SUBJECT AREA TO BE ADDRESSED: Subject areas covered in the proposed rules include listing, delisting, and reclassifying procedures; designation of Candidate Species, Endangered Species, Threatened Species and Species of Special Concern; and prohibitions, permits, and rewards associated with such species.

SPECIFIC AUTHORITY: Art. IV, Sec. 9, Florida Constitution; 379.1025 FS.
LAW IMPLEMENTED: Art. IV, Sec. 9, Florida Constitution; 379.2292 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE WEEKLY.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: James V. Antista, General Counsel, Fish and Wildlife Conservation Commission, 620 South Meridian Street, Tallahassee, Florida 32399-1600, (850)487-1764

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS NOT AVAILABLE.

FISH AND WILDLIFE CONSERVATION COMMISSION

Freshwater Fish and Wildlife

RULE NO.: RULE TITLE:
68A-31.001 Regulations Related to Commission Managed Shooting Ranges

PURPOSE AND EFFECT: The purpose and effect is to require course outlines for all courses, and to permit nursing programs to submit letters of intent from clinical facilities in lieu of previously executed contracts; to permit new, small programs to combine statistics from two graduating classes to determine if the program meets the required passing rates on the national licensing exam; to extend the program approval period from three to five years or to be concurrent with national or regional accreditation, and to clarify documentation required with applications for approval.

SUMMARY: Course outlines for all courses are required, and nursing programs to submit letters of intent from clinical facilities in lieu of previously executed contracts are permitted; new, small programs to combine statistics from two graduating classes to determine if the program meets the required passing rates on the national licensing exam is permitted; the program approval period from three to five years or to be concurrent with national or regional accreditation is extended, and documentation required with applications for approval is clarified.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 464.006, 464.019(2) FS.
LAW IMPLEMENTED: 464.019 FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rick Garcia, Executive Director, Board of Nursing, 4052 Bald Cypress Way, Bin C07, Tallahassee, Florida 32399-3259

THE FULL TEXT OF THE PROPOSED RULE IS:

64B9-2.002 Certification for Approval.
(1) Provisional approval – Provisional approval will be granted to an institution to initiate a nursing program when it has presented documentation satisfactory to the Board that it meets the following requirements:
(a) No change.
1. through 2. No change.
3. Course outlines for all first level courses shall be completed.
4. Contractual agreements, or a letter of intent to establish a contract once program approval has been received, with facilities and agencies to be used for clinical instruction for first level courses shall be in force.
5. No change.
(b) No change.
1. No change.
2. Course outlines for total curriculum shall be completed.
2. Contractual agreements with facilities and agencies to be used for clinical instruction in the total curriculum shall be in force.
3. Evidence of compliance with all rules in this rule chapter with the exception Rule 64B9-2.009, F.A.C., shall be demonstrated.
(c) Programs which have been granted provisional approval may be granted full approval when they have demonstrated they are in compliance with these rules and the licensure examination results of the first graduating class have met or exceeded the national average the standard as set forth in Rule 64B9-2.009, F.A.C. If the first graduating class has fewer than 21 students who have taken the licensure examination, the results of the next graduating class will be included in the determination of the program’s passing rate on the licensure examination.
(2) Approval – An institution seeking renewed approval of a nursing program shall present documentation of compliance with these rules at least every five years, except programs with national accreditation from an accrediting body recognized by the U. S. Department of Education may have program approval concurrent with the period of national accreditation. If good cause the Board may extend the period to five years. The administrator shall notify the Board within 30 days of any change, loss or lapse in accreditation status and shall submit to the Board within 30 days any report from a national accrediting agency citing deficiencies or recommendations. Such documentation shall also be presented upon request.

(3) No change.
(4) The Board may decline to approve any program on provisional status, or decline to renew or rescind approval of any program on probationary status which fails to meet required standards or which fails to make satisfactory progress for corrections of deficiencies within the time period outlined by the Board.

(5) No change.
(6) Programs reapplying for approval shall submit a proposal and required fee pursuant to subsection 64B9-7.001(14) and shall meet required standards in Rules 64B9-2.011 and 64B9-2.015, as outlined in paragraph 64B9-2.002(1)(a), F.A.C., prior to renewal of the program approval by the Board. As a condition of renewal, a program may be placed on probation if it does not meet the required standards.

Specific Authority 464.006, 464.019(2) FS. Law Implemented 464.019 FS. History–New 7-15-80, Amended 11-22-84, Formerly 21O-7.21, Amended 2-5-87, 6-8-88, 3-24-91, Formerly 21O-7.021, 61F7-2.002, 59S-2.002, Amended 12-11-97, 1-26-98, 7-7-02, ___.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 8, 2006
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 21, 2008

DEPARTMENT OF HEALTH
Board of Nursing
RULE NO.: RULE TITLE:
64B9-3.0085 State Requirements Not Substantially Equivalent
PURPOSE AND EFFECT: The Board proposes the rule promulgation to implement Section 464.009(2), F.S., by identifying a state that does not have licensure requirements substantially equivalent to Florida’s requirement.
SUMMARY: To implement Section 464.009(2), F.S., by identifying a state that does not have licensure requirements substantially equivalent to Florida’s requirement.

6366 Section II - Proposed Rules
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 464.009(2) FS.
LAW IMPLEMENTED: 464.009(2) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rick Garcia, Executive Director, Board of Nursing, 4052 Bald Cypress Way, Bin C02, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

64B9-3.0085 State Requirements Not Substantially Equivalent.
The licensure requirements of the following states and territories are not presumed to be substantially equivalent to the licensure requirements in Florida.
New Mexico,
Specific Authority 464.009(2) FS. Law Implemented 464.009(2) FS. History–New _______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 10, 2008
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 31, 2008

DEPARTMENT OF HEALTH
Board of Nursing
RULE NO.: 64B9-4.002 Requirements for Certification
PURPOSE AND EFFECT: The Board proposes the rule amendment to identify an additional certifying body for ARNPs.
SUMMARY: To identify an additional certifying body for ARNPs.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 456.048, 464.006, 464.012 FS.
LAW IMPLEMENTED: 456.048, 456.072(1)(f), (2), 464.012, 464.018(1)(b), (2) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rick Garcia, Executive Director, Board of Nursing, 4052 Bald Cypress Way, Bin C02, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

64B9-4.002 Requirements for Certification.
(1) through (2)(e) No change.
(f) American Academy of Nurse Practitioners (nurse practitioner level examination only).
(4) through (5) No change.
Specific Authority 456.048, 464.006, 464.012 FS. Law Implemented 456.048, 456.072(1)(f), (2), 464.012, 464.018(1)(b), (2) FS. History–New, 8-31-80, Amended 3-16-81, 10-6-82, 6-18-85, Formerly 210-11.23, Amended 3-19-87, 4-6-92, Formerly 210-11.023, Amended 3-7-94, 7-4-94, Formerly 61F7-4.002, Amended 5-1-95, 5-29-96, Formerly 59S-4.002, Amended 2-18-98, 11-12-98, 4-5-00, 3-23-06, _______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 10, 2008
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 24, 2008

DEPARTMENT OF HEALTH
Board of Nursing
RULE NO.: 64B9-5.001 Definitions
PURPOSE AND EFFECT: To conform to the Board’s continuing education standards to the national standards of the American Nurses Credentialing Center.
SUMMARY: To conform the Board’s continuing education standards to the national standards of the American Nurses Credentialing Center.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
SPECIFIC AUTHORITY: 464.006 FS.
LAW IMPLEMENTED: 464.013(3) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rick Garcia, Executive Director, Board of Nursing, 4052 Bald Cypress Way, Bin C02, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:

64B9-5.001 Definitions.
(1) through (3) No change.
(4) Contact Hour. One (1) contact hour equals sixty (60) a minimum of fifty (50) minutes. One half (1/2 or .5) contact hour equals thirty (30) a minimum of twenty-five (25) minutes.
(5) through (9) No change.

Specific Authority 464.006 FS. Law Implemented 464.013(3) FS. History–New 9-12-79, Amended 10-6-82, Formerly 21O-13.08, Amended 3-3-87, Formerly 21O-13.008, Amended 9-28-93, Formerly 61F7-5.001, Amended 5-2-95, 1-1-96, Formerly 59S-5.001, Amended __________.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 9, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 24, 2008

DEPARTMENT OF HEALTH

Board of Nursing

RULE NO.: RULE TITLE: 64B9-8.009 Payment of Fines

PURPOSE AND EFFECT: The Board proposes the rule amendment to extend time in which to pay fines.

SUMMARY: To extend time in which to pay fines.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 456.072(4), 464.006 FS.


NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 10, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 31, 2008

DEPARTMENT OF HEALTH

Board of Nursing

RULE NO.: RULE TITLE: 64B9-8.011 Reinstatement of Suspended and Revoked Licenses

PURPOSE AND EFFECT: The Board proposed the rule amendment to delete a requirement no longer necessary for the reinstatement of a license.

SUMMARY: To delete a requirement no longer necessary for the reinstatement of a license.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 464.006 FS.

LAW IMPLEMENTED: 112.011(1)(b), 464.018, 464.0185 FS. IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rick Garcia, Executive Director, Board of Nursing, 4052 Bald Cypress Way, Bin C02, Tallahassee, Florida 32399

THE FULL TEXT OF THE PROPOSED RULE IS:
64B9-8.011 Reinstatement of Suspended and Revoked Licenses

(1) No change.

(2) (a) through (d) No change.

(e) Other educational achievements, employment background, references, successful completion of criminal sanctions imposed by the courts and restoration of civil rights of a convicted felon, or other factors which would demonstrate rehabilitation and present ability to engage in the safe practice of nursing.

(3) through (5) No change.


NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Nursing

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Nursing

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 14, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 24, 2008

DEPARTMENT OF HEALTH
Board of Orthotists and Prosthetists

RULE NO.: RULE TITLE:
64B14-4.100 Requirements for Prosthetic or Orthotic Residency or Internship

PURPOSE AND EFFECT: The Board proposes the rule amendment to implement the statutory amendments in Section 1, 2008-121, Law of Florida.

SUMMARY: To implement the statutory amendments in Section 1, 2008-121, Laws of Florida.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 468.802, 468.803 FS.

LAW IMPLEMENTED: 468.803 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Joe Baker, Jr., Executive Director, Board of Orthotists and Prosthetists, 4052 Bald Cypress Way, Bin C07, Tallahassee, Florida 32399-3259

THE FULL TEXT OF THE PROPOSED RULE IS:

(1) No change.

(2) An internship must consist of orthotic or prosthetic, clinical experience practicing under the general supervision of a licensed or ABC-certified orthotist or prosthetist, respectively. The internship must consist of a minimum of 1,900 hours and may not exceed 2,700 hours. The intern is eligible to take the approved licensure examination upon completion of 1,900 hours. If the intern has not taken and passed the applicable licensure examination at the expiration of 2,700 hours of clinical experience, the intern may not practice as an orthotist or prosthetist in the state.

(3) through (7) No change.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Joe Baker, Jr., Executive Director, Board of Orthotists and Prosthetists, 4052 Bald Cypress Way, Bin C07, Tallahassee, Florida 32399-3259

THE FULL TEXT OF THE PROPOSED RULE IS:

64B14-7.0011 Practitioner and Resident Identification.

(1) Each licensed practitioner and each resident shall conspicuously display a current license issued by the Department and a photograph at his or her practice location.

(2) Each licensed practitioner and each resident shall wear an identification badge containing the information required by Section 468.8095, F.S., and a personal photograph of no less than 3/4 inch in size, that is a minimum size of 2 by 3 inches with the text in a font equal to at least Times New Roman 14 point font or Courier New 12 point font.

(3) All unlicensed support personnel shall wear an identification badge that identifies the person as support personnel and meets the requirements set forth in subsection (2) above.

Specific Authority 468.808, 468.8095 FS. Law Implemented 468.808, 468.8095 FS. History–New.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Orthotists and Prosthetists

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Orthotists and Prosthetists

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: July 31, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 24, 2008

DEPARTMENT OF HEALTH
Board of Psychology

RULE NO.: RULE TITLE: 64B14-7.0011 Practitioner and Resident Identification

PURPOSE AND EFFECT: The Board proposes the rule promulgation to provide instruction concerning application closure after 24 months.

SUMMARY: The rule promulgation will provide instruction concerning application closure after 24 months.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: A Statement of Estimated Regulatory Cost was prepared. A copy can be obtained from Allen Hall, Executive Director at the address listed below. Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 490.004(4), 490.005(3) FS.

LAW IMPLEMENTED: 490.005(3) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allen Hall, Executive Director, Board of Psychology, 4052 Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B19-11.007 Application Closure After 24 Months.

(1) The Board shall close the application file of and issue a final order of denial to any applicant for licensure by examination who fails to pass the Examination for Professional Practice in Psychology and the Florida laws and rules examination or who fails to submit evidence of completion of the postdoctoral, supervised experience within 24 months of the issuance of the Board’s letter advising that the applicant has been approved for examination.

(2) The Board may grant an additional twelve (12) months to comply with the requirements of subsection (1) above, of up to 36 months, to any applicant who files a written request for extension and demonstrates that the applicant has made a good faith effort to comply but has failed to comply because of illness or unusual hardship.

Specific Authority 490.004(4), 490.005(3) FS. Law Implemented 490.005(3) FS. History–New.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Psychology

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Psychology

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 24, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: November 14, 2008

DEPARTMENT OF HEALTH
Board of Speech-Language Pathology and Audiology

RULE NO.: RULE TITLE: 64B19-11.007 Application Closure After 24 Months

PURPOSE AND EFFECT: The proposed rule amendment would specify attendance at a board meeting when covering in the area of ethics.

SUMMARY: The proposed rule amendment would specify attendance at a board meeting when covering in the area of ethics.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

**SPECIFIC AUTHORITY:** 456.013(7), 468.1135(4)(a), 468.1195(1), (3), 468.1205(1) FS.

**LAW IMPLEMENTED:** 456.013(7), 456.072(1), (2), 468.1195(1), (3), 468.1205(1), 468.1295(1), (2) FS.

**IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.**

**THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS:** Pamela King, Executive Director, Board of Speech Language Pathology and Audiology, 4052 Bald Cypress Way, Bin #06, Tallahassee, Florida 32399-3253

**THE FULL TEXT OF THE PROPOSED RULE IS:**

64B20-6.001 Continuing Education as a Condition for Renewal or Reactivation.

(1) through (3) No change.

(4) Two hours of continuing education credit per year in the area of ethics shall be granted a licensee or certified assistant for attendance at a regularly scheduled face-to-face Board meeting. Licensees or certified assistants appearing before the Board on any disciplinary proceeding shall not be entitled to claim any continuing education credit for that particular Board meeting. Licensees must attend at least two hours of a Board meeting to be granted credit under this section. Proof of attendance shall be documented on Form SPA 10/AHCA, entitled, Proof of Attendance, effective 3-28-95, which is incorporated by reference herein. Copies of said form shall be provided at Board meetings.

(5) through (12) No change.

Specific Authority 456.013(7), 468.1135(4)(a), 468.1195(1), (3), 468.1205(1) FS. Law Implemented 456.013(7), 456.072(1), (2), 468.1195(1), (3), 468.1205(1), 468.1295(1), (2) FS. History–New 3-14-91, Amended 8-11-91, 5-28-92, 2-24-93, Formerly 21LL-6.001, Amended 1-31-94, 7-5-94, Formerly 61F14-6.001, Amended 3-28-95, 10-1-95, 11-20-95, 4-1-96, Formerly 59BB-6.001, Amended 7-7-98, 1-6-00, 4-4-02, 3-28-04, 5-26-05, 4-4-06, __________.

**NAME OF PERSON ORIGINATING PROPOSED RULE:** Board of Speech Language Pathology and Audiology

**DATE PROPOSED RULE APPROVED BY AGENCY HEAD:** November 14, 2008

**DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW:** July 18, 2008

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**DEPARTMENT OF HEALTH**

**Council of Licensed Midwifery**

**RULE NO.:** 64B24-7.018

**RULE TITLE:** Address of Record

**PURPOSE AND EFFECT:** To define the current mailing address and place of practice for a licensed midwife.

**SUMMARY:** This rule requires licensed midwives to provide the department with a current mailing address and defines current mailing address and place of practice as an address where mail is deliverable to the licensee.

**SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS:** No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

**SPECIFIC AUTHORITY:** 456.035, 467.005 FS.

**LAW IMPLEMENTED:** 456.035 FS.

**IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.**

**THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS:** Christy Robinson, Acting Executive Director, 4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256

**THE FULL TEXT OF THE PROPOSED RULE IS:**

64B24-7.018 Address of Record.

Each licensed midwife shall provide Council staff with either written or electronic notification of one current mailing address. The current mailing address and place of practice is defined as an address acceptable to the United States postal service where the licensed midwife shall be served with notices pertaining to licensure.

Specific Authority 456.035, 467.005 FS. Law Implemented 456.035 FS. History–New __________.

**NAME OF PERSON ORIGINATING PROPOSED RULE:** Christy Robinson

**DATE PROPOSED RULE APPROVED BY AGENCY HEAD:** November 19, 2008

**DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW:** June 27, 2008
DEPARTMENT OF HEALTH
Division of Environmental Health

RULE NOS.: RULE TITLES:
64E-5.1601 Definitions
64E-5.1602 Administrative Requirements
64E-5.1603 Training and Education
64E-5.1604 General Technical Requirements for Electronic Brachytherapy Facilities

PURPOSE AND EFFECT: There have been no substantive changes to the rules affecting radiation therapy in at least 13 years. In that time, the use of such machines has changed, and new technologies, such as the miniature x-ray tubes used in electronic brachytherapy, have been created. New rules are proposed for electronic brachytherapy devices, practices, procedures, personnel, facilities, and related equipment, to ensure all are used safely and in compliance with the current radiation requirements of Chapter 404, F.S.

SUMMARY: A new Part XVI of Chapter 64E-5, F.A.C., is created which establishes rules for: electronic brachytherapy devices and associated equipment; installation, maintenance and repair; treatment planning & simulation; computer systems; general administrative and facility requirements; shielding and safety design; technical requirements; safety procedures; radiation protection devices; personnel licensure, education, training and supervision; quality assurance & management; authorized users, operators, medical physicists & radiation safety officers; radiation protection programs, including authority and responsibilities; surveys and survey instruments; calibration; definitions; forms; fees; registration; records; notifications; reporting; medical & recordable events; signage & posting; written & oral directives; mobile services; and radiation dose & dosimetry.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 404.051(4), 404.22 FS.
LAW IMPLEMENTED: 404.031, 404.051, 404.22, 404.081(1) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW (IF NOT REQUESTED, THIS HEARING WILL NOT BE HELD):
DATE AND TIME: January 6, 2009, 11:00 a.m. – 12:00 Noon
PLACE: Room 240P, 4042 Bald Cypress Way, Tallahassee, FL

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 7 days before the workshop/meeting by contacting: James Futch, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741; (850)245-4266. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: James Futch, Bin C21 4052 Bald Cypress Way, Tallahassee, FL 32399-1741; (850)245-4266

THE FULL TEXT OF THE PROPOSED RULES IS:

PART XVI
ELECTRONIC BRACHYTHERAPY

64E-5.1601 Definitions.
The following definitions apply only in this part.

(1) “AAPM” means the American Association of Physicists in Medicine, www.aapm.org.

(2) “Authorized user” means a person who has met the requirements of subsection 64E-5.1603(1), F.A.C.

(3) “Authorized medical physicist” means a person who has met the requirements of subsection 64E-5.1603(2), F.A.C.

(4) “Authorized operator” means a person who has met the requirements of subsection 64E-5.1603(3), F.A.C.

(5) “Electronic brachytherapy” means a method of radiation therapy using electrically-generated x-rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

(6) “Electronic brachytherapy device” or “device” means the system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

(7) “Electronic brachytherapy source” or “source” means the x-ray tube component used in an electronic brachytherapy device.

(8) “Medical event” means any event, except for an event that results from patient intervention, in which the administration of radiation results in:
   (a) A total dose delivered that differs from the prescribed dose by 20 percent or more;
   (b) A fractionated dose delivered that differs from the prescribed dose, for a single fraction, by 50 percent or more; or
   (c) A dose to the wrong individual or the wrong treatment site.

(9) “Mobile electronic brachytherapy device” means a device which is transported from one address to be used at another address.

(10) “Portable shielding” means shielding that can be easily moved into the primary or secondary beam in order to reduce the radiation exposure to the patient, occupational worker or a member of the public.
64E-5.1602 Administrative Requirements.
(1) Registration and Notification.
(a) No electronic brachytherapy device may be used on a human without a current certificate of registration from the department.
(b) An electronic brachytherapy device that is not operational and that is under the control of a registered vendor prior to final installation is exempt from the registration and fee requirements of this section.
(c) A separate registration and radiation protection program are required for facilities for which one or more of the following applies:
   1. The facilities are not at the same physical address;
   2. The facilities are not under the same radiation safety program; or
   3. The facilities are not under the same management.
(d) Each person who acquires an electronic brachytherapy device shall apply for registration of the radiation device with the department within 30 days after acquisition. Application for registration shall be on Form DH 1107, 03/07, “Radiation Machine Facility Registration,” as incorporated in subparagraph 64E-5.511(2)(a)1., F.A.C. The application must include the following documents:
   1. A list identifying the radiation safety officer and all authorized medical physicists, authorized operators, and authorized users except visiting authorized users, together with documentation of their training and education as described in Rule 64E-5.1603, F.A.C.;
   2. A copy of the most current record of surveys, calculations and quality assurance checks on each device;
   3. A current copy of the quality management program as described in subsection 64E-5.1604(3), F.A.C.;
   4. A current copy of the quality assurance program as described in subsection 64E-5.1604(4), F.A.C.; and
   5. A copy of the device manufacturer’s U.S. Food and Drug Administration certification; and
   6. Facility design information, which at a minimum must include:
      a. A diagram of the physical facility showing the location of the electronic brachytherapy treatment rooms;
      b. Whether the facility is a new structure or a modification to an existing structure, and;
      c. The type and thickness of the portable shielding used for compliance and a procedure demonstrating the use of the shielding prior to treatment.
   (e) The registrant shall update the registration on file with the department within 30 days of any change to any information reported in paragraph 64E-5.1602(1)(d), F.A.C.
(2) Installation, Maintenance or Repair.
   (a) Only a manufacturer’s representative registered as a vendor under subsection 64E-5.511(3), F.A.C., shall install an electronic brachytherapy device.
   (b) Only a manufacturer’s representative registered as a vendor under subsection 64E-5.511(3), F.A.C., or an authorized medical physicist shall adjust, repair, maintain, or service an electronic brachytherapy device in accordance with the manufacturer’s guidelines.
   (c) A registrant shall retain a record of the installation, maintenance, adjustment, service and repair of an electronic brachytherapy device for 5 years.
(3) Fees. The registrant of an electronic brachytherapy device shall comply with the requirements of paragraph 64E-5.511(2)(b), F.A.C., and pay the fees for a medical accelerator unit.

64E-5.1603 Training and Education.
(1) Qualification of Authorized User.
   (a) The registrant shall require the authorized user to be a physician who:
      1. Is licensed by the department as a medical doctor or doctor of osteopathy;
      2. Has completed a manufacturer’s device-specific training as specified in subsection 64E-5.1603(5), F.A.C., and;
      3. Is certified in:
         a. Radiation oncology or therapeutic radiology by the American Board of Radiology;
         b. Radiation oncology by the American Osteopathic Board of Radiology;
         c. Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
         d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons.
   (b) A physician shall not act as an authorized user for any electronic brachytherapy device until such time as said physician’s training has been reviewed and approved by the department.
(2) Qualification of Authorized Medical Physicist.
   (a) The registrant shall require the authorized medical physicist to be a person who:
      1. Is currently licensed pursuant to Section 483.901, F.S., as a therapeutic radiological physicist, and;
      2. Has completed a manufacturer’s device-specific training as specified in subsection 64E-5.1603(5), F.A.C.;
   (b) A medical physicist shall not act as an authorized medical physicist for any electronic brachytherapy device until such time as said physicist’s training has been reviewed and approved by the department.
(3) Qualification of Authorized Operator. A person, other than an authorized user, who operates an electronic brachytherapy device to apply ionizing radiation to a human, shall be:
(a) Certified in accordance with the Chapter 468, Part IV, Florida Statutes, as a radiation therapy technologist, and;
(b) Have completed a manufacturer’s device-specific training as specified in subsection 64E-5.1603(5), F.A.C.  
(4) Qualification of Radiation Safety Officer. The registrant shall require the radiation safety officer to be a person who has completed a manufacturer’s device specific training as specified in subsection 64E-5.1603(5), F.A.C., and be:
(a) An authorized user or authorized medical physicist, or;
(b) A person certified by:
1. The American Board of Radiology in Radiology, Diagnostic Radiology, Therapeutic Radiology, or Radiation Oncology;
2. The American Board of Health Physics in Comprehensive Health Physics;
3. The American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;
4. The American Board of Nuclear Medicine;
5. The American Board of Science in Nuclear Medicine, or;
6. The American Board of Medical Physicists, or:
(c) A person who has completed classroom and laboratory training consisting of the following:
1. One hundred hours of radiation physics and instrumentation;
2. Thirty hours of radiation protection;
3. Twenty hours of mathematics pertaining to the use and measurement of radiation;
4. Twenty hours of radiation biology;
5. Thirty hours of medical therapy training; and
6. One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer;
(5) Manufacturer’s Training. The registrant shall require training in electronic brachytherapy device operation, safety procedures, and US Food & Drug Administration-approved clinical uses. All training taken to satisfy this requirement must have been completed within the 7 years preceding the date of application. This training requirement must be approved by the department and must be satisfied by:
(a) Completion of a training program provided by the manufacturer, or;
(b) Completion of a training program which is provided by an institution approved by the manufacturer, or;
(c) Receiving training that is substantially equivalent to the manufacturer’s training program from an authorized user or authorized medical physicist who is authorized to use the device on a department registration.
(6) Annual Training.
(a) The registrant shall provide radiation safety training, initially and at least annually, to all personnel providing patient care and treatment planning to patients.
(b) The training should include device operation, safety procedures and clinical use updates.
(7) Training Records. The registrant shall retain for three years a record of each individual receiving initial manufacturer’s training and annual training.

Specific Authority 404.051(4), 404.22 FS. Law Implemented 404.051, 404.081(1), 404.22 FS. History–New _______.

64E-5.1604 General Technical Requirements for Electronic Brachytherapy Facilities.
(1) Radiation Surveys.
(a) The registrant shall ensure that a survey, as defined in subsection 64E-5.101(151), F.A.C., of all new facilities and existing facilities not previously surveyed, is performed with an operable radiation measurement survey instrument according to the requirements of Part III of Chapter 64E-5, F.A.C.
(b) The survey shall be performed by, or under the direction of, an authorized medical physicist or radiation safety officer who shall determine and record whether radiation levels are in compliance with the dose limits of Part III of Chapter 64E-5, F.A.C. Portable shielding may be used to comply with these radiation dose limits. Such surveys shall be conducted with the electronic brachytherapy device controls, source position, portable shielding and site-specific scattering phantom all set so as to produce the highest radiation exposure level that could occur during treatment.
(c) The survey record shall include: the date of the measurements; the reason the survey is required; the manufacturer’s name, model number and serial number of the electronic brachytherapy device; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey.
(d) A survey shall also be performed prior to any subsequent medical use, when:
1. Making any change in the portable shielding;
2. Making any change in the location where the electronic brachytherapy device is used within the treatment room, or;
3. Relocating the electronic brachytherapy device.
(e) The registrant shall maintain the record of each survey for the duration of the registration.

(2) Dosimetry Equipment.

(a) For electronic brachytherapy devices, the calibration of the dosimetry system shall be for the source and energy or energies in use according to a current published protocol from a nationally-recognized professional association with expertise in electronic brachytherapy, such as the AAPM. In the absence of such a published protocol, the manufacturer’s current protocol shall be followed.

(b) The registrant shall have available for use a dosimetry system for quality assurance check measurements. The quality assurance check system may be the same system used to meet the requirement for calibration.

(c) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. Each record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared; the names of the individuals who performed the calibration, intercomparison, or comparison; and, evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, an authorized medical physicist of record.

(3) Quality Management Program.

(a) Each registrant under this part shall establish and maintain a written quality management program to provide a high confidence that electronic brachytherapy devices will be used as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:

1. Except where a delay to provide a written directive as defined in subsection 64E-5.101(173), F.A.C., would jeopardize the patient’s health as specified in subparagraphs 64E-5.1604(3)(a)2. and 3., F.A.C., a written directive is prepared prior to administration of a therapeutic radiation dose;

2. An oral directive is only acceptable when a delay to provide a written directive would jeopardize the patient’s health because of the emergent nature of the patient’s condition. The information contained in the oral directive must be documented immediately in the patient’s record and a written directive prepared within 24 hours of the oral directive;

3. An oral revision to an existing written directive is only acceptable when a delay to provide a written revision to an existing written directive would jeopardize the patient’s health. The oral revision must be documented immediately in the patient’s record and a revised written directive must be signed by the authorized user within 48 hours of the oral revision;

4. A written directive that changes an existing written directive for any therapeutic radiation procedure is only acceptable if the revision is dated and signed by an authorized user prior to the administration of the therapeutic electronic brachytherapy dose, or the next electronic brachytherapy fractional dose;

5. The patient’s identity is verified by more than one method as the individual named in the written directive prior to administration;

6. The final plans of treatment and related calculations agree with the respective written directives;

7. Each administration agrees with the written directive; and

8. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

(b) The registrant shall retain for 3 years each written directive in an auditable form.

(c) The registrant shall develop procedures for and conduct a review of the quality management program including an evaluation of the following:

1. A representative sample of patient administrations within the review period, as described in a procedure submitted to the Department;

2. All recordable events, as defined in subsection 64E-5.101(123), F.A.C., within the review period; and

3. All medical events within the review period to verify compliance with all aspects of the quality management program.

(d) The review of the quality management program shall be conducted at intervals not to exceed 12 months. The registrant shall maintain a record of each dated review for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

(e) The registrant shall evaluate each of these reviews to determine the effectiveness of the quality management program and make modifications to meet the objectives of the program.

(f) The registrant may make modifications to the quality management program to increase the program’s efficiency as long as the program’s effectiveness is not diminished. The registrant is required to submit any modifications to the quality management program to the department within 30 days after the modifications have been made.

(g) Within 30 days of discovery of each recordable event, as defined in subsection 64E-5.101(123), F.A.C., the registrant shall:

1. Assemble the relevant facts including the cause;

2. Identify and implement any corrective action required to prevent recurrence, and:

3. Retain a record in an auditable form for 3 years of the relevant facts and any corrective action taken.

(h) Each registrant shall maintain records and reports of medical events until the termination of the registration.

(4) Quality Assurance Program.
(a) Each registrant shall develop and administer a written quality assurance program as a method of minimizing deviations from facility procedures and to document preventative measures taken prior to serious patient injury or medical event. The quality assurance program must include written procedures for performing:

1. Treatment planning, chart and treatment field parameters;
2. Patient simulation, verification of catheter placement and device exchange;
3. Dose calculation and review, and;
4. Review of daily treatment records.

(b) Deviations from the prescribed treatment or from the facility’s quality assurance and operating procedures shall be investigated and brought to the attention of the authorized user, authorized medical physicist and radiation safety officer.

(c) A review of the quality assurance program shall be conducted at intervals not to exceed 3 months and shall include all the deviations from the prescribed treatment. A signed record of each dated review shall be maintained for inspection by the department in an auditable form for 3 years and shall include evaluations and findings of the review.

(5) Authority and Responsibilities.

(a) Radiation Safety Officer.

1. A registrant shall appoint a radiation safety officer responsible for implementing the radiation safety program. The registrant, through the radiation safety officer, shall ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the electronic brachytherapy devices.

2. The radiation safety officer shall promptly investigate and implement corrective actions as necessary regarding:

   a. Incidents as defined in Rule 64E-5.344, F.A.C.;
   b. Reportable events as defined in Rule 64E-5.345, F.A.C.; and
   c. Other deviations from approved radiation safety practice. A written report of these investigations and the corrective actions taken shall be given to management within 30 days of the incident, event or deviation.

3. The radiation safety officer shall implement written policies and procedures to:

   a. Use electronic brachytherapy devices safely;
   b. Perform radiation surveys whenever necessary;
   c. Perform checks of survey instruments and other safety equipment;
   d. Train personnel who work in or frequent areas where radiation is present; and
   e. Keep a copy of all records and reports required by department regulations, a copy of these regulations, and a copy of each registration correspondence to the department, and the written policies and procedures required by the regulations.

4. The radiation safety officer shall review at least every 3 months the occupational radiation exposure records of all personnel working with radiation therapy devices.

(b) Authorized User. Authorized users shall:

1. Be physically present during the initiation of each patient treatment;
2. Be physically present during the continuation of each patient treatment or identify in writing a physician under the supervision of the authorized user who is trained in the operation of and emergency response for the device who will be physically present during the continuation of each patient treatment;
3. Personally review the patient’s case to assure that the therapeutic radiation procedure is appropriate; and
4. Review the progress of the patient receiving therapy and modify the originally prescribed dose, if needed.

(c) Visiting Authorized User.

1. A registrant may permit any visiting authorized user to use an electronic brachytherapy device for medical use under the terms of the registrant’s registration and radiation protection program for 60 days each year if:
   a. The visiting authorized user has the prior written permission of the registrant’s management;
   b. The registrant has a copy of an electronic brachytherapy device registration issued by the department or another state that identifies the visiting authorized user by name as an authorized user for medical use of an electronic brachytherapy device; and
   c. The visiting authorized user performs only those procedures for which he is specifically authorized by the registration described in sub-subparagraph 64E-5.1604(5)(c)1., F.A.C.

   (2) A registrant shall retain copies of the records specified in subparagraph 64E-5.1604(5)(c)1., F.A.C., for 5 years after the last visit of the visiting authorized user.

(d) Authorized Medical Physicist. The authorized medical physicist shall:

1. Be physically present during the initiation and continuation of each patient treatment;
2. Evaluate the output from the electronic brachytherapy device source;
3. Generate the necessary dosimetry information;
4. Review treatment calculations prior to initial treatment of any treatment site;
5. Establish the quality assurance spot checks and review the data from those checks as required by the submitted procedures;
6. Consult with the authorized user in treatment planning, as needed, and;
7. Perform calculations and assessments regarding patient treatments that may constitute medical events;
(6) Operating Procedures. The registrant shall ensure compliance with the following procedures.

(a) An electronic brachytherapy device shall only be used according to the US Food and Drug Administration approved criteria for human use.

(b) When not in operation, the electronic brachytherapy device shall be secured from unauthorized use.

(c) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(d) A copy of the current operating and emergency procedures shall be kept in close proximity to the electronic brachytherapy device and easily accessible to the operator.

(e) No individual other than the patient shall be exposed during the treatment.

(f) The radiation safety officer or his/her designee, and an authorized user, shall be notified as soon as possible but no later than 24 hours after a patient’s, or human research subject’s, medical emergency or death.

(g) Only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist shall be present in the treatment room during treatment and a written log shall be kept of all personnel present during treatment.

(h) Simultaneous operation of more than one radiation-producing device in a treatment room shall be prohibited; and

(i) The registrant shall develop, implement, and maintain written procedures for responding to any situation in which the operator is unable to complete the treatment in compliance with the written directive. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to, and posting of, the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the device operates abnormally.

(7) Possession of a Survey Instrument. Each facility location authorized to use an electronic brachytherapy device shall possess portable monitoring equipment. At a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 0.1 microsievert (0.01 millirem) per hour to 10 millisievert (1000 millirem) per hour. All survey instruments shall be operable and calibrated annually.

(8) Calibration.

(a) Validation of the electronic brachytherapy source output shall be performed by an authorized medical physicist.

(b) Calibration validation measurements shall be made for each x-ray tube, or after any repair affecting the x-ray beam generation, or when indicated by the spot checks.

(c) Calibration validation must include determination of:

1. The output within 2% of the expected value, or determination of the output if there is no expected value;

2. Timer accuracy and linearity over the typical range of use;

3. Proper operation of back-up exposure control devices;

4. Evaluation that the relative dose distribution about the source is within 5% of that expected; and:

5. Source positioning accuracy to within 1 millimeter within the applicator.

(d) The validation of the output shall use a dosimetry system as described by the facility’s procedures to measure the output. Such procedures shall use a current published protocol from a nationally-recognized professional association with expertise in electronic brachytherapy, such as the AAPM. In the absence of such a published protocol, the manufacturer’s current protocol shall be followed.

(e) The registrant shall make calibration measurements required by this section according to a current published protocol from a nationally-recognized professional association with expertise in electronic brachytherapy, such as the AAPM. In the absence of such a published protocol, the manufacturer’s current testing protocol shall be followed.

(9) Routine and Day-of-Use Periodic Spot Checks for Electronic Brachytherapy Devices and Dosimetry Equipment.

(a) A registrant authorized to use electronic brachytherapy devices shall have a program to perform spot checks on each unit:

1. At the beginning of each day of use of an electronic brachytherapy unit:

2. Each time the unit is moved to a new room or site, and:

3. After each x-ray tube installation.

(b) The authorized medical physicist shall:

1. Establish written procedures for performing the spot checks;

2. Supervise the making of the spot checks and review the spot check results within 2 days of completion, and;

3. Notify the registrant in writing of any failures detected during the spot checks, within 24 hours of the identification of the spot check failure.

(c) The authorized user will prevent the clinical use of a malfunctioning device until the malfunction identified in the spot check has been evaluated and corrected or, if necessary, the equipment repaired.

(d) The spot checks must, at a minimum, assure proper operation of:

1. Radiation exposure indicator lights on the electronic brachytherapy device and on the control console, and;
2. The integrity of all cables, catheters or parts of the device.

(e) Spot checks of dosimetry must include checks that the output of the electronic brachytherapy source falls within 3% of expected values, which include:
1. Output as a function of time, or output as a function of setting on a monitor chamber, and;
2. Verification of the consistency of the dose distribution to within 3% of that found during calibration;
3. Validation of the operation of positioning methods to assure that the treatment dose exposes the intended location within 1 mm; and
4. Inspection of all treatment components (e.g., connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, treatment spacers) on the day of use for any imperfections.

(f) A registrant shall retain a record of each spot check for 3 years. The record shall include:
1. The date of the check;
2. The manufacturer's name, model number, and serial number of the electronic brachytherapy source;
3. Notations indicating the operability of electronic brachytherapy source exposure indicator lights, applicators, source-transfer tubes, transfer tube-applicator interfaces, and source-positioning accuracy; and
4. The name and signature of the individual who performed the check.

(10) Mobile Electronic Brachytherapy Devices. A registrant providing mobile electronic brachytherapy services shall:
(a) Check all survey instruments before medical use at each address of use and on each day of use;
(b) Account for the x-ray tube in the device before departure from the client’s address, and;
(c) Perform, at each location, all of the required periodic spot checks specified in subsection 64E-5.1604(9), F.A.C., to assure proper operation of the device.

(11) Treatment Planning.
(a) The authorized medical physicist shall perform acceptance testing on the treatment planning system of therapy-related computer systems according to a current published protocol from a nationally-recognized professional association with expertise in electronic brachytherapy, such as the AAPM. In the absence of such a published protocol, the manufacturer’s current protocol shall be followed. At a minimum, the acceptance testing shall include verification of:
1. The electronic brachytherapy source-specific input parameters required by the dose-calculation algorithm;
2. The accuracy of dose, dwell-time, and treatment-time calculations at representative points;
3. The accuracy of isodose plots and graphic displays;
4. The accuracy of the software used to determine source positions from images; and
5. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment-delivery parameters to the treatment-delivery unit from the treatment-planning system.

(b) The authorized medical physicist shall compare the position indicators in the applicator to the actual position of the source or planned dwell positions at the time of commissioning.

(c) Prior to each patient treatment regimen, the authorized medical physicist shall confirm the accuracy of the treatment parameters and dose.

Specific Authority 404.051(4), 404.22 FS. Law Implemented 404.051, 404.081(1), 404.22 FS. History–New __________.

NAME OF PERSON ORIGINATING PROPOSED RULE: James Futch
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ana Viamonte Ros, M.D., M.P.H.
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: November 12, 2008
DATE NOTICES OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 5, 2007 and October 3, 2008

DEPARTMENT OF HEALTH
Division of Emergency Medical Operations

RULE NOS.: RULE TITLES:
64J-2.007 Trauma Agency Formation and Plan Requirements
64J-2.008 Trauma Agency Plan Approval and Denial Process
64J-2.009 Trauma Agency Implementation and Operation Requirements

PURPOSE AND EFFECT: To clarify the trauma agency formation; plan development, submission and approval process; and the implementation and operation requirements of Florida's trauma agencies.

SUMMARY: The proposed revisions:
1. Delineate the initial process of obtaining local authority to operate and form a trauma agency from the renewal process; and the plan development, submission and approval of the initial and five-year plan updates;
2. Clarify content requirements of the initial and the five-year plan updates;
3. Clarify the trauma agency’s role in the review of trauma center applications from any hospital within the defined geographical area of the trauma agency.
4. Clarify and amends the requirements of the annual performance evaluation and the submission of an annual report on the status of the Trauma agency’s trauma system; and
5. Technical amendments for the purpose of consistency and to update the submission process of the trauma agency plan from hard copy to electronic submission.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

SPECIFIC AUTHORITY: 395.401, 395.405 FS.


IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAW.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 2 days before the workshop/meeting by contacting: Janet Collins (850)245-4444, ext. 2775. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice). If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULES IS: Susan McDevitt, Office of Trauma, Department of Health, 4052 Bald Cypress Way, Bin C-18, Tallahassee, Florida 32399-1738, (850)245-4440, ext. 2760; Email: susan_mcdevitt@doh.state.fl.us; Fax: (850)488-2512

THE FULL TEXT OF THE PROPOSED RULES IS:

64J-2.007 Trauma Agency Formation and Plan Requirements.

(1) To form a trauma agency, and for submission of the trauma agency 5-year plan update, a county or counties (if regional), or an entity with which the county or counties contract for the purpose of trauma service administration shall:

(a) Obtain formal authority to create the agency from the county commission of each of the counties in which the agency plans to operate.

(b) Establish interlocal agreements between county governments if the proposed agency shall provide service to more than one county.

(2) For the formation and for continuation of a trauma agency, a county or counties, or an entity with which the county or counties contract for the purpose of trauma agency service administration, shall submit a trauma agency plan initially and an update at five-year intervals thereafter to the department for approval. Prior to the submission of the trauma agency plan or five-year plan update to the department, the county or counties, an entity with which the county or counties contract or the existing trauma agency shall:

(a) Hold a public hearing and give adequate notice of the hearing to the public in the defined geographic area to be served by county or counties in which the proposed trauma agency shall operate. Adequate notice shall consist of publishing the notice, at least 30 days prior to the public hearing, in at least one newspaper of general circulation in each affected county. If a newspaper is not published in a county in which an existing or proposed trauma agency shall operate, adequate notice may be given by publishing the notice in at least one newspaper of general circulation in adjoining affected counties.

(b) Develop and submit an electronic original and four copies of the trauma agency plan or five-year plan update to the department for review and approval.

(3) The trauma agency initial plan or five-year plan update shall contain the following information in the following order:

(a) Table of Contents;

(b) Population and Geographic Area to be Served.

1. Describe the population and defined geographic area to be served by the trauma agency;

2. Include a map showing the defined geographic area of the proposed trauma agency, each major geographical barrier, all medical facilities, all prehospital ground and air facilities, and all other significant factors that affect the determination of the geographic area boundaries; and

3. Describe the historical patient flow, patient referral, and transfer patterns used to define the geographic areas of the proposed trauma agency.

(c) Organizational Structure:

1. Provide a detailed description of the managerial and administrative structure of the proposed agency;

2. Include a table of organization, the names of the board of directors and each member’s affiliation, and identify the individuals who will administer or operate the trauma agency, if known;

3. Provide the names, job descriptions and responsibilities of officials who shall be directly responsible for trauma agency personnel, and the names, job descriptions and responsibilities of individuals who shall be responsible for managing and operating the trauma agency on a daily basis; and

4. Describe in detail the specific authority that trauma agency personnel shall have in directing the operation of prehospital and hospital entities within the purview of the trauma agency, if approved, be it a single or multi-county trauma agency.

(d) Trauma System Structure:

1. Describe the operational functions of the system; the components of the system; the integration of the components and operational functions; and the coordination and integration of the activities and responsibilities of trauma centers, hospitals, and prehospital EMS providers; and
2. Include a list of all participating and non-participating trauma care resources within the defined geographical area of the proposed trauma agency and documentation showing that these entities have been given the opportunity to participate in the system. Trauma care resources shall include, but are not limited to, hospitals, trauma centers, EMS prehospital providers, training centers, emergency medical dispatch, and planning entities; and

3. Include the proposed trauma agency’s recommendation and justification for the number and location of trauma centers required to serve its defined geographical area.

(e) Objectives, Proposed Actions, and Implementation Schedule. Provide a description of the objectives of the plan, a detailed list of the proposed actions necessary to accomplish each objective, and a timetable for the implementation of the objectives and action. The timetable shall identify the scheduling of the annual audit and evaluation, including the completion date and submission date to the department.

(f) Describe the proposed source of income and anticipated expenses by category for the proposed trauma agency:

(g) Describe the proposed trauma agency’s fiscal impact on the trauma system which includes a description of any increased costs related to providing trauma care.

(h) Transportation System Design:
1. Describe the EMS ground, water, and air transportation system design of the trauma system; and

2. Include trauma patient flow patterns, emergency inter-hospital transfer agreements and procedures, and the number, type, and level of service of the prehospital EMS providers within the trauma system.

(i) TTPs:
1. Provide confirmation that existing department-approved TTPs for each EMS provider, within the defined geographical area of the proposed trauma agency, are accurate and shall be adopted by the proposed trauma agency, pending department approval of the plan;

2. A proposed trauma agency may develop uniform TTPs for department approval that shall be adhered to by all EMS providers that serve the geographical area of the proposed trauma agency. If uniform TTPs are submitted to the department for approval, the TTPs shall include the name of each EMS provider that shall operate according to the uniform TTPs, and proof of consultation with each EMS provider’s medical director. TTPs developed and submitted by a proposed trauma agency shall be processed in accordance with Rule 64J-2.003, F.A.C.; and

3. The proposed trauma agency shall provide a copy of any county ordinance governing the transport of trauma patients within the defined geographic area of the proposed trauma agency.

(j) Medical Control and Accountability. Identify and describe the qualifications, responsibilities and authority of individuals and institutions providing off-line (system) medical direction and on-line (direct) medical control of all hospitals and prehospital EMS providers operating under the purview of the trauma agency.

(k) Emergency Medical Communications:
1. Describe the EMS communication system within the proposed trauma agency’s trauma service area; and

2. Describe the proposed trauma agency’s compliance with the State of Florida Communications Plan, requirements for normal operating conditions, mass casualty and disaster situations in which commercial power, telephone lines, or telephone services are not available, including outages of base stations controlled by leased telephone lines. The specific areas to be addressed are:
   a. Statewide medical coordination (SMC);
   b. Local medical coordination (LMC);
   c. Vehicle dispatch and response (VDR);
   d. Medical resource coordination;
   e. Local scene coordination;
   f. Medical alert paging;
   g. Communications coverage;
   h. LMC and VDR channels;
   i. SMC channel;
   j. Cellular phone use if applicable; and
   k. Locations and types of communications equipment within the proposed trauma agency’s geographical area.

2. Verify that the existing communications within the trauma agency’s trauma service area meet all the requirements for compliance with the State of Florida’s EMS Communication Plan, to include all hospitals with emergency departments.

(l) Data Collection. Describe the trauma data management system developed for the purpose of documenting and evaluating the trauma systems operation.

(m) Trauma System Evaluation. Describe the methodology by which the proposed trauma agency shall evaluate the trauma system.

(n) Mass Casualty and Disaster Plan Coordination. Describe the proposed trauma agency’s role with local and/or regional emergency management entities in the coordination of the prehospital and hospital component’s mass casualty and disaster plan for the defined geographic area it represents.

(o) Public Information and Education. Describe the proposed trauma agency’s programs designed to increase public awareness of the trauma system and public education programs designed to prevent, reduce the incidence of, and care for traumatic injuries within the defined geographic area it represents.

(p) Attachments. Include the following:
1. A sample copy of each type of contract and agreement entered into by the proposed trauma agency, pending department approval of the proposed trauma agency, for the benefit and operation of the trauma system. A description of these agreements may be substituted and.

2. Documentation showing that the county commission of the county or counties in the geographic area to be served by the trauma agency have endorsed the initial plan or five-year plan update, pending department approval of the same; and

3. A copy of the public hearing notice and minutes of the hearing for the initial plan or five-year plan update.


64J-2.008 Trauma Agency Plan Approval and Denial Process.

(1) The department shall, within 30 days of receipt of the initial formation of a trauma agency plan and the five-year plan update, pending department approval of the same; and

3. A copy of the public hearing notice and minutes of the hearing for the initial plan or five-year plan update.

64J-2.009 Trauma Agency Implementation and Operation Requirements.

(1) To implement a trauma system, a department-approved trauma agency shall:

(a) Implement the trauma system in accordance with its department-approved planned timetable for implementation.

(b) Submit proposed changes to the department-approved plan to the department for approval, as provided in Rule 64J-2.008, F.A.C. The trauma agency may, at its own risk, institute proposed changes to the plan and submit a request for department approval within 30 days after a change is instituted if a delay in approval would have an adverse impact on the current level of care. The trauma agency’s request shall explain how the delay in approval would have adversely affected the current level of care. Each request shall document that affected trauma care resources within the defined geographical area of the agency concur with these proposed changes.

(2) Each trauma agency shall operate the trauma system in accordance with the department-approved plan, and shall:

(a) Conduct reviews of trauma center applications from any hospital within the defined geographic area of the trauma agency. Submission of a trauma center’s application to the trauma agency by a hospital seeking approval shall be in accordance with the time frames described in paragraph 64J-2.012(1)(c), F.A.C. The department will coordinate the prospective trauma center’s application development and review process with the relevant trauma agency to facilitate sufficient time to increase familiarity with the application and conduct the final review. Results of the trauma agency’s review shall be submitted to the department no later than April 7 of each year, in order to be considered by the department.

(b) Conduct annual performance evaluations and submit annual reports on the status of the trauma agency’s trauma system to the department to be included in the department’s Florida Trauma System annual reports for approval, as provided in Rule 64J-2.008, F.A.C. The trauma agency annual evaluation report shall be submitted by June 1, following the end of the previous calendar year. This evaluation shall include at least the following:

1. Description of any funding sources and any other related issues, such as: the fiscal impact on the trauma agency’s system, including increased costs related to providing trauma care, the reduction or increase in budget or human resources, specialty physician coverage, etc. Results of monitoring each EMS provider, trauma center and hospital within the defined geographic area of the trauma agency for compliance with trauma scorecard methodology requirements as provided in Rule 64J-2.001 and 64J-2.005, F.A.C.

2. Results of monitoring each EMS provider, trauma center and hospital within the defined geographic area of the trauma agency for compliance with TTP requirements as provided in Rule 64J-2.002, F.A.C.

3. Collection of data on both prehospital and hospital patient care data, as defined by the trauma agency plan.

4. Documentation of the continuum of care and quality of medical care for all trauma patients from injury through rehabilitation or death.

2. Documentation that all trauma centers in the geographic area participate of the trauma agency participate in trauma agency’s quality assurance and improvement processes.

3. Description of public and healthcare education, injury prevention activities, and outreach programs, conducted in the trauma agency’s geographical area, which are designed to prevent, reduce the incidence of and improve the care for traumatic injuries within the defined geographic area.

4. Documentation of data, including the nature of injuries and trends identified in the trauma agency’s defined geographic area.

5. Documentation of monitoring the effectiveness of the adult and pediatric trauma alert criteria with regard to determination of appropriate destinations.

6. Results of monitoring for compliance with trauma registry reporting requirements.

(3) Each trauma agency shall have personnel or arrange for management service personnel with clear authority and responsibility to operate the trauma agency. The administrative function of the trauma agency shall not be carried out or performed under the direct supervision of any individual who administers or operates any health care entity in the trauma system, whether a single or multi-county system.