensure as classified by the criteria for their original ~~certification~~ credential every two years.

(2) Document completing 40 hours of education pursuant to Section .0400 of this Chapter, during the current ~~certification~~ licensing period. A minimum of 30 hours shall be substance abuse specific. This education may include a combination of hours including attending ~~workshops, receiving clinical supervision~~ and providing workshops.

(3) Meet re-licensing educational guidelines as a substance abuse professional as follows:

(A) No more than 25 percent may be ~~inservice~~ in-service education, received within the applicant's organization by staff of the same employment.

(B) No more than 25 percent receiving supervision with two hours of supervision translating to one hour of education.

(C) No more than 25 percent of workshop presentation with one hour of presentation translating to one hour of education. Workshop presentation shall be pursuant to Rule .0213 of this Chapter.

~~(D) No more than 25 percent of Alcohol/Drug Education Traffic School (ADETS) and Drug Education School (DES) events.~~

~~(E)~~(D) All applicants shall include ~~six~~ three hours of HIV/AIDS/STDS/TB/Bloodborne pathogens training and ~~education and~~ education, three hours of professional ethics training and ~~education for each~~

~~certification.~~ education, and three hours of education to be selected from the list appearing in Rule 21 NCAC 68 .0305(1)(c) for each re-credentialing.

(4) A completed application form with continuing education documented.

(5) A non-refundable one hundred twenty-five dollar ($125.00) ~~recertification~~ re-credentialing fee.

*Authority G.S. 90-113.30; 90-113.33; 90-113.37; 90-113.38; 90-113.39; 90-113.41A; 90-113.43.*

**SECTION .0500 - ETHICAL PRINCIPLES OF CONDUCT FOR THE SUBSTANCE ABUSE PROFESSIONAL**

**21 NCAC 68 .0512 RESPONSIBILITIES OF SUPERVISOR AND SUPERVISEE**

(a) A professional who has received a credential from the Board and who is serving as a clinical or practice supervisor shall:

(1) Be aware of his or her influential position with respect to supervisees and therefore not exploit the trust and reliance of such persons.

(2) Avoid dual relationships that could impair professional judgment, increase the risk of exploitation, or cause harm to the supervisee. To implement this standard the supervisor shall not:

(A) Instruct or supervise family members who are related by blood to the second degree or marriage or a person living in the supervisor's household;

(B) Provide therapy or therapeutic counseling services to supervisees; or

(C) Solicit or engage in sexual activity or contact with supervisees during the period of supervision.

(3) Be trained in and knowledgeable about supervision methods and techniques.

(4) Supervise or consult only within his or her knowledge, training, and competency.

(5) Guide his or her supervisee to perform services responsibly, competently, and ethically. As authorized by the supervisee's employer, the supervisor shall assign to his or her supervisees only those tasks or duties that these individuals can be expected to perform competently, based on the supervisee's education, experience, or training, either independently or with the level of supervision being provided.

(6) Not disclose the confidential information provided by a supervisee except:

(A) As mandated by law;

(B) To prevent harm to a client or other person involved with the supervision;

(C) In educational or training settings where there are multiple supervisors, and then only to other professional colleagues who share responsibility for the performance or training of the supervisee; or

(D) If consent is obtained.

(7) Establish and facilitate a process for providing evaluation of performance and feedback to a supervisee. To implement this process the supervisee shall be informed of the timing of evaluations, methods, and levels of competency expected. Supervision documentation shall be signed by the supervisor and supervisee and include the date, time, duration, method, and topic of the supervision session.

(8) Not endorse supervisees for credentialing, employment, or completion of an academic training program if they believe the supervisees are not qualified for the endorsement. A supervisor shall develop a plan to assist a supervisee who is not qualified for endorsement to become qualified.

(9) Make financial arrangements for any remuneration with supervisees and organizations only if these arrangements are clear and in writing. All fees shall be disclosed to the supervisee prior to the beginning of supervision if practicable.

(b) The Supervisor of Record shall provide notice to the office of the Board within 30 days from the date of the last session of clinical supervision that supervision has terminated. Upon receipt of this notice, as soon as is practicable, the Board shall mail a certified notice to the supervisee that he or she has 30 days to obtain supervision to retain the current credential. The supervisee shall provide the Board with a Board-approved supervision contract signed and dated by the supervisor and supervisee to maintain the supervisee's credential. This contract shall be postmarked, indicating that it was mailed, to the office within the 30-day time period.

*Authority G.S. 90-113.30; 90-113.33; 90-113.38; 90-113.39; 90-113.40.*

*This Section contains information for the meeting of the Rules Review Commission on May 16, 2013 at 1711 New Hope Church Road, RRC Commission Room, Raleigh, NC. Anyone wishing to submit written comment on any rule before the Commission should submit those comments to the RRC staff, the agency, and the individual Commissioners. Specific instructions and addresses may be obtained from the Rules Review Commission at 919-431-3000. Anyone wishing to address the Commission should notify the RRC staff and the agency no later than 5:00 p.m. of the 2nd business day before the meeting. Please refer to RRC rules codified in 26 NCAC 05.*

**RULES REVIEW COMMISSION MEMBERS**

| **Appointed by Senate** | **Appointed by House** |
|---|---|
| Addison Bell | Ralph A. Walker |
| Margaret Currin | Anna Baird Choi |
| Pete Osborne | Jeanette Doran |
| Bob Rippy | Garth K. Dunklin |
| Faylene Whitaker | Stephanie Simpson |

**COMMISSION COUNSEL**

Joe Deluca (919)431-3081
Amanda Reeder (919)431-3079

**RULES REVIEW COMMISSION MEETING DATES**

May 16, 2013 June 20, 2013
July 18, 2013 August 15, 2013

**RULES REVIEW COMMISSION**
**April 18, 2013**
**MINUTES**

The Rules Review Commission met on Thursday, April 18, 2013, in the Commission Room at 1711 New Hope Church Road, Raleigh, North Carolina. Commissioners present were: Margaret Currin, Jeanette Doran, Garth Dunklin, Pete Osborne, Bob Rippy and Commissioner Addison Bell via Skype.

Staff members present were: Joe DeLuca and Amanda Reeder, Commission Counsel; Dana Vojtko, Julie Edwards and Tammara Chalmers.

The meeting was called to order at 10:14 a.m. with Vice-Chairman Currin presiding. She reminded the Commission members that they have a duty to avoid conflicts of interest and the appearances of conflicts as required by NCGS 138A-15(e).

**APPROVAL OF MINUTES**
Vice-Chairman Currin asked for any discussion, comments, or corrections concerning the minutes of the March 21, 2013. There were none and the minutes were approved as distributed.

**FOLLOW-UP MATTERS**
10A NCAC 09 .3004 – Child Care Commission. There has been no response from the agency and no action was taken.

11 NCAC 08 .1116 – Home Inspector Licensure Board – The Commission unanimously approved the re-written rule.

21 NCAC 22F .0120 – Hearing Aid Dealers and Fitters Board – The Board responded to the Commission's objection by proposing to repeal 21 NCAC 22F .0120 and adopting nine new rules to fully address the issues raised by the Commission's objection. Pursuant to G.S. 150B-21.12(c), the Commission found that the submission was responsive to the Commission's objection. The Commission also found that the changes were substantial, creating an effect that could not have reasonably been foreseen from the text of Rule 21 NCAC 22F .0120. The Commission authorized the proposed changes to be published pursuant to G.S. 150B-21.1(a3) and will review the rules again for approval after publication.

Catherine Jorgensen addressed the Commission.

21 NCAC 58A .0110, .1402 – Real Estate Commission – The Commission unanimously approved the re-written rules.

Prior to the review of the rules from the Real Estate Commission, Commissioner Dunklin recused himself and did not participate in any discussion or vote concerning these rules because he is a practicing attorney before the Commission.

21 NCAC 65 .0601, .0602 – Board of Recreational Therapy Licensure - The Commission unanimously approved the re-written rules. Rule .0901 was withdrawn by the agency.

**LOG OF FILINGS**
Vice-Chairman Currin presided over the review of the log of permanent rules.

**Board of Agriculture**
All rules were unanimously approved.

**Department of Commerce – Division of Employment Security**
All rules were approved unanimously with the following exceptions:

The Commission objected to Rule 04 NCAC 24E .0102 based on ambiguity and lack of statutory authority. Specifically, it is not clear within the Rule what the standards will be for a "reasonable" amount of effort to find the records or to begin the search for those records. It is unclear which third parties will routinely receive the information in Paragraph (g). Further, the rule allows third parties to request the confidential records of applicants and recipients of unemployment compensation if the third party includes a statement that the applicant or employer has waived confidentiality. 20 CFR 603.5 provides that the State may release confidential information to third parties when there is a signed release by the party that includes information to ensure informed consent. There is no such requirement for a signed release or informed consent in this Rule.

The Commission objected to Rule 04 NCAC 24E .0104 based on ambiguity. It is unclear in Paragraph (b) what standards will be used to "assure to the satisfaction of the individual retrieving the information" that payment will be made. It is also unclear what constitutes a "substantial search," which triggers this payment.

The agency requested that the Commission waive its rules and review the rewritten rule at the meeting. Commission moved to deny the request. The motion was seconded and unanimously approved.

Thelma Hill, Deputy Chief Counsel addressed the Commission.

**Office of Information Technology Services**
The Commission extended the period of review on all the rules. They did so in order to give the agency additional time to understand staff's comments concerning the rules, make technical changes, make any other changes the agency wished to satisfy staff's concerns, and to prepare any other response to staff's comments.

Richard Bradford, an attorney from the Department of Justice representing the agency, addressed the Commission. He stated that the agency was in concurrence with the recommendation to extend the period of review.

**Child Care Commission**
All rules were unanimously approved.

**Environmental Management Commission**
All rules were unanimously approved.

Jolle Burleson addressed the Commission.

**Marine Fisheries Commission**
All rules were unanimously approved.

Catherine Blum addressed the Commission.

**Coastal Resources Commission**
All rules were unanimously approved.

Commissioner Dunklin was not present during the discussion and did not vote. He returned prior to the discussion of and vote on the Wildlife Resource Commission rules.

**Wildlife Resources Commission**
All rules were unanimously approved.

**Board of Physical Therapy Examiners**
All rules were unanimously approved with the following exceptions:

The Commission objected to 21 NCAC 48A .0106 based on ambiguity and lack of statutory authority. G.S. 90-640 requires that a licensee engaged in health care wear a name badge displaying the licensee's full name and level of licensure. In Paragraph (b) of the Rule, it unclear who will determine whether the first name only and level of licensure is necessary to ensure the licensee's safety and in what instances that may occur. Technically speaking, the only rulemaking authority conferred by the cited statute to regulating bodies is to create these exemptions. Here, the Board did not create the exemptions, but instead recited the statutory language.

In addition, Paragraph (c) states that a name badge is not required to be worn in the licensee's office if his or her name is prominently displayed in the office. G.S. 90-640(c) includes several options that can be used to allow a licensee not to wear an identification badge in the licensee's office. It is unclear if the Board intended a licensee to wear a badge stating only licensure status or if it intended to require no identification at all. All statutory options require that an individual be able to determine the licensee's name and licensure status, and the Board does not have authority to amend the statutory requirement in the rule.

Ben Massey addressed the Commission.

**RRC CERTIFICATION**

**State Board of Education**
These rules were deferred to the May 16th meeting at the agency's request.

The meeting adjourned at 12:12 p.m.
The next scheduled meeting of the Commission is Thursday, May 16th at 10:00 a.m.

There is a digital recording of the entire meeting available from the Office of Administrative Hearings / Rules Division.
Respectfully Submitted,

_____
Julie Edwards
Editorial Assistant

Minutes approved by the Rules Review Commission.

_____
Margaret Currin/Vice-Chair

Rules Review Commission
Meeting
Please **Print** Legibly APRIL 18, 2013

| Name | Agency |
|---|---|
| CATHERINE BLUM | NCDENR/DMF |
| Adam Phillips | NCDA |
| Jim MELVIN | NCDA ICS |
| Denise Stanford | NC HILB |
| Camilla F. McClain | NC Dept of Commerce/DES |
| Thelma M. Hill | NC Dept of Commerce/DES |
| Ben F. Massey JR | N.C. Board of P.T. Examiners |
| Richard Blackwood | Office of Information Technology Svcs |
| Becky Garrett | NC Board of Recreational Therapy |
| Janet Thoren | NCRFC |
| Curtis Alderdice | NCREC |
| Karen Wadaus | NCDOI |
| Lorie Pugh | NC DCDEE |
| DEBRA HASTEN | NC DCDEE |
| Katie Cornetto | NC State Board of Education |
| Lou Martin | " |
| Joelle Burleson | NCDENR Division of Air Quality |
| Jennifer Everett | NC DENR |
| Mike Haydon | NC HILB |
| Jennifer Hollyfield | NC HILB |
| Betsy Haywood | NC WRC |

Rules Review Commission
Meeting
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| Name | Agency |
|---|---|
| Catherine Jorgensen | LHADFB |
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**LIST OF APPROVED PERMANENT RULES**
**April 18, 2013 Meeting**

**AGRICULTURE, BOARD OF**

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|---|---|---|---|
| Adoptions by Reference | 02 | NCAC 09B | .0116 |
| General | 02 | NCAC 09F | .0101 |
| Physical and Chemical Requirements | 02 | NCAC 09F | .0102 |
| Performance Requirements | 02 | NCAC 09F | .0103 |
| General | 02 | NCAC 09F | .0201 |
| Physical and Chemical Requirements | 02 | NCAC 09F | .0202 |
| Performance Requirements | 02 | NCAC 09F | .0203 |
| Methods of Testing | 02 | NCAC 09F | .0204 |
| Physical and Chemical Requirements | 02 | NCAC 09F | .0305 |
| Performance Requirements | 02 | NCAC 09F | .0306 |

**COMMERCE - EMPLOYMENT SECURITY, DIVISION OF**

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| Confidentiality of Unemployment Insurance Information | 04 | NCAC 24E | .0101 |
| Fees for Copies and Services | 04 | NCAC 24E | .0103 |

**CHILD CARE COMMISSION**

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| Definitions | 10A | NCAC 09 | .0102 |
| General Statutory Requirements | 10A | NCAC 09 | .0703 |
| General Provisions Related to Licensure of Homes | 10A | NCAC 09 | .1701 |
| Caregiving Activities for Preschool-Aged Children | 10A | NCAC 09 | .2806 |

**HOME INSPECTOR LICENSURE BOARD**

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| Code of Ethics | 11 | NCAC 08 | .1116 |

**ENVIRONMENTAL MANAGEMENT COMMISSION**

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| Applicability | 15A | NCAC 02D | .0902 |
| Recordkeeping: Reporting: Monitoring | 15A | NCAC 02D | .0903 |
| Compliance Schedules for Sources In Ozone Nonattainment a... | 15A | NCAC 02D | .0909 |
| RACT for Sources of Volatile Organic Compounds | 15A | NCAC 02D | .0951 |
| Offset Lithographic Printing and Letterpress Printing | 15A | NCAC 02D | .0961 |
| Industrial Cleaning Solvents | 15A | NCAC 02D | .0962 |
| Activities Exempted from Permit Requirements | 15A | NCAC 02Q | .0102 |

**MARINE FISHERIES COMMISSION**

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| Recordkeeping Requirements | 15A | NCAC 03I | .0114 |
| Albemarle Sound/Chowan River Herring Management Areas | 15A | NCAC 03J | .0209 |
| Recreational Shrimp Limits | 15A | NCAC 03L | .0105 |
| General | 15A | NCAC 03M | .0201 |
| Season, Size and Harvest Limit: Internal Coastal Waters | 15A | NCAC 03M | .0202 |
| Descriptive Boundaries for Coastal-Joint-Inland Waters | 15A | NCAC 03Q | .0202 |
| Attended Gill Net Areas | 15A | NCAC 03R | .0112 |
| Striped Bass Management Areas | 15A | NCAC 03R | .0201 |

**COASTAL RESOURCES COMMISSION**

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| Specific Use Standards for Ocean Hazard Areas | 15A NCAC 07H .0308 |
| Specific Conditions | 15A NCAC 07H .1705 |

**WILDLIFE RESOURCES COMMISSION**

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| Granville, Vance and Warren Counties | 15A NCAC 10F .0311 |
| Warren County | 15A NCAC 10F .0318 |
| Chowan County | 15A NCAC 10F .0325 |
| Chatham and Wake Counties | 15A NCAC 10F .0345 |
| Camden County | 15A NCAC 10F .0352 |

**PHYSICAL THERAPY EXAMINERS, BOARD OF**

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| Executive Director | 21 NCAC 48A .0104 |
| Definitions | 21 NCAC 48A .0105 |
| Suspension of Authority to Expend Funds | 21 NCAC 48A .0106 |
| Licenses by Examination | 21 NCAC 48B .0103 |
| Responsibilities | 21 NCAC 48C .0102 |
| Computer Examination | 21 NCAC 48D .0112 |
| Filing Application | 21 NCAC 48E .0101 |
| Examination Scores | 21 NCAC 48E .0104 |
| Verification of Licensure | 21 NCAC 48E .0105 |
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| Multiple Claims | 21 NCAC 58A .1402 |

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| Continuing Education Requirements for Licensed Recreation... | 21 NCAC 65 .0601 |
| Renewal Requirements for Licensed Recreational Therapist ... | 21 NCAC 65 .0602 |

*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) 431-3000. Also, the Contested Case Decisions are available on the Internet at http://www.ncoah.com/hearings.*

***OFFICE OF ADMINISTRATIVE HEARINGS***

***Chief Administrative Law Judge***
*JULIAN MANN, III*

***Senior Administrative Law Judge***
*FRED G. MORRISON JR.*

ADMINISTRATIVE LAW JUDGES

Beecher R. Gray
Selina Brooks
Melissa Owens Lassiter
Don Overby
Randall May
A. B. Elkins II
Joe Webster

| AGENCY | CASE NUMBER | DATE | PUBLISHED DECISION REGISTER CITATION |
|---|---|---|---|
| **ALCOHOLIC BEVERAGE CONTROL COMMISSION** | | | |
| James Ivery Smith, Ivy Lee Armstrong v. ABC Commission | 11 ABC 08266 | 04/12/12 | |
| Trawick Enterprises LLC v. ABC Commission | 11 ABC 08901 | 05/11/12 | 27:01 NCR 39 |
| Dawson Street Mini Mart Lovell Glover v. ABC Commission | 11 ABC 12597 | 05/23/12 | |
| ABC Commission v. Christian Broome Hunt T/A Ricky's Sports Bar and Grill | 11 ABC 13161 | 05/03/12 | |
| Alabarati Brothers, LLC T/A Day N Nite Food Mart, v. ABC Commission | 11 ABC 13545 | 05/01/12 | |
| Playground LLC, T/A Playground v. ABC Commission | 11 ABC 14031 | 05/16/12 | 27:01 NCR 64 |
| ABC Commission v. Quick Quality, Inc., T/A Rock Star Grill and Bar | 11 ABC 14036 | 07/05/12 | |
| ABC Commission v. D's Drive Thru Inc. T/A D's Drive Thru | 12 ABC 00060 | 05/29/12 | |
| ABC Commission v. Choudhary, LLC T/A Speedway | 12 ABC 00721 | 05/01/12 | |
| ABC Commission v. Dos Perros Restaurant LLC T/A Dos Perros Restaurant | 12 ABC 05312 | 09/25/12 | |
| ABC Commission v. Bobby Warren Joyner T/A Hillsdale Club | 12 ABC 06153 | 11/06/12 | |
| ABC Commission v. Quick Quality, Inc., T/A Rock Star Grill and Bar | 12 ABC 07260 | 12/11/12 | |
| ABC Commission v. Fat Cats Grill and Oyster Bar Inc, T/A Fat Cats Grill and Oyster Bar | 12 ABC 08988 | 12/19/12 | |
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**DEPARTMENT OF STATE TREASURER**

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| Dwight Marvin Wright v. Department of Commerce, Division of Employment Security | 12 ESC 05042 | 07/27/12 | |
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| Stephen R. West v. The University of North Carolina at Chapel Hill | 10 OSP 01567 | 11/26/12 | 27:21 NCR 1959 |
| Larry F. Murphy v. Employment Security Commission of North Carolina | 10 OSP 03213 | 06/04/12 | |
| Walter Bruce Williams v. Dept. of Crime Control and Public Safety Butner Public Safety Division | 10 OSP 03551 | 04/23/12 | 27:01 NCR 148 |
| Teresa J. Barrett v. DENR | 10 OSP 04754 | 10/22/12 | 27:16 NCR 1726 |
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| Beatrice T. Jackson v. Durham County Health Department | 11 OSP 3835 | 06/08/12 | |
| Brenda D. Triplett v. DOC | 11 OSP 4605 | 03/20/12 | 27:06 NCR 669 |
| Tommie J. Porter v. DOC | 11 OSP 5352 | 06/05/12 | 27:06 NCR 678 |
| Fortae McWilliams v. DOC | 11 OSP 06236 | 05/30/12 | 27:06 NCR 684 |
| Kimberly F. Loflin v. DOT, DMV | 11 OSP 06762 | 07/10/12 | |
| John Hardin Swain v. DOC, Hyde Correctional Inst. | 11 OSP 07956 | 04/23/12 | 27:06 NCR 693 |
| John Fargher v. DOT | 11 OSP 08111 | 04/18/12 | |
| Tammy Cagle v. Swain County, Department of Social Services | 11 OSP 10307 | 09/26/12 | 27:16 NCR 1747 |
| Doris Wearing v. Polk Correctional Inst. Mr. Soloman Superintendent | 11 OSP 11023 | 10/19/12 | |
| Fredericka Florentina Demmings v. County of Durham | 11 OSP 11498 | 06/12/12 | |
| Derick A Proctor v. Crime Control and Public Safety, State Capital Police Division | 11 OSP 11499 | 12/06/12 | |
| David B. Stone v. Department of Cultural Resources | 11 OSP 11926 | 08/10/12 | 27:12 NCR 1245 |
| Pattie Hollingsworth v. Fayetteville State University | 11 OSP 12152 | 02/27/13 | |
| William C. Spender v. Dept. of Agriculture & Consumer Services, Veterinary Division | 11 OSP 12479 | 04/27/12 | |
| Terrence McDonald v. NCSU | 11 OSP 12682 | 05/21/12 | |
| Terrence McDonald v. DHHS, Emery Milliken | 11 OSP 12683 | 05/18/12 | |
| Phyllis Campbell v. DOC | 11 OSP 13381 | 08/27/12 | 27:15 NCR 1579 |
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| Marva G. Scott v. Edgecombe County Social Services Board (Larry Woodley, Fate Taylor, Ernest Taylor, Viola Harris and Evelyn Johnson), Edgecombe County Commissioners and Edgecombe county manager, Lorenzo Carmon | 12 OSP 00430 | 12/20/12 | 27:22 NCR 2153 |

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| Sherry Baker v. Department of Public Safety | 12 OSP 00841 | 10/09/12 | |
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| Donnette J Amaro v. Onslow County Department of Social Services | 12 OSP 02578 | 11/21/12 | |
| Ronald Gilliard v. N.C. Alcoholic Law Enforcement | 12 OSP 02618 | 09/26/12 | |
| Kimberly Hinton v. DOT | 12 OSP 02848 | 10/05/12 | |
| James B. Bushardt III v. DENR, Division of Water Quality | 12 OSP 02872 | 02/19/13 | |
| Natalie Wallace-Gomes v. Winston Salem State University | 12 OSP 02950 | 08/01/12 | |
| Jaymar v. Department of Corrections, Central Prison | 12 OSP 03381 | 07/20/12 | |
| Ronald Wayne Crabtree Jr., v. Butner Public Safety | 12 OSP 03846 | 10/09/12 | |
| Natalie Wallace-Gomes v. Winston Salem State University | 12 OSP 03910 | 10/22/12 | |
| Natalie Wallace-Gomes v. Winston Salem State University | 12 OSP 04107 | 10/22/12 | |
| Michelle Houser v. Department of Public Safety, Division of Prisons | 12 OSP 04826 | 09/26/12 | |
| Audrey Melissa Tate v. Department of Public Safety, Division of Juvenile Justice | 12 OSP 05182 | 08/03/12 | |
| Jonathan Ashley Stephenson v. UNC-Chapel Hill | 12 OSP 05223 | 01/15/13 | |
| Charles E. Rouse v. DMV, Dist Sup Stacey Wooten | 12 OSP 05315 | 09/05/12 | |
| Edwards Robert Esslinger v. DPI | 12 OSP 05459 | 09/12/12 | |
| Barry L. Pruett v. DMV, Driver and Vehicle Services | 12 OSP 05785 | 09/11/12 | |
| Joseph Sandy v. UNC Chapel Hill | 12 OSP 06152 | 09/05/12 | |
| Natalie Wallace-Gomes v. Winston Salem State University | 12 OSP 06309 | 10/22/12 | |
| Paul Jeffrey Treadway v. Department of Public Safety, Division of Adult Supervision | 12 OSP 06634 | 12/18/12 | |
| Phillip W Smith v. Department of Commerce, Division of Employment Security | 12 OSP 06821 | 09/20/12 | |
| Shirley M. Parker v. Department of Public Safety Caledonia Correctional Institution | 12 OSP 07617 | 04/04/13 | |
| Christopher Rashad Pippins v. PCS BOE PCS Facility Services | 12 OSP 07744 | 10/18/12 | |
| Wanda Edwards v. UNC School of Dentistry | 12 OSP 07851 | 01/09/13 | |
| Gary C. Clement v. DHHS | 12 OSP 08105 | 11/14/12 | |
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| James Cooper III Sui Juris v. Department of Revenue | 11 REV 13792 | 11/14/12 | |
| Brian Daniel Reeves v. Department of Revenue | 12 REV 01539 | 06/04/12 | |
| David Roser v. Department of Revenue | 12 REV 01694 | 09/10/12 | |
| Ronnie Lee Nixon v. Department of Revenue | 12 REV 01881 | 10/03/12 | |
| William S. Hall v. Department of Revenue | 12 REV 04115 | 08/27/12 | |
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| Onyedika C Nwaebube v. UNC Hospitals | 12 UNC 01110 | 06/25/12 | |
| Nephatiya Wade v. UNC Hospitals Chapel Hill NC | 12 UNC 01209 | 07/17/12 | |
| Fredia R Wall v. UNC Physicians & Associates | 12 UNC 02256 | 10/04/12 | |
| Carolyn A. Green v. UNC Hospitals | 12 UNC 02259 | 09/19/12 | |
| Annie E. Jarrett v. UNC Hospitals | 12 UNC 03716 | 10/09/12 | |
| Vikki J Goings v. UNC Hospital | 12 UNC 04109 | 09/18/12 | |
| Elonnie Alston v. UNC Hospitals | 12 UNC 04551 | 09/11/12 | |
| Diara Z Andrews v. UNC Hospitals | 12 UNC 04827 | 08/15/12 | |

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| David Ryan Pierce v. UNC Hospitals, Patient Account Services, SODCA | 12 UNC 05306 | 03/20/13 | |
| Shonte Hayes v. UNC P&A | 12 UNC 05746 | 09/10/12 | |
| Tracy A. Spaine (Currier) v. UNC Hospitals | 12 UNC 06822 | 11/06/12 | |

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| People for the Ethical Treatment of Animals, Inc., v. NC Wildlife Resources Commission | 12 WRC 07077 | 11/13/12 | 27:22 NCR 2166 |

NORTH CAROLINA

HARNETT COUNTY

IN THE OFFICE OF

ADMINISTRATIVE HEARINGS

12 DHR 1965

BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC., D/B/A FMC ANDERSON CREEK,
Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,
Respondent,

and

TOTAL RENAL CARE OF NORTH CAROLINA, LLC,
Respondent-Intervenor.

**FINAL DECISION**

This matter came for hearing before the Honorable Donald W. Overby, Administrative Law Judge ("ALJ"), on October 29-November 2, 2012, in Raleigh, North Carolina. Having heard all of the evidence in this case and having considered the exhibits, arguments, and relevant law, the Undersigned makes the Findings of Fact, by a preponderance of the evidence, enters his Conclusions of Law thereon, and makes the following final decision, pursuant to N.C. Gen. Stat. §§ 150B-34 and 131E-188.

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## APPEARANCES

For Petitioner Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Anderson Creek ("BMA"):

Marcus C. Hewitt
Elizabeth Sims Hedrick
Williams Mullen
P.O. Box 1000
Raleigh, NC 27602

For Respondent N.C. Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "CON Section" or "Agency"):

Scott Stroud
North Carolina Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629

For Respondent-Intervenor Total Renal Care of North Carolina, LLC ("TRC"):

William R. Shenton
Poyner Spruill LLP
Post Office Box 1801
Raleigh, NC 27602-1801

## APPLICABLE LAW

1. The procedural statutory law applicable to this contested case is the North Carolina Administrative Procedure Act, N.C. Gen. Stat. § 150B-2 *et seq.* and § 131E-188 of the North Carolina Certificate of Need Law.

2. The substantive statutory law applicable to this contested case is the North Carolina Certificate of Need Law, N.C. Gen. Stat. § 131E-175 *et seq.*

3. The administrative regulations applicable to this contested case are the North Carolina Certificate of Need Program Administrative Regulations, 10 N.C.A.C. 14C.0101 *et seq.* and the Office of Administrative Hearing Rules, 26 NCAC 3.0100, *et seq.*

## BURDEN OF PROOF

As petitioner, BMA bears the burden of proof by a preponderance of the evidence. *See* N.C. Gen. Stat. § 150B-23(a); N.C. Gen. Stat. § 150B-29(a); N.C. Gen. Stat. § 150B-34(a); *Overcash v. N.C. Dep't of Env't & Natural Res.*, 179 N.C. App. 697, 704, 635 S.E.2d 442, 447-48 (2006).

## ISSUES PRESENTED IN THIS CONTESTED CASE

The parties set forth the following issues for resolution in this contested case in the Pre-Hearing Order:

### A. BMA'S LIST OF ISSUES

BMA presented the following issues for resolution in this contested case:

1. Whether the Respondent substantially prejudiced BMA's rights; exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in finding TRC's CON application, Project I.D. M-8743-11, conforming with all applicable statutory criteria and regulatory standards.

2. Whether the Respondent substantially prejudiced BMA's rights; exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in finding BMA's CON application, Project I.D. M-8752-11, nonconforming to certain applicable statutory criteria and/or regulatory standards.

3. Whether the Respondent substantially prejudiced BMA's rights; exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in finding any TRC's CON application, Project I.D. M-8743-11, comparatively superior to the CON application of BMA, Project I.D. M-8752-11, and by approving TRC's CON application.

### B. CON SECTION'S LIST OF ISSUES

The CON Section presented the following issue for resolution in this contested case:

The issue to be resolved is whether Respondent substantially prejudiced Petitioner's rights, and exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule when Respondent denied the CON application filed by BMA and approved the application of TRC for Project I.D. Nos. M-8752-11 and M-8743-11.

### C. TRC'S LIST OF ISSUES

TRC presented the following issues for resolution in this contested case:

1. Whether the CON Section substantially prejudiced BMA's rights when it conditionally approved the CON application filed by TRC, identified as Project I.D. No. M-8743-11, and denied the application filed by BMA, identified as Project I.D. No. M-8752-11.

2. Whether, based upon the information presented to or reasonably available to the CON Section, it correctly found the TRC Application conforming or conditionally conforming with all applicable statutory and regulatory review criteria, and correctly approved the TRC Application.

3. Whether, based upon the information presented to or reasonably available to the CON Section, it correctly found the BMA Application nonconforming with N.C. Gen. Stat. § 131E-183(a)(4) and 10A NCAC 14C .2202(b)(1), and correctly denied the BMA Application.

4. Whether, based upon the information presented to or reasonably available to the CON Section, it correctly decided that the TRC Application was the most effective alternative in the 2011 Harnett County Dialysis Review and should be approved, and that the BMA Application was not the most effective alternative and should not be approved.

**D. EXHIBITS ADMITTED AT THE HEARING**

In addition, the following exhibits were admitted into evidence:

**Joint Exhibits**

1. Agency File

2. BMA d/b/a FMC Anderson Creek CON Application, Project I.D. No. M-8752-11

3. TRC d/b/a Spring Lake Dialysis CON Application, Project I.D. No. M-8743-11

4. Agency Findings – 2010 Randolph County ESRD Review

5. Agency Findings – 2007 Johnston County MRI Review

6. **[Official Notice Taken]** Federal Register Vol. 75, No. 155 dated August 12, 2010

7. C.V. of James William Swann, Jr.

8. ***[Confidential – Attorneys' Eyes Only]*** De Novo Project Summary (BMA 1611)

10. Comparative Table of County Census Data

11. Agency Findings – 2010 Cabarrus County ESRD Review

12. Agency Findings – 2011 Northampton County ESRD Review

17. ***[Confidential]*** BMA De Novo Feasibility Model for FMC Anderson Creek

19. Excerpts from TRC's Application 2009 Alexander County Dialysis application (BMA 1482-1487)

28. Analysis prepared by Capital Health Consultants

31. Email from Wells to Swann (9/14/11 at 12:38 pm) (BMA 1224-1226)

34. Template for Affiliation Agreement with Central Carolina Hospital

(BMA 1467-1471)

44. Unexecuted Affiliation Agreement between Cape Fear Valley Medical Center and FMC Anderson Creek Dialysis, Inc. (BMA 1462-1466)

49. **[Official Notice Taken]** Excerpt from Federal Register, Vol. 76, No. 218 dated November 10, 2011

**BMA's Exhibits**

101. **[Official Notice Taken]** Excerpts from Federal Register Vol. 73, No. 73 dated April 15, 2008

102. **[Official Notice Taken]** 42 CFR Part 494 (2011) (Conditions for Coverage for End-Stage Renal Disease Facilities)

103. **[Official Notice Taken]** 42 CFR Part 405, Subpart U (2008) (Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services)

104. ESRD Payment Overview from CMS website

105. MLN Matters article regarding bundled PPS from CMS website

106. Dialysis application form developed by CON Section

107. July 2011 Semi-Annual Dialysis Report

108. Deposition transcript of Tanya Rupp dated July 17, 2012

109. Deposition transcript of Craig R. Smith dated July 25, 2012

119. Illustrative Exhibit of Compared Demographics for Randolph/Montgomery, Harnett/Moore and Northampton/Hertford

**TRC's Exhibits**

200. Facility Map of Harnett and Contiguous Counties (TRC 3093 version2)

201. Excerpts from SDRs from 1993-2012 (TRC 3233-3265 and 3153-3227)

202. Zip code map of Harnett County (TRC 318)

203. SEKC Data for Harnett, Cumberland, Moore and Lee Counties (TRC 527-548)

205. ***[Confidential]*** – 7/18/2011 Email string from Hyland to Hines (TRC 2990-2991)

206. SEKC Data and Table B from July 2011 SDR (TRC 518-526)

207. Section X from TRC Applications filed 3/15/11 (TRC 549-584)

209. Criterion 5 Excerpts from Agency Findings for TRC Applications filed 3/15/11 (TRC 3356-3371)

210. Section X from TRC Applications filed 9/15/11 (TRC 585-620)

212. Criterion 5 Excerpts from Agency Findings for TRC Applications filed 9/15/11 (TRC 3372-3388)

214. Section VI from BMA's Brunswick County CON Application [Project ID No. O-7965-07] (TRC 3053-3057)

215. Section VI from BMA's Angier (Harnett County) CON Application [Project ID No. M-8596-10] (TRC 3058-3063)

216. **[Accepted for impeachment purposes only]** Section VI from BMA's Macon County CON Application [Project ID No. A-8795-12] (TRC 3064-3068)

219. Spreadsheet: Anderson Creek Tables, Tab: Funding Letter Info

**CON Section's Exhibits**

No CON Section exhibits were admitted

**WITNESSES**

**Witnesses for Petitioner**

Tanya Rupp, Project Analyst, CON Section
Craig R. Smith, Chief of the CON Section
Jim Swann, Director of Market Development and Certificate of Need, Fresenius Medical Care
Robert J. Cimasi, President, Health Capital Consultants
David Wells, Director of Operations for the Wake Area, Fresenius Medical Care

**Witnesses for Respondent**

Craig R. Smith, Chief of the CON Section

**Witnesses for Respondent-Intervenor**

Richard D. Adams, Group Finance Director, DaVita, Inc.
William L. Hyland, Director of Healthcare Planning, DaVita, Inc.

**SUMMARY OF THE CONTESTED CASE**

The parties to this contested case are 1) the Petitioner, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Anderson Creek, ("BMA"); 2) the Respondent, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section, ("Agency" or "CON Section"); and 3) the Respondent-Intervenor, Total Renal Care of North Carolina, LLC, ("TRC").

The contested case arises from the Agency's decision to approve, with conditions, an application by TRC ("the TRC Application") to develop a new dialysis facility in southwest Harnett County, and to disapprove a competing application by BMA ("the BMA Application") to develop a new dialysis facility in the same area of Harnett County. These applications were submitted based on a need identified in the July, 2011 Semi-Annual Dialysis Report ("SDR") and were reviewed as competitive applications because the approval of one application would result in the disapproval of the other application. *See* 10A NCAC 14C .0202(f).

BMA appealed the Agency decision to approve the TRC Application and disapprove the BMA Application pursuant to N.C. Gen. Stat. § 150B-23(a), N.C. Gen. Stat. § 131E-188, and 26 NCAC 03 .0103(a). Pursuant to N.C. Gen. Stat. § 131E-188(a) and § 150B-23 through 37, a contested case hearing was held in this matter on October 29, 2012 through November 2, 2012, in Raleigh, North Carolina, before the undersigned Administrative Law Judge. On December 3, 2012, the parties submitted proposed forms of Final Decisions and briefs.

**BASED UPON** careful consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the Undersigned makes the following Findings of Fact. In making the Findings of Fact, the Undersigned has weighed all the evidence and has assessed the credibility, including but not limited to, the demeanor of the witnesses, any interests, bias, or prejudice the witness may have, the opportunity of the witness to see, hear, know, or remember the facts or occurrences about which the witness testified, whether the testimony of the witness is reasonable, and whether the testimony is consistent with all other credible evidence in the case.

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## FINDINGS OF FACT

### E. BACKGROUND

**Parties, Procedural Points and Other Undisputed Information**

1. All the parties are properly before the Office of Administrative Hearings ("OAH"), and OAH has jurisdiction of the parties and of the subject matter.

2. All parties have been correctly designated and there is no question as to misjoinder or non-joinder of parties.

3. Petitioner BMA is a Delaware limited liability company with its principal place of business in Waltham, Massachusetts and is authorized to do business in the State of North Carolina. (Jt. Ex. 2, p. 107) BMA is in the business of providing dialysis services. (*Id.* at pp. 4-5)

4. Respondent CON Section is the Agency within the North Carolina Department of Health and Human Services that is responsible for administration of North Carolina's Certificate of Need Law, and which is at least in part to review and approve the development of new institutional health services under the CON Law, codified at N.C. Gen. Stat. § 131E-175 *et. seq.*

5. Respondent-Intervenor TRC is a Delaware limited liability company with its principal place of business in Denver Colorado and is authorized to do business in the State of North Carolina. (Jt. Ex. 3, p. 119) TRC is in the business of providing dialysis services. (*Id.* at p. 5)

**The Witnesses**

6. Tanya Rupp is the project analyst at the Agency who was assigned to this competitive review and she has been a project analyst for the Agency for approximately six years. Ms. Rupp reviewed the BMA and TRC Applications and was primarily responsible for preparing the Required State Agency Findings. (Rupp, Vol. 1, p. 41)

7. Craig R. Smith is the Chief of the Certificate of Need Section of the Division of Health Service Regulation and oversaw Ms. Rupp's work on the BMA and TRC applications. Mr. Smith has worked for the CON Section for 24 years, and during the course of his work there he has participated in the review of approximately a thousand dialysis applications, 15-20 of which were in competitive reviews. (Smith, Vol. 5, pp. 818-819) Mr. Smith has been Chief of CON Section for nearly three years. (Smith, Vol. 1, pp. 183-184) Prior to his current position, he held the position of Assistant Chief of the CON Section for 15 years. (Smith, Vol. 5, p. 818)

8. James Swann is Director of Market Development and Certificate of Need for Fresenius Medical Care. He has worked in this capacity since April 2004, and he was the primary author of the BMA Application at issue in this matter. He was tendered and accepted as an expert in the preparation, review, and analysis of certificate of need applications, health planning, need and utilization projections, and cost and feasibility analysis of health services.

(Swann, Vol. 2, pp. 301-302, 312) Mr. Swann was responsible for drafting and compiling the information in the BMA Application. (Swann, Vol. 2, pp. 313-314).

9. Robert James Cimasi is the President and principal consultant with Health Capital Consultants. He founded the company in October of 1993. He was tendered and accepted as an expert in the financial and economic aspects of health care entities, including but not limited to financial analysis and forecasting, Medicare reimbursement, certificate of need and regulatory and policy planning. (Cimasi, Vol. 3, pp. 505-506, 517)

10. David Russell Wells is the Director of Operations for the Wake area for Fresenius Medical Care. He has held this position since June of 2009. In this position Mr. Wells oversees the day-to-day operations of the clinics, with specific focus on the operational aspects of the business as well as regulatory and compliance issues. Mr. Wells also is involved in coordinating care with other health care providers, which typically entails obtaining agreements with hospitals and other ancillary health care facilities to ensure that patients have access to the services they need. (Wells, Vol. 3, pp. 580-581)

11. William L. Hyland is the Director of Healthcare Planning for DaVita, the 85% owner of TRC. He has worked in this capacity for 13 years and prepared the TRC Application. He was tendered and accepted as an expert in health planning for dialysis services and facilities and the preparation and analysis of certificate of need applications. (Hyland, Vol. 4, pp. 661, 668-670)

12. Richard D. Adams is a Group Finance Director with DaVita. He is in charge of a team of financial analysts that oversee the financial results of operations, capital, deployment modeling, and budgeting forecasting for a division of DaVita. In his position, Mr. Adams performs analytics and review of revenues, including Medicare and other payors. (Adams, Vol. 4, p. 637)

**Procedural and Factual Background**

13. A Certificate of Need ("CON") is required for certain "new institutional health services" as that term is defined by N.C. Gen. Stat. § 131E-176(16). The statute requires a facility to first obtain a CON when the entity is constructing, developing, or establishing a new health service facility or offering dialysis services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility. N.C. Gen. Stat. §§ 131E-176(16)(a), (d) and 131E-178(a).

14. The construction of a dialysis facility is *per se* reviewable under the CON law and is subject to the methodologies and need determinations contained in the applicable State Medical Facilities Plan ("SMFP") and Semi-Annual Dialysis Report ("SDR").

15. Dialysis is a therapy used to treat patients who have lost the function of their kidneys. The kidney is a critical organ because it draws off excess fluid and waste byproducts of metabolism from the blood stream. Patients whose kidneys have failed require some form of dialysis or a kidney transplant in order to survive. (Swann, pp. 312-313)

16. Dialysis can be provided for patients in a dialysis facility ("in-center") or conducted by the patients themselves at home. Patients who desire to dialyze at home need to be trained for this, whether it is home peritoneal dialysis or home hemodialysis. If a facility does not have a home training program, its patients can be referred to a facility that does have a home training program. (Swann, Vol. 2, pp. 315-317)

17. The SMFP is the official plan developed and published each year which inventories certain services, facilities, and equipment that are subject to CON regulation as well as the utilization of those services, facilities, and equipment. The SMFP also projects future needs for additional services, facilities, and equipment in each service area.

18. The SMFP is developed under the direction of the State Health Coordinating Council ("SHCC"), which is comprised of healthcare professionals and other citizens, each of whom is appointed by the Governor with the approval of the Senate. N.C. Gen. Stat. §§ 131E-176(17), (25); 131E-177(4). The SHCC submits a proposed SMFP for review by the Governor, who has the ultimate authority to approve and finalize the SMFP.

19. The N.C. Department of Health & Human Services develops the Semi-Annual Dialysis Report ("SDR"). Currently, the SDRs are published in January and July of each calendar year. They contain detailed information about the number of patients who are receiving dialysis services in each county as well as the dialysis facilities that are in operation, or which have received a certificate of need approval to begin operations, in each county. (Rupp, Vol. 1, pp. 43-44) (Jt. Ex. 3, pp. 93-115) The SDRs also provide information about the capacity of dialysis facilities which is expressed in terms of the number of dialysis stations which they are permitted to operate. (Jt. Ex. 3, pp. 102-115)

20. The SDRs contain methodologies that are used to project the need for additional dialysis stations in each county in the future, based on the size and capacity of the existing dialysis facilities, as well as the projected dialysis patient population in the future. (Jt. Ex. 3, pp. 93-101) The estimate of future dialysis patients is derived by applying the average rates of change in each county over the prior five years ("the Five-Year Average Annual Change Rate"), to the current numbers of dialysis patients residing in each county.

21. New facilities must have a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care. (Jt. Ex. 3, p. 97)

22. In order for there to be a "county need" determination, there must not only be a projected station deficit of 10 or greater, but in addition, the utilization of each dialysis facility in the county must be 80 percent or greater. (Jt. Ex. 3, p. 100)

23. Based on the application of the SDR methodology the July, 2011 SDR showed a need for 11 additional dialysis stations in Harnett County. (Rupp, Vol. 1, p. 45) (Jt. Ex. 3, p. 114)

24. This is the first "county need" determination in Harnett County since at least 1993. (Hyland, Vol. 4, p. 672; Ex. 201)

25. On September 15, 2011, BMA and TRC each submitted CON applications for all 11 dialysis stations. (Joint Exs. 2, 3). The Agency batched the BMA application and the TRC application for purposes of a competitive review.

26. BMA and TRC both provide kidney dialysis services to end-stage renal disease ("ESRD") patients at facilities throughout North Carolina. BMA, a subsidiary of Fresenius Medical Care North America ("Fresenius"), is the largest dialysis provider in the state, and TRC, a subsidiary of DaVita, Inc. ("DaVita") is the second-largest. (Swann T. Vol. 3 p. 319).

27. BMA's CON application proposed to develop an 11-station dialysis facility in Harnett County (the "BMA Application"), designated Project ID No. M-8752-11. (Joint Ex. 1 pp. 447).

28. The BMA application also proposed to offer in-center hemodialysis and training in peritoneal dialysis. In addition, BMA proposed to dedicate one of the eleven stations for use solely as a home hemo-dialysis training station. (Jt. Ex. 2, p. 2) BMA also projected providing dialysis treatments to residents of Cumberland County in addition to Harnett County residents, at its proposed facility. (Jt. Ex. 2, p. 14)

29. TRC's CON application likewise proposed to develop an 11-station dialysis facility in Harnett County, North Carolina (the "TRC Application"), designated Project ID No. M-8743-11. (Joint Ex. 1 pp. 447).

30. The TRC application proposes to offer in-center hemodialysis and training in peritoneal dialysis to Harnett County residents at its Spring Lake Facility. (Jt. Ex. 3, pp. 3 and 17)

31. Once applications have been filed, the CON Section reviews them to determine if they are complete, whether required applications fees have been paid, and whether a public hearing is necessary. (Smith, Vol. 5, p. 822) The Agency determined that TRC's application and BMA's application were each complete as of September 20, 2011 and the review period began on October 1, 2011. (Jt. Ex. 1, pp. 7 and 38)

32. The public comment period lasts 30 days from the date the review period began. (Smith, Vol. 5, p. 822).

33. If there is a county need determination, a public hearing is required. (Smith, Vol. 5, p. 822) The Agency held a public hearing for this review on November 16, 2011. (Jt. Ex. 1, pp. 80-81)

34. After the public hearing, the analyst reviews each application to determine its conformity with statutory and regulatory criteria, as well as any written and public hearing comments. (Smith, Vol. 5, p. 823) In competitive reviews, the analyst also performs a comparative analysis. (*Id.* at p. 824)

35. Even where there is a need determination in the SMFP or the SDR, the Agency cannot approve an application unless the applicant demonstrates it is conforming or conditionally conforming to the applicable review criteria. *See* N.C. Gen. Stat. § 131E-183.

36. The applicant bears the burden of demonstrating conformity with the review criteria. *Presbyterian-Orthopaedic Hosp. v. N.C. Dep't of Human Res.*, 122 N.C. App. 529, 534, 470 S.E.2d 831, 834 (1996).

37. Project Analyst Tanya Rupp and CON Section Chief Craig R. Smith were the Agency employees who reviewed the BMA Application and the TRC Application. (Rupp T. Vol. 1 p. 42: *see also* Joint Ex. 1 p. 447).

38. On October 1, as scheduled under the July 2011 SDR, the Agency began its review of the applications. The Review was competitive because the July 2011 SDR identified a need for only eleven additional dialysis stations in Harnett County, and each applicant sought approval for a total of eleven dialysis stations. Thus, both of the applications could not be approved. (Joint Ex. 1 pp. 447-48).

39. During this Review, both TRC and BMA filed written comments regarding the competing application. (Joint Ex. 1 pp. 60-70).

40. Ms. Rupp reviewed each application in its entirety and determined whether each individual application, standing alone, conformed to the applicable statutory and regulatory review criteria. After drafting a set of findings regarding conformity to the applicable review criteria for each application, Ms. Rupp conducted a comparative analysis of the two applications. (Rupp T. Vol. 1 pp. 49-50).

41. To receive a CON for a proposed project, an applicant's proposal must satisfy all applicable statutory review criteria specified in N.C. Gen. Stat. § 131E-183(a) as well as all applicable regulatory review criteria established pursuant to N.C. Gen. Stat. § 131E-183(b). *See also Bio-Medical Applications of N.C.*, 136 N.C. App. 103, 523 S.E.2d 677 (1999).

42. By decision letters dated February 27, 2012, and the Required State Agency Findings issued the same day, the CON Section approved the TRC Application and disapproved the BMA Application. (Joint Ex. 1 pp. 447-501; Rupp T. Vol. 1 p. 51).

43. In the Required State Agency Findings, the CON Section found TRC conforming to all applicable statutory and regulatory review critieria but found BMA non-conforming to one of the applicable regulatory review criteria and thus also non-conforming to statutory review Criterion 4. (Joint Ex. 1 pp. 447-501).

44. On March 28, 2012, BMA filed a petition for a contested case hearing challenging the approval of the TRC Application and the denial of BMA Application. The contested case was identified as 12 DHR 1965.

45. On April 4, 2012, TRC filed an Unopposed Motion to Intervene in this contested case hearing. The Order allowing the intervention was entered on April 9, 2012.

**The BMA Application**

46. The Agency found the BMA Application conforming to all applicable statutory and regulatory review criteria except for the regulation found at 10A N.C.A.C. 14C .2202(b)(1)

("Rule 2202(b)(1)") and the statutory criterion at N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4"). (Joint Ex. 1 pp. 467-68, 487-88).

47. The only reason the Agency found the BMA Application nonconforming to Criterion 4 was its determination that the BMA Application was nonconforming to Rule .2202(b)(1). Otherwise, BMA would have been found fully conforming to all of the applicable review criteria. (Rupp T. Vol. 1 p. 78; Smith T. Vol. 1 p. 185-86).

**Rule .2202(b)(1)**

48. 10A NCAC 14C .2202(b)(1) is a properly promulgated rule that has been adopted by the Agency. Rule .2202(b)(1) requires that an applicant provide:

> For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

10A N.C.A.C. 14C.2202(b)(1).

49. In response to this rule, BMA provided a signed agreement with WakeMed Hospital in Raleigh entitled "Transfer Agreement" (the "Agreement"). (*See* Joint Ex. 2 pp. 11, 362-65).

50. Ms. Rupp determined that the Agreement did not satisfy the requirements of Rule .2202(b)(1) because it was entitled "transfer agreement" and because she believed it did not describe the services that the hospital would provide with enough specificity. (Rupp T. Vol. 1 pp. 57; 60-61; Ex. 115, Rupp Dep. pp. 153-55, 157, 161-62).

51. Ms. Rupp contends that "transfer agreement" was not among those listed in the sections of the C.F.R. which she consulted; however the sections she consulted were not current. In its Findings the Agency faulted BMA for providing a "transfer agreement" instead of an "affiliation agreement." Rule .2202(b)(1) makes no such distinction. (10A N.C.A.C. 14C .2202(b)(1); Wells T. Vol. 3 pp. 589).

52. Mr. Smith acknowledges that the label is not controlling but that it is the substance of the contract which determines whether or not it complies with the rules. To make that determination, one must actually look at both the applicable state rules and the Code of Federal Regulations (C.F.R.) Mr. Smith acknowledged at this contested case hearing that he believes that the "transfer agreement" presented by BMA satisfies all of the requirements of the applicable rules.

53. Contrary to what Ms. Rupp expected from the BMA application as she reviewed it, Rule .2202(b)(1) does not state any specific services that must be identified in an agreement or letter of intent in order to establish conformity to Rule .2202(b)(1). Neither Ms. Rupp nor Mr.

Smith was able to identify the level of specificity required to demonstrate conformity with Rule .2202(b)(1). (10A N.C.A.C. 14C. 2202(b)(1); Rupp T. Vol. 1 p. 57; Smith T. Vol. 1 pp. 191-94; Ex. 115, Rupp Dep. p. 162; Ex. 116, Smith Dep. p. 34).

54. The agreement between BMA and WakeMed "specifies the relationship" between the hospital and the dialysis facility and it "describes the services that the hospital will provide" to those patients. It is a "reasonable assumption" that WakeMed is an acute care hospital. That is all that is required by the plain language of Rule .2202(b)(1), with the exception of compliance with 42 C.F.R., Section 405.2100.

55. Ms. Rupp testified that she believes Rule .2202(b)(1) is simply intended to ensure compliance with the requirements for an agreement with a hospital in the Code of Federal Regulations ("CFR"). (Rupp T. Vol. 1 p. 58).

56. Likewise, Mr. Smith testified at his deposition that Rule .2202(b)(1) is simply intended to ensure that the applicant will comply with the federal regulations that require dialysis facilities to have an agreement with an acute care hospital to serve patients of the facility in the event of an emergency, and that Rule .2202(b)(1) imposes no requirements above and beyond those of the federal regulations. (Ex. 116, Smith Dep. pp. 32-33, 40). At this contested case hearing he amended that position to acknowledge that indeed Rule .2202(b)(1) did state conditions that are particular to the rule and not the same as the CFR requirements.

57. Rule .2202(b)(1) refers to compliance with 42 C.F.R. § 405.2100, but at the time of this review that section of the CFR no longer contained any requirement for such an agreement. The Centers for Medicare and Medicaid Services ("CMS") have adopted certain Conditions for Coverage for End Stage Renal Disease Facilities with which dialysis facilities must comply in order to participate in the Medicare program, that are set forth in Title 42 of the Code of Federal Regulations. *See* 42 C.R.F. § 494.1 *et seq.*

58. By Final Rule effective 14 October 2008, the Centers for Medicare & Medicaid Services revised the Medicare Conditions for Coverage for End State Renal Disease (ESRD) services that were previously found at 42 C.F.R. § 405.2100 *et seq.* Among other things, the regulation requiring an agreement with a hospital was revised and relocated to 42 C.F.R. part 494.

59. During the review, Ms. Rupp reviewed the definition of "agreement" in the 2008 publication of 42 CFR § 405.2102, in evaluating the BMA application's conformity with Rule .2202(b)(1). (Rupp T. Vol. 1 pp. 58-60; *see also* Joint Ex. 1 pp. 199-201). However, Ms. Rupp did not review any of the current applicable sections of the CFR that set forth requirements for an agreement between a dialysis facility and an acute care hospital. (Rupp T. Vol. 1 pp. 59-60, 62, 68-69). The definition of "agreement" that Ms. Rupp consulted in her review was no longer applicable. (*See* Ex. 101 p. 20451).

60. At the time of this review, 42 C.F.R. § 494.180, the applicable provision, required:

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

42 C.F.R. § 494.180

61. Thus, at the time of the review, the federal Conditions for Coverage regulations required a dialysis facility to enter into "an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week." (Ex. 102, 42 C.F.R. § 494.180(g)(3); Emphasis added).

62. The only further requirements for such an agreement are that it (1) ensures that hospital services are available promptly to the dialysis facility's patients when needed and (2) includes reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies. (Ex. 102, 42 C.F.R. § 494.180(g)(3)). Except for the foregoing, nothing in the federal regulation purports to require an agreement to describe or identify any particular services.

63. At the time of the review, neither Ms. Rupp nor Chief Smith was aware of the 2008 change to the Federal Conditions for Coverage requiring an ESRD facility to have a hospital agreement, and neither consulted the proper federal regulation in evaluating BMA's conformity with Rule .2202(b)(1). (Rupp T. Vol. 1 pp. 65-68; Smith T. Vol. 1 pp. 193-94).

64. WakeMed is an acute care hospital that can provide inpatient care, dialysis and other hospital services, and emergency medical care. (Joint Ex. 2, p. 49; Swann T. Vol. 3 p. 440-42; Wells T. Vol. 3, pp. 596-97). As required by 42 CFR 494.180(g)(3), the Agreement provided by BMA included provisions to ensure that hospital services are available promptly to BMA's patients and reasonable assurances that BMA's patients will be accepted and treated in emergencies. (Joint Ex. 2 pp. 362-65).

65. The Agreement recited that WakeMed would admit patients from BMA's proposed facility "as promptly as practicable," dependent on "the urgency of the need" and explicitly stated that WakeMed would (1) see patients experiencing an emergency medical condition in the Emergency Department for a medical screening exam and (2) accept transfers for inpatient and outpatient elective procedures. (Joint Ex. 2 pp. 363-64).

66. To the extent that the language in Rule .2202(b)(1) that a hospital agreement must "specif[y] the relationship with the dialysis facility and describe[ ] the services that the hospital will provide" requires something beyond what is required by the CFR, BMA's Agreement adequately specified such relationship and described such services. The Agreement set forth the nature of the parties' arrangement and the types of emergency and routine services to which BMA's patients would have access. (Joint Ex. 2 pp. 362-65).

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67. When questioned at the hearing as to whether BMA's Agreement specified the relationship between the hospital and the dialysis facility and described the services that the hospital would provide, Section Chief Smith acknowledged that it did both; and could not explain why BMA's Agreement failed to comply with Rule .2202(b)(1). (Smith T. Vol. 1 pp. 197-98).

68. Furthermore, both Mr. Smith and Ms. Rupp testified that the Agency could find an applicant conforming to Rule .2202(b)(1) conditioned upon the provision of a conforming agreement. (Rupp T. Vol. 1. p. 72; Smith T. Vol. 1 p. 199; Ex. 116, Smith Dep. pp. 40-41; Ex. 115, Rupp Dep. p. 166). Thus, had the Agency determined that the BMA Application was the comparatively superior application, it could have found BMA conditionally conforming to this Rule and the related non-conformities. (Smith T. Vol. 1 p. 199; *see also* Ex. 115, Rupp Dep. pp. 167-68; Ex. 116, Smith Dep. pp. 40-41). Thus, even under the conditions that both Mr. Smith and Ms. Rupp erroneously believed to be the case, BMA could have been found conditionally approvable to provide the further information, even though neither Mr. Smith nor Ms. Rupp could specify exactly how they were deficient.

69. Respondent CON Section and Respondent Intervenor point to page eleven of the CON application which asks for the applicant to list various services which may or may not be provided on site. If the services are not to be provided on site, then the applicant is to explain how the patients will receive those services. Question one on page eleven does not specifically ask for any information that some services may be performed off site, and the applicant is to explain how those services will be given to the patients. The question does not rely nor request the contract with any hospital. It does not require even the name of a particular hospital. It seemingly asks for general information to insure that the patients are going to receive proper care.

70. The more important question in the application that is germane to the issues at hand is found on page twelve of the application, specifically question two, subparts (a) and (b), principally a restatement of Rule .2202(b)(1). The question erroneously refers to compliance with 42 C.F.R. Section 405.2100, which was not the controlling federal regulation at the time of this review. The CON application should be in conformance with the state and federal regulations and should not expand the requirements set forth therein. As stated above, there is no requirement in the state and/or federal regulations that require the contract between the facility and the hospital to specifically list the various services that will be provided.

**The TRC Application**

71. The Agency found the TRC Application conforming to all applicable Statutory Review Criteria and Regulatory Review Criteria. (Joint Ex. 1 pp. 447-501).

72. At the contested hearing in this case, BMA challenged the Agency's decision with respect to Statutory Review Criteria 5 and 13(c).

**Criterion 5**

73. Criterion 5 requires an applicant to demonstrate (1) the availability of funds for the capital-related needs of the proposed project and (2) that the proposed project is financially

feasible, "based on reasonable projections of the costs of and charges for providing health services " N.C. Gen. Stat. § 131E-183(a)(5). Both applicants were found to be conforming in the availability of funds for capital related needs and no issue has been raised concerning the capital funds.

74. In dialysis CON reviews, the CON Section evaluates the financial feasibility component of Criterion 5 based on financial projections for the project for the first two years of operations. (*See, e.g.*, Rupp T. Vol. 1 p. 82).

75. If an applicant projects that revenues will exceed expenses in the second operating year, the applicant will be found conforming. (*See, e.g.*, Joint Ex. 1 pp. 468-470; Swann T. Vol. 2 pp. 344-45; *see also, e.g.*, *Parkway Urology, P.A. v. N.C. Dep't of Health & Human Servs.*, 205 N.C. App. 529, 544, 696 S.E.2d 187, 197-98 (linear accelerator application projected profitability as required by Criterion 5)).

76. Both Ms. Rupp and Mr. Smith, Agency witnesses, testified that an applicant's financial projections must be reasonable and based on supported assumptions in order to conform to Criterion 5. (Smith T. Vol. 2 p. 234; Rupp T. Vol. 1 p. 82). If an applicant's financial projections are unreasonable, whether the application is conforming with Criterion 5 depends on whether the project would remain profitable after taking the unreasonable projections into account. (*See, e.g.,* Smith T. Vol. 5 p. 845-46 (if an applicant projected a profit, but underestimated staffing requirements, its conformity with Criterion 5 would depend on whether the applicant would remain profitable after taking the necessary additional staffing expense into account)).

77. TRC's projections were prepared by Mr. William L. Hyland, the Director of Healthcare Planning for TRC's parent company. (*See, e.g.*, Hyland T. Vol. 4 pp. 774-75; Adams T. Vol. 4 p. 647).

78. As required by the CON application form, TRC projected the costs and charges associated with the treatments it projected to provide in the first two years. TRC proposed to begin operation on 1 July 2013 and projected that the facility would show a profit of $116,381 in its second year of operation, 1 July 2014 to 30 June 2015. (Joint Ex. 3 pp. 44, 48-49, 77; Joint Ex. 1 p. 469).

79. In projecting revenues, TRC projected the number of treatments it would provide to patients by each payor category and projected the annual revenue for each payor category based on the allowable charge per treatment. (Joint Ex. 3 pp. 74-75, Tables X.1, X.2, X.3).

80. TRC projected a per treatment reimbursement rate of $136.00 for all treatments reimbursed by Medicare. (Joint Ex. 3 p. 74).

81. TRC separately projected revenue for "EPO and Other Ancillaries" in the amount of $1,126,400 in operating year 2. (*See* Joint Ex. 3 p. 74, Table X.2). Even though these revenues represented approximately half the facility's total projected revenues, and even though the application form directs applicants to describe each assumption used to project revenues, TRC did not provide any assumptions or explanations whatsoever as to how this figure was

calculated, and did not divide the particular source of revenue by payor category. (Rupp T. Vol. 1 pp. 86-87, Joint Ex. 3 pp. 74-75, Tables X.2 and X.3).

82. TRC projected that 88.2% of all its projected dialysis treatments would be reimbursed at Medicare rates (Joint Ex. 3 p. 75, Table X.3), and like treatments reimbursed by other payors, TRC projected separate reimbursement for the treatment itself and for EPO and Other Ancillaries. (*See* Hyland T. Vol. 4 p. 751).

83. The projected revenues in TRC's Application were therefore largely dependent on projected reimbursement by Medicare for dialysis treatments and for "EPO and Other Ancillaries." (Joint Ex. 3 p. 74).

*The Bundled PPS*

84. Prior to 2011, Medicare reimbursed ESRD treatments at a certain rate and separately reimbursed providers at a separate rate for dialysis drugs and separately billable services involved in treatments (EPO and Other Ancillaries). (Joint Ex. 6 p. 49030).

85. Effective January 1, 2011, CMS instituted a new bundled prospective payment system (PPS) for reimbursement for end stage renal disease (ESRD) treatments. This new PPS reimbursement system applies to the reimbursement of dialysis treatments under Medicare, but it does not affect revenues from other payor sources such as Medicaid, VA, and private insurers. (Cimasi, Vol. 3, pp. 528-529) (Jt. Ex. 2, p. 71)

86. Under the bundled PPS, there is no separate reimbursement for ancillary services and drugs, including epoetin alfa ("EPO"), a erythropoiesis stimulating agent used in dialysis treatments. (Joint Ex. 28 p. 3; Joint Ex. 6 pp. 49030, 49036).

87. Under the bundled PPS, the Medicare reimbursement rate for dialysis treatments and related services and drugs is set yearly by means of a "base rate" established by regulation, to which various adjustment factors would be applied for individual facilities and treatments. (Joint Ex. 6 pp. 49071-83; Joint Ex. 28 pp. 4-5).

88. At the time of the CON Section's decision on 27 January 2012, the most recent published base rate for the ESRD PPS was $234.81 per treatment, for calendar year 2012 (Adams T. Vol. 4 pp. 650-51; Cimasi T. Vol. 3 p. 534).

*EPO & Other Ancillaries*

89. Although not stated specifically in its application (*see* Joint Ex. 3 pp. 74-75), in projecting Medicare reimbursement for "EPO and Other Ancillaries," TRC assumed that these drugs would be reimbursed at $160.00 per treatment, the same rate that it projected for EPO and Other Ancillaries reimbursed by other payors. (Hyland T. Vol. 4 p. 751).

90. Combining TRC's projected $136.00 per treatment Medicare rate with its assumption of $160.00 per treatment for "EPO and Other Ancillaries," TRC projected revenues of $296.00 per treatment for Medicare treatments. (Hyland T. Vol. 4 p. 767; Joint Ex. 3 pp. 74-75). These projections were similar to TRC's projected revenues in other CON applications

submitted by TRC in reviews prior to the implementation of the bundled PPS. (*See, e.g.*, Joint Ex. 19, Alexander Co. Application, Section X, pp. BMA 1483-84; Hyland T. Vol. 4 pp. 761-63).

91. Mr. Hyland testified that he based projected Medicare reimbursement on guidance he had received from financial analysts at TRC sometime in 2010 and that he did not obtain any guidance directly related to the preparation of this particular application. (Hyland T. Vol. 4 pp. 753-55, 757-60).

92. TRC's projected reimbursement is not consistent with Medicare reimbursement for dialysis treatments since the implementation of the bundled PPS. (*See* Adams T. Vol. 4 pp. 651-52).

93. Under the bundled PPS, Medicare no longer reimburses for drugs and ancillary services separately from a per treatment reimbursement rate. Instead, the dialysis treatment, dialysis drugs, and ancillary services are reimbursed via a single payment based on a "base rate." (Cimasi T. Vol. 3 pp. 521-22; Joint Ex. 28 pp. 2-5). Respondent Intervenor's contention that there is no standard or fixed rate that is applicable to each dialysis patient's treatment is not correct, although it is correct that there are several adjustments available which might impact the rate of reimbursement.

94. Mr. Hyland acknowledged that at the time he prepared the application, he had no knowledge of the actual reimbursement rate and that he made no attempt to try to find the actual reimbursement rate. He felt that the reimbursement rate he was using was reasonable based solely on the advice he was given from DaVita, even though that advice was eight months old at the time. Further, he was not aware that EPO and Other Ancillaries would no longer be reimbursed separately at the time he prepared TRC's financial projections. (Hyland T. Vol. 4 pp. 760-61).

*Adjustment for Bundling*

95. TRC's financial projections also included a line item titled "Adjustment for Bundling" which reduced the facility's projected revenues by $45,756 in the second operating year. (Joint Ex. 3 p. 74, Table X.2). The projected amount constituted a two percent reduction of TRC's projected "Total Revenue" of $2,287,810. (Joint Ex. 3 p. 74; Hyland T. Vol. 4 pp. 716, 752).

96. The TRC Application did not, however, include any assumptions or explanation for the "Adjustment for Bundling" line item. (Rupp T. Vol. 1 p. 96; Smith T. Vol. 2 pp. 243-44; Hyland T. Vol. 4 p. 752).

97. The CON Application form (Question X.3) specifically requires the applicant to provide the assumptions underlying its revenue projections. TRC did not provide those assumptions in this application. Both Mr. Smith and Ms. Rupp, Agency witnesses, confirmed that an applicant's financial projections must be based on reasonable and supported assumptions. (Smith T. Vol. 2 p. 234; Rupp T. Vol. 1 p. 82). Mr. Hyland testified that the 2 percent revenue reduction for "Adjustment for Bundling" was based on guidance he received from a DaVita financial analyst in January or early February 2011. (Hyland T. Vol. p. 715, 763-64). Mr. Hyland testified that the "Total Revenues" and "Adjustment for Bundling" line items in TRC's

projections are dependent on each revenue line item in Table X.2 on page 74 of TRC's application. (Joint Ex. 3 p. 74; Hyland T. Vol. 4 p. 752).

98. Following the advice given to Mr. Hyland, TRC filed several other applications on March 15, 2011, most of which represented that TRC "[does] not know the total effect the new bundled reimbursement system implemented by the Centers for Medicare and Medicaid Services on January 1, 2011 will have on our revenue. However we have been instructed to expect to receive a revenue reduction of approximately 2%." (*See, e.g.*, Ex. 207 pp. 550-51).

99. All of the March 15, 2011 applications were non-competitive bids, and no one opposed or commented on those applications. All were found to be conforming based upon these projections. At that time, PPS had only been in effect for two and a half months and it was reasonable to use those projections when actual numbers were not available.

100. The TRC Application at issue herein was filed on 15 September 2011, more than eight months after the implementation of the bundled PPS. TRC acknowledged that all of DaVita's North Carolina facilities participated in the bundled PPS effective 1 January 2011; i.e., none were using the "transitional" phase-in period . (Hyland T. Vol. 4 pp. 764-65; Adams T. Vol. 4 p. 648-49).

101. TRC filed numerous applications on September 15, 2011, all using the same methodology, and all were found conforming. The mere fact that the agency found these several applications conforming is of no consequence since they may have consistently used an incorrect methodology. The fact that an error is made numerous times does not correct or legitimize the error.

102. Mr. Richard Adams, Group Finance Director for DaVita, testified DaVita facilities were all participating in bundling from day one. He was aware that EPO and other ancillaries were not billed nor reimbursed separately. He was aware that the reimbursement rate for 2011 was $229, and that the rate for 2012 was higher, but he was not sure of the exact amount.

103. Mr. Adams testified that Mr. Hyland could have accessed actual financial data regarding TRC's experience under the bundled PPS through August 2011 when he filed the TRC Application, including several months of actual revenues after billing and reimbursement "caught up" with the change to the bundled PPS. (Adams T. Vol. 4 pp. 653-59).

104. Mr. Adams testified that one cannot discern the breakdown of the numbers on the application or how the numbers are derived. He also does not know why the two percent adjustment was used in this application since the actual numbers were available.

105. Mr. Hyland made no attempt to obtain any such data or to verify if TRC's revenue projections were consistent with TRC's actual experience, and he had no knowledge of the actual reimbursement TRC was receiving under the bundled PPS (Hyland T. Vol. 4 pp. 765-66). Further, Mr. Hyland, TRC's only expert witness at the contested case hearing, had no opinion as to whether TRC's projected reimbursement for Medicare treatments was reasonable. (Hyland T. Vol. 4 pp. 767-69).

106. Therefore, TRC failed to base its revenue projections on reasonable and supported assumptions, and the CON Section had no basis upon which to judge the reasonableness of TRC's "Adjustment for Bundling," or its underlying projected revenues.

*BMA's Comments regarding TRC's Financial Projections*

107. In its written competitive comments to the CON Section during the Review, BMA commented that TRC's projected revenues were inconsistent with the ESRD PPS that took effect in January 2011. (Smith T. Vol. 2 pp. 250-51, Rupp T. Vol. 1 pp. 92-93; Joint Ex. 1 pp. 63-64).

108. BMA's written comments specifically noted that TRC's projected Medicare revenues were likely overstated in light of BMA's own experience under the bundled PPS, in which Medicare reimbursed approximately $234.00 per treatment, much less than the revenues projected by TRC; and that TRC should be found nonconforming with Criterion 5 because the project would lose money in the second operating year if correct Medicare reimbursement rates were taken into account. (Joint Ex. 1 pp. 63-64).

109. Ms. Rupp reviewed the comments submitted by BMA on this issue, but only after having already drafted proposed Agency findings in which she determined that TRC's projected reimbursement was "consistent with the standard Medicare/Medicaid rates." (Rupp T. Vol. 1 p. 50, 80-81). In actuality and contrary to Ms. Rupp's findings, TRC's projected reimbursement was not consistent with the standard Medicare/Medicaid rates.

110. Ms. Rupp made no attempt to investigate or determine whether TRC's projected charges and revenues were reasonable (*see* Ex. 115, Rupp Dep. p. 122-23, 139-140), even though the information for current Medicare reimbursement rates was readily available to her. (Rupp T. Vol. 1 p. 92).

111. Ms. Rupp concedes that she was not familiar with the new system for reimbursement (PPS) prior to this review. Even though she was not previously familiar, she simply made assumptions without testing the data supplied. She assumed that the projections for "EPO & Other Ancillaries" and "Adjustment for Bundling" were reasonable because she found the rest of the information submitted to be reasonable. She brought BMA's comments and concerns to the attention of the CON Section Chief, Mr. Smith. (Rupp T. Vol. 1 pp. 87-88, 96-97, 105).

112. Mr. Smith reviewed BMA's comments, but assumed that TRC was undergoing a phase-in or "transition period" in which existing dialysis facilities could elect to transition to the bundled PPS over several years. (Smith T. Vol. 2 p. 262). As a result of this assumption, Mr. Smith was not concerned that TRC's projected Medicare revenues were similar to those in its previous applications. (Smith T. Vol. 2 p. 262). Therefore, Mr. Smith also made no attempt to investigate or determine whether TRC's projected revenues were reasonable. (Ex. 116, Smith Dep. pp. 80, 94-96).

113. Mr. Smith made no changes to Ms. Rupp's draft findings, and the Agency concluded that "[TRC]'s rates in Section X.1 of the application were consistent with the standard Medicare/Medicaid rates." The Agency thus found TRC conforming with Criterion 5. (*See, e.g.*, Joint Ex. 1 pp. 468-69; Rupp T. Vol. 1 p. 105).

114. Although BMA's comments specifically represented that TRC's parent company had elected to participate in the bundled PPS 100 percent at its inception, and therefore no transition period would have applied, Mr. Smith testified that he had simply not noticed that part of BMA's comments during the review. (Joint Ex. 1 pp. 63-64; Smith T. Vol. 2 p. 262).

115. Mr. Smith acknowledged at the hearing that his assumption that TRC had opted into a transition period for the implementation of the bundled payment system was incorrect, and that information before the Agency during the Review showed that TRC's projected Medicare revenues could not be the result of a transition period to the new ESRD PPS. (Smith T. Vol. 2 pp. 262-63).

116. Mr. Smith also acknowledged that the available transition period would have ended in 2013, before the beginning of TRC's projected operating year 2, the period upon which financial feasibility is judged. (Smith T. Vol. 2 pp. 266-67; *see also* Ex. 105 pp. 2, 4-5; Joint Ex. 6 pp. 49162-64).

117. Mr. Smith testified that, had he correctly understood the information presented to the CON Section during the Review, he would have tried to determine if the correct Medicare rates had been used. (Smith T. Vol. 2 p. 263-64).

118. Further, Mr. Smith testified that TRC did not sufficiently address the Medicare bundled PPS in its Application, and that the use of the correct Medicare rates could impact TRC's conformity with Criterion 5. (Smith T. Vol. 2 pp. 268-69; Smith Dep. pp. 100-101).

*Effect of the Bundled PPS on TRC's Financial Projections*

119. BMA's expert witness, Robert J. Cimasi, testified and provided a detailed analysis demonstrating that if TRC's projections had taken into account the correct Medicare reimbursement rates under the ESRD PPS, the project would show an operating loss in its second year. (Cimasi T. Vol. 3 p. 541-42; Joint Ex. 28).

120. Mr. Cimasi's analysis assumed that TRC's average Medicare reimbursement per procedure in the first operating year would equal the 2012 ESRD PPS base rate of $234.81, increased by one percent (to $237.16) in the second operating year, rather than projecting revenue per treatment separately from reimbursement for EPO and Other Ancillaries and reducing revenues by 2 percent as TRC did in its Adjustment for Bundling line item. (Joint Ex. 28 pp. 5-7; Joint Ex. 3 pp. 74-75).

121. Mr. Cimasi's analysis corrected for TRC's erroneous projections of per-treatment reimbursement and separate reimbursement for "EPO and Other Ancillaries" and its erroneous "Adjustment for Bundling." Mr. Cimasi made no changes to TRC's projected expenses except for removing the projected income tax to account for the projected loss. (Joint Ex. 28 pp. 5-7, Schedules 1-4; Cimasi T. Vol. 3 pp. 538-39).

122. Mr. Cimasi concluded that, using proper Medicare reimbursement rates under the ESRD PPS, TRC would suffer a loss of $127,860 in its second operating year instead of the $116,381 profit projected by TRC in its application. (Cimasi T. Vol. 3 pp. 541-42; Joint Ex. 28 p. 7, Schedules 3-4).

123. As set forth above, TRC purported to reduce its total revenue projection by two percent to account for the bundled PPS. TRC failed to provide any assumptions or explanation to support its projected 2 percent reduction or explain its significance, and similarly failed to give any explanation or assumptions to support its projected revenue for "EPO and Other Ancillaries." (Joint Ex. 3 pp. 74-75, Tables X.1, X.2, X.3).

124. Although TRC projected a $45,756 reduction for "Adjustment for Bundling," Mr. Cimasi's report demonstrated that TRC overstated its revenue projections by over one hundred thousand Dollars, even taking into account TRC's "Adjustment for Bundling." (*See, e.g.*, Joint Ex. 28 p. 7, Schedules 3-4; Cimasi T. Vol. 3 pp. 542-44).

125. It is found as fact that TRC's revenue projections were inconsistent with the Medicare bundled PPS in effect at the time of the Review, and were unreasonable, unsupported and overstated. Further, TRC's "Adjustment for Bundling" set forth in Table X.2 of its application was unreasonable, unsupported, and failed to adequately account for actual Medicare reimbursement in effect during the Review. Had TRC's revenue projections correctly taken into account actual Medicare reimbursement, TRC's projections would have shown an operating loss in operating year 2, and TRC's proposed project would have been deemed not financially feasible.

126. Both Mr. Smith and Ms. Rupp testified that it was possible for an applicant to not showing a profit at the end of the second year and still be considered financially feasible. Alternatively, Mr. Smith offered that if the applicant was not profitable at the end of the second year then the agency could look to a third year for projected financial feasibility. Neither of these options is reasonable or justified.

127. The Agency strives very diligently to have consistency with Findings from similar applications. This allows those seeking a CON to feel some level of comfort in their respective applications so long as they are consistent with the prior findings of the agency. To have such consistency, the agency projects to the applicants what it expects to see in like applications in order to be successful.

128. Both Mr. Smith and Ms. Rupp acknowledge that to their collective knowledge there has never been an application where the applicant projected a loss in the second year. Further, the application requests the financials through the second year.

129. The credible and believable evidence is that to this point it has not been an accepted practice to show a loss at the end of year two and still be considered feasible, and it has not been the practice to allow consideration of a third year's financials. To interject such into consideration of future applications would interject a completely new dynamic into the CON process. Such would conceivable significantly change the approach many applicants would use in their applications. Such would also be completely inconsistent with what has been required and reviewed since the very inception of CON applications.

130. Mr. Smith also raises the point that the aggregate number derived in both applications is only about seven dollars apart, which raises the rather rhetorical question of whether or not it matters how you get there, so long as you get the same answer. (Agency File,

Findings, pp. 498-99) The answer in this case is "yes" it does matter. If the Medicaid numbers are flawed, then there have to be adjustments to the other numbers from the other payor groups—the money has to be compensated from some source. Of major import is that the numbers used in this case have no justification, no basis. To find that the methodology is flawed but that it is alright because it produces ultimately the correct number without justification opens the agency to yet another unanticipated dynamic. It would be unreasonable to allow applications to submit numbers to justify financial feasibility without any justification. TRC's application failed in that regard and it would not be prudent to now try to justify that failing by opening up prospective applications to follow that same path. It would also not be consistent with what has been required in applications historically.

131. TRC's approach in this case of not justifying the source of its numbers allows TRC to completely ignore the federal regulations process for getting reimbursed, and it has been allowed to do so from the outset of the change of the regulations. Mr. Hyland even stated that it is his intention to continue to use this same methodology in applications. For the agency to allow and in essence endorse this methodology is error.

**Criterion 13(c)**

132. Criterion 13(c) requires an applicant to demonstrate "[t]hat the elderly and the medically underserved groups . . . will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services." N.C. Gen. Stat. § 131E-183(a)(13)(c).

133. In evaluating applicants' conformity with Criterion 13(c), the CON Section requires projections of the percentage of the total projected dialysis treatments an applicant expects to provide for each payor source, including Medicare, Medicaid, indigent, VA, and commercial insurance ("payor mix"). (Ex. 106 p. 13; Rupp T. Vol. 1 pp. 114-15).

134. The CON Section requires that an applicant's payor mix projections be based on reasonable and supported assumptions. (Rupp T. Vol. 1 p. 115).

135. Mr. Hyland prepared TRC's payor mix projections. (Hyland T. Vol. 4 p. 705).

136. BMA based its projected payor mix on actual historical payor mix at an existing BMA facility in Harnett County. TRC has no existing facilities inside Harnett County and therefore based its projected payor mix on the payor mix at an existing TRC facility in Moore County, which is outside the service area but contiguous to Harnett County. (Joint Ex. 2 pp. 56-57; Joint Ex. 3 p. 60; Hyland T. Vol. 4 pp. 704-05).

137. Moore and Harnett Counties are both rural counties. Moore County is contiguous to Harnett County and located to the southwest of Harnett County, and TRC's proposed Harnett County facility will be located in the southwest part of Harnett County. (Rupp, Vol. 1, p. 116; Jt. Ex. 3, pp. 40, 60).

138. TRC projected its payor mix by taking the patient population on a single day, August 2, 2011, at an existing DaVita facility in Moore County and projecting an identical payor

mix for its proposed facility in Harnett County. (Hyland T. Vol. 4 pp. 704-05, 783; Joint Ex. 3 p. 60).

139. The TRC Application provided no data or other information to demonstrate that the patient populations of Harnett County and Moore County are similar or that the populations of each county were economically or demographically comparable, other than noting that Moore County is contiguous to and located to the Southwest of Harnett County. (Joint Ex. 3 p. 60; *see, e.g.*, Rupp T. Vol. 1 pp. 115-16).

140. Mr. Hyland admitted that he did no analysis to determine if the demographics of Moore County and Harnett County were sufficiently similar to justify using a Moore County payor mix without making any adjustments. (Hyland T. Vol. 4 pp. 788-97).

141. Mr. Hyland did not attempt to consult historical payor mix information from multiple existing dialysis facilities in Harnett County in projecting payor mix for the proposed TRC facility. (Hyland T. Vol. 4 pp. 785-88).

142. During the Review, BMA's written comments noted that TRC's payor mix projections were not reasonable since they were based on TRC's experience outside the county which standing alone may not be significant. However, BMA further noted a prior 2010 Randolph County dialysis CON review (the "Randolph County Review") in which an applicant was found nonconforming with Criterion 13(c) because it similarly based its payor mix projections on a facility outside the county at issue, located in a contiguous county, just as here. (Joint Ex. 1 p. 62; Joint Ex. 4, pp. 33-35).

143. Ms. Rupp read BMA's comments but did not review the Agency's findings from the Randolph County Review, and she made no attempt to analyze whether Moore and Harnett Counties were demographically similar. (Rupp T. Vol. 1 pp. 115-16, 125-26).

144. Ms. Rupp reviewed demographic data for Harnett County and included it in the Agency's working papers, but she did not review any similar data for Moore County. (Joint Ex. 1 p. 197; Rupp T. Vol. 1 p. 173) Instead, Ms. Rupp simply "assumed or concluded that the applicant based its projections on a similar experience" and found the TRC Application conforming to Criterion 13(c). (Rupp T. Vol. 1 p. 137; Ex. 115, Rupp Dep. p. 92).

145. When asked in her deposition what she considers in payor mixes, Ms. Rupp responded that it "hasn't been her practice to look at other things." She stated more than once that the reviewers simply do not have time to look into everything. Whether or not her approach to this issue is reasonable will be addressed below.

146. The Agency made no attempt to determine whether it was reasonable to assume that the payor mix at the proposed TRC facility in Harnett County would have a similar payor mix to a facility in Moore County. (*See, e.g.*, Rupp T. Vol. 1 pp. 115-16; Ex. 115, Rupp Dep. pp. 87-88; Ex. 116 Smith Dep. pp. 57-58).

147. In multiple prior CON reviews, the Agency refused to accept similar payor mix projections at face value and independently investigated publicly available data to determine if

an applicant's reliance on historical payor mix at a facility in a contiguous county was reasonable. (*See, e.g.*, Joint Exs. 4-5, 12).

148. For example, the Randolph County Review also involved TRC and BMA. In that review, TRC essentially used the exact same methodology as the instant case, contending that Randolph and Montgomery counties are both rural and contiguous, with no other justification. In that review, the Agency found TRC non-conforming to Criterion 13(c) because it based its payor mix on a TRC facility in Montgomery County without demonstrating that the economic status of residents or the payor mix in Montgomery County was comparable to that of Randolph County. (Joint Ex. 4 pp. 33-34).

149. In the Randolph County Review, the Agency analyst reviewed U.S. Census Bureau data and identified significant differences in the poverty level, income level, and racial make-up of the populations in the two counties. (Joint Ex. 4 p. 34). As a result, the Agency determined that "it is not reasonable to assume that these two counties, although contiguous, are comparable in economic status." (Joint Ex. 4 p. 34). The Agency concluded that TRC failed to show that its payor mix projections were based on reasonable and supported assumptions, and therefore found TRC non-conforming to Criterion 13(c). (Joint Ex. 4 p. 34).

150. The Randolph County Review was in 2010, approximately one year prior to the review at issue herein. Based upon the Randolph County Review, TRC was aware that the Agency found its application deficient, but TRC continued to use the same methodology. The Randolph County Review was not conducted by Ms. Rupp, but she had access to this review and did not rely on it.

151. Likewise, the Agency took a similar approach in the 2011 Northampton County dialysis CON review (the "Northampton County Review"), which was conducted simultaneously with the Review at issue, and which also involved the same two companies. (*See* Joint Ex. 12).

152. In the Northampton County Review, Mr. Hyland prepared the application of another DaVita entity and based its payor mix on an existing DaVita facility in neighboring Hertford County. (*See* Joint Ex. 12 pp. 33-34; Hyland T. Vol. 4 pp. 747, 790).

153. The decision in the Northampton County Review was issued the same day as the decision at issue in this contested case; however the Agency took a different approach to Criterion 13(c). Ms. Rupp was not the analyst who reviewed the Northampton County applications.

154. In the Northampton County review, the Agency ultimately found the DaVita applicant conforming to Criterion 13(c), but only after analyzing U.S. Census Bureau data that showed that Northampton and Hertford Counties were very similar in terms of income, poverty levels, population, and Medicaid eligibility, and therefore determining that "it is reasonable to assume that these two contiguous counties are comparable in terms of economic status." (Joint Ex. 12 p. 34).

155. The information used by the analysts in the Randolph County Review and the Northampton County Review was readily and easily accessible to Ms. Rupp, but she chose not to rely on that information.

156. The Agency considers consistency to be important, and the Agency strives to be consistent in the way it deals with issues from review to review. (*See, e.g.*, Rupp T. Vol. 1 p. 173; Ex. 115, Rupp Dep. pp. 31-32; Ex. 116, Smith Dep. p. 17).

157. Despite the fact that this Review, the Randolph County Review, and the Northampton County Review all involved the same company using the same approach for projecting payor mix, the Agency was not consistent in its analysis between the reviews. (Smith T. Vol. 5 p. 892).

158. Mr. Swann, an expert for BMA, testified that publicly available U.S. Census Bureau data for Harnett County and Moore County show that on similar factors (county population, per capita income, percentage below poverty, percentage African American), Harnett and Moore Counties are significantly different, and that if the Agency acted consistently with its other reviews, it would have found TRC nonconforming with Criterion 13c, as it did a year earlier in the 2010 Randolph County review. (Swann T. Vol. 3 pp. 388-96; *see also* Ex. 119; Joint Ex. 10).

159. For example, Harnett County's population is 33 percent larger than that of Moore County, and Moore County has a much higher percentage of white residents and lower percentage of African Americans than does Harnett County. (Ex. 119; Joint Ex. 10) Statistically, African Americans require a significantly higher use of dialysis than whites. Furthermore, the per capita income in Moore County is 33 percent higher than in Harnett County, and it has a lower rate of poverty than Harnett County. (Ex. 119; Joint Ex. 10).

160. The Agency's analysis in the Randolph County and Northampton County reviews has also been mirrored in other non-dialysis CON reviews. For example, in a 2007 Johnston County MRI review (the "Johnston County Review"), the Agency found an applicant nonconforming to Criterion 13(c) where its projected payor mix for a proposed Johnston County facility was based on its payor mix at an existing facility in neighboring Wake County. (*See* Joint Ex. 5, pp. 25-26).

161. In the Johnston County Review, the Agency noted that the applicant did not demonstrate that the demographics of Wake and Johnston Counties were sufficiently similar to justify using a Wake County payor mix. (Joint Ex. 5 p. 26).

162. Other reviews have found applicants to be conforming with what may have been less comparative information than in the Randolph and Northampton County reviews; however, based upon the facts and circumstances of this contested case it is found as fact that TRC's projected payor mix was not based on reasonable and supported assumptions, and the Agency failed to analyze the basis and reasonableness of TRC's payor mix projections, inconsistently with prior and concurrent reviews.

**Reasonable Assumptions**

163. The following discussion is included to clarify the decision making process for both the Agency and this Tribunal. The Undersigned has not undertaken such an evaluation previously but feels that it is particularly important in this contested case, and to hopefully insure consistency.

164. In her discussions of Criterion 5 and Criterion 13(c), Ms. Rupp tries to justify her findings by rather dismissively stating that she did not have the time to look at everything in the applications. In Criterion 5, she found it "reasonable to assume" that the numbers provided by TRC were "reasonable" and therefore justified without any information to substantiate where or how the numbers were derived. In Criterion 13(c) she found it "reasonable to assume" the demographics of two counties in North Carolina were sufficiently similar solely because they were both rural and contiguous.

165. The position Ms. Rupp assumes, and thus the Agency, begs the question of what is "reasonable" in conducting the CON reviews. At what point is it sufficient to merely rely on the information provided by the applicants without further test? And if such is the practice, where does the Agency draw the line? How does one determine that information appears to be reasonable, and then assume it to be reasonable and move on?

166. To answer those questions becomes a purely subjective decision made by each individual analyst. The question then becomes whether or not the decision made by the analyst is "reasonable."

167. Preliminarily, one must determine whether or not it is even appropriate for this Tribunal to question those decisions.

168. N.C. Gen. Stat. Ann. § 150B-34 states that "[t]he administrative law judge shall decide the case based upon the preponderance of the evidence, giving due regard to the demonstrated knowledge and expertise of the agency with respect to facts and inferences within the specialized knowledge of the agency." The facts and inferences within Criteria 5 and 13(c) are certainly not specialized knowledge particular to the agency. There has been no showing, or even inference, that the agency has any particular expertise or knowledge regarding those facts. In fact, just the opposite is true.

169. Based upon N.C. Gen. Stat. Ann. § 150B-34 as applied to this contested case, the assumptions made by the agency regarding Criteria 5 and 13(c) are not entitled to any special deference other than to assess them according to a test of reasonableness.

170. As to whether or not the agency is entitled to any particular "deference" in how it has addressed these issues in this particular contested case is a separate issue.

171. Far and away, the majority of appellate cases on "agency deference" speak in terms of the reviewing court looking at what the agency did as a final decision. Essentially, so long as the agency gives a reasonable interpretation of statute or rule, then the agency may be afforded "deference". The reviewing appellate court does not have to adopt the agency's interpretation, especially if it is clearly erroneous. The reviewing appellate court does not have to adopt the agency's interpretation if the statute or rule is plain, un-ambiguous and not subject to interpretation; i.e., the agency is not free to interpret what the General Assembly intended unless there is ambiguity. *See for example*: Rainey v. N.C. Dep't of Pub. Instruction, 361 N.C. 679, 681, 652 S.E.2d 251, 252–3 (2007); Cashwell v. Dep't of State Treasurer, Ret. Sys. Div., 196 N.C. App. 81, 89, 675 S.E.2d 73, 78-79 (2009); Hensley v. N. Carolina Dep't of Env't & Natural Res., 201 N.C. App. 1, 34, 685 S.E.2d 570, 593-94 (2009) rev'd sub nom. Hensley v. N. Carolina

*Dept. of Env't & Natural Res., Div. of Land Res.*, 364 N.C. 285, 698 S.E.2d 41 (2010). *Britthaven, Inc. v. N.C. Dept. Of Human Resources*, 118 N.C. App. 379, 385, 455 S.E.2d 455, 461; *Total Renal Care Of N. Carolina, LLC v. N. Carolina Dept. of Health & Human Services, Div. of Facility* Services, Certificate of Need Section, 171 N.C. App. 734, 740, 615 S.E.2d 81, 85 (2005)

172. *Wells v. Consol. Judicial Ret. Sys. of N. Carolina*, 354 N.C. 313, 319-20, 553 S.E.2d 877, 881 (2001) states:

> Nevertheless, it is ultimately the duty of courts to construe administrative statutes; courts cannot defer that responsibility to the agency charged with administering those statutes. This does not mean, however, that courts, in construing those statutes, cannot accord great weight to the administrative interpretation, especially when, as here, the agency's position has been long-standing and has been met with legislative acquiescence. (Internal citations omitted).

173. None of the appellate cases impute deference to staff and the day to day operations of any agency. The interpretation of the policies or rules or statutes by the individual person doing the work is not the concern of the appellate courts in "agency deference." In *Canady v. N. Carolina Coastal Res. Comm'n*, 206 N.C. App. 329, 698 S.E.2d 557 (2010), an unpublished opinion, the Court of Appeals acknowledged that typically the deference was to the agency's appellate panel and not the staff. While the unpublished opinion is not cited as legal authority, the Canady case is consistent with the reported cases on agency deference.

174. Even if the agency's staff was entitled to some deference, which it was not, Ms. Rupp was not relying on an agency interpretation of a rule of a statute, nor substituting her own interpretation. She merely chose to in essence accept the applicant's information at face value without further testing, even though it was not supported in the application.

175. The agency's approach to Criteria 5 and 13(c) to simply accept TRC's numbers and county demographics for payor mix is not entitled to any special consideration. As stated above, it is a question of whether or not the agency's decisions were reasonable under the facts and circumstances of this particular case.

176. "Reason" is defined as "A faculty of the mind by which it distinguishes truth from falsehood, good from evil, and which enables the possessor to deduce inferences from facts or from propositions." (thelawdictionary.org)

177. "Reasonable" is defined as "agreeable to reason; just; proper; or ordinary or usual." (thelawdictionary.org). To be reasonable one then must be able to distinguish truth from falsehood, and the reasonable person must be able to deduce inferences from the propositions.

178. From the information provided in Criterion 5and Criterion 13(c), it was not "reasonable" for Ms. Rupp to assume the facts given by TRC were valid without anything further. There were no bases given by TRC. There were no assumptions provided by TRC. In making the assumptions in Criterion 5, Ms. Rupp relied on law that was no longer valid. In

making the assumptions in Criterion 13(c), she would have been quite capable of finding the information needed to justify or confirm the information provided by TRC but chose not to. The information was readily and easily available. The assumptions made by Ms. Rupp in Criterion 5 and Criterion 13(c) were not reasonable.

179. The Agency's findings were not supported by substantial evidence, that is "relevant evidence a reasonable mind might accept as adequate to support a conclusion." For the most part, the assumptions made by the agency were supported by little to no other evidence to substantiate TRC's contentions in Criteria 5 and 13(c). *Total Renal Care Of N. Carolina, LLC v. N. Carolina Dept. of Health & Human Services, Div. of Facility Services, Certificate of Need Section, 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005)*

180. This Tribunal is not so presumptuous as to attempt to establish guidelines as to when and under what circumstances the agency can or should consider information provided by an applicant at face value without further testing. These findings are particular to this contested case. However, the agency must be mindful that the mere fact that the agency says something is fact does not establish it as fact without further scrutiny. Indeed, maybe the analyst do not have time to check into every nuance of an application; however, in choosing to not test any particular fact and conclude that it is based upon "reasonable assumptions" may in fact be an unreasonable assumption in and of itself.

**The Comparative Analysis**

181. In competitive reviews, the Agency first analyzes each application for conformity with the applicable statutory and regulatory review criteria, and then engages in a comparative analysis to determine which application is comparatively superior. (Rupp T. Vol. 1 pp. 139-140).

182. If an application is not conforming or conditionally conforming to all of the applicable review criteria, it cannot be found comparatively superior or approved for a CON. (*See, e.g.*, Rupp T. Vol. 1 pp. 73-78; Smith T. Vol. 1 pp. 184-85; Smith T. vol. 5 p. 905).

183. In the Review, the Agency found BMA nonconforming with certain review criteria and TRC fully conforming. (Joint Ex. 1, pp. 447-501). The Agency found TRC to be the comparatively superior applicant and therefore awarded it the CON. (Joint Ex. 1 pp. 495-501).

184. If TRC had been found nonconforming to either Criterion 5 or Criterion 13(c), it would not have been an approvable applicant and could not have been found comparatively superior. (*See, e.g.*, Rupp T. Vol. 1 p. 73).

185. Accordingly, the Undersigned finds as fact that, if BMA is fully conforming with all applicable statutory and regulatory review criteria and TRC is nonconforming, BMA is the only approvable applicant and would be the comparatively superior applicant.

Based upon the foregoing Findings of Fact, the Court makes the following

**CONCLUSIONS OF LAW**

1. To the extent that certain portions of the foregoing Findings of Fact constitute mixed issues of law and fact, such Findings of Fact shall be deemed incorporated herein by reference as Conclusions of Law. Similarly, to the extent that some of these Conclusions of Law are Findings of Fact, they shall be so considered without regard to the given label.

2. A court need not make findings as to every fact which arises from the evidence and need only find those facts which are material to the settlement of the dispute. *Flanders v. Gabriel*, 110 N.C. App. 438, 440, 429 S.E.2d 611, 612 (1993).

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

4. The Office of Administrative Hearings has jurisdiction over all the parties and the subject matter jurisdiction of this action.

5. As Petitioner, BMA bears the burden of proof on each and every element of its case. *Overcash v. N.C. Dep't of Env't & Natural Res.*, 179 N.C. App. 697, 704, 635 S.E.2d 442, 447-48 (2006).

6. Pursuant to N.C. Gen. Stat. § 150B-23(a), in a contested case hearing, "the ALJ is to determine whether the petitioner has met its burden in showing that the agency substantially prejudiced petitioner's rights, and that the agency acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule." *Britthaven v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995).

7. "The administrative law judge shall decide the case based upon the preponderance of the evidence, giving due regard to the demonstrated knowledge and expertise of the agency with respect to facts and inferences within the specialized knowledge of the agency." N.C. Gen. Stat. § 150B-134(a). The burden of persuasion placed upon a petitioner is the "greater weight of the evidence." *Dillingham v. N.C. Dep't of Human Res.*, 132 N.C. App. 704, 712, 513 S.E.2d 823, 828 (1999).

8. In a CON contested case, while the court is limited to a review of the information available to the CON Section at the time of the review, it is not limited to information that the Agency actually reviewed or relied upon in making its decision regarding an application. *Dialysis Care of N.C. v. N.C. Dep't of Health & Human Servs.*, 137 N.C. App. 638, 648, 529 S.E.2d 257, 262 (2000).

9. The Agency must evaluate CON applications pursuant to North Carolina's CON statute. *See* N.C. Gen. Stat. §§ 131E-182, 131E-183; *see also Living Centers-Southeast, Inc. v. N.C. Dep't of Health and Human Servs.*, 138 N.C. App. 572, 574, 532 S.E.2d 192, 194 (2000). In the initial review of the applications, the Agency must review each application individually to test it against the review criteria, without regard to any competing application.

10. The Agency must determine whether an application is consistent with, or not in conflict with, the review criteria set forth in N.C. General Statutes § 131E-183 and the standards, plans and criteria promulgated there under in effect at the time the review commences. 10A N.C.A.C. 14C.0207.

11. The review criteria are not optional, and the applicant must either conform to each separate criterion or be able to be found conditionally conforming in order for the application to be approved. *See Parkway Urology, P.A. v. N.C. Dep't of Health and Human Servs.*, 205 N.C. App. 529, 696 S.E.2d 187 (2010).

12. While there is a presumption that "an administrative agency has properly performed its official duties," that presumption is rebuttable by the requirement that petitioners must establish that the CON Section's decision is subject to reversal under one or more of the standards enumerated in N.C. Gen. Stat. § 150B–23(a) in order to mount a successful challenge to the CON Section's decision. (Citing *Britthaven*, 118 N.C. App. at 382, 455 S.E. 2d at 460). *East Carolina Internal Med., P.A. v. N. Carolina Dept. of Health & Human Services, Div. of Health Serv. Regulation, Certificate of Need Section*, 710 S.E.2d 245, 255 (N.C. Ct. App. 2011)

**THE BMA APPLICATION**

13. The Agency erred in determining that the BMA Application was nonconforming to 10A N.C.A.C. 14C .2202(b)(1) ("Rule .2202(b)(1)").

14. Rule .2202(b)(1) requires that an applicant proposing to develop a new dialysis facility provide an agreement or letter of intent to enter into an agreement with an acute care hospital that specifies the relationship between the two facilities and describes the services that the hospital will provide to patients of the dialysis facility. The rule incorporates by reference provisions of the federal Conditions for Coverage for Dialysis facilities which formerly included 42 CFR 405.2100, but which had been revised and moved to 42 CFR part 494 prior to the time of the Review.

15. Rule .2202(b)(1) is intended to ensure that the applicant will comply with the requirement in the federal Conditions for Coverage that a dialysis facility have agreement with an acute care hospital to serve the facility's patients in the event of an emergency. Rule .2202(b)(1) imposes no requirements in excess of the federal regulations.

16. The Agency's stated reasons for finding the BMA Application non-conforming are (1) that it was entitled a transfer agreement rather than an affiliation agreement and (2) that it did not sufficiently describe the relationship or the services the hospital would provide.

17. As to the former, neither 42 CFR 494.180(g)(3) nor Rule .2202(b)(1) itself makes any distinction between a transfer agreement or affiliation agreement. As to the latter, The CON Section Chief testified that the Agreement included in the BMA Application both described the relationship and described the services the hospital would provide.

18. Neither Rule .2202(b)(1) nor the federal regulations incorporated therein require any minimum set of services that must be described or identified in the hospital agreement.

19. BMA's Agreement complied with the plain language of Rule .2202(b)(1) and the federal Conditions for Coverage at 42 CFR 494.180(g)(3). Therefore, the Agency's determination that BMA's application did not conform with Rule .2202(b)(1) was unsupported by the evidence, and the Agency acted erroneously.

20. Further, the Agency erred as a matter of law in relying on the definition of "agreement" in 42 CFR 405.2102, which no longer applied, instead of 42 CFR.494.180(g), which sets forth the current requirements for a hospital agreement in the federal Conditions for Coverage for dialysis facilities.

21. In light of the decision in this contested case, it is not necessary to address whether or not BMA should have been found conditionally conforming; however, even if the BMA Application had failed to conform with Rule .2202(b)(1), the Agency could nonetheless have found BMA conforming to Rule .2202(b)(1) conditioned upon the provision of a conforming agreement.

22. Because the Agency erred in finding BMA non-conforming to Rule .2202(b)(1), it likewise erred in finding the BMA Application non-conforming to N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4"). The Agency's determination that the BMA Application was nonconforming to Criterion 4 was based solely on its erroneous determination that the BMA Application was nonconforming to Rule .2202(b)(1).

23. The greater weight of the evidence shows that the Agency properly found the BMA Application conforming to all other applicable statutory and regulatory review criteria.

24. Therefore, the Undersigned concludes that the Agency substantially prejudiced BMA's rights, acted erroneously, and failed to act as required by law or rule by failing to find that the BMA Application fully conformed with all applicable statutory and regulatory review criteria, and was an approvable application.

**THE TRC APPLICATION**

25. The Agency erred in finding the TRC Application conforming to N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5").

26. Criterion 5 requires, in part, that an applicant demonstrate that its proposed project is financially feasible based on reasonable projections of the costs of and charges for providing health services. N.C. Gen. Stat. § 131E-183(a)(5).

27. An applicant's financial projections must be based on reasonable and supported assumptions.

28. TRC failed to provide reasonable projections of the costs of and charges for providing health services, and failed to base its financial projections on reasonable and supported assumptions. Its revenue projections for Medicare treatments and for "EPO and Other

Ancillaries", which comprised the large majority of its total projected revenues, were overstated, unreasonable and unsupported, and its "Adjustment for Bundling" line item was unreasonable and unsupported, and failed to account for actual Medicare reimbursement for dialysis services at the time of the Review.

29. The greater weight of the evidence shows that had TRC's financial projections properly accounted for Medicare reimbursement under the ESRD PPS in effect at the time, it would have projected a significant operating loss in the second year of operation.

30. Had the Agency investigated actual Medicare reimbursement in effect at the time of the Review, the greater weight of the evidence demonstrates that it would have reached the conclusions that (a) TRC's revenue projections were inconsistent with the Medicare ESRD PPS, and were therefore not based on reasonable and supported assumptions; (b) TRC overstated its projected revenues, and if the correct Medicare reimbursement rates been projected, its projections would have shown a loss in operating year two; and (c) TRC's projected 2 percent "adjustment for bundling" was not based on reasonable or supported assumptions and failed to correct TRC's overstated revenue projections.

31. Therefore, the greater weight of the evidence demonstrates that TRC failed to demonstrate that its project would be financially feasible, and the Agency's conclusion that the TRC application was conforming with Criterion 5 was erroneous and not supported by the evidence.

32. The Agency erred in finding the TRC Application conforming to N.C. Gen. Stat. § 131E-183(a)(13)c ("Criterion 13(c)").

33. Criterion 13(c) requires an applicant to demonstrate the extent to which the elderly and medically underserved will have access to the proposed services and the extent to which such groups are expected to utilize the proposed services. N.C. Gen. Stat. § 131E-183(a)(13)c. For that purpose, the Agency requires an applicant to project, by percentage, the total projected dialysis treatments an applicant will provide for each payor source, including Medicare, Medicaid, indigent, VA, and commercial insurance.

34. An applicant's projections of payor mix must be based upon reasonable and supported assumptions. However, TRC provided no information or assumptions to demonstrate that the demographics of Moore County and Harnett County were sufficiently similar that it was reasonable to assume that the payor mix of the proposed Harnett County facility would mirror the payor mix of its existing Moore County facility.

35. Although it could have done so and had done so in multiple, analogous CON reviews, the Agency failed to investigate or analyze whether TRC's payor mix projections were reasonable, but instead simply accepted the projections at face value.

36. The greater weight of the evidence demonstrates that there are significant differences in the demographics of Moore County and Harnett County, such that it was not reasonable to assume a payor mix identical to TRC's existing facility in Moore County.

37. By failing to analyze the basis for TRC's payor mix projections, the Agency not only failed to evaluate whether TRC's projections were based on reasonable and supported assumptions, but also applied Criterion 13(c) inconsistently with other similar reviews. In doing so, the Agency acted erroneously, arbitrarily, and capriciously.

38. Therefore, the Undersigned concludes that the Agency substantially prejudiced BMA's rights, acted erroneously, and failed to act as required by law or rule by finding the TRC Application conforming with N.C. Gen. Stat. §§ 131E-183(a)(5) and 131E-183(a)(13)c, and therefore that it was an approvable application.

**THE COMPARATIVE ANALYSIS**

39. Because the TRC Application was nonconforming to Criteria 5 and 13(c), it is not an approvable applicant and cannot be found comparatively superior. N.C. Gen. Stat. § 131E-183(a).

40. Because the TRC Application is not approvable and the BMA Application was approvable, the Agency erred in failing to find the BMA Application the more superior application and award it the CON.

41. Therefore, the Undersigned concludes that the Agency substantially prejudiced BMA's rights, acted erroneously, exceeded its authority or jurisdiction, and failed to act as required by law or rule by failing to find the BMA Application to be the comparatively superior Application, and by failing to approve the BMA Application and deny the TRC Application

**FINAL DECISION**

Based upon the foregoing findings of fact and conclusions of law, the Undersigned hereby enters the following FINAL DECISION pursuant to N.C. Gen. Stat. §§ 150B-134 and 131E-188, based upon the preponderance of the evidence, having given due regard to the demonstrated knowledge and expertise of the agency with respect to facts and inferences within the specialized knowledge of the agency.

IT IS HEREBY ORDERED as follows:

1. The decision of the North Carolina Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need Section in the Review is hereby **REVERSED**;

2. The TRC Application is hereby denied; and

3. Within five (5) business days of the date of this Final Decision, the Agency shall, via written communication to the Parties, approve or "approve with conditions" the BMA Application, pursuant to N.C. Gen. Stat. § 131E-186, for a Certificate of Need for a new dialysis facility with eleven dialysis stations in Harnett County. The Agency shall not impose any condition on such approval that is inconsistent with this Final Decision.

35

**NOTICE**

Under the provisions of North Carolina General Statute 131E-188(b), any party wishing to appeal the final decision of the Administrative Law Judge must file a Notice of Appeal with the Office of Administrative Hearings and serve the Notice on the N.C. Department of Health and Human Services and all other affected persons who were parties to the contested case. The appealing party must file the Notice within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision. Pursuant to N.C. Gen. Stat. 131E-188(b1) before filing an appeal of a final decision granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. In conformity with the Office of Administrative Hearings' rule 26 N.C.A.C. 03.012 and the Rules of Civil Procedure, N.C. Gen. Stat. 1A-1, Article 2, this Final Decision was served on the parties the date it was placed in the mail as indicated by the date on the Certificate of Service attached to this Final Decision.

IT IS SO ORDERED.

This the 17th day of December, 2012.

Donald W. Overby
Administrative Law Judge

On this date mailed to:

Elizabeth Sims Hedrick
Marcus C. Hewitt
Williams Mullen
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Raleigh, NC 27602-1000
Attorneys for Petitioner

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Attorney for Respondent-Intervenor

This the 17th day of December, 2012.

Vicki Bullock
N. C. Office of Administrative Hearings
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| | |
|---|---|
| **STATE OF NORTH CAROLINA** | **IN THE OFFICE OF ADMINISTRATIVE HEARINGS** |
| **COUNTY OF COLUMBUS** | **12 DOJ 03843** |
| **MATTHEW BRIAN HAYES,** | |
| **Petitioner,** | |
| **v.** | **PROPOSAL FOR DECISION** |
| **N.C. CRIMINAL JUSTICE EDUCATION AND TRAINING STANDARDS COMMISSION,** | |
| **Respondent.** | |

In accordance with North Carolina General Statute § 150B-40(e), Respondent requested the designation of an administrative law judge to preside at an Article 3A, North Carolina General Statute 150B contested case hearing of this matter. Based upon the Respondent's request, Senior Administrative Law Judge Fred G Morrison Jr. heard this contested case in Raleigh, North Carolina on September 6, 2012.

## APPEARANCES

Petitioner: Matthew Brian Hayes
393 Pete Strickland Road
Cerro Gordo, North Carolina 28430-9632

Respondent: Catherine F. Jordan, Assistant Attorney General
N.C. Department of Justice
9001 Mail Service Center
Raleigh, North Carolina 27699-9001

## ISSUE

Did Respondent properly find Petitioner's certification as a correctional officer was subject to denial, suspension or revocation because Petitioner committed the felony offense of possession of a stolen firearm?

BASED UPON careful consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the undersigned Administrative Law Judge makes the following FINDINGS OF FACT.

In making the FINDINGS OF FACT, the undersigned Administrative Law Judge has weighed all the evidence and has assessed the credibility of the witnesses by taking into account the appropriate factors for judging credibility, including, but not limited to, the demeanor of the witness, any interests, bias, or prejudice the witness may have, the opportunity of the witness to see, hear, know or remember the facts or occurrences about which the witness testified, whether the testimony of the witness is reasonable, and whether the testimony is consistent with all other believable evidence in the case.

**RULES AT ISSUE**

12 NCAC 09G .0504(a)
12 NCAC 09G .0505(a)(1)
N.C.G.S. § 14-71.1 (2011)

**FINDINGS OF FACT**

1. Both parties are properly before this Administrative Law Judge, in that jurisdiction and venue are proper, both parties received Notice of Hearing, and Petitioner received the notification of Proposed Revocation of Correctional Officer Certification through a letter mailed by Respondent on March 14, 2012. (Respondent's Exhibit 16)

2. The North Carolina Criminal Justice Education and Training Standards Commission has the authority granted under Chapter 17C of the North Carolina General Statutes and Title 12 of the North Carolina Administrative Code, Chapter 9G, to certify correctional officers and to revoke, suspend, or deny such certification.

3. 12 NCAC 09G .0504(a) states: "The Commission shall revoke the certification of a correctional officer, probation/parole officer, or probation/parole officer-intermediate when the Commission finds that the officer has committed or been convicted of a felony offense."

4. N.C.G.S. § 14-71.1 (2011) sets forth the felony offense of possession of stolen goods, and states: "If any person shall possess any chattel, property, money, valuable security or other thing whatsoever, the stealing or taking whereof amounts to larceny or a felony, either at common law or by virtue of any statute made or hereafter to be made, such person knowing or having reasonable grounds to believe the same to have been feloniously stolen or taken, he shall be guilty of a Class H felony, and may be indicted and convicted, whether the felon stealing and taking such chattels, property, money,

valuable security or other thing shall or shall not have been previously convicted, or shall or shall not be amenable to justice; and any such possessor may be dealt with, indicted, tried and punished in any county in which he shall have, or shall have had, any such property in his possession or in any county in which the thief may be tried, in the same manner as such possessor may be dealt with, indicted, tried and punished in the county where he actually possessed such chattel, money, security, or other thing; and such possessor shall be punished as one convicted of larceny."

5. 12 NCAC 09G .0505(a)(1) states: "When the Commission revokes or denies the certification of a corrections officer pursuant to 12 NCAC 09G .0504 of this Section, the period of the sanction shall be 10 years where the cause of sanction is . . . commission or conviction of a felony offense."

**RESPONDENT'S EVIDENCE**

6. On or about May 17, 2004, Respondent received a Report of Appointment Form F-5A for Petitioner for his application for certification as a correctional officer. (Respondent's exhibit 1)

7. On May 20, 2004, Petitioner received his probationary certification as a correctional officer with Respondent. (Respondent's exhibit 2)

8. On May 17, 2005, Petitioner received his general certification as a correctional officer with Respondent. (Respondent's exhibit 3)

9. Respondent's Officer's Complete History form showed that Petitioner is employed with the North Carolina Department of Corrections, and that his date of appointment was May 17, 2004. (Respondent's exhibit 4)

10. On September 19, 2008, Columbus County Sheriff's Office Deputy Aaron Herring ("Deputy Herring") responded to a call after a breaking and entering occurred at 455 Greens Mill Road in Clarkton, North Carolina, the residence of Miles Dewey Little ("Little"). (Respondent's exhibit 5) On September 19, 2008, Deputy Herring completed an incident/investigation report. (Respondent's exhibit 5) The report listed stolen property including a Browning .270 Auto with Scope Rifle with serial number 137PT06545 valued at $1500.00 and a Browning .270 Bolt Action with Scope with serial number 12587NT8C7 valued at $800.00. The incident report listed a total of eight stolen firearms and listed damage to Little's dwelling's rear door valued at $600.00.

11. On September 19, 2008, Deputy Herring wrote in his investigation report that "On 9-19-08 I Deputy Aaron Herring responded to 455 Greens Mill Road and spoke to Miles Dewey Little he told me that while he was gone from his residence for about for [sic] hours someone entered his home without permission by breaking the window out of the door at the rear of the home and unlocked the door. Suspects entered the home and took

items listed. Mr. Little stated that he does not have any serial numbers to the firearms and does not know who could have done this. No physical evidence found at the scene." (Respondent's exhibit 5) The incident report also stated that "[t]he victim reported that above property as being stolen in this incident also. The fire proof box was in the victim's bedroom closet. The victim also provides serial numbers for the two 270 caliber rifles. 1st rifle Browning Semi Auto 270 caliber serial number 137PT06545. 2nd rifle Browning bolt action 270 caliber serial number 12587NT8C7."

12. On September 27, 2008, Columbus County Sheriff's Office Deputy Robbie Sellers ("Deputy Sellers") obtained a magistrate's order on Petitioner for felony Possession of a Stolen Firearm under N.C.G.S. § 14-17.1 (Respondent's exhibit 7) The magistrate's order stated that Petitioner "has been arrested without a warrant and the [Petitioner]'s detention is justified because there is probable cause to believe that on or about the date of the offense shown and in the county named above the defendant named above unlawfully, willfully and feloniously did possess SEMI AUTO 270 RIFLE W/SCOPE (BROWNING BAR RIFLE SERIAL #137PT06545), the personal property of MILES DEWY LITTLE, which property was stolen property, knowing and having reasonable grounds to believe the property to have been feloniously stolen, taken, and carried away in that it was a SEMI AUTO 270 RIFLE W/ SCOPE (BROWNING BAR RIFLE SERIAL #137PT06545), a firearm." On September 27, 2008, Deputy Sellers also completed an arrest report for Petitioner for the felony charge of possession of a stolen firearm. (Respondent's exhibit 6)

13. On September 30, 2008, Petitioner provided an Employee Witness Statement concerning his felony charge which stated: "Approximately one week ago I obtained a Browning .270 weapon from a man. I was told I could keep it until payday and purchase it then. At 1:30pm Sat. 9-27-08 I was approached by deputy R. Sellers of the Columbus County Sheriff's Department. Deputy Sellers ask [sic] me about the gun which was unfortunantely [sic] in my possesion [sic]. I immediatly [sic] relinquished the weapon to Deputy Sellers. At this time Deputy Sellers informed me that I was in possession of a stolen fire-arm and placed me under arrest at approximately 1:45 pm. I was placed under a $3,000.00 cash bond, and I was detained for about 3 hours. I got home at approximately 4:00 pm and contacted Captain D. Benton and made him aware of the situation. He instructed me to call the unit . . . ." (Respondent's exhibit 8)

14. On October 1, 2008, Deputy Robbie Sellers wrote in the investigation report that he:

"[R]eceived information from Andy Edwards and VI Miles Little reference a stolen rife [sic] according to Mr. Edwards he was in Tractor Supply of Whiteville on Monday or Tuesday of this week when a [sic] employee Matthew Hayes approached Mr. Edwards and asked if he hunted when Mr. Edwards replied yes Mr. Hayes stated he had two rifle scopes he wanted to sell. Mr. Edwards and Mr. Hayes went to Mr. Hayes's vehicle and was shown the scopes one was mounted on a Browning bar rifle and told Mr. Edwards he wanted $75.00 a piece for the scopes. Mr. Edwards stated that Mr. Hayes told him if he

could sell the scopes he (Mr. Hayes) was going to buy the Browning rifle for $100.00. Mr. Edwards told Mr. Hayes that those were $300.00 scopes. Mr. Edwards left and Mr. Hayes was going to call him. When Mr. Edwards returned home he went next door to Mr. Little's residence and told him about that incident that occurred at Tractor Supply. When he described the scopes and rifle Mr. Little thought that was his rifle. I/O contacted the manager Dixie at Tractor Supply and she verified his (Mr. Hayes) employment. And gave his location I/O went to 4000 block of Rough And Ready Road and spoke to Mr. Hayes (4965 Rough And Ready Road). I/O informed Mr. Hayes of a investigation and asked if he had a rifle in his possession. Mr. Hayes replied yes and returned a Browning bar 270 cal rifle without a scope. I/O ran serial #137PT06545 through 911 central and received hit confirmation. I/O questioned Mr. Hayes of his involvement and he stated **'I rather not say'** however Mr. Hayes stated he could get the scope back but would not hive [sic] any information. Mr. Hayes was arrested and charged. The rifle was placed into evidence and V1 was notified. Same was also cleared from NCIC NC # G021862093 locker number 14 along with completed property evidence sheet." (Respondent's exhibit 5)

15. On November 25, 2008, Respondent received notification from Nora Hunt, Superintendent with the Columbus Correctional Institution that Petitioner had been arrested and charged with Possession of Stolen Firearm on September 27, 2008, by the Columbus County Sheriff's Office. (Respondent's exhibit 9) The notification stated that Petitioner admitted that "he had obtained a Browning .270 from someone and was told the [sic] he could keep it until payday and purchase the weapon then. He states that Deputy Sellers asked him about a gun in his possession and he immediately relinquished the weapon to him. He states that at that point, Deputy Sellers informed him that the gun was stolen and arrested him. He states that at no time was he aware that the weapon was stolen." (Respondent's exhibit 9)

16. On February 21, 2011, Petitioner's criminal charge of felony Possession of a Stolen Firearm was dismissed by the prosecutor. (Respondent's exhibits 12)

17. On April 7, 2011, Petitioner provided a statement to Respondent. He stated that "[i]n mid September 2008 I obtained a Browning BAR .270 deer rifle from Buster (Otis) Todd. I was told I could keep it til payday and purchase it then. At 1:30pm Sat. 9-27-08 I was approached by deputy R. Sellers of the Columbus County Sheriff's Dept. Deputy Sellers quistioned [sic] me about the gun in my possession, and I immediately relinquished it to him. He informed me that I was in possesion [sic] of a stolen firearm and arrested me. I was placed under a 3,000.00 cash bond. On 9-29-08 I spoke with attorney Dennis Worley. My 1st court appearance was at 9:30am 9-29-08. At no time was I aware that this gun was stolen. My case was dismissed due to 'lack of sufficient evidence' on Feb. 2, 2011 [sic]."(Respondent's exhibit 15)

18. On February 22, 2012, Respondent's investigator Edward Zapolsky ("Zapolsky") submitted a probable cause memorandum to Respondent's Probable Cause committee for

the offense of felony possession of a stolen firearm. On February 22, 2012, Respondent's Probable Cause committee found probable caused existed to revoke Petitioner's correctional officer certification because the evidence tended to show that Petitioner committed the felony offense of possession of a stolen firearm.

19. On March 14, 2012, a notice of Probable Cause was sent to Petitioner. (Respondent's exhibit 16) Petitioner requested an administrative hearing. (Respondent's exhibit 17)

20. At the hearing, Zapolsky, Deputy Herring, Deputy Sellers, Columbus County Sheriff's Office Deputy Scott Norris, Miles Little, and Andy Edwards testified for the Respondent. Otis Todd testified for Petitioner, and Petitioner testified on his own behalf. The witnesses were sequestered.

**Zapolsky's testimony**

21. Zapolsky investigates administrative rules violations for Department of Correction officers. Zapolsky collected the documents from Petitioner's criminal charge and drafted a memorandum to be submitted to Respondent's probable cause committee.

**Deputy Herring's testimony**

22. Deputy Aaron Herring has been employed with the Columbus County Sheriff's Office for five years and currently serves as a vice narcotics detective. His duties include investigating narcotics activity in the county, serving process, conducting criminal investigations, and enforcing traffic laws. Deputy Herring was working on September 19, 2008, as a patrol officer. He received a call for a breaking and entering on September 19, 2008, at 12:40pm, and responded within nine minutes to 455 Greens Mill Road in Clarkton, which is Miles Little's residence. He spoke with Little and learned that Little left the residence for four hours, returned home, and that the back window was unlocked from inside. Little checked his weapons and saw that firearms were missing. Deputy Herring made a report at that time and took inventory of the property stolen. The items stolen included a .270 auto Browning rifle with scope. Deputy Herring obtained an approximate value for the Browning .270 as $1500.00. Little reported that three scopes were missing, one for each rifle stolen.

23. Deputy Herring had general knowledge of scopes from training and knew that a scope is the magnifying glass attached to a rifle. Deputy Herring had knowledge of the value of scopes in that they range from approximately $150.00 to $1500.00. He stated that there is one scope per rifle.

24. Tthe Browning .270 auto rifle was found in Petitioner's possession on or about September 27, 2008. The missing scopes were never found. On March 1, 2010, Little's stolen .22 caliber pistol was found after the execution of a search warrant. No one was charged with breaking and entering Little's residence.

**Deputy Sellers's testimony**

25. Deputy Robbie Sellers has been employed as a Columbus County Sheriff's Office Deputy for eight years and has served for approximately twenty years in law enforcement. Deputy Sellers obtained information that Petitioner approached Andy Edwards at Tractor Supply and asked if Edwards wanted to purchase rifle scopes. Petitioner offered a price of $75.00 each for the scopes. Edwards thought that the retail price of a scope was $300.00. No bill of sale for the scope was presented. Edwards did not purchase the scope before returning to his residence. Edwards contacted Little and described the scope and the rifle. Little responded that the rifle described might be his stolen rifle. Deputy Sellers contacted Petitioner's supervisor at Tractor Supply and obtained Petitioner's girlfriend's address where he could be found. On September 27, 2008, Deputy Sellers went to Petitioner's girlfriend's house, found Petitioner there, and told him that he was investigating a stolen firearm. Deputy Sellers asked Petitioner whether he had a rifle, Petitioner stated yes and retrieved the rifle from his vehicle. Deputy Sellers called Little to confirm that the rifle in Petitioner's possession was his stolen rifle, and learned that it was in fact Little's stolen Browning .270 rifle by confirming the serial number. Deputy Sellers asked Petitioner how he came into possession of the firearm and he stated that he would **"rather not say."** Petitioner said he could get the scope back, but would not have any information. Deputy Sellers obtained a warrant for Petitioner for felony possession of a stolen firearm.

**Deputy Norris's testimony**

26. Columbus County Sheriff's Office Deputy Scott Norris ("Deputy Norris") had been a detective with the Columbus County Sheriff's Office since June 2006. On September 27, 2008, he spoke with Petitioner at the Columbus County courthouse because he was investigating the charge of possession of a stolen firearm. Deputy Norris stated that Petitioner admitted that he bought the rifle from someone, but he would not state who he bought it from. Petitioner stated that he would give a name to him so that he could finish his report, but he would not tell him where he received the rifle. Petitioner stated that his case would be dismissed anyway and he would not advise where he received the rifle. (Respondent's exhibit 18)

27. Deputy Norris also spoke with Otis Todd ("Todd"). (Respondent's exhibit 18) Todd stated that "he bought the gun from Brad Blackwell's son in the Food Lion Parking Lot and [Todd] advised that he paid $200.00." Otis Todd provided the following statement:

[Todd] advised he was at Food Lion getting two cases of Bush Beer in the can. [Todd] was talking with Brad Blackwell's son about the beer and when they walked out to the car [Todd] advised that the suspect asked [Todd] if he did any hunting and [Todd] said yes. Suspect asked if [Todd] would be interested in buying a Rifle. [Todd] said yes. Suspect said he had to go home to get the rifle. [Todd] asked how much he wanted for

the Rifle. Suspect told [Todd] $200.00. [Todd] went to BB&T bank ATM and got the money. Suspect went home to get the rifle. [Todd] and the suspect met back at Food Lion Parking Lot and [Todd] gave him 200.00 in twenty dollar bills. Suspect was driving a little blue car. Suspect had a skinny blonde headed girl with him. Suspect said he needed money for rent and swore up and down the gun was not stolen. [Todd] advised he gave the gun to [Petitioner] because [Petitioner] would always bring deer to [Todd] each year for the past five years. [Todd] advised that he bought the gun used and thought it was a good price and [Todd] bought the gun to give to [Petitioner] out of friendship for years of brotherly love. [Todd] advised that he had told [Petitioner] every year that he would buy him a box of ammo for his rifle for the deer [Petitioner] would bring. [Petitioner] would refuse the offer and was doing it out of friendship. [Todd] advised he bought the gun and gave it to [Petitioner] as a gift and [Petitioner] did not know the weapon was stolen.

28. Deputy Norris determined that no receipt existed for the sale, no bill of sale existed, and no documentation existed to legitimate the sale.

**Little's testimony**

30. Little resides at 455 Greens Mill Road in Clarkton, North Carolina. He has lived in Clarkton for approximately fifty years and at the time of the theft on September 19, 2008, Edwards was his neighbor and lived approximately 400 to 500 yards away from him. Before September 19, 2008, Little had owned firearms for approximately forty or fifty years and had owned about eight or nine of them. He hunts a lot and is very familiar with guns. Little owned scopes on all of his rifles and he bought his Browning .270 in Lumberton. Little testified that he paid $400.00 for the bolt action, and the scope on that rifle was a Nikkon scope costing $200.00. The value of the Browning .270 on September 19, 2008, was about $595 or $600, not including the scope. The separate Nikkon scope was valued at approximately $300.00, with a faceplate of $30. In combination, the rifle, scope, and faceplate was valued at $930.00. Little kept serial numbers of his firearms.

31. Edwards' father came to Little's residence and Little told him that his house had been broken into. Later, Edwards came over to Little's residence and asked whether his house had been broken into, and Little replied yes. Edwards asked if any guns were stolen and Little said yes. Edwards said that he may know where Little's guns were located. Edwards told Little that when he was at Tractor Supply, a man, whose name on his shirt read Matt, and who was later identified as Petitioner, approached him and asked if he hunts. Edwards replied yes, and Petitioner said that he may have something that he would be interested in. Edwards followed Petitioner to Petitioner's car in the parking lot, and Petitioner reached into the back of his SUV and pulled out a semi-automatic rifle with a mounted scope. Petitioner took out another scope and told Edwards that he wanted to sell the scopes for $75.00 each.

32. Little and Edwards went to the Sheriff's Office together on Saturday morning and spoke

with Deputy Robbie Sellers. Edwards told Sellers about the incident at Tractor Supply.

33. After Deputy Sellers retrieved the stolen rifle from Petitioner, Little asked him whether Petitioner would return the scopes. Deputy Sellers said that Petitioner said that he could return the two scopes to him, but Petitioner never returned the scopes. According to Little, one of his scopes was worth $200.00 and the other was worth $300.00.

**Edwards's testimony**

34. Edwards lives in Clarkton, North Carolina and was one of Little's neighbors in 2008. He has owned firearms, hunting rifles, pistols, and shotguns for all of his life. He had bought and sold firearms in the past and had bought a firearm from a dealer. He had knowledge of the value of firearms and scopes because he had owned about twelve to thirteen scopes and had owned about twenty to twenty-five firearms including shotguns, rifles, and pistols over the years.

35. Edwards was at Tractor Supply in Whiteville, North Carolina, on a Monday or Tuesday in 2008 when Petitioner approached him. He did not know Petitioner, but Petitioner told him that he looked like a hunter, and Edwards said he was. Petitioner said that he had a deal on some scopes that he was trying to sell. Petitioner said that the scopes were located in the parking lot, so Edwards and Petitioner walked out to the parking lot. Edwards saw two scopes in Petitioner's possession, one scope was off of the rifle and the other scope was still mounted to the rifle. Edwards did not purchase either scope because he thought that the price being offered by Petitioner was too low. Petitioner stated that he was trying to buy the rifle for $300.00, but that he did not own it yet and was selling the scope or scopes in order to help pay for the rifle.

36. After Edwards decided that he did not want to buy a scope, he went home and his father told him that Little's house had been broken into. Edwards went to Little's residence and told him that a guy had approached him and tried to sell two scopes to him. Edwards described the rifle that he saw in Petitioner's possession.

37. Edwards described that on Monday morning Little's house was broken into; that a few days later, Petitioner approached Edwards in Tractor Supply and asked whether he wanted to purchase two scopes for $75.00 each; and on Friday, he went to Little's house to tell him about the Tractor Supply incident. On Saturday morning, Edwards and Little went to the Sheriff's Office to tell Deputy Sellers about Petitioner approaching him in Tractor Supply to try to sell the scopes, and told Deputy Sellers that he thought that the scopes were Little's scopes. Edwards identified the rifle and scopes as Little's rifle and scopes because they had been deer hunting together and Edwards had seen Little's rifles and scopes. Because the quoted price for the scopes was so low, Edwards concluded that they had likely been stolen. After Edwards went to Little's house, he called Petitioner upon Little's instruction and offered Petitioner $700.00 for both scopes and the rifle. Petitioner declined this offer.

**PETITIONER'S EVIDENCE**

**Todd's testimony**

38. Todd's story is that he went to Food Lion with his neighbor Tony, and that Tony began talking with "some guy." Tony said that the guy "was a cousin." Tony and Brad Blackwell approached Todd and asked if he was interested in buying a rifle for $200.00. Todd agreed and Blackwell left and returned with the rifle. The rifle had a scope on it. Todd went to the bank, withdrew the money, and gave him the money for the rifle and the scope. Todd asked whether the gun was stolen, and Blackwell said no. Todd did not get a bill of sale on the rifle, although he had obtained a bill of sale for the firearms that he had purchased in the past. Todd then went to Petitioner's residence and gave the gun to Petitioner in exchange for the hunting and fishing meat Petitioner had previously given him, and left with the gun unpaid for. Todd also discussed with Petitioner a purchase price for the rifle around $300, but that a deal was never fully reached. Todd left Petitioner's residence and found out that the gun was stolen when Detective Norris came to Todd's house and asked about the firearm. Todd was charged with possession of a stolen firearm, but the charges were dismissed for lack of sufficient evidence.

39. When Petitioner asked Todd where he got the rifle, Todd told him that he received the firearm from "a friend." According to Todd he did not tell Petitioner that he received the rifle from Brad Blackwell because Petitioner did not ask him the name of the individual from whom he bought the firearm.

**Petitioner's testimony**

40. Petitioner story was that he received the rifle and scope from Todd, that a $300 price was discussed, but that nothing was set, and Petitioner did not give Todd any money for the rifle and scope. Petitioner could keep the rifle and pay him when he had received enough funds on payday.

41. Petitioner contends that he only offered to sell one scope to Edwards, not both scopes. He stated that he sought to sell the scope to buy the rifle and because he wanted a better scope. Petitioner offered to sell the scope for $75.00. Edwards left without purchasing the scope because he said he needed to speak with his wife, but that he called him later to offer to buy the rifle and scope for $700.00. Petitioner did not accept Edwards's offer. A few days later Deputy Sellers arrived at Petitioner's girlfriend's house and stated that he was investigating a Browning .270 that had been stolen. Petitioner gave the rifle to Deputy Sellers at that time.

42. When asked whether Petitioner had reasonable grounds to believe that the rifle was

stolen, he admitted that he thought that the price of the firearm of $300 was low, which prompted him to ask Todd whether it was stolen. When Todd said that it was not stolen, Petitioner asked Todd where he obtained the rifle, and Todd did not tell him. Petitioner initially testified that he had the scopes in his possession for a week or more, then he testified that he had the scope and rifle for three to four days.

43. When asked whether he had been employed in the past in any capacity dealing with the purchase and sale of firearms, Petitioner stated that he had been a Sales Associate in the firearms department of Wal-Mart for an extended period. Petitioner also stated that he owns multiple firearms himself and has bought and sold them in the past.

44. It is uncontested that on September 19, 2008, a Browning .270 rifle was stolen from Little's residence. It is uncontested that on September 27, 2008, Little and Edwards went to the Sheriff's Office to report that Petitioner had attempted to sell the scopes attached to the Browning .270 rifle to Edwards in the Tractor Supply parking lot. Petitioner knew or had reasonable grounds to believe the rifle to have been feloniously stolen when he took possession of it only a few days after the theft.

BASED UPON the foregoing FINDINGS OF FACT and upon the preponderance or greater weight of the evidence in the whole record, the Undersigned makes the following:

## CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has personal and subject matter jurisdiction over this contested case. The parties received proper notice of the hearing in the matter. To the extent that the Findings of Fact contain Conclusions of Law, or that the Conclusions of Law are Findings of Fact, they should be so considered without regard to the labels.

2. The North Carolina Criminal Justice Education and Training Standards Commission has the authority granted under Chapter 17C of the North Carolina General Statutes and Title 12 of the North Carolina Administrative Code, Chapter 09G, to certify correctional officers and to revoke, suspend, or deny such certification.

3. 12 NCAC 09G .0504(a) states: "The Commission shall revoke the certification of a correctional officer, probation/parole officer, or probation/parole officer-intermediate when the Commission finds that the officer has committed or been convicted of a felony offense."

4. Petitioner performed the acts necessary to satisfy the elements of felonious possession of a stolen firearm prohibited by N.C.G.S. § 14-71.1 (2011).

5. 12 NCAC 09G .0505(a)(1) states: "When the Commission revokes or denies the certification of a corrections officer pursuant to 12 NCAC 09G .0504 of this Section, the period of the sanction shall be 10 years where the cause of sanction is . . . commission or

conviction of a felony offense."

6. Reasonable grounds exist for Petitioner to have known or believed that the rifle was stolen because: (i) Todd told Petitioner that he purchased the rifle from "a friend," although Todd refused to disclose the name of the friend to Petitioner; (ii) Petitioner tried to sell the scopes to Edwards for a price that was sufficiently low to prompt Edwards to decline the offer because he correctly thought that the low price indicated the scopes were stolen; (iii) as a former Sales Associate at a merchant in the business of selling new and used firearms, and as a purchaser of new and used firearms himself, Petitioner possessed the requisite expertise to believe that the $200 and $300 prices for the .270 rifle and scope offered by Todd would indicate that the items were obtained illegally; (iv) Petitioner inquired of Todd whether the rifle was "legal", due to the low prices involved; (v) Petitioner was evasive with officers about how he got possession of the rifle; (vi) his education, training, certification, and experience as a prison guard would alert him.

7. It was not erroneous for the Respondent's Probable Cause committee to conclude that probable cause existed to revoke Petitioner's certification based on its authority to execute such revocation under 12 NCAC 09G .0504(a).

8. The party with the burden of proof in a contested case must establish the facts required by N.C.G.S. 150B-23(a) by a preponderance of the evidence. N.C.G.S. 150B-29(a). The administrative law judge shall decide the case based upon the preponderance of the evidence. N.C.G.S. 150B-34(a). Respondent had the burden of proof and met its burden.

**PROPOSAL FOR DECISION**

It is proposed that Respondent's decision to revoke Petitioner's certification be affirmed.

**NOTICE**

The Agency making the Final Decision in this contested case is required to give each party an opportunity to file Exceptions to the Proposal for Decision, to submit Proposed Findings of Fact and to present oral and written arguments to the Agency. N.C. Gen. Stat. §150B-40(e).

The Agency that will make the Final Decision in this contested case is the North Carolina Criminal Justice Education and Training Standards Commission.

This the 27th day of November, 2012.

Fred G Morrison Jr.
Senior Administrative Law Judge

On this date mailed to:

Matthew Brian Hayes
393 Pete Strickland Road
Cerro Gordo, NC 28430-
Petitioner

Catherine F Jordan
Assistant Attorney General
NC Department of Justice
9001 Mail Service Center
Raleigh, NC 27699
Attorney for Respondent

This the 27th day of November, 2012.

N. C. Office of Administrative Hearings
6714 Mail Service Center
Raleigh NC 27699-6714
919 431 3000
Facsimile: 919 431 3100

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|---|---|
| **STATE OF NORTH CAROLINA** | **IN THE OFFICE OF ADMINISTRATIVE HEARINGS** |
| **COUNTY OF EDGECOMBE** | **12 OSP 00430** |

MARVA G. SCOTT,

Petitioner,

**v.**

EDGECOMBE COUNTY SOCIAL SERVICES BOARD (LARRY WOODLEY, FAYE TAYLOR, ERNEST TAYLOR, VIOLA HARRIS AND EVELYN JOHNSON), EDGECOMBE COUNTY COMMISSIONERS AND EDGECOMBE COUNTY MANAGER LORENZO CARMON,

Respondents.

**FINAL DECISION**

**ORDER GRANTING PETITIONER'S MOTION FOR SUMMARY JUDGMENT**

**THIS MATTER** came on to be heard before the undersigned Administrative Law Judge, Augustus B. Elkins II, on August 29, 2012 in Raleigh North Carolina, for consideration of Petitioner's Motion for Summary Judgment filed on August 3, 2012, and Respondents' Response filed on August 27, 2012, and Respondents' cross-motion for summary judgment, made orally at the hearing on August 29, 2012. Having considered the respective submissions of the parties and matters of record proper for consideration of this pending motion, this Tribunal concludes that there is no genuine issue of material fact and that, therefore, summary judgment in favor of Petitioner is appropriate. A hearing was conducted on December 4, 2012 regarding Petitioner Marva G. Scott's Second Amended Motion for Award of Attorneys' Fees.

## APPEARANCES

**For Petitioner:** Gary K. Shipman
Kyle J. Nutt
Shipman and Wright, LLP
575 Military Cutoff Rd., Suite 106
Wilmington, NC 28405

**For Respondents:** Mary Craven Adams
Womble Carlyle Sandridge & Rice, LLP
One West Fourth Street
Winston-Salem, NC 27101

## ISSUE

Whether "just cause" exists for Petitioner's termination as Director of the Department of Social Services for Edgecombe County, North Carolina?

**PRIOR TO THE HEARING**, by way of a stipulation filed on August 28, 2012, Respondents removed from consideration five (5) of the seven (7) grounds set forth in their February 29, 2012 letter terminating Petitioner, and during the hearing conceded to the Undersigned that one of the two remaining stated grounds was not an independent "just cause" for Petitioner's termination, and was offered as "corroboration" of the other remaining ground. As such, the only issue before the Undersigned was whether the following basis, stated in the February 29, 2012 letter of termination to the Petitioner, construing the facts in the light most favorable to Respondents, constituted "just cause" for Petitioner's termination:

> "Further, it appears that you [Petitioner] have intentionally bent rules for at least one of your church members, to-wit, encouraging C.B. to apply for a position after the deadline of the posting period had closed, allowing the application to be considered after the posting period, and then selecting C.B. over qualified applicants that submitted their applications in a timely manner. In doing this, you have intentionally broken rules and/or policies, and have done so to serve your own interests and to further your own agendas rather than the interests of DSS."

## UNCONTROVERTED FACTS

1. Petitioner has been the director of the Edgecombe County Department of Social Services ("the Agency") since March of 2007.

2. At the time that Petitioner became director of the Agency, it was one of the lowest performing agencies in the State, and over the years, the Agency has substantially improved.

3. The Edgecombe County Social Services Board (the "DSS Board) is a body politic created and existing by virtue of the laws of North Carolina, and is vested with the sole power to hire and fire the Agency Director, subject to limitations imposed by the provisions of the North Carolina General Statutes, the North Carolina Administrative Code and other controlling law, including the State Personnel Act.

4. Petitioner attends a church in Goldsboro, North Carolina, with approximately 1800 members, where Petitioner serves as a church "greeter."

5. Petitioner's church is also attended by the individual identified as C.B, who the parties agree is Chester Brown (herein "Brown").

6. Sometime prior to January 27, 2011, Brown approached Petitioner at church and inquired if the Agency was hiring, to which Petitioner replied that Brown could submit an application. Petitioner did not encourage Brown to apply for any specific position, nor did Petitioner discuss any specific open positions with Brown.

7. Prior to the date Brown spoke to the Petitioner at church, the Petitioner and Brown had never spoken outside of brief greetings in passing at church, the two were not friends, had never been friends, were not friends with each other's family members, and had not been to each other's homes for meals or attended each other's family events, and had no other business or personal relationship.

8. Brown applied for a position at the Agency by emailing Petitioner an application on January 27, 2012, which did not identify any specific job posting which Brown was applying for.

9. Prior to receipt of Brown's application, the Agency had posted an opening for a "Social Worker II" position, with an application period of December 30, 2010 to January 10, 2011.

10. On January 14, 2011, four (4) candidates who qualified for the Social Worker II position were scheduled to be interviewed.

11. The Agency's Recruitment Process Policy Manual requires four (4) interviews for an open position to be conducted if at all possible.

12. One of the four (4) candidates did not arrive for the scheduled interview; one candidate had already worked for, and quit, the Agency twice, with documented problems with a manager; and one applicant's listed reference could not be contacted.

13. Sometime after January 27, 2011, Petitioner approached the Deputy Director of the Agency, Betty Battle, who is in charge of personnel at the Agency, and inquired if Brown had been given an interview.

14. Petitioner and Ms. Battle then engaged in a conversation about whether or not Brown's application had been lost. At the time Petitioner asked Ms. Battle, the Deputy Director, to see that Brown got an interview as the "interview team" for the open Social Worker II position had not made a determination to hire or recommend the hire of any of the other candidates interviewed.

15. Chester Brown was qualified for the open Social Worker II position.

16. On February 16, 2011 Brown was interviewed by the interview team, which consisted of two supervisors. Petitioner did not participate in any aspect of the interview of Brown.

17. Petitioner did not instruct the Deputy Director or the interview team to select

Brown for the open Social Worker II position; nor did Petitioner tell the Deputy Director or the interview team that she preferred Brown for the open Social Worker II position.

18. Petitioner's longstanding policy at the Agency was to allow the interview team to select the candidate they preferred, as the candidate selected would ultimately work under one or more of the supervisors on the interview team.

19. No witness was aware of any situation in which Petitioner had ever overridden the interview team's selection of a candidate for an open position.

20. Petitioner's practice was to "sign off" on the interview team's selection.

21. The interview team ultimately selected Brown for the open Social Worker II position.

22. One member of the interview team assumed Petitioner wanted Brown to be selected for the open Social Worker II position because his application was accepted after the deadline. However, that member of the interview team did not inform Petitioner of her assumption, did not document her assumption, or otherwise protest the circumstances surrounding Brown's hire. Petitioner had no preference for Brown being hired one way or the other.

23. Brown has worked for the Agency since his hiring in March, 2011, without any disciplinary actions or complaints about his work and is regarded by his supervisor as a good employee.

24. Larry Dewitt Woodley ("Woodley") has been a member of the DSS Board since April, 2009, and at all times relevant to this action, was the Chairman of the DSS Board.

25. On May 2, 2011, Woodley sent the Petitioner a Written Warning for her "conduct and behavior at our regular [sic] scheduled board meeting on April 18, 2011 while in the Tarboro DSS Office." Woodley alleged Mrs. Scott's conduct consisted of her "speaking in an extremely loud and boisterous tone which was directed at the board chair, Larry Woodley and Commissioner Viola Harris." The letter then stated "[y]ou have the right of appeal under the rules outlined in State Personnel Policy 25 NCAC 01J.0610." The letter was signed individually by Woodley with no indication the full DSS Board had agreed to, or was aware, of the decision to implement discipline.

26. The Petitioner sent written appeals of this Written Warning to Woodley and the DSS Board on four (4) separate occasions, the last of which was sent on October 25, 2011.

27. During the months of October and November, 2011, the Petitioner and the DSS Board had a series of discussions and meetings over a vendor for the Agency named "It Starts With U" (hereinafter "ISWU"). On October 24, 2011, the DSS Board voted to "amend" a contract with the vendor, and ordered the Petitioner to pay this vendor certain funds, even though

County boards of social services do not have the legal authority, power or duty to approve or execute contracts involving the County social services department.

28. The Petitioner informed the DSS Board that she could not pay the vendor, as to do so would have been an illegal use of Federal monies.

29. On December 19, 2011, the DSS Board "moved to give full authority over DSS to County Manager, Lorenzo Carmon, effective immediately" and that "a disciplinary letter would be presented and read to Marva Scott for a period of suspension up to as much as 30 days." Mrs. Scott was then issued a letter purporting to serve as "official notification of the Edgecombe County Department of Social Services Board of Directors' unanimous vote to execute disciplinary action against you . . . . [for] [p]ersonal conduct unbecoming an employee that is detrimental to the Agency's Service . . . ." The Petitioner was informed that she was "placed on administrative leave without pay for a period of thirty (30) days."

30. The DSS Board instructed Mr. Carmon to conduct an investigation of the Petitioner.

31. By letter dated January 9, 2012, after Petitioner formally appealed her suspension in writing, the DSS Board informed the Petitioner, in writing, that she was being reinstated with full back pay, but that her suspension would continue, as other disciplinary action was being contemplated against her, and in connection with that possibility, the Petitioner was being placed in investigatory leave effective January 10, 2012, with the January 9, 2012 letter containing new allegations against the Petitioner.

32. On February 23, 2012, approximately thirteen (13) months after Petitioner accepted Brown's application, the DSS Board provided another letter to Petitioner, notifying her for the first time of the Respondents intention to terminate her, including totally new grounds beyond those stated in its January 9, 2012 letter, including, as set forth above, the stated ground surrounding the hiring of Brown, along with six (6) other stated grounds of "just cause."

33. Respondents conducted a pre-dismissal conference with Petitioner on February 27, 2012, in which Petitioner outlined her objections and responses to the seven (7) grounds set forth by Respondents as "just cause" for her termination, both verbally and in writing.

34. Respondents terminated Petitioner by letter dated February 29, 2012, asserting the same seven (7) grounds as "just cause" for her termination.

35. No disciplinary action was taken against the Deputy Director or the interview team.

36. Although Mr. Carmon conducted an "investigation" of Petitioner for more than two months (from December, 2011 until February, 2012), there is no report of his investigation; no notes of any interviews that he conducted, documents that he reviewed or conclusions that he reached. There has been no evidence provided in the record regarding any documentation or other information provided by Mr. Carmon to the DSS Board prior to February 23, 2012, nor

minutes of any Executive Session in which the results of this investigation were discussed, together with the disciplinary action that the DSS Board proposed to impose.

37. The parties have engaged in extensive discovery in this case, and it is further uncontroverted that much of Respondents' knowledge surrounding the facts underlying the sole remaining allegation against the Petitioner was not fully developed until the discovery phase of this litigation, months after Petitioner was terminated.

38. During Mr. Carmon's investigation of Petitioner, Petitioner was never contacted by him for her version of events or for information concerning the events in question.

39. The Chairman of the Respondent Edgecombe County Board of Social Services acknowledged that Petitioner's responses and objections to the stated grounds for her termination were not independently looked into after the pre-dismissal conference; instead, the unspecified and unidentified information previously provided by the interim director/investigator, Lorenzo Carmon, was relied upon without further investigation.

40. The Petitioner, Marva G. Scott, is the prevailing party in the above captioned action.

41. Petitioner incurred significant costs in litigating not only the remaining issue for consideration in their motion for summary judgment but the six issues which Respondents abandoned prior to and during the hearing, including legal research, the deposition of fourteen witnesses, drafting discovery requests, reviewing documents and recordings, and drafting motions and memorandum in support of them and other matters.

## CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has jurisdiction over the parties and the subject matter of this action. The parties received proper notice of all hearings in this matter. To the extent that the findings of fact contain conclusions of law, or that the conclusions of law are findings of fact, they should be so considered without regard to the given labels.

2. At the time of the termination of her employment, Petitioner was subject to the State Personnel Act in accord with N.C.G.S. § 126-5(a)(2). N.C.G.S. §126-35 provides that no career State employee subject to the State Personnel Act shall be discharged, suspended or demoted for disciplinary reasons, except for just cause.

3. The Petitioner is a "career state employee" as defined by N.C. Gen. Stat. § 126-1.1 and is subject to and governed by the provisions of the State Personnel Act, codified at N.C. Gen. Stat. § 126-1 *et seq*. The Petitioner's claim is that Respondent lacked "just cause" pursuant to N.C. Gen. Stat. § 126-35 to dismiss her for one or more alleged acts of "unacceptable personal conduct."

4. Petitioner and all employees of Respondent are subject to the State Personnel Act pursuant to N.C.G.S. § 126-5(a)(2). Respondent is subject to the State Personnel Act as codified in N.C.G.S. § 126-1 *et seq.* and all applicable regulations. Notice is taken that Respondent presented no evidence that either Respondent Department nor the Board of County Commissioners had applied for "substantial equivalency" designation from the State of North Carolina's Office of State Personnel as to its employment policies regarding the matters in this case and they had not otherwise received a substantial equivalent exemption different from Chapter 126 pursuant to N.C. Gen. Stat. § 126-11. As Respondent was not exempt from the provisions of Chapter 126 for purposes of this matter, the Undersigned is guided by the law, regulations, guidelines and/or policies established by the Office of State Personnel.

5. N.C.G.S. §126 states that in contested cases pursuant to Chapter 150B of the General Statutes, the burden of showing that a career employee subject to the State Personnel Act was discharged, suspended, or demoted for just cause rests with the department or agency employer.

6. Petitioner's employment with the Edgecombe County Department of Social Services is subject to Title 25, Chapter 1, subsection 1I of the North Carolina Administrative Code, "Service to Local Government."

7. Under the Administrative Code, "The willful violation of known or written work rules" constitutes unacceptable personal conduct." 25 N.C. Admin. Code 1I.2304(a)(4).

8. Summary Judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that any party is entitled to a judgment as a matter of law." N.C. R. Civ. P. 56(c).

9. "[A]n issue is genuine if it is supported by substantial evidence." DeWitt v. Eveready Battery Co., Inc., 355 N.C. 672, 681, 565 S.E.2d 140, 146 (2002) (citing Koontz v. City of Winston-Salem, 280 N.C. 513, 518 186 S.E.2d 897, 901 (1972).

10. "'Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,' . . . and means 'more than a scintilla or a permissible inference.'" Id. (citations omitted).

11. The burden is upon the movant, in this case, the Petitioner, to come forward with evidence that establishes that she is entitled to judgment as a matter of law, with the Undersigned considering the entire record in the light most favorable to the nonmoving party, the Respondents, with all reasonable inferences drawn in that party's favor. Whitley v. Cubberly, 24 N.C. App. 204, 206, 210 S.E.2d 289, 291 (1974).

12. The moving party can meet its burden by one of two means: (1) by showing that an essential element of the opposing party's claim is non-existent; or (2) by demonstrating that the opposing party cannot produce evidence sufficient to support an essential element of the

claim or overcome an affirmative defense which would work to bar its claim. Wilhelm v. City of Fayetteville, 121 N.C. App. 87, 90, 464 S.E.2d 299, 300 (1995) (citing Roumillat v. Simplistic Enterprises, Inc., 331 N.C. 57, 414 S.E.2d 339 (1992)).

13. Once the moving party satisfies its burden, the burden shifts to the non-moving party to "produce a forecast of evidence demonstrating that the [non-moving party] will be able to make out at least a prima facie case at trial." Roumillat, 331 N.C. at 63, 414 S.E.2d at 342 (quoting Collingwood v. G.E. Real Estate Equities, 324 N.C. 63, 66, 376 S.E.2d 425, 427 (1989)).

14. Here, Respondents alleged Petitioner "bent rules" for a church member, and "intentionally broke[] rules and/or policies." However, Respondents failed to cite any rule that Petitioner allegedly "bent", or any rule that specifically prohibited Petitioner, as Director of the Agency, from considering an application submitted after the deadline.

15. When questioned by the Undersigned what "rule" Petitioner violated, Respondents cited a provision under sub-chapter "1H" of Title 25, Chapter 1 of the North Carolina Administrative Code, entitled "Recruitment and Selection." However, it is sub-chapter "1I", not subchapter 1H, of Title 25, Chapter 1 of the North Carolina Administrative Code (Service to Local Government) which applies to local Department of Social Services agencies and their employees, and therefore the "rule" that Petitioner allegedly violated, as recited by Respondents, does not apply, and there is no other evidence before the Office of Administrative Hearings as to any other "rule" that the DSS Board was informed that the Petitioner had allegedly violated.

16. Pursuant to the provisions of Subchapter 1I of Title 25, Chapter 1 of the North Carolina Administrative Code, local government agencies have their own Recruitment and Selection policies. Pursuant to the provisions of 25 NCAC 1I.1903(d), which contain the only controlling provision of the North Carolina Administrative Code that addresses the consequences of an application for vacancies at local government agencies being submitted after the deadline, applicants may be, but are not automatically, disqualified if an application is not submitted "within the prescribed time limits. 25 N.C.A.C. 1I.1903(d) ( "An applicant may be disqualified if he: . . . (3) fails to submit an application correctly or within the prescribed time limits;").

17. "The use of the word '*may*' generally connotes permissive or discretionary action and does not mandate or compel a particular act." Brock and Scott Holding, Inc. v. Stone, 203 N.C. App. 135, 137, 691 S.E.2d 37, 39 (2010) (quoting Campbell v. First Baptist Church of the City of Durham, 298 N.C. 476, 483, 259 S.E.2d 558, 563 (1979)) (emphasis added).

18. An applicant is not automatically disqualified by submitting an application outside of the deadline, and discretion to disqualify or accept such an application is vested in the Agency and its Director.

19. "General Statute 108A-14(2) gives the director of a county department of social services the exclusive power to hire and fire the department's personnel." In re Brunswick County, 81 N.C. App. 391, 397, 344 S.E.2d 584, 588 (1986).

20. The discretion to disqualify an applicant provided by 25 N.C.A.C 1I.1903(d) is held solely by the Director of Social Services, (i.e., the Petitioner).

21. The discretionary nature of 25 N.C.A.C. 1I.1903 was not disputed by Respondents; in fact, two of Respondents' witnesses, including Respondents' own expert, acknowledged that the referenced section of the Code gave the Petitioner the discretion to disqualify or accept an application submitted after the deadline.

22. Respondent Edgecombe County Board of Social Services "does not have the authority to overrule the director's decisions or interfere with the director's management of the department when state law vests authority for the department's management or administration in the director;" or to "establish personnel policies for county social services employees." John L. Saxon, Handbook for County Social Services Boards 61, 68 (University of North Carolina School of Government, 2009); *See also* N.C. Gen. Stat. § 108A-9 (enumerating the limited duties and responsibilities of county boards of social services).

23. Additionally, the Agency's official Recruitment Process policy manual does not contain any provision which specifically circumscribes the director's discretion to disqualify a late application under 25 N.C.A.C 1I.1903.

24. The Agency's official Recruitment Policy manual does, however, state "[t]he interview team will interview no less than (4) qualified applicants per position or combination of positions if available if at all possible."

25. At the time Petitioner accepted Brown's application, only three candidates had been interviewed, thus, her actions in causing Brown to be interviewed actually resulted in compliance with the Agency's written rules as stated in the Recruitment Policy manual.

26. Respondents contended Petitioner did not disqualify Brown's late application because he was a church member. As previously stated, the Director has the discretion to disqualify late applications, but is not required to do so as a matter of law; the fact that the applicant happened to attend the same church as Petitioner does not alter the law.

27. Regardless, there was insufficient evidence submitted to support the allegation that Petitioner failed to disqualify Brown because he was a church member and to "serve her own interests."

28. Respondents' relied on speculation in alleging Brown's application was not disqualified because he attended the same church as Petitioner. Such speculation is no more than an inference, thus it is not "substantial evidence," and is contrary to the only evidence submitted.

29. The evidence in the record establishes that Petitioner and Brown had no relationship other than Petitioner's greetings of all members of the church at the time of Brown's application, and she otherwise did not know him or have anything to gain by accepting his application.

30. Respondents offered no other evidence to support the contention that, at the time Brown submitted his application, Petitioner had any motive to "bend" or "break" the rules in favor of Brown, or that she "served her personal interests" or what those interests even were.

31. Respondents' "evidence leaves it all in the realm of mere conjecture, surmise, and speculation, and one surmise may be as good as another. Nobody knows. . . . A resort to a choice of possibilities is guesswork, not a decision." Monk v. Flanagan, 263 N.C. 797, 798, 140 S.E.2d 414, 415 (1965).

32. Finally, irrespective of the Undersigned's findings that Petitioner's conduct could not have constituted "unacceptable personal conduct," the alleged conduct fails to constitute "just cause" for Petitioner's dismissal.

33. "In order to discharge, suspend, or demote a career state employee for disciplinary reasons based on unacceptable personal conduct, the specific misconduct must constitute just cause for the specific disciplinary sanction imposed." Warren v. N.C. Dep't of Crime Control & Pub. Safety, 726 S.E.2d 920, 925 (N.C. App. 2012).

34. It is undisputed that Petitioner had the authority to accept an application submitted after the application deadline.

35. Petitioner took no part in the selection of Brown with the exception of "signing off" on the interview team's decision, which was her practice in 100% of previous selections.

36. Brown was qualified for the position, and the uncontroverted facts established that Petitioner did not instruct the Deputy Director or any members of the interview team to select Brown, nor did she inform anyone that she preferred Brown over any other candidate, nor was there any evidence that she would have rejected a different selection by the interview team.

37. While the responsibility for hiring decisions ultimately rests with the Director, the evidence established that Petitioner made no intentional decision to select Brown over any other qualified candidate, and instead relied upon the interview team's decision. Petitioner's conduct in accepting an application after the posting deadline, cannot not serve as "just cause" for her dismissal.

38. In accordance with N.C. Gen. Stat. § 126-37 entitled, "Administrative Law Judge's final decision", "The administrative law judge is hereby authorized to reinstate any employee to the position from which the employee has been removed, to order the employment, promotion, transfer, or salary adjustment of any individual to whom it has been wrongfully denied or to direct other suitable action to correct the abuse which may include the requirement of payment for any loss of salary which has resulted from the improperly discriminatory action of the appointing authority."

39. In accordance with N.C. Gen. Stat. § 150B-33(b)(11), an administrative law judge may "order the assessment of reasonable attorneys' fees and witnesses' fees against the State

agency involved in contested cases decided under Chapter 126 where the administrative law judge …orders reinstatement or back pay."

40. The starting point for determining the amount of a reasonable fee is the calculation of "the number of hours reasonable expended on the litigation multiplied by a reasonable hourly rate." Hensley v. Eckerhart, 461 U.S. 424, 433, 103 S.Ct. 1933, 76 L.Ed2d 40 (1983).

41. The determination of a reasonable attorney's fee is a matter of discretion with the Court. *See* Robinson v. Equifax Info. Services, 560 F.3d 235, 243 (4th Cir. 2009). In determining what is reasonable, the Fourth Circuit has instructed that a Court should be guided by the following factors, known as the "Johnson factors": (1) the time and labor expended; (2) the novelty and difficulty of the questions raised; (3) the skill required to properly perform the legal services rendered; (4) the attorney's opportunity costs in pressing the instant litigation; (5) the customary fee for like work; (6) the attorney's expectations at the outset of the litigation;(7) the time limitations imposed by the client or circumstances; (8) the amount in controversy and the results obtained; (9) the experience, reputation and ability of the attorney; (10) the undesirability of the case within the legal community in which the suit arose; (11) the nature and length of the professional relationship between attorney and client; and (12) attorneys' fees awards in similar cases. Grissom v. The Mills Corp., 549 F.3d 313, 321 (4th Cir. 2008) (applying twelve-factor test set forth in Johnson v. Georgia Highway Express, Inc., 488 F.2d 714, 717-19 (5th Cir.1974)) (citation omitted).

42. Petitioner seeks an award of attorneys' fees and related costs in the amount of $62,750.00 based upon legal services and travel related to the handling of this case. The primary attorneys in this matter, Kyle J. Nutt and Gary K. Shipman, as well as the associated attorneys, Angel Adams and James Monroe, are all licensed in the State of North Carolina and are attorneys in good standing with the North Carolina Courts.

43. In support of Petitioner's claim for attorneys' fees, Mr. Nutt has submitted a Second Amended Motion for Award of Attorneys' Fees which includes the General Contract for Legal Services between Petitioner Marva G. Scott and the firm of Shipman & Wright, L.L.P., as well as some fifty-eight (58) pages of detailed billing records. The Undersigned is satisfied that the time spent for legal services plus travel was reasonably expended in furtherance of this litigation.

44. An award of attorney fees should be based on rates prevailing in the community where the action takes place. In the December 4, 2012 hearing on Petitioner's Second Amended Motion for Award of Attorneys' Fees, Mr. Nutt reviewed the qualifications and experience of the attorneys involved in the matter as well as the associated paralegals and office staff. Based on the information provided and the Undersigned's own knowledge of and experience with prevailing rates charged in the relevant community, the Undersigned finds the requested hourly fees to be reasonable.

45. Petitioner seeks to recover costs incurred by her attorneys for filing fees, postage, coping, faxes, and the like. The Undersigned finds the claimed costs are reasonable.

**FINAL DECISION by Summary Judgment**

The Undersigned finds and holds that there is sufficient evidence in the record to properly and lawfully support the Conclusions of Law cited above.

**IT IS HEREBY ORDERED, ADJUDGED AND DECREED** that the Petitioner's Motion for Summary Judgment is **ALLOWED,** Respondents' Motion for Summary Judgment is **DENIED**, and that Respondents' decision to dismiss Petitioner is **REVERSED**.

Petitioner is entitled to be reinstated, effective immediately, to her position of employment as Director of the Edgecombe County Department of Social Services, with the same pay. She is to be paid all compensation to which she would otherwise have been entitled since the date of her termination, including but not limited to back pay and any and all benefits to which she would have been entitled.

**IT IS FURTHER ORDERED** that Petitioner Marva G. Scott's Second Amended Motion for Award of Attorneys' Fees is **GRANTED** and Petitioner shall have and recover of the Respondents the sum of **Sixty-Two Thousand, Seven Hundred and Fifty Dollars** ($62,750.00) in attorneys' fees and costs.

**NOTICE**

**THIS IS A FINAL DECISION** issued under the authority of N.C. GEN. STAT. § 150B-34. Under the provisions of North Carolina General Statutes Chapter 150B, Article 4, any party wishing to appeal the final decision of the Administrative Law Judge must file a Petition for Judicial Review in the Superior Court of Wake County or in the Superior Court of the county in which the party resides. The appealing party must file the petition within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision. In conformity with the Office of Administrative Hearings' Rule, 26 N.C. Admin. Code 03.012, and the Rules of Civil Procedure, N.C. General Statute 1A-1, Article 2, this Final Decision was served on the parties the date it was placed in the mail as indicated by the date on the Certificate of Service attached to this Final Decision. N.C. Gen. Stat. §150B-46 describes the contents of the Petition and requires service of the Petition on all parties. Under N.C. Gen. Stat. §150B-47, the Office of Administrative Hearings is required to file the official record in the contested case with the Clerk of Superior Court within 30 days of receipt of the Petition for Judicial Review. Consequently, a copy of the Petition for Judicial Review must be sent to the Office of Administrative Hearings at the time the appeal is initiated in order to ensure the timely filing of the record.

**IT IS SO ORDERED.**

This the 19th day of December 2012.

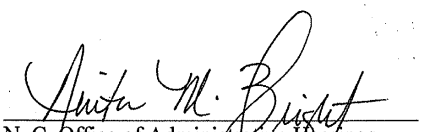
Augustus B. Elkins II
Administrative Law Judge

On this date mailed to:

Kyle J. Nutt
Shipman and Wright, LLP
575 Military Cutoff Rd. Suite 106
Wilmington, NC 28405-
Attorney - Petitioner

Mary Craven Adams
Womble Carlyle Sandridge & Rice, PLLC
One West Fourth St
Winston Salem, NC 27101-
Attorney - Respondent

This the 20th day of December, 2012.



N. C. Office of Administrative Hearings
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STATE OF NORTH CAROLINA

COUNTY OF WAKE

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
12 WRC 07077

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, INC.,
Petitioner,

v.

NORTH CAROLINA WILDLIFE RESOURCES COMMISSION,
Respondent .

**FINAL AGENCY DECISION GRANTING SUMMARY JUDGMENT**

This matter comes on for determination before Fred G. Morrison Jr., Senior Administrative Law Judge, upon cross-motions for summary judgment filed by Petitioner, People for the Ethical Treatment of Animals, Inc. ("Petitioner" or "PETA"), and Respondent, North Carolina Wildlife Resources Commission ("Respondent" or "WRC"). Based upon the undisputed facts, set forth below, and the arguments of the parties, IT IS DECIDED AND ORDERED AS FOLLOWS:

**FINDINGS OF FACT**

1. North Carolina businessman Clay Logan ("Logan") conducts an annual New Year's Eve event known as the "Opossum Drop," at his gas station and grocery store in Brasstown, Clay County, in order to garner publicity and market his business for financial gain. [Affidavit of Calley Gerber in Support of Petitioner's Cross-Motion for Summary Judgment ("Gerber Aff. I"), Exhibit C (PETA v. Myers, et al., Clay Logan's Answer to Plaintiff's Amended Complaint) at p. 1, ¶ 1; p. 2, ¶ 14; p. 6, ¶ 9; *see also* Respondent's Pre-Hearing

Statement at p. 2; *and see* Gerber Aff. I, Exhibit F (Transcript of September 25, 2012 Hearing ("Hearing Tr.")) at pp. 10:25 to 11:1-16].

2. During the event, a live-captured wild opossum is confined in a clear box and suspended above a stage for several hours before the animal is lowered at approximately midnight. [*See, e.g., id.,* Respondent's Pre-Hearing Statement at p. 2; Gerber Aff. I, Exhibit F (Hearing Tr. at pp. 10-11)].

3. For purposes of conducting the Opossum Drop event on December 31, 2011, Logan was in possession of a wild-captured opossum from at least December 15, 2011, through January 1, 2012. [Stipulation of Facts, No. 18].

4. When Logan captured the opossum, the animal "was not unfit for immediate release into his natural habitat at, or immediately after, the time [the animal was taken]." [Stipulation of Facts, No. 51].

5. Logan did not hold the opossum in captivity for rehabilitation purposes.

6. At the time Logan captured the opossum he had a Sportsman License that allowed the hunting and capture of the opossum; however, the Sportsman License did not allow Logan to retain a live opossum in captivity. [Gerber Aff. I, Exhibit E, Admission No. 2, at p. 1; Gerber Aff. I, Exhibit A (PETA v. Myers, WRC Responses to Interrogatories, Interrogatory No. 11, at pp. 4-5)]. It has been WRC's practice in the past that when "an animal [is] lawfully taken alive by hunting or trapping, and the person taking such animal wishes to retain it alive notifies WRC, WRC takes the position that some sort of permit is required[.]"

7. Logan submitted a "captivity permit application" to WRC on December 15th, 2011. [Gerber Aff. I, Exhibit A (PETA v. Myers, et al., Myers' Response to Interrogatory No.4,

at p. 2; Interrogatory No. 7, at p. 3); *see also* Stipulation of Facts, No. 1]. WRC did not grant Logan's request for a captivity permit.

8. At the time Logan applied for a Captivity Permit, the opossum was not in need of rehabilitation. [Stipulation of Facts, Nos. 21, 22].

9. The period of time for which Logan requested to hold the opossum in captivity was not required for rehabilitation, but rather was for the period of time Logan needed for using the opossum in the Opossum Drop event. [*See id.,* Nos. 23, 24, 25].

10. WRC was aware that Logan did not intend to hold the opossum in captivity for rehabilitation purposes, but for display to the public during the Opossum Drop. [*Id.,* No. 26].

11. The activity for which Logan sought the Captivity Permit was to "possess" an opossum he had taken alive from the wild and to hold the opossum in captivity from December 15, 2011, through January 2, 2012. [Stipulation of Facts, Nos. 2 and 3].

12. The purpose for seeking the permit was to conduct the Opossum Drop event.

13. Logan did not meet "any of the required conditions for a Captivity Permit." [Stipulation of Facts, No. 28].

14. "[I]t was clear" to WRC that Logan "would not qualify for either a captivity license or a captivity permit." [WRC Brief at p. 13; *see also id.* at p. 16 (stating that Logan "was not eligible for a captivity license or permit")].

15. During the time that Logan was in possession of the opossum, he did not have a Captivity Permit or Captivity License allowing him to hold the animal in captivity for his special purposes. [Stipulation of Facts, Nos.15, 16, 19, 20].

16. Instead of requiring Logan to release the opossum immediately or kill it, WRC created a special type of permit for the occasion, dubbed "Temporary Possession and Release Permit." [Gerber Aff. I, Exhibit G].

17. WRC "did not see necessarily any benefit to either the Wildlife resource, that is the population of the opossums as a whole or the individual opossum[,]" when it issued the permit. [Gerber Aff. II, Exhibit D (Superior Court, TRO Hearing Transcript at p. 28:16-20)

18. Although WRC claims to have issued "Temporary Possession and Release Permits" on prior occasions, WRC has provided no competent evidence to substantiate this claim. It has no such prior permits in its files. Even if a WRC employee wanted to issue such a permit, there are no "training or educational materials, policy manuals, or guidelines describing the circumstances or requirements for applying for, or issuing, or revoking the permit."

19. The Temporary Possession and Release Permit purported to allow Logan to have "continued possession" and "to hold" the opossum from December 15, 2011, until January 2, 2012, and "to exhibit" the opossum prior to its release. [Stipulation of Facts, Nos. 9, 10, 11].

20. The permit also purported to specifically authorize Logan that the opossum "may be . . . publicly displayed" from December 16, 2011, through January 2, 2012. [*See id.,* No. 46].

21. As authority for issuing the permit, WRC relied on N.C. Gen. Stat. § 113-274(c)(4). [*See* Gerber Aff. I, Exhibit G; *see also* Exhibit F (Hearing Tr. at p. 13:8-9)].

## CONCLUSIONS OF LAW

**1. A live native animal may only be possessed under circumstances that are "specifically permitted" by Subchapter IV of Chapter 113 of the North Carolina statutes or WRC rules enacted pursuant to Subchapter IV -- and WRC has no discretion to bypass**

**those statutes and regulations in the guise of creating and issuing a new type of "Other" permit pursuant to N.C. Gen. Stat. 113-274(c)(4).**

a. N.C. Gen. Stat. § 113-291 states that "[e]xcept as specifically permitted in this Subchapter [IV] or in rules made under the authority of this Subchapter, no person may . . . possess . . . any wildlife – whether dead or alive. . ."

b. Similarly, according to N.C. Gen. Stat. § 113-291.3 (a), "[l]ive wildlife . . . may be . . . possessed . . . only as specifically authorized in this Subchapter [IV] or its implementing rules."

c. Therefore, the authority for creating new permits for exhibiting or possessing a live native animal may not be inferred or implied.

d. The activity of possessing a live native animal is only allowed to the extent that it is specifically permitted or authorized by Subchapter IV or its implementing administrative regulations.

e. Since the activity of publicly displaying and holding the opossum in captivity for purposes of public display was not specifically permitted or authorized by the applicable statutes or regulations, WRC had no authority to create and issue an "Other" permit that would allow the (otherwise prohibited) activity to occur.

**2. Logan could not lawfully possess the opossum because he did not have, and did not qualify for, a Captivity Permit or Captivity License.**

a. 15A N.C. Admin. Code 10H.0301 specifies that possessing any species of wild animal that is native to North Carolina is "unlawful" – unless the individual in possession has obtained either a Captivity Permit or a Captivity License.

b. Accordingly, Logan could not retain possession of the opossum after capture, unless he qualified for, and obtained, either a Captivity Permit or Captivity License.

c. Categories of permits that govern the activity of taking could not serve as substitute for meeting the requirements for, and obtaining, either a Captivity Permit or Captivity License.

d. Since Logan did not meet the requirements for a Captivity Permit or Captivity License, he could not lawfully retain possession of the opossum—let alone use the animal for public exhibition. WRC should therefore have instructed Logan to immediately release the opossum into the wild where the opossum had been captured, or kill it.

**3. WRC has a mandatory duty to refuse to issue permits for the possession of native wild animals to persons who do not qualify for a Captivity Permit or Captivity License – and WRC should not circumvent this duty by inventing a new "Temporary Possession and Release Permit."**

a. WRC has no discretion to create exceptions and waive the statutory requirements for possessing native wild animals by issuing an "Other" permit to fill in perceived gaps in the permitting scheme for activities that are "unique" (as Logan's were described by WRC's counsel) and not expressly permitted by the applicable statutes and regulations.

b. The possession of a live native animal for purposes of exhibition (or otherwise) must be specifically authorized by Subchapter IV or its implementing regulations, and even with respect to such "specifically" authorized possession, WRC's authority is limited to issuing permits only to persons who qualify for them.

c. Before issuing any license or permit to persons subject to "administrative control," WRC has a nondiscretionary mandatory duty to ensure that those persons meet the qualifications for such permits.

d. WRC has no discretion to bypass specific statutory and regulatory requirements in the form of an "Other" permit that purports to authorize applicants to possess and exhibit native wild animals even though such applicants do not qualify for either a Captivity Permit or Captivity License, or other exemption.

**4. Section 113-274(c)(4) does not authorize WRC to issue a "special" permit for the possession and exhibition of a native wild animal.**

a. WRC's reliance on N.C. Gen. Stat. § 113-274(c)(4) as authority for issuing the "Temporary Possession and Release Permit" to Logan, is misplaced.

b. On its face, section 113-274(c)(4) does not regulate the possession and/or exhibition of animals. *See* N.C. Gen. Stat. § 113-274(c)(4) (stating that WRC may issue "Other Permits" for "taking, purchase, or sale of wildlife resources if the activity is lawfully authorized"). By specifically listing "taking, purchase, or sale of wildlife resources" the drafters are deemed to have specifically intended to exclude from the scope of this provision all activities that are not enumerated, including the activity of "possession" and public "display" of wildlife resources. *See, e.g., Granville Farms, Inc. v. County of Granville,* 170 N.C.App. 109, 114-115, 612 S.E.2d 156, 160 (2005) (the fact that the legislature provided for specific certified programs demonstrates that it did not intend that uncertified programs should be included).

c. Interpreting "temporary possession" and public "display" of a wild animal to come within the activities regulated by N.C. Gen. Stat. § 113-274(c)(4) runs afoul of the

established rule of statutory construction that when "a statute is intelligible without any additional words, no additional words may be supplied." *First Mount Vernon Indus. Loan Ass'n v. ProDev XXII, LLC,* 703 S.E.2d 836, 840 (N.C. Ct. App. 2011); *State v. Camp,* 286 N.C. 148, 151, 209 S.E.2d 754, 756 (1974) (same). Since section 113-274(c)(4) does not contain a provision for "possession" or "display" of a live native animal, WRC has no authority to add or infer such a provision in the guise of "interpreting" the statute.

d. Nevertheless, WRC argues it has such authority pursuant to the last sentence in the provision that states: "In addition, if a specific statute so provides, a permit under this subdivision may be required in addition to a license when there is a need for closer control than provided by the license." N.C. Gen. Stat. § 113-274(c)(4). This argument must be rejected for several reasons.

e. The provision upon which WRC relies unequivocally refers only to the authority to grant an additional (i.e., supplemental) permit to impose **additional** conditions ("closer control") beyond those that are already specified in an – already required – license. Nothing in this provision allows WRC to issue an "additional" § 113-274(c)(4) permit in order to lessen the controls provided by an existing licensing requirement or previously issued license. Nor does this sentence allow WRC to issue a § 113-274(c)(4) permit in lieu of a permit or license that may otherwise be required.

f. It is clear that the "Temporary Possession and Release Permit" was not issued "in addition" to another license that would qualify Logan to retain the opossum in captivity and to exhibit the animal during the Opossum Drop. It therefore cannot be said as a matter of law that the "Temporary Possession and Release Permit" was issued because WRC wanted to exert "closer control" over the exhibition and possession of the opossum

than that already provided by another license. Since no other permit or license for possessing the animal was in effect from the December 16 through January 2 period for which the "Temporary Possession and Release Permit" was issued, it would be legally impossible for WRC to issue an "additional" permit to Logan for that period.

g. Irrespective of whether WRC may have the authority to impose **additional** requirements upon Logan by issuing an "Other" permit, this did not give it the authority to exempt Logan from having to meet the threshold requirements for possessing a captured live opossum. Since Logan did not qualify for any permit or license to possess and exhibit the opossum, the question of whether WRC could issue an "additional" Other permit in order to provide "closer control" of the activity, is legally irrelevant.

h. Furthermore, N.C. Gen. Stat. § 113-274(c)(4) makes clear that even the authority to issue an "additional" permit arises only "if a specific statute so provides." *See* N.C. Gen. Stat. § 113-274(c)(4). WRC's claims that N.C. Gen. Stat. 113-261 and 113-275(i) make such provisions are not persuasive arguments. To the contrary, by arguing at the September 25th Hearing that it was "necessary" to create special permits for activities that "do not fit" into any existing permit category, WRC essentially concedes (as it must) that it has no specific statutory authority in order to issue a permit for such conduct. WRC's attempt to create a permit for the possession and exhibition of a live wild animal that is not specifically permitted or authorized by existing Subchapter IV or its implementing regulations must therefore be found to be without proper authority..

i. Furthermore, while N.C. Gen. Stat. § 113-274(c)(4) grants WRC the authority to add to (and thus make more stringent) the conditions of the license that the applicable statutes already require for conducting the activity, it does not give WRC the authority to

lessen control of the activities or to eliminate the requirements of a statutorily mandated license by issuing special permits to persons who do not qualify for the statutorily mandated license.

**5. Section 113-133.1 does not authorize WRC to disregard or waive mandatory permitting requirements of Subchapter IV and its implementing regulations.**

a. WRC argued that its permitting decisions are based (and in this case were based) on "a balancing test of all the competing interests involved." *See* WRC Brief at p. 20. WRC argued that this balancing test is authorized by N.C. Gen. Stat. § 113-133.1, which instructs WRC to administer the governing statutes in a manner that equitably serves "the various competing interests of the people[.]" G.S. § 113-133.1. We reject the contention that this provision would allow WRC to make permitting decisions on the basis of a balancing test, rather than based on whether an applicant meets the mandatory qualifications set forth in the permitting statutes and regulations. This is especially so in the absence of training or educational materials, policy manuals, or guidelines describing the circumstances for applying for, issuing, or revoking an "Other" permit.

b. Furthermore, the maxims of statutory construction require "that a more specific statute controls over a statute of general applicability." *Stewart v. Johnston County Bd. Of Educ.,* 129 N.C.App. 108, 110, 498 S.E.2d 382, 384 (1998). "When two statutes apparently overlap, it is well established that the statute [that is] special and particular shall control over the statute general in nature." *Technocom Business Systems, Inc. v. North Carolina Dept. of Revenue,* — N.C.App. —, —, 723 S.E.2d 151, 155 (N.C.App. 2012).

c. Section 113-133.1 is a statute of general applicability which speaks to the equitable administration of statutes in general. It does not control over statutes that deal more directly and specifically with the question of when, where, and how wild animals may be held captive. *See id; see also Oxendine v. TWL, Inc.,* 184 N.C.App. 162, 165, 645 S.E.2d 864, 866 (2007) ("[w]here one of two statutes might apply to the same situation, the statute which deals more directly and specifically with the situation controls over the statute of more general applicability").

d. Nothing in section 113-133.1 gives the Agency discretion to disregard the "special" and "particular" requirements for the possession of wildlife set forth in 15A N.C. Admin. Code 10H.0301(a)(1). If the General Assembly had wanted the Executive Director to apply a balancing test instead, it could and would have said so. It did not, and its clearly expressed intent to the contrary governs. *See, e.g., Sara Lee Corp. v. Carter*, 351 N.C. 27, 35, 519 S.E.2d 308, 313 (N.C. 1999) (when language in a statute is clear and unambiguous, courts must refrain from judicial construction and accord words "their plain and definite meaning"). When the language of a statute is plain, unequivocal and comprehensive, "[t]here seems to be no room for construction. If the Legislature had meant otherwise, it would have said so." *Grimes v. Andrews*, 88 S.E. 513, 514 (N.C. 1916).

**6. Section 113-261 provides no authority for WRC's issuance of the Temporary Possession and Release Permit.**

As support for the permit to Logan, WRC also relied on N.C. Gen. Stat. § 113-261, a statute that on its face does not apply to the activity of possessing and exhibiting live wild animals. Section 113-261 regulates the "taking" of wildlife resources for

"scientific purposes" in a "normally unauthorized manner". As such, it has no bearing on the activities for which Logan requested a permit.

**7. Section 113-275(i) provides no authority for issuing the Temporary Possession and Release Permit.**

a. N.C. Gen. Stat. § 113-275(i) states that "[i]t is unlawful to refuse to comply with any provisions of this Article or of rules and administrative requirements reasonably promulgated under the authority of this Article." WRC purports to have relied on this provision when it issued the permit, but does not explain the basis for such reliance.

b. We agree with Petitioner that far from providing authority for issuing the permit, N.C. Gen. Stat. § 113-275(i) supports the opposite conclusion. As the statute makes clear, compliance with the provisions in Article 21 and the rules and requirements promulgated thereunder is mandatory, and failure to comply with these provisions is "unlawful."

c. As such, section 113-275(i) only buttresses the conclusion that WRC has no authority to exempt permit applicants from these mandatory provisions.

**8. Capturing an animal alive pursuant to a Sportsman License does not entitle a hunter to lawfully retain possession of the animal.**

a. Logan's sportsman license is irrelevant since it merely regulates the taking of the animal, not possession and exhibition.

b. While Logan could lawfully take the opossum alive pursuant to a Sportsman License, this did not entitle Logan to retain possession of the animal beyond the short period of time "immediately" after the animal was captured. This is so because a

Sportsman License does not govern the retaining or holding of live wildlife in captivity. It only entitles the hunter "to take" an animal. This is consistent with WRC's historical interpretation of the applicable laws, since it has been WRC's practice in the past when "an animal [is] lawfully taken alive by hunting or trapping, and the person taking such animal wishes to retain it alive notifies WRC, WRC takes the position that some sort of permit is required[.]

c. WRC may not contradict its prior admission that on December 15, 2011, Logan had no permit that would allow him to legally maintain possession of the opossum unless he had taken its life by lawful means. "To take" is clearly defined as activities **immediately** preceding, during, and after an animal is taken.

d. Furthermore, "[w]ords and phrases of a statute may not be interpreted out of context," as the Agency has attempted to do. *See Fort v. County of Cumberland,* — N.C. App. —, —, 721 S.E.2d 350, 355 (N.C.App. 2012). WRC takes the phrase "reduce to possession" from the definition of the term "to take" (set forth in section 113-130 (7)) out of context to suggest that reducing an animal to possession is the legal equivalent of taking a live animal home and retaining the animal in captivity. WRC's strained interpretation violates the statutory construction principle that words in a statute must be "interpreted as a composite whole so as to harmonize with other statutory provisions and effectuate legislative intent." *Fort*, 721 S.E.2d at 355. WRC's interpretation would eviscerate – rather than harmonize with – the statutory scheme that regulates the possession of wild animals that are taken alive.

**9. WRC has no authority to issue any permit to Logan for the unlawful public display of a native wild animal at the Opossum Drop Event.**

a. North Carolina law provides no authority allowing WRC to issue an "Other" permit authorizing a person to publicly display or exhibit a native wild animal under any conditions, including publicity, marketing or public "celebration" purposes.

b. Since public display and exhibition of live wildlife is not "specifically permitted" or "specifically authorized" in Subchapter IV or its implementing rules, the "Temporary Possession and Release Permit" – which purported to permit the public display of the opossum during the Opossum Drop event – must be deemed unauthorized. N.C. Gen. Stat. § 113-291 ("[e]xcept as specifically permitted in this Subchapter [IV] or in rules made under the authority of this Subchapter, no person may . . . possess . . . any wildlife – whether dead or alive. . ."); N.C. Gen. Stat. § 113-291.3 (a) ("[l]ive wildlife . . . may be . . . possessed . . . only as specifically authorized in this Subchapter [IV] or its implementing rules").

c. Nothing in the statutes and regulations gives WRC officials discretion to waive mandatory permitting requirements or to invent "special" permits for activities that "do not fit" into (i.e., comply with) the existing permitting regulations.

d. Contrary to WRC's argument that asks us to infer that WRC has discretion to issue special permits for unique circumstances, the sole discretion WRC has been given is to **increase** the strictures imposed for conducting certain activities by issuing "additional" permits pursuant to N.C. Gen. Stat. § 113-274(c)(4)—but not to waive or exempt North Carolina citizens from having to comply with the existing strictures imposed by Subchapter IV and its implementing regulations.

e. While it is well-settled that we give due consideration to the construction of a statute or regulation by agencies vested with authority to administer them, no

consideration is due where (as here) the agency's interpretation boils down to ignoring the plainly stated intent of the statute or regulation.

f. WRC's contention that Logan could continue to possess the opossum "lawfully" as long as WRC issued him some "Other" type of permit, contradicts the plainly stated intent of 15A N.C. Admin. Code 10H.0301, as well as N.C. Gen. Stat. § §113-291, 113-291.3 and 113-276.2(b). As such, WRC's "interpretation" that would simply disregard mandatory permitting provisions is not entitled to deference.

g. Furthermore, WRC has provided no competent evidence to demonstrate that the "interpretation" it has proffered in this case is anything other than a *post hoc* attempt to justify the challenged conduct. Nothing would support the conclusion that the proffered interpretation has ever been applied by WRC officials in any other case where an applicant who did not qualify for a Captivity Permit or Captivity License was given an "Other" permit, under another provision, that purported to allow the applicant to possess a live wild native animal.

h. In summary, according to Genesis 1:26 (NRSV) humans have been given "dominion over the fish of the sea, and over the birds of the air, and over the cattle, and over all the wild animals of the earth--." Our General Assembly created the WRC to "...manage, restore, develop, cultivate, conserve, protect, and regulate the wildlife resources of the State of North Carolina, and to administer the laws relating to game, game and freshwater fishes, and other wildlife resources enacted..." The General Assembly has further provided: "The enjoyment of the wildlife resources of the State belongs to all of the people of the State." Citizens are prohibited from capturing and

using wild animals for pets or amusement. Hunters must afford wild animals the same right Patrick Henry yearned for: "Give me liberty, or give me death!"

**DECISION**

Petitioner's motion for summary judgment is GRANTED. Respondent's motion for summary judgment is DENIED. Accordingly:

**WRC should not issue any permit or license for possessing and publicly displaying a live opossum for use in an "Opossum Drop" event or for any other public display of a live opossum or other native wild animal, without obtaining specific authority to do so through its rulemaking procedures or additional legislation by the General Assembly.**

**NOTICE**

Under the provisions of North Carolina General Statute 150B-45, any party wishing to appeal the final decision of the Administrative Law Judge must file a Petition for Judicial Review in the Superior Court of Wake County or in the Superior Court of the county in which the party resides. **The appealing party must file the petition within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision.** In conformity with the Office of Administrative Hearings' rule 26 N.C. Admin. Code 03.012, and the Rules of Civil Procedure, N.C. General Statute 1A-1, Article 2, **this Final Decision was served on the parties the date it was placed in the mail as indicated by the date on the Certificate of Service attached to this Final Decision.** N.C. Gen. Stat. §150B-46 describes the contents of the Petition and requires service of the Petition on all parties. Under N.C. Gen. Stat. §150B-47, the Office of Administrative Hearings is required to file the official record in the contested case with the Clerk of Superior Court within 30 days of receipt of the Petition for Judicial Review.

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Consequently, a copy of the Petition for Judicial Review must be sent to the Office of Administrative Hearings at the time the appeal is initiated in order to ensure the timely filing of the record.

Dated this 13th day of November, 2012.

Fred G. Morrison Jr.
Senior Administrative Law Judge

On this date mailed to:

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This the 13th day of November, 2012.

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