69V-560.1013 Electronic Filing of Forms and Fees.

(1) For purposes of this rule, "REAL System" means the Office of Financial Regulation's Regulatory Enforcement and Licensing System, which is accessible through the Office's website at www.flofr.com.

(2) All forms adopted under paragraphs 69V-560.1012(1)(a) through (1)(g), F.A.C., must be filed electronically with the Office through the REAL system.

(3) All fees required to be filed with the Office under Chapter 69V-560, F.A.C., must be paid electronically through the REAL System.

(4) Any person may request an exemption from the ~~petition for a waiver of the requirement of~~ electronic filing requirements of this rule by submitting a written request to: Office of Financial Regulation, Division of Finance, Bureau of Regulatory Review, 200 E. Gaines Street, Tallahassee, Florida 32399-0351. The request must set forth the person's technological or financial hardship that makes it difficult for the person to file forms and pay fees electronically. The request must be legible and include the applicant's or licensee's name, contact person, address and telephone number. The Office of Financial Regulation will provide any person granted an exemption under this subsection with instructions on how to file forms and fees in paper format ~~of any form or fee under Chapter 69V-560, F.A.C., by filing a petition under Rule 28-106.301, F.A.C. The petition must demonstrate a technological or financial hardship that entitles the person to file the form or fees in a paper format. The Office will provide any person granted a waiver under this subsection a hardcopy version of the applicable form.~~

Rulemaking ~~Specific~~ Authority 560.105 FS. Law Implemented 560.105 FS. History–New 1-13-09, Amended _____.

Section II
Proposed Rules

BOARD OF TRUSTEES OF THE INTERNAL IMPROVEMENT TRUST FUND

Notices for the Board of Trustees of the Internal Improvement Trust Fund between December 28, 2001 and June 30, 2006, go to http://www.dep.state.fl.us/ under the link or button titled "Official Notices."

AGENCY FOR HEALTH CARE ADMINISTRATION

Health Care Responsibility Program

RULE NOS.:	RULE TITLES:
59H-2.003	Definitions
59H-2.004	County Financial Participation and Lead Agency Responsibilities
59H-2.005	Hospital Participation
59H-2.006	Covered Services
59H-2.007	Determination of Eligibility
59H-2.009	Reimbursement Procedures
59H-2.010	Administrative Hearing; Applicant's Rights and Responsibilities
59H-2.011	Utilization Review

PURPOSE AND EFFECT: To repeal Rules 59H-2.003, 59H-2.004, 59H-2.005, 59H-2.006, 59H-2.007, 59H-2.009, 59H-2.010, 59H-2.011, F.A.C., because the Shared County and State Health Care Program was never funded and has never been an active program.

SUMMARY: Chapter 59H-2 – Shared County and State Health Care Program.

This rule is being repealed. The Shared County and State Health Care Program (Program) Rule was implemented under Section 409.2673, F.S., and was created in March of 1989. The Program was created to cover hospital costs for low income persons who did not meet the criteria for Medicaid or other state-funded or federally funded programs which included hospital care. The funding for the Program was based on a formula whereby a county provided 35% and the State provided 65%, or under certain circumstances, the State would provide 100% funding. This Program has never been funded and was never active.

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.

RULEMAKING AUTHORITY: 409.2673(4)(c) FS.

LAW IMPLEMENTED: 409.2673 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 RULES IS: Hazel Greenberg, Program Administrator, Agency for Health Care Administration, Bureau of Managed Health Care, 2727 Mahan Drive, Mail Stop Code 26, Tallahassee, FL 32308, (850)487-0640

THE FULL TEXT OF THE PROPOSED RULES IS:

59H-2.003 Definitions.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673 FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.003, Amended 6-7-00, Repealed _____.

59H-2.004 County Financial Participation and Lead Agency Responsibilities.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(4), (7), (9) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.004, Amended 6-7-00, Repealed _____.

59H-2.005 Hospital Participation.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(9) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.005, Amended 6-7-00, Repealed _____.

59H-2.006 Covered Services.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(2) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.006, Amended 6-7-00, Repealed _____.

59H-2.007 Determination of Eligibility.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(2), (8), (9) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.008, Amended 6-7-00, Repealed _____.

59H-2.009 Reimbursement Procedures.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(2), (9), (10) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.009, Amended 6-7-00, Repealed _____.

59H-2.010 Administrative Hearing; Applicant's Rights and Responsibilities.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(2) FS. History–New 3-29-89, Amended 12-24-90, Formerly 10C-34.010, Amended 6-7-00, Repealed _____.

59H-2.011 Utilization Review.

Rulemaking ~~Specific~~ Authority Chapter 88-294, Section 27, Laws of Florida. Law Implemented 409.2673(2) FS. History–New 3-29-89, Formerly 10C-34.011, Repealed _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Hazel Greenberg, Program Administrator, Bureau of Managed Health Care

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Holly Benson, Secretary, Agency For Health Care Administration

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 17, 2009

DEPARTMENT OF MANAGEMENT SERVICES

Personnel Management System

RULE NOS.:	RULE TITLES:
60L-39.001	Scope and Purpose
60L-39.0015	Definitions
60L-39.002	General Requirements
60L-39.003	Statewide Steering Committee
60L-39.004	Eligibility Criteria for Participation in the Campaign Organizations
60L-39.0041	Eligibility Criteria for the Receipt of Tier One Undesignated Funds
60L-39.005	Application Procedures
60L-39.006	Department Duties and Responsibilities
60L-39.007	Appeals
60L-39.008	Local Steering Committees
60L-39.009	Campaign Supported Activities

PURPOSE AND EFFECT: Amends current rule to streamline campaign processes and align provisions with statutory language.

SUMMARY: Substantive revisions made to align the definitions of all terms with the statute, clarify terms, remove criteria redundant with or inconsistent with statute, delineate each party's authority and role, and provide guidance that will facilitate uniform practices. Also revised application forms to simplify the application processes and clarify instructions. The Division of Human Resource Management has consulted with the Small Business Regulatory Council and has determined that this amendment has no impact on small businesses as defined by Section 288.703, F.S., nor on small counties or small cities as defined by Section 120.52, F.S., since the affected entities are non-profit organizations.

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.

RULEMAKING AUTHORITY: 110.181(3)(a) FS.

LAW IMPLEMENTED: 110.181 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: October 28, 2009, 8:30 a.m. – 12:00 Noon

PLACE: 4050 Esplanade Way, Room 101, Tallahassee, FL 32399-0950

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 5 days before the workshop/meeting by

contacting: Mr. Matt Gregory at matthew.gregory@dms.myflorida.com. 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: Mr. Matt Gregory, HR Consultant, 4050 Esplanade Way, Suite 235, Tallahassee, FL 32399-0950, phone (850)921-4618

THE FULL TEXT OF THE PROPOSED RULES IS:

(Substantial rewording of Rule 60L-39.001 follows. See Florida Administrative Code for present text.)

60L-39.001 Scope and Purpose.

In order to provide a means by which employees may voluntarily engage in charitable giving, the State of Florida has an interest in establishing a consolidated charitable campaign with minimal workplace disruption and administrative costs. To that end, this chapter sets forth the rules governing the Florida State Employees' Charitable Campaign (FSECC or "the Campaign") in accordance with Section 110.181, F.S.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-1-02, Amended 1-23-07, _____.

(Substantial rewording of Rule 60L-39.0015 follows. See Florida Administrative Code for present text.)

60L-39.0015 Definitions.

(1) The following definitions apply to this rule chapter:

(a) Activities. The specific pursuit of actions by the charitable organization in terms of the services provided through its charitable work. This phrase does not refer to internal structure or membership of the charitable organization.

(b) Campaign. The Florida State Employees' Charitable Campaign, as set forth in Section 110.181, F.S., and Rule Chapter 60L-39, F.A.C.

(c) Campaign brochure. The compiled listings and descriptions of all approved charitable organizations to which employees may contribute and which may vary in content by fiscal agent area.

(d) Campaign Cycle. A time period that begins in the fall of the calendar year in which charitable organizations are approved to participate and concludes at the end of the following calendar year once all payroll deductions are collected.

(e) Charitable Organization. A non-profit entity as defined in Section 496.404(1), F.S., that is properly registered as a charitable organization pursuant to Section 496.405, F.S., or an entity that is the umbrella group for such entities.

(f) Completed Application. A Form DMS-ADM-100 (rev. 9/09) or Form DMS-ADM-102 (rev. 9/09) on which charitable organizations have provided the requested information for every applicable question and data field, including the required supporting documentation.

(g) Designated Funds. Those contributions which the employee designates to specific charitable organizations participating in the FSECC.

(h) Direct services. Identifiable and specific services of a charitable organization made available by the performance of specific activities in at least one local fiscal agent's area.

(i) Fiscal Agent. A nonprofit charitable organization participating in the FSECC or a business entity selected by the Department of Management Services through the competitive procurement process and placed under contract to administer the receipt of, accounting for and distribution of the charitable contributions to the participating charitable organizations and to perform other appropriate administrative services as negotiated through contract.

(j) Fiscal Agent Area. A geographic region of the state as designated in Form DMS-ADM-102 (rev. 9/09) for administrative convenience and used to administer the contracted services through local fiscal agents.

(k) Fraternal. Relating or belonging to a fraternity or an association of persons formed for mutual aid and benefit, but not for profit.

(l) Incidentally. Of a minor or subordinate nature to a charitable organization's charitable activities.

(m) Independent unaffiliated Agency. A charitable organization which is not an umbrella group or a member of any umbrella group.

(n) International Service Agency. A charitable organization with any programs outside the United States.

(o) National Agency. A charitable organization with programs that provide services outside of Florida but within the United States.

(p) Political. Relating to a national or state political party or any organization, explicitly calling for or attempting to influence the election or defeat of a particular candidate or issue within a specific election or relating to an organization engaged in lobbying as defined in Section 11.045(1)(f), F.S.

(q) Primarily. Chiefly, principally or mainly as it relates to the activities of the charitable organization and not its internal structure or membership.

(r) Professional. Relating to an occupation requiring considerable training and specialized study which is subject to an association, the purpose of which is to promote a common business interest and to improve business conditions in one or more lines of business, e.g., law, medicine or engineering, not to engage in a regular business of a kind ordinarily carried on for profit.

(s) Religious. Relating to religion as practiced by any church, ecclesiastical or denominational organization with an established physical place where religious worship is regularly conducted.

(t) Statewide Steering Committee. The Steering Committee established in Section 110.181(4), F.S.

(u) Tier One Undesignated Funds. Those contributions for which employees did not designate a specific charitable organization and which are distributed by the Statewide Steering Committee on a pro rata basis pursuant to Section 110. 181(2)(e), F.S.

(v) Tier Two Undesignated Funds. Those monies remaining after Tier One distribution of undesignated funds and which are distributed by the local steering committees, pursuant to Section 110.181(2)(e), F.S.

(w) Umbrella Group. An entity that is a federated fundraising organization as defined in Section 496.404(10), F.S.

(2) All other terms shall have their commonly understood meaning.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-23-07, Amended _____.

60L-39.002 General Requirements.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-6-02, Amended 1-9-05, 1-23-07, Repealed _____.

(Substantial rewording of Rule 60L-39.003 follows. See Florida Administrative Code for present text.)

60L-39.003 Statewide Steering Committee.

(1) The members of the Statewide Steering Committee shall serve staggered four-year terms.

(2) To facilitate effective and efficient departmental oversight and maintenance of the campaign, the Secretary shall designate one of the Department's appointees to serve as the chairperson of the committee. The Chairperson may call meetings of the Statewide Steering Committee on behalf of the Secretary, coordinate meeting agendas and preside over the meetings.

(3) The Statewide Steering Committee shall assist the Department in an advisory role regarding the development of procedures and guidelines that support administration of the campaign.

(4) The Statewide Steering Committee shall approve the calendar of events and the training and marketing materials proposed by either the Department or the fiscal agent.

(5) The Statewide Steering Committee shall review all Form DMS-ADM-100 (rev. 9/09) applications before June 1 of each campaign cycle and recommend approval or denial on the basis of compliance with the established criteria, completeness and timely submission.

(6) The Statewide Steering Committee shall review all Form DMS-ADM-102 (rev. 9/09) applications for receipt of Tier One undesignated funds before January 31 of each campaign cycle and recommend approval or denial on the basis of compliance with the established criteria, completeness, and timely submission.

(7) If needed for purposes of determining eligibility, the Statewide Steering Committee may request clarification of any information provided by a charitable organization which has filed a completed application. If requested, umbrella groups shall provide contact information for member organizations with whom the Statewide Steering Committee may wish to correspond directly. In order to be considered, the requested clarification shall be submitted to the Department within five working days of the receipt of the Committee's request. Submitted means electronically submitted or postmarked no later than 11:59 p.m. on the fifth day.

(8) The Statewide Steering Committee shall recommend to the Department approval or denial of any reviewed Form DMS-ADM-100 (rev. 9/09) and Form DMS-ADM-102 (rev. 9/09).

(9) Except for the campaign materials approved by the Statewide Steering Committee, charitable organizations shall not permit, plan, or conduct distribution of any materials, solicitation, or services within State facilities as part of the campaign. Charitable organizations are encouraged, however, to publicize their activities and solicit employee participation in the FSECC through the news media or other private outlets outside State facilities. Charitable organizations shall not contact employees at the work place for any purpose. However, the fiscal agent may contact employees for the express purpose of requesting clarifying information regarding authorized payroll deduction information from the agency FSECC coordinators.

(10) The Statewide Steering Committee shall ensure that campaign brochures and materials, whether produced by the department or the fiscal agent, treat all participating charitable organizations equally and fairly. Campaign brochures shall provide the same type, size, and color print for all participating charitable organizations.

(a) The campaign brochure in each fiscal agent area shall group charitable organizations by their respective umbrella group into separate sections of the brochure. The order of the umbrella groups shall be alphabetical. The individual charities that comprise an umbrella group shall be listed in alphabetical order within the umbrella group listing, except that the umbrella group itself will be listed first, if applicable. Independent unaffilated agencies shall be grouped together alphabetically as one listing and appear as the last section of the brochures.

(b) A campaign brochure that is specific to a geographic area shall not list both the state or national charitable organization and its local affiliate or other subunit.

(c) Similarly-named charitable organizations shall not be listed, unless the Statewide Steering Committee determines they do not deliver services to overlapping or identical geographical areas.

(d) In cases where a charitiable organization has submitted more than one application, such charitiable organization shall be listed under the United Way, if applicable. Otherwise, their listing in the brochure shall be determined on the basis of the approved application which was received by the department first. In no case shall a charitiable organation be given a dual listing in the same campaign brochure.

(e) Campaign brochures shall be uniform in structure as determined by the Statewide Steering Committee and shall include the words Florida State Employees' Charitable Campaign and the official FSECC logo on the front cover. Campaign brochures shall exclude any local fiscal agent logo and slogan. Fiscal agent or local fiscal agent name may be used only as contact information within the brochure.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-6-02, Amended 3-5-04, 1-9-05, 2-13-06, 1-23-07,_____.

(Substantial rewording of Rule 60L-39.004 follows. See Florida Administrative Code for present text.)

60L-39.004 Eligibility Criteria for Participation in the Campaign ~~by Charitable~~ Organizations.

(1) For purposes of ensuring compliance with the eligibility criteria of Section 110.181(1)(c)-(h), F.S., charitable organizations are subject to the following:

(a) Charitable organizations with fundraising and administrative expenses in excess of 25% shall provide justification to demonstrate extraordinary circumstances beyond the charitable organization's control.

(b) Religious charitable organizations which provide services described in Section 110.181, F.S., shall not be excluded because of religious viewpoint.

(c) Organizations which comply with all applicable state and federal nondiscrimination laws shall be deemed in compliance with Section 110.181(1)(h)3., F.S.

(d) Organizations which are required to register pursuant to the Solicitation of Contributions Act, Chapter 496, F.S., shall have a registration number that is valid on March 1, of the application year. Organizations which are not required to register shall be deemed in compliance with Section 110.181(1)(h)4., F.S., with proper documentation.

(e) Organizations which are duly registered under section 501(c)(3), Internal Revenue Code, shall be deemed in compliance with Section 110.181(1)(h)5., F.S.

(2) Once approved for participation, any charitable organization may be disqualified by majority vote of the Steering Committee for:

(a) Failing to maintain eligibility for participation in the campaign, if such failure occurs prior to publication of the campaign brochure; or,

(b) Filing an application to participate in the FSECC that contains false or misleading information that is material to the applicant's eligibility.

(3) Pursuant to federal law, participating charitable organizations shall not be on the list of persons and entities designated under Executive Order 13224, the United States Treasury Department's "master list" of specially designated nationals and blocked persons, and the United States State Department's list of foreign terrorist organizations. In addition, participating charitable organizations shall certify that they protect against fraud with respect to the provision of financial, technical, in-kind or other material support or resources to persons or organizations on such lists, and ensure that they do not knowingly provide financial, technical, in-kind or other material support or resources to any individual or entity that they know beforehand is supporting or funding terrorism.

(4) Independent Unaffiliated agencies shall be deemed to be providing services throughout the year and throughout the state in accordance with Section 110.181(1)(d), F.S., if they demonstrate that their services were provided every month of the calendar year and in every fiscal agent area.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-6-02, Amended 1-23-07,_____.

60L-39.0041 Eligibility Criteria for Receipt of Tier One Undesignated Funds.

(1) In order to be eligible for Tier One undesignated funds to be awarded by the Statewide Steering Committee, the charitable organization must be approved for participation in the current campaign cycle and, in accordance with Section 110.181(2)(e), F.S., must have provided direct services in a local fiscal agent's area in the preceding calendar year.

(2) For the purposes of administering Section 110.181(2)(e), F.S., direct services include:

(a) Providing family, foster care or adult/child care;

(b) Providing transportation, information, referral, or counseling services for the disadvantaged population;

(c) Providing adoption services;

(d) Preparing or delivering meals; feeding the hungry;

(e) Providing emergency shelter care or relief services;

(f) Providing safety or protective services for adults and/or children;

(g) Providing neighborhood or community health and welfare, care, grants, and/or recreation services;

(h) Providing rehabilitation services;

(i) Providing health education, or patient services or support;

(j) Providing social adjustment, counseling, rehabilitation, or job training;

(k) Providing a combination of services designed to meet the needs of special groups such as the elderly or persons with disability;

(l) Providing scholarships, grants or a combination of financial/material assistance to provide education or job training for the disadvantaged population;

(m) Providing individual or family legal counseling for the indigent;

(n) Conserving, protecting, or restoring the State's environment;

(o) Any other well-defined substantial, direct, or hands-on specific act performed in the specific fiscal agent area in which the charitable organization is applying.

(3) For the purpose of administering Section 110.181(2)(e), F.S., if the only services that a charitable organization provided are one or more of the following activities, such services shall not constitute direct services:

(a) Maintaining, defending or settling any proceeding;

(b) Holding meetings of the board of directors or members, or carrying on other activities concerning internal corporate affairs;

(c) Maintaining bank accounts:

(d) Fundraising;

(e) Distributing informational materials;

(f) Operating internet websites;

(g) Distributing advocacy materials;

(h) Lobbying for passage or defeat of legislation;

(i) Engaging in activities intended to shape public policy;

(j) Conducting corporate affairs in interstate commerce.

(4) Once determined to be providing direct services in a fiscal agent area, any charitable organization may be disqualified by majority vote of the Steering Committee for:

(a) Failing to comply with the procedures contained in this chapter; or

(b) Filing an application to participate in the FSECC that contains false or intentionally misleading information.

Rulemaking Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New _____.

(Substantial rewording of Rule 60L-39.005 follows. See Florida Administrative Code for present text.)

60L-39.005 Application Procedures.

(1) Application for annual participation in the FSECC shall be submitted no later than March 1 of each year on Form DMS-ADM-100 (rev. 9/09), Application for Participation in the Florida State Employees' Charitable Campaign, effective _____, which is incorporated by reference. This form shall be available on the Department's website http://dms.myflorida.com/human_resource_support/human_resource_management/for_state_personnel_system_employees/state_employees_charitable_campaign or upon request.

(a) Electronic applications shall be submitted to the electronic address specified by the Department on the application form by 11:59 P.M., eastern standard time, on March 1.

(b) In the event the application form and supporting documentation is submitted as a paper package, the submission must be postmarked by March 1.

(c) An umbrella group may submit applications on behalf of its members.

(d) Each charitable organization shall submit a copy of its most recently filed IRS Form 990 provided that it is for a fiscal period ending not more than 24 months prior to March 1. Charitable organizations which are not required to file an IRS Form 990 or which file an IRS Form 990 EZ or an IRS Form 990 PF shall document administrative expenses, fundraising expenses, and total revenue on the applicable pages of an IRS Form 990 and shall submit these pages with their application, in accordance with instructions on the DMS-ADM-100 (rev. 9/09).

(e) Charitable organizations that are exempt from registering with the Department of Agriculture and Consumer Services, pursuant to Section 496.406, F.S., shall provide a copy of an exemption letter from the Department of Agriculture and Consumer Services as part of their application. Failure to do so will result in an incomplete application.

(f) Applications from charitable organizations that have an automatic exclusion from the registration requirements pursuant to Section 496.403, F.S., shall include a letter from the Department of Agriculture and Consumer Services concurring with that exclusion in order to be considered a completed application.

(g) In the event a charitable organization submits a Form DMS-ADM-100 (rev. 9/09) that is missing required information or documentation, the organization shall have five business days from the date they receive a certified, written notice by the Department, to submit the required information or documentation to the Department. Such documentation or information shall be submitted to the electronic address specified by the Department by 11:59 P.M., eastern standard time, on the fifth business day or, if submitted on paper, it must be postmarked no later than the fifth business day.

(2) Application for Receipt of Tier One Undesignated Funds, pursuant to Section 110.181(2)(e), F.S., shall be made on Form DMS-ADM-102 (rev. 9/09), Direct Local Services Certification Form, effective _____, which is incorporated by reference. This form shall be available on the Department's official website: http://dms.myflorida.com/human_resource_support/human_resource_management/for_state_personnel_system_employees/state_employees_charitable_campaign or upon request.

(a) In order to be considered for the receipt of Tier One undesignated funds, umbrella groups, on behalf of their member agencies, and all independent unaffiliated agencies shall annually submit completed DMS-ADM-102 applications to the electronic address specified by the Department on the application form by 11:59 P.M., eastern standard time, on October 1 of the same calendar year in which their DMS-ADM-100 (rev. 9/09) application was approved.

(b) In the event the application and/or any applicable supporting documentation is submitted as a paper package, the submission must be postmarked by October 1.

(c) Local United Way organizations are by definition providing direct services in a local fiscal agent area and are presumed to meet the statutory criteria for the receipt of Tier One undesignated funds. Therefore, such charitable organizations are exempt from this application requirement.

(3) The Statewide Steering Committee shall only consider complete applications for inclusion in the Campaign or for the receipt of Tier One undesignated funds. Incomplete applications shall be deemed denied without further action from the Statewide Steering Committee.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-1-02, Amended 3-5-04, 1-9-05, 2-13-06, 1-23-07, _____.

(Substantial rewording of Rule 60L-39.006 follows. See Florida Administrative Code for present text.)

60L-39.006 Department Duties and Responsibilities ~~of the Fiscal Agent~~.

(1) The Department shall be responsible for effectively and efficiently administering the Campaign by procuring, through the competitive bid process, a fiscal agent that shall:

(a) Provide state level coordination of the campaign and oversee the activities of local fiscal agents, which receive, account for, and distribute charitable contributions among participating charitable organizations;

(b) Select, train and manage local steering committees composed of state employees in each fiscal agent area to assist in conducting the campaign and to direct the distribution of Tier Two undesignated funds. Members of the local steering committees shall be selected from among recommendations provided by interested participating charitable organizations, if any, with the approval of the Statewide Steering Committee. Charitable organizations shall submit the names of potential steering committee members, if any, to the local fiscal agent by July 1 of each year;

(c) Train agency coordinators and volunteers in the methods of non-coercive solicitation;

(d) Honor employee designations;

(e) Help to ensure that no employee is coerced or questioned as to the employee's designation or its amount, other than for arithmetical inconsistencies;

(f) Respond in a timely and appropriate manner to inquiries from employees, participating charitable organizations, umbrella groups or the Steering Committee;

(g) Provide all participating charitable organizations with the names and contact information of the local steering committee chairpersons and provide timely notification of the date, time and location of all local steering committee meetings.

(h) Provide a minimum of a two-week notice to umbrella groups for meetings during which Tier One or Tier Two undesignated funds will be discussed.

(i) Distribute Tier One undesignated funds awarded by the Statewide Steering Committee to participating charitable organizations in the same percentage as the designated funds received by those participating charitable organizations.

(j) Distribute Tier Two undesignated funds awarded by the local steering committees to appropriate charitable organizations in the campaign;

(k) Distribute campaign funds to participating charitable organizations on at least a quarterly basis. If a local fiscal agent's prior year's collections from the FSECC fall below the prior year's median raised by all local fiscal agents (an amount to be determined by the state fiscal agent by calculating the median amount raised by all local fiscal agents), the local fiscal agent is authorized to make distributions on a less than quarterly basis, so long as all distributions are made within the funding year;

(l) Withhold the reasonable costs for conducting the campaign and for accounting and distribution to the participating charitable organizations. These costs shall be shared proportionately by the participating charitable organizations based on their percentage share of the gross campaign;

(m) In cases where the local fiscal agents host events on behalf of the campaign, ensure that an opportunity to participate is extended to all charitable organizations in the applicable fiscal agent area, regardless of the umbrella group if any, with which they are affiliated;

(n) Perform other services or duties assigned by the Department.

(2) The Department shall ensure that all application reviews have taken into consideration all applicable criteria as stipulated in Section 110.181, F.S., this rule or other federal regulations.

(3) The Department shall send notice by certified mail to any charitable organizations that submitted Form DMS-ADM-100 (rev. 9/09) or DMS-ADM-102 (rev. 9/09) by the respective deadline, but whose submission is missing required information or documentation.

(a) Such notice shall provide 5 business days from receipt of the notice for the charitable organization to provide the required information or documention.

(b) Charitable organizations shall respond within the prescribed period in order for their submission to be considered a completed application.

(4) The Department shall notify all applicant charitable organizations and their umbrella group, if applicable, of all determinations of the Statewide Steering Committee. Denied charitable organizations shall be notified by certified letter and advised of their appeal rights.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-6-02, Amended 3-5-04, 1-9-05, 2-13-06, 1-23-07, _____.

(Substantial rewording of Rule 60L-39.007 follows. See Florida Administrative Code for present text.)

60L-39.007 Appeals.

(1) A charitable organization declared ineligible by the Statewide Steering Committee to participate in the campaign or to receive pro rata Tier One undesignated funds may appeal within seven working days after the receipt of the notice of ineligibility.

(2) Charitable organizations or their respective umbrella group may not introduce new material designed to complete an application during the appeal process. This provision is established specifically to preclude the use of the appeal process to expand the time available to assemble a complete application by the required deadlines.

(3) All appeals for participation in the campaign shall be concluded by June 30 to allow timely publication of authorized participating charitable organizations in the FSECC brochures.

Rulemaking ~~Specific~~ Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New 1-6-02, Amended 3-5-04, _____.

60L-39.008 Local Steering Committees.

(1) Local steering committees shall, with the assistance of the local fiscal agent, notify participating charitable organizations of the name and contact information of the local steering committee chairperson and members. The local steering committee shall ensure public access to all local steering committee meetings. For meetings during which Tier Two undesignated funds will be discussed, the local steering committee shall, with the assistance of the local fiscal agent, ensure a minimum of a two-week notice is provided to participating charitable organizations or their respective umbrella group, if applicable. Such notice shall include a posting on the Department's official website.

(2) Charitable organizations seeking a distribution of Tier Two undesignated funds from the local steering committee shall submit any written materials in support of the request to the local fiscal agent and the local steering committee no later than 48 hours in advance of any meeting at which distribution of Tier Two undesignated funds will be discussed. The local steering committee may accept written materials submitted within less than 48 hours in advance of said meetings upon a finding that such late submissions will not prejudice the deliberations of the local steering committee.

(3) In distributing Tier Two undesignated funds, each local steering committee shall address in a written recommendation the following subjects, as applicable under the facts pertaining to each fiscal agent area:

(a) Natural disasters or emergencies in the fiscal agent area requiring care or relief services;

(b) Needs of special groups or populations in the fiscal agent area;

(c) Special conservation or environmental needs in the fiscal agent area;

(d) The substance of specific presentations, if any, made in person or in writing by the charitable organization seeking a distribution of Tier Two undesignated funds from the local steering committee; and

(e) The history of any charitable organization in providing well-defined and substantial services in the specific fiscal agent area in which the charitable organization is requesting to receive Tier Two undesignated funds.

(4) Any local steering committee member shall disclose any affiliation with a participating charitable organization prior to voting on Tier Two undesignated funds.

(5) The decisions of local steering committees regarding distribution of Tier Two undesignated funds may be reviewed by the Statewide Steering Committee for abuse of discretion within the time frames set forth in subsection 60L-39.007(1), Florida Administrative Code.

Rulemaking Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New _____.

60L-39.009 Campaign Supported Activities.

(1) The FSECC shall be the only workplace charitable fundraising program in state government that receives official state coordination and support at any given time.

(2) Agencies are authorized to sponsor voluntary events during work hours to raise awareness of the campaign, generate funds, and promote payroll pledges. The agency head shall approve such activities and shall ensure that:

(a) No employee is coerced to participate or otherwise singled out for not participating in events or declining to contribute or pledge funds;

(b) Workplace events benefit the FSECC as a whole and do not target any particular participating charity(ies); and

(c) Before determining whether participation in a workplace event shall constitute work time, or shall require the use of accrued leave or leave without pay, in accordance with Chapter 60L-34, F.A.C., take into consideration the duration of the employees' absence from their work station, whether or not travel outside of the workplace facilities is necessary, and any significant potential for injury.

(3) Workplace events at Department managed facilities shall be pre-authorized by and coordinated with the Division of Real Estate Development and Management, pursuant to Chapter 60H-6, F.A.C.

(4) Time spent by employees who the agency has assigned to coordinate, communicate, or provide training related to the campaign, or who attend training or events held to recognize their role or contribution to the campaign, shall be considered work time.

Rulemaking Authority 110.181(3) FS. Law Implemented 110.181 FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Ms. Sharon D. Larson, Director of Human Resource Management, Department of Management Services

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ms. Linda H. South, Secretary, Department of Management Services

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 1, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: September 25, 2009

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Division of Hotels and Restaurants

RULE NO.: RULE TITLE:

61C-1.005 Disciplinary Guidelines

PURPOSE AND EFFECT: The proposed rule amendment reflects changes made to Chapter 509, F.S., by Chapter 2009-195, Laws of Florida, by eliminating the Hospitality Education Program disciplinary training requirements.

SUMMARY: The proposed rule amendment eliminates Hospitality Education Program disciplinary training requirements.

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.

RULEMAKING AUTHORITY: 455.2273, 509.032 FS.

LAW IMPLEMENTED: 386.207, 509.032, 509.261, 509.281, 509.292 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: Michelle Comingore, Operations Review Specialist, Division of Hotels and Restaurants, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399-1012, telephone: (850)488-1133

THE FULL TEXT OF THE PROPOSED RULE IS:

61C-1.005 Disciplinary Guidelines.

(1) through (5) No change.

(6) Standard penalties. This section specifies the penalties routinely imposed against licensees and applies to all violations of law subject to a penalty under Chapter 509, F.S. Any violation requiring an emergency suspension or closure, as authorized by Chapter 509, F.S., shall be assessed at the highest allowable fine amount.

(a) Non-critical violation. ~~In addition to the penalties outlined below, the licensee may be required to attend an educational program sponsored by the Hospitality Education Program.~~

1. through 3. No change.

(b) Critical violation. ~~In addition to the penalties outlined below, the licensee may be required to attend an educational program sponsored by the Hospitality Education Program.~~ Fines may be imposed for each day or portion of a day that the violation exists, beginning on the date of the initial inspection and continuing until the violation is corrected.

1. through 3. No change.

(c) Misrepresenting food or food product. ~~In addition to the penalties outlined below, the licensee may be required to attend an educational program sponsored by the Hospitality Education Program.~~ Fines may be imposed for each day or portion of a day that the violation exists, beginning on the date of the initial inspection and continuing until the violation is corrected.

1. through 3. No change.

(d) through (f) No change.

(g) Operating a public lodging establishment or public food service establishment in violation of an Emergency Order of Suspension, Emergency Order of Closure, administrative suspension, order to close, or other administrative action which prohibits operation of the establishment. ~~In addition to the penalties outlined below, the licensee may be required to attend an educational program sponsored by the Hospitality Education Program.~~ Fines shall be imposed for each day or portion of a day that an establishment operates in violation of the order or administrative action.

1. through 2. No change.

(h) through (i) No change.

(7) through (11) No change.

Rulemaking Authority 455.2273, 509.032 FS. Law Implemented 386.207, 509.032, 509.261, 509.281, 509.292 FS. History–New 6-28-09, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Bill L. Veach, Director, Division of Hotels and Restaurants, Department of Business and Professional Regulation

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Charles W. Drago, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 22, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 14, 2009

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Division of Hotels and Restaurants

RULE NO.: RULE TITLE:
61C-8.004 Program Requirements

PURPOSE AND EFFECT: The proposed rule amendment reflects changes made to Chapter 509, F.S., by Chapter 2009-195, Laws of Florida. The proposed rule updates the Hospitality Education Program grants administered by the program and the school-to-career grant specifications.

SUMMARY: The proposed rule updates the Hospitality Education Program grants administered by the program and the school-to-career grant application and evaluation process.

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.

RULEMAKING AUTHORITY: 509.032, 509.302 FS.

LAW IMPLEMENTED: 509.302 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: Michelle Comingore, Operations Review Specialist, Division of Hotels and Restaurants, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399-1012, telephone: (850)488-1133

THE FULL TEXT OF THE PROPOSED RULE IS:

61C-8.004 Program Requirements.

(1) School-to-Career Transition Program Grant Application Requirements. Pursuant to Section 509.302, F.S., the division may award one or more school-to-career transition program grants ~~of up to $250,000 annually~~ for a period of four years to one or more nonprofit statewide organizations. For the purpose of this rule, statewide organization means an organization, agency, educational institution, or industry association that represents a hospitality industry of this state, which is open and available, and provides services or programs throughout this state, to residents of this state or licensees of the division.~~; one food safety training programs grant of up to $50,000 annually for a period of four years; and one nontransient public lodging training programs grant of up to $50,000 annually for a period of four years~~.

(a) At least thirty (30) days prior to the grant application period, the division shall publish in the Florida Administrative Weekly notification of the upcoming grant application period. This notification shall include the deadline for submitting grant applications; the anticipated first year maximum grant amount, if available; and information on obtaining grant applications, other forms, and additional information and assistance. The division may submit grant solicitation letters to potential applicants identified by the division. Receipt of a grant solicitation letter does not confirm eligibility.

(b)~~(a)~~ Grant applications shall be submitted on DBPR Form HR 5025-200, GRANT APPLICATION, incorporated herein by reference and effective October 1, 2009 ~~October 4, 2007~~, to the ~~Program Administrator,~~ Hospitality Education Program (HEP), Division of Hotels and Restaurants, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399-1011 ~~1014~~.

(c)~~(b)~~ All grant applications must address the applicant's experience and history in representing the food service or lodging industry; ~~and~~ demonstrated ability to provide services statewide with industry support and participation; and~~.~~

~~(c) School-to-Career Transition Programs Grant. The application cycle will begin January 1 and end on March 1. Applications must be received by the division by the close of business on March 1 to be considered in the grant recipient selection process. All applications must address applicant's~~ prior commitment to school-to-career transition programs in the food service or lodging industry. All applications must also ~~and~~ address and identify how the recipient intends to demonstrate compliance with the following criteria:

1. Provide hospitality education opportunities for ~~middle or~~ high school (or equivalent) students;

2. Provide school-to-career transition opportunities to prepare students to be recruited, trained or employed for a career in the hospitality industry~~. Hospitality industry means any public lodging or public food service establishment as described in Chapter 509, Part I, F.S.~~;

3. Provide education about progressive career options describing opportunities for professional advancement in the hospitality industry;

4. Provide opportunity for students to receive certification in an area of the hospitality industry. Certification means documentation that the student has successfully completed requirements in a specific area of the hospitality industry and in accordance with the goals established by the program awarded grant funds. All certifications must be completed through programs established and recognized in the State of Florida, hospitality-industry-sponsored programs, or national certification programs, such as Certified Professional Food Manager, food service employee food handler certification, or apartment manager certification;

5. Provide a description of the objectives of the grant and the methodology to assess the achievement of certification objectives;

6. Provide an emphasis on spending grant funds on direct student services;

7. Provide or possess the capability to provide value beyond the grant term;

8. Identify potential methods and sources for acquiring independent funding beyond the grant term to finance the continued operation of the program, provided the program is designed to be continued; and

9. Provide the program services for the full four-year grant term.

~~(d) Other Hospitality Training Programs Grants. The application cycle will begin July 1 and end on December 31. Applications must be received by the division by the close of business on December 31 to be considered in the grant recipient selection process. All applications for grants to support food service training programs available through statewide organizations in the hospitality service field must address and identify how the recipient intends to demonstrate compliance with the following criteria:~~

~~1. Provide food safety training programs through statewide organizations to food service employees other than Certified Professional Food Service Managers;~~

~~2. Develop training programs based on the food safety protection standards set forth in Chapters 61C-1 and 61C-4, F.A.C., to train food service employees on the proper procedures for receiving, storing, preparing, handling and serving food at public food service establishments;~~

~~3. Provide additional training topics which will include but not be limited to: personal hygiene, illness reporting, proper dishwashing, sanitation, safety and maintenance procedures; and~~

~~4. Provide the program services for the full four-year grant term.~~

(d)~~(e)~~ All grant recipients must have a functional advisory committee to assist in the development and operation of the grant-funded program. The advisory committee must include three or more hospitality industry professionals related to the sector of industry addressed by the training program, of which at least one shall not be employed by the grant recipient or any of its affiliates. The committee members must have agreed in writing to serve in this capacity.

(e)~~(f)~~ The application must be accompanied by DBPR Form HR 5025-201, PROPOSAL NARRATIVE FORMAT, incorporated herein by reference and effective October 1, 2009 ~~October 4, 2007~~.

(f) The grant application and all supplemental materials must be submitted to the division no later than the grant application deadline for the current application cycle as noticed in the Florida Administrative Weekly, in the grant solicitation letter, and on the division's website.

(g) All materials developed through the grant recipient's program become the property of the Hospitality Education Program.

(2) Review and Processing of Grant Applications.

(a) The division ~~program administrator~~ shall receive, process, review and determine the sufficiency of the grant applications.

(b) DBPR Form HR 5025-206, EVALUATION FORM, incorporated herein by reference and effective October 1, 2009 ~~October 4, 2007~~, shall be used by all reviewers to evaluate all school-to-career transition program ~~programs~~ grant applications submitted. ~~DBPR Form HR 5025-204, EVALUATION FORM, incorporated herein by reference and effective October 4, 2007, shall be used by all reviewers to evaluate all other grant applications submitted.~~

(c) The division ~~program administrator~~ shall provide the HEP subcommittee members of the division's advisory council ~~Advisory Council~~ a copy of each grant application received and a list of prioritized programs with recommended funding levels no later than thirty days after the application deadline ~~by March 31 of each application cycle for School-to-Career Transition Programs grants and by January 31 of each application cycle for all other grants~~.

(d) The HEP subcommittee will meet to approve the applications and forward its recommendations to the Director of the Division of Hotels and Restaurants (division director) and the advisory council ~~Advisory Council~~ described in Section 509.291, F.S. The final determination of grant awards shall be made by the division director, with the consent of the advisory council ~~Advisory Council~~. Grant recipients shall be notified no later than 60 days after the application deadline ~~by May 1 for School-to-Career Transition Programs grants and by March 1 for all other grants~~.

(3) Program Review and Disbursement of Funds.

(a) The applicant shall ensure that the terms of the grant contract executed under this chapter are enforced.

(b) The division reserves the right to review programs for grant contract compliance at any time during the grant period. This review shall focus on the completion of stated tasks within the approved timetable, fulfillment of stated goals and objectives, and proper expenditure of grant monies.

(c) The ~~program administrator may recommend termination of the grant contract to the~~ division director may terminate the grant contract at any time during the grant period for failure to meet all program objectives or comply with the terms of the grant contract or any established rules or statutory requirements. In the event the grant contract is terminated, the grant application process shall restart according to the schedule set out in this rule.

(d) Each recipient of grant funds shall maintain accurate records of all expenditures of grant funds and shall make these records available for inspection, review or audit by the division and other authorized personnel. Records shall be kept for a period of at least 5 years following the end of the grant period. All grant funds will be subject to state audit requirements.

(e) Grant funds shall be distributed quarterly, consistent with the terms of the grant proposal and contract. An amendment to the grant shall be approved, so long as such amendment does not change the scope of the grant or, create a substantial deviation from the original proposal, or result in a payment greater than the original contract amount.

(f) All aspects of the grant-funded program shall comply with Chapter 509, Part I, F.S., and the rules adopted thereunder.

(g) Written status reports shall be submitted as indicated on the grant application, but not more than 60 days following the end of each quarter, using DBPR Form HR 5025-202, QUARTERLY STATUS REPORT FORM, incorporated herein by reference and effective October 1, 2009 October 4, 2007. Quarterly requests for payment shall be submitted with the status reports. Such requests shall contain an invoice requesting payment and a detailed accounting of quarterly expenditures. Payment requests for expenditures accrued during the first quarter of the grant period shall include only those expenditures accrued on or after July 1 or the date of grant contract execution, whichever is later. All other payment requests shall contain only those expenditures accrued during the previous quarter.

(4) Annual Program Reports. An annual report shall be submitted within 60 days following the end of each state fiscal year and the grant period using DBPR Form HR 5025-203, ANNUAL PROGRAM REPORT FORM, incorporated herein by reference and effective October 1, 2009 October 4, 2007.

(5) Obtaining forms. All forms incorporated in this section are available from the Division of Hotels and Restaurants Internet website www.MyFloridaLicense.com/dbpr/hr; by e-mail to call.center@dbpr.state.fl.us; by phone request to the department at (850)487-1395; or upon written request to the Hospitality Education Program, Division of Hotels and Restaurants, Department of Business and Professional Regulation, 1940 North Monroe Street, Tallahassee, Florida 32399-1011 1014.

Rulemaking Specific Authority 509.032, 509.302 FS. Law Implemented 509.302 FS. History–New 2-27-92, Amended 8-11-92, Formerly 7C-8.004, Amended 3-31-94, 9-25-96, 1-18-98, 5-7-08, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Bill L. Veach, Director, Division of Hotels and Restaurants, Department of Business and Professional Regulation

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Charles W. Drago, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 22, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 14, 2009

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Barbers' Board

RULE NO.: RULE TITLE:
61G3-21.001 Normal Penalty Ranges

PURPOSE AND EFFECT: The proposed rule amendment implements penalties for failure to comply with Rule 61G3-19.009, F.A.C.

SUMMARY: The proposed rule amendment implements penalties for failure to comply with Rule 61G3-19.009, F.A.C.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: A Statement of Estimated Regulatory Costs has been prepared. The Board determined the proposed changes to the rule will have an impact on small businesses, if, for a second time, the individual(s) fail to comply with Rule 61G3-21.012, F.A.C., a citation will be issued. The non-compliant individual(s) would also be fined $100 up to a $500 cap.

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.

RULEMAKING AUTHORITY: 455.2273, 476.064(4) FS.

LAW IMPLEMENTED: 455.2273 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: Robyn Barineau, Executive Director, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

THE FULL TEXT OF THE PROPOSED RULE IS:

61G3-21.001 Normal Penalty Ranges.

The following guidelines shall be used in disciplinary cases, absent aggravating or mitigating circumstances and subject to the other provisions of this chapter.

(1) through (11) No change.

(12) Rule 61G3-19.009, F.A.C.: Failure to place license in conspicuous place for public viewing. Display of License. $100.00 $50.00 fine per violation up to a $500.00 $250.00 cap.

(13) through (14) No change.

Rulemaking Specific Authority 455.2273, 476.064(4) FS. Law Implemented 455.2273 FS. History–New 11-25-86, Amended 7-4-90, 12-23-90, Formerly 21C-21.001, Amended 10-30-95, 3-29-04, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Barbers' Board

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Barbers' Board

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 3, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 7, 2009

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Barbers' Board

RULE NO.: RULE TITLE:
61G3-21.012 Notice of Non-Compliance

PURPOSE AND EFFECT: The proposed rule amendment requires the barbers laminate and display their license until the license is inactive.

SUMMARY: The proposed rule amendment imposes penalties on licensees who do not laminate their licenses accordance with Rule 61G3-19.009, F.A.C.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: A Statement of Estimated Regulatory Costs has been prepared. Approximately 101 notices of non-compliance will be issued for barbers, restricted barbers, and barber assistants not having their current license laminated within a 12 month period after the rule became effective. The following reflects the number of notices of non-compliance that were issued to barbers for minor violations for the last Fiscal Years:

Fiscal Year 2005 to 2006, 230 notices of non-compliance was issued;

Fiscal Year 2006 to 2007, 191 notices of non-compliance was issued and;

Fiscal Year 2007 to 2008, 251 notices of non-compliance was issued.

The number of barbers who failed to comply with the new lamination requirement, pursuant to Rule 61G3-19.009, F.A.C., which became effective July 1, 2008, is expected to decrease after the first year as barbers become more familiar with the new requirement. The Board determined the proposed change to the rule is not expected to have an impact on small businesses unless a citation is issued. If a citation is issued the fine will be $50.00 to $250.00 per violation, and costs.

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.

RULEMAKING AUTHORITY: 476.064(4) FS.

LAW IMPLEMENTED: 455.225(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: Robyn Barineau, Executive Director, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

THE FULL TEXT OF THE PROPOSED RULE IS:

61G3-21.012 Notice of Non-Compliance.

(1)(a) through (b) No change.

(c) Rule 61G3-19.009, F.A.C. – failure to laminate and display license as long as license is current.

(d) No change.

(2) No change.

Rulemaking ~~Specific~~ Authority 476.064(4) FS. Law Implemented 455.225(3) FS. History–New 12-22-94, Amended 2-14-96, 5-1-96, 11-6-97, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Barbers' Board

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Barbers' Board

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

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 3, 2008

DEPARTMENT OF ENVIRONMENTAL PROTECTION

Notices for the Department of Environmental Protection between December 28, 2001 and June 30, 2006, go to http://www.dep.state.fl.us/ under the link or button titled "Official Notices."

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:
64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates)

PURPOSE AND EFFECT: The Board proposes the rule promulgation to incorporate new application and to provide the requirements for Pharmacy Intern registration and internship for foreign pharmacy graduates.

SUMMARY: A new application will be incorporated into the rule; requirements for pharmacy intern registration and internship for foreign pharmacy graduates will be provided.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 456.033, 465.005, 465.0075 FS.

LAW IMPLEMENTED: 456.013(1), 456.033, 465.007, 465.0075, 465.002 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: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates).

A foreign pharmacy graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(1) All applicants for intern registration must be made on form DH-MQA 102, "Pharmacy Intern Application for Foreign Graduates and Instructions," effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) An applicant for foreign pharmacy graduate intern registration in Florida must submit proof of:

(a) Eligibility by the Foreign Pharmacy Graduate Equivalency Committee to sit for the Foreign Pharmacy Graduate Equivalency Examination, or

(b) A passing score on the Foreign Pharmacy Graduate Equivalency Examination to be considered a graduate of an accredited college or school of pharmacy.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (1), and submitted a completed application as required in subsection (2) unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at an accredited college or school of pharmacy shall assure that community or institutional pharmacies utilized for the obtaining of internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(e) No pharmacist may be responsible for the supervision of more than one intern at any one time.

(7) The program shall assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(7) In the event a program meets all the requirements set forth in subsection (2) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 1580 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 1580 hours when combined with the internship hours.

(8) All internship hours may be obtained prior to the applicant's graduation.

(9) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(10) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(11) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(12) The Board may conduct periodic review of programs to assure compliance with these rules.

(13) Proof of current licensure in another state and work as a pharmacist for up to 1580 hours may substitute for all or part of the internship hours requirement.

(14) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (1) of this rule.

(15) All foreign pharmacy graduates must complete 500 hours of supervised work activity within the state of Florida as provided by Section 465.007(b)2., F.S. The supervised work activity program experience shall be documented on form DH-MQA 1153, "Foreign Pharmacy Graduate Registered Intern Work Activity Manual," effective April 2009 which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

Further, no supervised work activity program shall be approved for any applicant until said applicant has obtained the passing score on the Foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007, F.S.

Rulemaking Authority 456.033, 465.005, 465.0075 FS. Law Implemented 456.013(1), 456.033, 465.007, 465.0075, 465.002 FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: July 17, 2009

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16-26.204 Licensure by Endorsement

PURPOSE AND EFFECT: The Board proposes the rule amendment to add new application and to clarify CE requirements.

SUMMARY: A new application will be incorporated into the rule; CE requirements will be clarified.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 456.033, 465.005, 465.0075 FS.

LAW IMPLEMENTED: 456.013(1), 456.033, 465.007, 465.0075, 465.022 FS.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-26.204 Licensure by Endorsement.

An applicant for licensure by endorsement must be at least 18 years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education.

(1) All applications for licensure by endorsement shall be made on board approved form DH-MQA 100 effective September 2009, ~~DOH/MQA/PH100 (Rev. 01/2009)~~. ~~The instructions and application form, entitled Florida~~ Pharmacist Licensure by Endorsement Application and Instructions (U.S. and Puerto Rico), which is hereby incorporated by reference, can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must ~~and shall~~ be accompanied with a non-refundable ~~endorsement~~ application fee and initial licensure fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) The applicant must submit satisfactory proof that one of the following requirements has been met:

(a) Two (2) years of active practice, as defined in Section 465.0075(1)(c), F.S., within the immediately preceding five (5) years. If the applicant meets the requirements of this section, proof of completion of 30 hours of Florida Board of Pharmacy, ACPE, or other state board of pharmacy approved continuing education obtained in the two calendar years immediately preceding application, must also be submitted.

(b) Successful completion of an internship meeting the requirements of Section 465.007(1)(c), F.S., within the immediately preceding two (2) years.

(3) Completion of a Board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidenced by a letter attesting to subject matter covered from the Dean of the University. ~~The applicant must submit satisfactory proof of completion of the following: A course of no less than two (2) hours on medication errors covering the subjects set forth in Rule 64B16-26.103, F.A.C. The course shall be completed no earlier than 12 months prior to application.~~

(4) through (8) No change.

Rulemaking Authority 456.033, 465.005, 465.0075 FS. Law Implemented 456.013(1), 456.033, 465.007, 465.0075, 465.022 FS. History–New 11-8-01, Amended 1-11-05, 2-18-08, 5-26-09, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 7, 2009

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.:	RULE TITLE:
64B16-26.205	Application for Pharmacist Licensure by Endorsement (Foreign Pharmacy Graduates)

PURPOSE AND EFFECT: The Board proposes the rule promulgation to create rule stating requirements for foreign pharmacy graduates licensure by endorsement.

SUMMARY: Requirements for foreign pharmacy graduates licensure for endorsement will be stated in the rule.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 456.033, 465.005, 465.0075 FS.

LAW IMPLEMENTED: 456.024 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: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-26.205 Application for Pharmacist Licensure by Endorsement (Foreign Pharmacy Graduates).

An applicant for licensure by endorsement for a foreign graduate must be at least 18 years of age and a recipient of a degree from a school or college of pharmacy located outside the United States and have met the requirements listed in Rule 64B16-26.2031, F.A.C.

(1) All applications for licensure by endorsement must be made on form DH-MQA 1196, effective September 2009, Pharmacist Licensure by Endorsement Application and Instructions (Foreign Graduates), which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy, and shall be accompanied with a non-refundable endorsement application fee and initial licensure fee as set forth in Rules 64B16-26.1001 and 64B16.1002, F.A.C.

(2) The applicant must submit satisfactory proof that one of the following requirements has been met:

(a) Two years of active practice, as defined in Section 465.0075(1)(c), F.S., within the immediately preceding five (5) years. If the applicant meets the requirements of this section, proof of completion of 30 hours of Florida Board of Pharmacy, Accreditation Council for Pharmaceutical Education, or other state board of pharmacy approve continuing education obtained in the two calendar years immediately preceding application, must also be submitted.

(b) Evidence of successful completion of board-approved postgraduate training.

(c) Evidence of a board-approved clinical competency examination within the year immediately preceding application for licensure.

(d) Successful completion of an internship meeting the requirements of Rule 64B16-26.2033, F.A.C. within the immediately preceding two (2) years.

(3) The Applicant must provide proof of completion of 500 hours of supervised work activity in the State of Florida as provided by Section 465.007(1)(b)2., F.S. The supervised work activity program experience shall be documented on form DH-MQA, 1153, "Foreign Pharmacy Graduate Registered Intern Work Activity Manual," effective April 2009 which is hereby incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy. Further, no supervised work activity program shall be approved for any applicant until said applicant has obtained the passing score of the foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007, F.S.

(4) The Applicant must submit proof of completion of a Board – approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention and patient safety. For applicants who apply within one year following the receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the board as an educational course under this section, provided such course work is no less that 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention and patient safety as evidenced by a letter attesting to subject matter from the Dean of the University.

(5) All requirements for licensure by endorsement must be met within one (1) year of the receipt of the application. Applicants failing to meet this requirement must reapply.

(6) Applicants applying under the provisions of Section 465.0075, F.S., must have obtained a passing score on the licensure examination as described in subsection 64B16-26.200(1), F.A.C.

(7) Applicants applying under the provisions of Section 465.0075, F.S., shall cause the Nation Association of Boards of Pharmacy, or other similar organization to issue a transfer of Pharmaceutical Licensure Certificate showing examination date, examination results, status of licensure, disciplinary actions and licensure status.

(8) Applicants deemed qualified for licensure by endorsement shall be required to complete the Multistate Pharmacy Jurisprudence Examination – Florida Version. Passing scores of this examination may be used upon reapplication only if the examination was completed within three (3) years of the reapplication.

Rulemaking Authority 456.033, 465.005, 465.0075 FS. Law Implemented 456.013(1), 456.033, 465.007, 465.0075, 465.002 FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 7, 2009

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NOS.:	RULE TITLES:
64B16-28.108	All Permits – Labels and Labeling of Medicinal Drugs
64B16-28.120	All Permits – Storage of Legend Drugs; Prepackaging
64B16-28.502	Class I Institutional Permit and Class II Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home
64B16-28.602	Institutional Class II Dispensing
64B16-28.6021	Institutional Class II Pharmacy – Emergency Department Dispensing

PURPOSE AND EFFECT: The Board proposes the rule amendment for clarification of requirements regarding the expiration date, storage of drugs, labels and labeling of medicinal drugs for inpatients of a nursing home, dispensing of medications, emergency department dispensing of medications.

SUMMARY: The requirements regarding the expiration date and the storage of drugs will be clarified.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 465.005, 465.019(4), 465.022 FS.

LAW IMPLEMENTED: 465.019(2)(b), 465.019(4), 465.0196, 465.022 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: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) No change.

(2) The label affixed to each container dispensed to a patient shall include:

(a) through (g) No change.

(h) Discard after ~~Expiration~~ date.

(i) No change.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) through (d) No change.

(e) Discard after ~~Expiration~~ date

(f) Lot number:

1. Manufacturer's lot number, or

2. Number assigned by the dispenser or repackager which references the manufacturer's lot number.

(4) through (9) No change.

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 9-18-84, 1-20-85, Formerly 21S-1.13, Amended 10-2-88, Formerly 21S-1.013, Amended 7-31-91, 10-1-92, 4-19-93, 7-12-93, Formerly 21S-28.108, 61F10-28.108, 59X-28.108, Amended 3-31-05, _____.

64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.

(1) No change.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

(a) through (b) No change.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as idenified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.003(7), 435.019(2) FS. History–New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, _____.

64B16-28.502 Class I Institutional Permit and Class II Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home ~~Institutional Permit I. (Nursing Homes)~~.

(1) The label affixed to a container used in conventional dispensing to a Class I Institutional permit or a Class II Institutional permit which, within the scope of its practice, services only the inpatients of a nursing home as defined by Section 400.021(5), F.S., shall contain at least the following information:

(a) through (g) No change.

(h) The quantity of the drug in the container.

(2) No change.

~~(3) All labels described in subsections (1) & (2) above shall have the quantity of the drug placed in the container on the labels.~~

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.502, 61F10-28.502, 59X-28.502, Amended _____.

64B16-28.602 Institutional Class II Dispensing ~~Class II Institutional Dispensing~~.

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed ~~registered~~ pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as

established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) No change.

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(b), 465.0196, 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended _____.

64B16-28.6021 Institutional Class II Pharmacy – Emergency Department Dispensing ~~Class II Institutional Pharmacy – Emergency Department Dispensing~~.

(1) through (4) No change.

~~(5) Violations of this section:~~

~~(a) Violations of this section by the prescriber/dispenser shall be referred to the prescriber/dispenser's regulatory board.~~

~~(b) Violations of this section by the Class II permit holder shall subject the permit holder to disciplinary action.~~

Rulemaking ~~Specific~~ Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.022(1), 465.019(2)(b), 465.019(4), 465.0196 FS. History–New 9-20-99, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 28, 2009

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.:	RULE TITLE:
64B16-28.902	Nuclear Pharmacy – Minimum Requirements

PURPOSE AND EFFECT: The Board proposes the rule amendment in order to provide updated references to requirements.

SUMMARY: Referenced requirements will be updated.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 465.0193, 465.022(1) 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: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.902 Nuclear Pharmacy – Minimum Requirements.

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) through (3) No change.

(4) Current references:

(a) through (e) No change.

(f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations, January 8, 2008;

(g) Title 21 C.F.R.Code of Federal Regulations, DEA Regulations, Jamuary 8, 2008;

(h)~~(g)~~ Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;

(i)~~(h)~~ United States Pharmacopeia/National Formulary;

~~(i) USP-DI.~~

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

Rulemaking ~~Specific~~ Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 28, 2009

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NOS.:	RULE TITLES:
64B16-30.001	Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances
64B16-30.003	Citations

PURPOSE AND EFFECT: The Board proposes the rule amendments in order to update guidelines, minor violations, and citations.

SUMMARY: Guidelines, minor violations and citations will be updated.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: No Statement of Estimated Regulatory Cost was prepared. The Board determined the proposed rule will not have an impact on small business.

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.

RULEMAKING AUTHORITY: 456.072, 456.073, 456.077, 456.079, 465.005 FS.

LAW IMPLEMENTED: 456.072, 456.077, 456.079 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 RULES IS: Rebecca R. Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3253

THE FULL TEXT OF THE PROPOSED RULES IS:

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees ~~practitioners~~ guilty of violating Chapter 465, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapter 465, F.S. The term license means any permit, registation, certificate, or license, including a provioisional license, issued by the Department. The minimum penalty range is based upon a first time single count violation of each provision listed. The maximum penalty range is based upon multiple or repeated violations of the same provision of Chapter 465, F.S., or the rules promulgated thereto. All penalties at the upper range of the sanctions set forth in the guidelines, i.e., suspension, revocation, etc., include lesser penalties, i.e., fine, probation or reprimand which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees for violation of the below mentioned statutes and rules:

VIOLATION	PENALTY RANGE MINIMUM	MAXIMUM
(a) Obtaining a license by misrepresentation fraud or error (Section 465.016(1)(a), F.S.) (Section 465.023(1)(a), F.S.)	Revocation	Revocation
(b) Procuring a license through false representation (Section 465.016(1)(b), F.S.) (Section 465.023(1)(b), F.S.	Revocation	Revocation
(c) Permitting unlicensed persons to practice pharmacy (Section 465.016(1)(c), F.S.)	$2,500 fine and 12 hours Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE)	Revocation ~~$5,000 and one (1) year suspension~~
(d) Being unfit or incompetent to practice pharmacy (Section 465.016(1)(d), (m), F.S.)	$250 fine, indefinite suspension with PRN review and board appearance	Revocation or, at the licensee's discretion, voluntarily relinquishment with reinstatement under the terms and conditions approved by the board
(e) Violating laws governing the practice of pharmacy (Section 465.016(1)(e), F.S.) (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise pharmacy technician (Section 465.014, F.S.)	$250 ~~1,500~~ fine and one (1) year probation and 12 hour Laws & Rules Course or MPJE	Revocation ~~$5,000 and one (1) year suspension~~
b. Operating a pharmacy without a permit (Section 465.015(1)(a), F.S.)	$500 per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice)	Revocation ~~(if no permit exists, refer to State's Attorney)~~

c. Operating a pharmacy where an unlicensed and unsupervised person practices pharmacy (Section 465.015(1)(b), F.S.)	$5,000 fine and one (1) year probation	Revocation ~~$5,000 and one (1) year suspension~~
d. Making a false or fraudulent statement to the board (Section 465.015(2)(a), F.S.)	$5,000 fine	Revocation
e. Practicing pharmacy as an inactive licensee (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $500 ~~$200~~/month	Revocation ~~or $5,000 maximum (penalty will require license to renew license or cease practice)~~
f. Selling or dispensing drugs without a prescription (Section 465.015(2)(c), F.S.)		
(i) Non-scheduled legend drugs	$1,500 fine	Revocation ~~$5,000 and one (1) year suspension~~
(ii) Scheduled (controlled substances) legend drugs	$5,000 fine and one (1) year probation	Revocation
g. Selling samples or complimentary drugs (Section 465.015(2)(d), F.S.)		~~Same as violation of 465.015(2)(c) F.S. (see sub-subparagraph 64B16-30.001, F.A.C. (2)(e)1.f., F.A.C., above)~~
(i) Non-scheduled legend drugs	$1,500 fine	Revocation
(ii) Scheduled (controlled Substances) legend drugs	$5,000 fine and one (1) year probation	Revocation
h. Failure to notify the board of or not to have a prescription department manager or consultant pharmacist (Section 465.022(4), F.S.)		
(i) Failure to notify Section 465.018 F.S.	Fine based on length of time prior to notifying board. $500 ~~$200~~ per month	$7,500 ~~$5,000~~ maximum (penalty requires notification or ceasing practice)
(ii) Failure to have prescription department manager or consultant pharmacist of record	Fine based on length of time prior to notifying board, $750 per month and one (1) year probation ~~$2,500 fine and one (1) year probation~~	Revocation ~~of permit~~

i. Failure to comply with required substitution of legend drug requirements (Section 465.025, F.S.)	$500 fine and 12 hour Laws & Rules Course or MPJE. ~~$1,000 fine~~	$2,500 fine
j. Failure to follow negative formulary requirements (Section 465.025(6), F.S.) 64B16-27.500, F.A.C.	$1000 fine and 12 hours Laws & Rules Course or MPJE ~~Reprimand~~	$2,500 fine and one (1) year probation
k. Failure to follow emergency prescription requirements (Section 465.0275, F.S.)	$500 fine	$1,000 fine and one (1) year probation
l. Engage in prohibited rebate scheme (Section 465.185, F.S.)	$1,500 fine	Revocation ~~$5,000 fine and one (1) year probation~~
m. Failure to comply with pharmacist dispensing requirements (Section 465.186, F.S.)		
(i) Failure to follow procedure, but dispense drug appearing on formulary (Section 465.186(3), F.S.) 64B16-27.210, F.A.C.	$500 fine ~~Reprimand~~	$1,000 fine, one (1) year probation and suspension of right to dispense
(ii) Dispensing drug not on the formulary (Section 465.186(2), F.S.) 64B16-27.220, F.A.C. 64B16-27.230, F.A.C.	$1,500 fine	Revocation ~~Same as violation of 465.015(2)(c), F.S. (see sub-subparagraph 64B16-30.001(2)(e)1.f., F.A.C., above)~~
2. Chapter 499, F.S.		
a. Adulteration of a drug (Section 499.005(2), (3), F.S.) (Section 499.006, F.S.)	$1,000 fine ~~$2,000 fine and one (1) year probation~~	Revocation
b. Misbranding a drug (Section 499.005(2), (3), F.S.) (Section 499.007, F.S.)		
(i) Incomplete or inaccurate labeling (Section 499.007, F.S.) 64B16-28.108, F.A.C.	$250 ~~$1,000~~ fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation

(ii) Fraudulent misbranding of legend drugs (499.007, F.S.)	$2,500 fine and One (1) year suspension	Revocation
c. Prescriptions Drug Pedigree	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
d. Recordkeeping requirement	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
e. Storage of drugs	$500 fine and 12 hour Laws & Course or MPJE	Revocation
3. Chapter 893, F.S. (Controlled substances)		
a. Filling a prescription for controlled substances that does not meet the requirements of Chapter 893, F.S.	$1,500 fine	$5,000 fine and one (1) probation
~~a. Filling a prescription not appropriately signed (Section 893.04(1)(b), F.S.)~~	~~$1,500 fine~~	~~$5,000 fine and one (1) year suspension~~
~~b. Filling an improper prescription (other 64B16-30.001(2)(e)3., F.A.C. above) (893.04(1)(b), (c), F.S.)~~		
b.~~c.~~ Failing to retain prescription records for two (2) years (Section 893.04(1)(d), F.S.)	$1,000 fine	Revocation ~~$2,500 fine and one (1) year probation~~
c.~~d.~~ Failing to appropriately label (Section 893.04(1)(e), F.S.)	$250 ~~500~~ fine and 12 hour Laws & Rules course or MPJE	$2,500 ~~$1,000~~ fine and one (1) year probation
d.~~e.~~ Dispensing a Schedule II drug inappropriately with a non-written prescription (Section 893.04(1)(f), F.S.)	$5,000 ~~$2,500~~ fine and one (1) year probation	Revocation ~~$5,000 fine and one (1) year probation (for dispensing without a prescription see sub-subparagraph 64B16-30.001, F.A.C. (2)(e)1.f., F.A.C., above)~~
e.~~f.~~ Inappropriate refilling of Schedule III, IV, or V drugs (Section 893.04(1)(g), F.S.)	$1,750 fine and one (1) year probation	One (1) year suspension
f.~~g.~~ Receiving controlled substances without an appropriate order form (Section 893.06(1), F.S.)	$2,500 ~~$1,500~~ fine	Revocation ~~$5,000 fine and one (1) year probation~~

g.~~h.~~ Unlawful possession of controlled substances (893.06(2), F.S.)	$2,500 fine and one (1) year probation	Revocation
h.~~i.~~ Failure to take a biennial inventory (893.07(1)(a), (2), (3), (4), (5), F.S.)	$1000 fine	$2,500 fine and one (1) year probation
i.~~j.~~ Failure to maintain a complete and accurate record of controlled substances (893.07(1)(b), (2), (3), (4), (5), F.S.)	$1,000 fine and one (1) year probation	Revocation
j.~~k.~~ Dispensing controlled substances in other than good faith (Section 893.08(3)(b), F.S.)	$5,000 ~~$2,500~~ fine and one (1) year probation	Revocation
k.~~l.~~ Inappropriate selling of Schedule V controlled substance (Section 893.08(3)(c), F.S.)	$1,500 fine and one (1) year probation	One (1) year suspension
l.~~m~~. Unlawful possession of controlled substance (Section 893.13, F.S.)	$5,000 ~~$2,500~~ fine and two (2) ~~one (1)~~ years probation	Revocation
4. Violation of Federal Drug Abuse Act 21 U. S. C. 821 et seq.	$500 ~~$1,000~~ fine and one (1) year probation	Revocation ~~$5,000 fine and one (1) year suspension~~
(f) Criminal conviction related to pharmacy (Section 465.016(1)(f), F.S.) (Section 465.023(1)(d), F.S.)	~~Misdemeanor: $1,000 fine~~	~~$5,000 fine, one (1) year suspension and two (2) years probation~~
(i) Misdemeanor	$1,000 fine	Revocation
(ii) Felony:	One (1) year suspension, two (2) years probation & $5,000 fine	Revocation
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as	$250 fine and complete approved CE course in the prevention of medication errors of no less than eight (8) hours ~~$1,000 fine and one (1) year probation~~	Revocation

authorized in Section 465.019(6), F.S., or 465.025, F.S., or compounding, dispensing or distributing legend drugs outside professional practice of pharmacy (465.016(1)(g), F.S.) (465.016(1)(i), F.S.)		
(h) Filing a false report or failing to file a report required by law		
1. Knowing violation	$2,000 fine and one (1) year probation	Revocation
2. Negligent violation	Reprimand	One (1) year probation and $1,000 fine
(i) Failure to make prescription price information available (Section 465.016(1)(k), F.S.)	$250 fine and 12 hour Laws & Rules Course or MPJE ~~Letter of guidance~~	$1,000 fine and one (1) year probation
(j) Improperly placing returned drugs into the stock of a pharmacy (Section 465.016(1)(l), F.S.)	$1,500 fine	$3,000 fine and one (1) year probation
(k) Violating a rule or order of the board or Department (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy		
a. 64B16-28.101 to 64B16-28.104 64B16-27.100 64B16-28.106 64B16-28.107 64B16-28.109 64B16-27.103 64B16-28.111 64B16-27.104 64B16-26.400 64B16-26.401 64B16-28.404 64B16-26.301 64B16-28.114 64B16-27.105	$500 ~~$1,000~~ fine and 12 hour Laws & Rules or MPJE	One (1) year probation and $2,000 fine

b. 64B16-28.105 (sanitation)	Suspension until compliance	Revocation
c. 64B16-27.101 (counterfeit drugs)	$1,000 fine	Revocation ~~Same as penalty for adulterated drugs (see subparagraph 64B16-30.001(2)(e)2., F.A.C.)~~
d. 64B16-28.110 (outdated pharmaceuticals)	$500 fine for possession $1,000 fine for dispensing	Revocation ~~One (1) year probation and $2,000 fine (if drugs dispensed, one (1) year suspension)~~
e. 64B16-28.112 (violations)		Same as underlying statutory or rule violation
f. 64B16-26.300 (Serving as consultant pharmacist without being licensed as a consultant pharmacist)	$500 per month up to ~~a~~ $5,000 fine ~~maximum~~ (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist	Revocation ~~One (1) year suspension of pharmacist license~~
g. 64B16-28.140 and 64B16-28.150 (Data processing systems)	$1,000 fine	Revocation ~~$5,000 fine and two (2) years probation~~
h. 64B16-28.120 (Location of legend drugs)	$1,000 fine	Revocation ~~$5,000 fine and two (2) years probation~~
i. 64B16-28.900, 64B16-28.901, 64B16-28.902 (Nuclear pharmacy)		
(i) Practicing nuclear pharmacy without being licensed as a nuclear pharmac~~y~~ist (Section 64B16-28.903, F.A.C.)	$500 per month up to $5000 fine (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist) ~~$1,000 fine and one (1) year probation~~	Revocation ~~of pharmacist's license or permit~~
(ii) Failure to follow technical requirements (64B16-28.901 and 64B16-28.902, F.A.C.)	One (1) year probation and $1,000 fine	Revocation ~~of license of practice nuclear pharmacy~~
j. 64B16-28.202 and 64B16-28.203 (transfer of	$1,500	Revocation of permit

prescription files and drugs)		
2. Violation of orders of Board or Department	$2,500 fine and one (1) year probation	Revocation
(l) License disciplined by another jurisdiction (Section 465.016(1)(h), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes	
(m) Failure to comply with Board's rule on patient counseling (64B16-27.800, 64B16-27.810, 64B16-27.820, F.A.C.)	$750 fine	$2,500 fine and, one year probation
(n) Violation 465.018 by and through 465.016 and 465.023	Penalty as closely as possible to those set forth in the Disciplinary Guidelines	~~Penalty as closely as possible to those set forth in the Disciplinary Guidelines~~
(o) Violating 456.072, F.S.		
1. Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.	$1,500 ~~$2,500~~ fine and one (1) year probation	Revocation ~~$5,000 fine and one (1) year suspension~~
2. Intentionally violating any rule adopted by the Board or the Department, ~~as appropriate~~.	$2,500 ~~$1,500~~ fine and two (2) ~~one (1)~~ years probation	Revocation ~~$2,500 fine and one (1) year probation~~
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.	~~Misdemeanor: $1,000 fine Felony: $3,000 fine and one (1) year probation~~	~~$5,000 fine and one (1) year suspension~~
(i) Misdemeanor	$1000 fine	Revocation
(ii) Felony	$3000 fine and one (1) year probation.	Revocation
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors.	$500 fine	$1,000 fine
5. Having a license or the	Same penalty as imposed in other	~~Same penalty as~~

authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.	jurisdiction or as closely as possible to penalties for similar violation	~~imposed in other jurisdiction or as closely as possible to penalties for similar violation~~
6. Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the Department against another licensee.	$3,000 fine	Revocation ~~$5,000 fine and six (6) month suspension~~
7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board.	Revocation or denial of license application	
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board.	$500 fine and one (1) year probation	Revocation ~~$1,000 fine and two (2) years probation~~
9. Aiding, assisting, procuring, employing, or advising any unlicensed	$2,000 fine	Revocation ~~$5,000 fine and one (1) year suspension~~

person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board.		
10. Failing to perform any statutory or legal obligation placed upon a licensee.	$2,000 fine	Revocation ~~$5,000 fine and one (1) year probation~~
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee.	$2,500 ~~$3,000~~ fine and two (2) years probation	Revocation ~~$5,000 fine and one (1) year suspension~~
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession.	$10,000 fine and two (2) years probation	Revocation ~~$10,000 fine and one (1) year suspension~~
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.	$3,000 fine and two (2) years probation	Revocation ~~$5,000 fine and one (1) year suspension~~
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.	$2,000 fine and two (2) years probation	Revocation ~~$5,000 fine and one (1) year suspension~~
15. Delegating or contracting for the performance of professional	$2,000 fine and two (2) years probation	Revocation ~~$5,000 fine and one (1) year suspension~~

responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them.		
16. Violating any provision of this part, the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department.	$1,000 fine	Revocation ~~$5,000 fine and two (2) years probation~~
17. Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.	$2,500 fine and two (2) years probation	Revocation ~~$5,000 fine and one (1) year suspension~~
18. Failing to report to the board in writing within 30 days after the licensee has been convicted or found guilty or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.	$1,000 fine	Revocation ~~$2,500 fine and one (1) year probation~~
19. Testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug.	$1,500 ~~$2,500~~ fine PRN evaluation and two (2) years probation or compliance with PRN contract	Revocation ~~$5,000 fine and one (1) year suspension~~
20. Being terminated from or failing to successfully complete an impaired practitioners treatment program (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and ~~a fine of up to $1,000.~~	Revocation

(3) No change.

(4) All fines imposed by the Board shall be paid within a period of ninety (90) ~~thirty (30)~~ days from the date of the final ordered entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Rulemaking ~~Specific~~ Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079 FS. History–New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, _____.

64B16-30.003 Citations.

(1) through (2) No change.

(3) The following violations with accompanying fines may be disposed of by citation:

(a) through (g) No change.

(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article prescription, an ingredient or article ingredient or article prescribed, except as authorized in Section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested.	$250 fine, Completion of an approved CE course in the prevention of medication errors or no less than 8 hours

~~1. No allegation of harm or ill effects is present;~~

~~2. The licensee has no prior disciplinary history; and~~

~~3. The event did not result in or pose a significant threat to the health and safety of the patient or the public.~~

~~The penalty shall be a letter of concern, payment of costs, and completion of an approved continuing education course in the prevention of medication dispensing errors, of no less than eight (8) hours.~~

(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Instution upon which it is drawn.	$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Aquired immune deficiency syndrome (HIV/AIDS), or medical errors	$500
(k) Failure to correct Minor violation as listed in Rule 64B16-30.002, F.A.C.	$250

(4) No change.

(5) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of Section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of Section 456.073 ~~455.225~~, F.S., shall apply.

Rulemaking ~~Specific~~ Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History–New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 10, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: August 28, 2009

DEPARTMENT OF HEALTH

Board of Psychology

RULE NO.: RULE TITLE:

64B19-11.005 Supervised Experience Requirements

PURPOSE AND EFFECT: The Board proposes the rule amendment to add new language to clarify the procedures for identification when interacting with clients and/or when signing documents.

SUMMARY: The rule amendment will add new language to clarify the procedures for identification when interacting with clients and/or when signing documents.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: A Statement of Estimated Regulatory Cost has been prepared and is available by contacting Allen Hall, Executive Director, at the address listed below. The following is a summary of the SERC:

• The proposed change would affect approximately 950 new applicants over the next five years and licensed psychologists who provide supervision for these applicants that will be required to ensure compliance with the proposed amendments .

• The only costs incurred by the Division of Medical Quality Assurance are rule-making costs.

• Transactional costs would be minimal administrative costs associated with updating procedures or putting procedures in place.

• The proposed changes could have a minor impact on private psychology practices that provide post-doctoral residency opportunities to applicants.

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.

RULEMAKING AUTHORITY: 490.004(4) FS.

LAW IMPLEMENTED: 490.005(1) 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/MQA, 4052 Bald Cypress Way, Bin #C05, Tallahassee, Florida 32399-3255

THE FULL TEXT OF THE PROPOSED RULE IS:

64B19-11.005 Supervised Experience Requirements.

The law requires 4,000 hours of supervised experience for licensure. The Board recognizes that the applicant's internship satisfies 2,000 of those hours. This rule concerns the remaining 2,000 hours.

(1) Definitions. Within the context of this rule, the following definitions apply:

(a) "Association" or "in association with": the supervisory relationship between the supervisor and the psychological resident.

(b) "Psychology ~~Psychological~~ Resident or Psychology Fellow ~~Applicant~~." A psychology ~~psychological~~ resident or psychology fellow is a person who has met Florida's educational requirements for licensure and intends from the outset of the supervised experience to meet that part of the supervised experience requirement for licensure which is not part of the person's internship.

(c) "Supervisor." A supervisor is either a licensed Florida psychologist in good standing with the Board, or a doctoral-level psychologist licensed in good standing in another state providing supervision for licensure in that state. However, where the psychology resident or psychology fellow ~~applicant~~ is on active duty with the armed services of the United States, the supervisor may be a doctoral-level psychologist licensed in good standing in any state, regardless of where the supervision is conducted.

(d) All applicants for licensure shall use the title psychology resident or psychology fellow until licensed as a psychologist.

(e) The psychology resident or psychology fellow shall inform all service users of her or his supervised status and provide the name of the supervising psychologist. All written work shall be co-signed by the supervising psychologist.

(2) Requirements and Prohibitions. All applicants for licensure must complete at least 2,000 hours of post doctoral experience under a supervisor whose supervision comports with subsection (3) of this rule.

(a) No change.

(b) A~~n~~ psychology resident or psychology fellow ~~applicant~~ may be supervised by more than one supervisor. If there is more than one supervisor, however, then one of the supervisors must be identified as the primary supervisor. The primary supervisor shall be the supervisor who enters into the agreement with the applicant for licensure, for supervision, and who integrates all of the applicant's supervisory experiences.

(c) No change.

(3) Supervisors' Responsibilities. The Board requires each primary supervisor to perform and to certify that the primary supervisor has:

(a) Entered into an agreement with the applicant for licensure, which details the applicant's obligations and remuneration as well as the supervisor's responsibilities to the applicant;

(b) Determined that the psychology resident or psychology fellow ~~applicant~~ was capable of providing competent and safe psychological service to that client;

(c) Maintained professional responsibility for the psychology resident or psychology fellow's ~~applicant's~~ work;

(d) No change.

(e) Prevailed in all professional disagreements with the psychology resident or psychology fellow ~~applicant~~;

(f) Kept informed of all the services performed by the psychology resident or psychology fellow ~~applicant~~;

(g) Advised the Board if the supervisor has received any complaints about the psychology resident or psychology fellow ~~psychological applicant~~ or has any reason to suspect that the resident is less than fully ethical, professional, or qualified for licensure.

(4) No change.

Rulemaking ~~Specific~~ Authority 490.004(4) FS. Law Implemented 490.005(1) FS. History–New 11-18-92, Amended 7-14-93, Formerly 21U-11.007, Amended 6-14-94, Formerly 61F13-11.007, Amended 1-7-96, Formerly 59AA-11.005, Amended 12-4-97, 8-5-01, 7-27-04, _____.

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: July 24, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: May 8, 2009

DEPARTMENT OF HEALTH

Division of Environmental Health

RULE NOS.:	RULE TITLES:
64E-5.101	Definitions
64E-5.207	Filing Application for Specific Licenses
64E-5.210	Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material

64E-5.213	Specific Terms and Conditions of License
64E-5.216	Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass
64E-5.312	Dose Limits for Individual Members of the Public
64E-5.331	Disposal of Specific Wastes
64E-5.344	Notification of Incidents
64E-5.345	Reports of Exposures, Radiation Levels, Concentrations of Radioactive Material Exceeding the Constraints or Limits, Medical Events and Dose to an Embryo/Fetus or a Nursing Child
64E-5.601	License Required
64E-5.6011	Definitions
64E-5.602	License Amendments
64E-5.603	Notification
64E-5.604	ALARA Program
64E-5.605	Radiation Safety Officer
64E-5.606	Radiation Safety Committee
64E-5.607	Authority and Responsibilities
64E-5.608	Supervision
64E-5.609	Visiting Authorized User, Visiting Authorized Medical Physicist, or Visiting RSO
64E-5.610	Mobile Medical Service Requirements
64E-5.611	Quality Management Program and Notifications, Records and Reports of Medical Events
64E-5.612	Suppliers
64E-5.614	Possession, Use, Calibration, and Check of Dose Calibrators in the Use of Unsealed Radiopharmaceuticals
64E-5.615	Use, Calibration and Check of Survey Instruments
64E-5.616	Determination of Dosages of Unsealed Radioactive Material for Medical Use
64E-5.617	Authorization for Calibration, Transmission and Reference Sources
64E-5.618	Requirements for Possession of Sealed Sources and Brachytherapy Sources
64E-5.621	Surveys for Contamination and Ambient Radiation Dose Rate
64E-5.622	Release of Patients or Human Research Subjects Treated with Radiopharmaceuticals, Implants or Remote Afterloader Units
64E-5.624	Decay in Storage
64E-5.625	Safety Instruction and Precautions for Liquid Iodine, Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery
64E-5.6251	Therapy Related Computer Systems
64E-5.626	Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies
64E-5.627	Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies
64E-5.628	Generators
64E-5.629	Control of Aerosols and Gases
64E-5.630	Use of Radiopharmaceuticals for Therapy
64E-5.631	Use of Sealed Sources for Diagnosis
64E-5.632	Use of Sources for Manual Brachytherapy
64E-5.633	Manual Brachytherapy Sources Inventory and Surveys
64E-5.6331	Calibration Measurements of Manual Brachytherapy Sources
64E-5.6332	Decay of Strontium-90 Sources for Ophthalmic Treatments
64E-5.634	Use of Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit
64E-5.635	Installation, Adjustment, Maintenance and Repair Restrictions
64E-5.636	Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
64E-5.637	Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
64E-5.638	Radiation Monitoring Devices
64E-5.639	Viewing Systems
64E-5.640	Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units

64E-5.641	Full Calibration Measurementson Teletherapy Units
64E-5.6411	Full Calibration Measurements on Remote Afterloader Units
64E-5.6412	Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
64E-5.642	Periodic Spot-Checks of Teletherapy Units
64E-5.6421	Periodic Spot-Checks for Remote Afterloader Units
64E-5.6422	Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units
64E-5.6423	Additional Technical Requirements for Mobile Remote Afterloader Units
64E-5.643	Radiation Surveys for Teletherapy Facilities
64E-5.644	Radiation Surveys for Remote Afterloader and Gamma Stereotactic Radiosurgery Facilities
64E-5.645	Therapy-Related Computer Systems
64E-5.647	Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
64E-5.648	Radiation Safety Officer
64E-5.649	Training for Uptake, Dilution, or Excretion Studies
64E-5.650	Training for Imaging and Localization Studies for Which a Written Directive is not Required
64E-5.651	Training for Therapeutic Use of Radiopharmaceuticals
64E-5.652	Training for Use of Brachytherapy Sources
64E-5.653	Training for Ophthalmic Use of Manual Strontium 90
64E-5.654	Training for Use of Sealed Sources for Diagnosis
64E-5.655	Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
64E-5.656	Training for an Authorized Medical Physicist
64E-5.657	Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist
64E-5.658	Recentness of Training
64E-5.659	Training for an Authorized Nuclear Pharmacist
64E-5.660	Training for Use of Unsealed Radioactive Material for Which A Written Directive is Required in Rules 63E-5.626, 64E-5.627 or 64E-5.630, F.A.C.
64E-5.661	Training for the Oral Administration of Sodium Iodide I-131 Requiring A Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries)
64E-5.662	Training for the Oral Administration of Sodium Iodide I-131 Requiring A Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries)
64E-5.663	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive
64E-5.664	Other Medical Uses of Radioactive Material or Radiation From Radioactive Material
64E-5.1301	Sealed or Unsealed Sources of Radioactive Material
64E-5.1320	Bioassy Program

PURPOSE AND EFFECT: The purpose of these proposed rule changes is to maintain required compatibility with the U.S. Nuclear Regulatory Commission by updating department rules for the medical use of radioactive materials and temporary jobsite requirements. Some proposed rule amendments will clarify how the department recognizes out of state licenses that use radioactive materials in the State of Florida. Other substantive changes will establish new rules and change some existing rules regarding training and experience requirements for users, requirements for use and calibration of high dose rate remote afterloaders, and gamma stereotactic radiosurgery units.

SUMMARY: Proposed rule amendments maintain compatibility with U.S. Nuclear Regulatory Commission requirements by updating department rules for the medical use of radioactive materials and temporary jobsite requirements. These rules were reviewed by the Advisory Council on Radiation Protection. The Council consists of physicians who use radioactive materials for diagnostic and therapeutic uses, medical physicists, nuclear medicine and radiation technologists, consultants in the use of radioactive materials and private citizens.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS: The department has approximately 1,200 radioactive materials licenses for medical use. The department also grants reciprocity recognition to approximately 30 out of state radioactive materials licenses. Existing and new medical facilities that use radioactive materials for medical use may be impacted by one or more of

the proposed rule amendments. Out of state companies possessing a license to use radioactive materials at temporary job sites in Florida may be impacted by one or more of the proposed rule amendments. In addition to approximately $7,000 in rule-promulgation costs, the Department anticipates expending $2,700 to create CD's and to mail the revised rules to licensees. Potential cost savings may also occur as the proposed rules present additional options of radioactive material receipt and use without license amendments and additional waste disposal options.

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.

RULEMAKING AUTHORITY: 404.042, 404.051(4), (11), 404.061(2), 404.071, 404.081(1), 404.141, 404.022 FS.

LAW IMPLEMENTED: 404.031, 404.051(1), (2), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.20, 404.22, 404.022, 404.081(1), 404.141, 404.071(1), (3), 404.30 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: November 9, 2009, 10:30 a.m. – 12:30 p.m.

PLACE: Capital Circle Office Complex, Building 4052, 4052 Bald Cypress Way, Room 301, Tallahassee, FL 32399

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 10 days before the workshop/meeting by contacting: Janice Livingston, Bureau of Radiation Control, 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: Michael Stephens, Bureau of Radiation Control, Bin C21, 4052 Bald Cypress Way, Tallahassee, FL 32399-1741; (850)245-4266 or (850)245-4043; email: Mike_Stephens@doh.state.fl.us

THE FULL TEXT OF THE PROPOSED RULES IS:

CONTROL OF RADIATION HAZARDS
PART I
GENERAL PROVISIONS

64E-5.101 Definitions.

As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain part are defined in that respective part.

(1) through (15) No change.

(16) "Authorized user" means an individual who is identified on a department, NRC, agreement state, or licensing state specific license that authorizes the use of radioactive material ~~a physician, dentist or podiatrist who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission, agreement state, or licensing state license that authorizes the medical use of radioactive material~~.

(17) through (20) No change.

~~(21) "Brachytherapy" means a method of radiation therapy in which sealed sources are used to deliver a radiation dose by surface, intracavitary, or interstitial application.~~

(22) through (39) renumbered (21) through (38) No change.

~~(40) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method and other instructions and precautions by which the licensee shall perform diagnostic clinical procedures. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.~~

(41) through (81) renumbered (39) through (79) No change.

(80)~~(82)~~ "Management" means the chief executive officer or other individual, or a delegate or the delegates of the chief executive officer or other individual, having the authority to manage, direct, or administer the licensee's activities ~~that individual's designee~~.

(82)~~(83)~~ No change.

~~(84) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.~~

(85) through (87) renumbered (83) through (85) No change.

(86)~~(88)~~ "Medical event ~~Misadministration~~" means the administration of:

(a) Radioactive materials or radiation from radioactive materials requiring a written directive that results in the following ~~Iodine 123, iodine 125 or iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels)~~:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin ~~Involving the wrong individual or wrong radiopharmaceutical~~; ~~or~~

2. When the total dose delivered differs from the prescribed dose by 20 percent or more; ~~When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and the prescribed dosage exceeds 30 microcuries.~~

3. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;

4. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more;

5. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin;

6. An administration of a wrong radioactive drug containing radioactive material;

7. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

8. An administration of a dose or dosage to the wrong individual or human research subject;

9. An administration of a dose or dosage delivered by the wrong mode of treatment;

10. A leaking sealed source where the patient or human research subject is contaminated;

11. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

12. Any medical use that results or will result in unintended permanent functional damage to an individuals organ or a physiological system, as determined by a physician.

(b) Radioactive materials or radiation from radioactive materials not requiring a written directive that result in either of the following ~~A therapeutic radiopharmaceutical dosage other than iodine 123, iodine 125 or iodine 131 as sodium iodide~~:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and ~~Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or~~

a. When the total dose delivered differs from the prescribed dose by 20 percent or more;

b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range;

c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more; or

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and ~~When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.~~;

a. An administration of a wrong radioactive drug containing radioactive material;

b. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

c. An administration of a dose or dosage to the wrong individual or human research subject;

d. An administration of a dose or dosage delivered by the wrong mode of treatment;

e. A leaking sealed source where the patient or human research subject is contaminated;

f. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

g. Any medical use that results or will result in unintended permanent functional damage to an individuals organ or a physiological system, as determined by a physician.

(c) Radiation from a therapeutic x-ray machine or particle accelerator that result in any of the following: ~~A gamma stereotactic radiosurgery radiation dose:~~

1. Any medical use that results or will result in unintended permanent functional damage to an individuals organ or a physiological system, as determined by a physician ~~Involving the wrong individual or wrong treatment site; or~~

2. An administration of a dose to the wrong individual or human research subject; ~~When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.~~

3. An administration of a dose delivered by the wrong mode of treatment, wrong treatment, or wrong treatment site;

4. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

5. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

6. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

~~(d) A teletherapy, particle accelerator or therapeutic x-ray machine radiation dose:~~

~~1. Involving the wrong individual, wrong mode of treatment, or wrong treatment;~~

~~2. When treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;~~

~~3. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or~~

~~4. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose~~

~~(e) A brachytherapy radiation dose:~~

~~1. Involving the wrong individual, wrong radioisotope, or wrong treatment site, excluding, for permanent implants, seeds that were implanted in the correct site but which migrated outside the treatment site;~~

~~2. Involving a sealed source that is leaking;~~

~~3. When, for a temporary implant, one or more seeds are not removed upon completion of the procedure; or~~

~~4. When the calculated administered dose differs from the prescribed dose by more than 20 percent from the prescribed dose.~~

~~(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of iodine 123, iodine 125 or iodine 131 as sodium iodide, both:~~

~~1. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and~~

~~2. When the dose to the individual exceeds 5 rems effective dose equivalent or 50 rem dose equivalent to any individual organ.~~

(89) through (98) renumbered (87) through (96) No change.

~~(99) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.~~

(100) through (106) renumbered (97) through (103) No change.

(104)~~(107)~~ "Prescribed Dosage" means the quantity of radiopharmaceutical activity as documented:

(a) No change.

(b) Either in the diagnostic clinical procedures manual or in any appropriate record as specified in the directions of the authorized user for diagnostic procedures in which a written directive is not required.

(105)~~(108)~~ "Prescribed dose" means:

(a) No change.

(b) For manual brachytherapy, either the total source strength and exposure time or the total dose as documented in the written directive; ~~or~~

(c) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose and dose per fraction as documented in the written directive; or~~.~~

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

(109) through (122) renumbered (106) through (119) No change.

(120)~~(123)~~ "Recordable event" means the administration of:

(a) through (b) No change.

(c) I~~odine 123, iodine 125 or i~~odine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels) when;

1. through 2. No change.

(d) A therapeutic administration of a radiopharmaceutical other than ~~iodine 123, iodine 125 or~~ iodine 131 as sodium iodide, when the administered dosage differs from the prescribed dosage by more than 10 percent from the prescribed dosage;

(e) No change.

(f) A teletherapy, particle accelerator, gamma stereotactic radiosurgery or therapeutic x-ray machine radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

(124) through (152) renumbered (121) through (149) No change.

~~(153) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.~~

(150)~~(154)~~ "Temporary job site" means a site, base or facility that is created and maintained to support a single job ~~lasting for less than 2 years~~.

(155) through (172) renumbered (151) through (168) No change.

(169)~~(173)~~ "Written directive" means a written order for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, which shall contain the following information:

(a) For a therapeutic administration of a radiopharmaceutical ~~other than iodine 123, iodine 125 or iodine 131 as sodium iodide~~, the radiopharmaceutical, dosage, and route of administration;

(b) For any administration of ~~iodine 123, iodine 125 or~~ iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels), the dosage;

(c) For gamma stereotactic radiosurgery, target coordinate~~s~~ settings per treatment for each anatomically distinct treatment site, collimator size, plug pattern, and total dose;

(d) For teletherapy, particle accelerator or therapeutic x-ray machine, the total dose, dose per fraction, treatment site, number of fractions and overall treatment period;

(e) For high dose rate remote afterloading brachytherapy, the radioisotope, treatment site, dose per fraction, number of fractions, and total dose; and

(f) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders,

1. Prior to implantation, the radioisotope, treatment site, dose, number of sources, and source strengths; and

2. No change.

(170)~~(174)~~ No change.

(171)~~(175)~~ No change.

(172)~~(176)~~ "Authorized nuclear pharmacist" means a pharmacist who satisfies the following: ~~is actively licensed as a nuclear pharmacist by the Board of Pharmacy as specified in Rule 64B16-28.903, F.A.C., and is authorized on a radioactive materials license by the Department.~~

(a) Meets the requirements in subsection 64E-5.659(1) and Rule 64E-5.658, F.A.C.; or

(b) Authorized on a radioactive materials license by the department or identified as an authorized nuclear pharmacist on one of the following:

1. A specific license issued by the NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;

2. A permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

3. A permit issued by a NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

4. A permit issued by a NRC master material broad scope licensee that authorizes medical use or the practice of nuclear pharmacy; or

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

(d) Is designated as an authorized nuclear pharmacist in accordance with paragraph 64E-5.210(10)(a)3., F.A.C.

(177) through (194) renumbered (173) through (190) No change.

(191) "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.

(192) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

(193) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Rulemaking ~~Specific~~ Authority 404.042, 404.051, 404.061 FS. Law Implemented 404.031, 404.051, 404.061, 404.20, 404.22 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.102, Amended 5-18-98, 10-8-00, 8-6-01, 9-11-01, 12-18-01, 9-28-06, 8-16-07, 2-28-08, _____.

PART II
LICENSING OF RADIOACTIVE MATERIALS
Subpart C
Specific Licenses

64E-5.207 Filing Application for Specific Licenses.

(1) An original and one copy of an a~~A~~pplication for specific licenses, license renewals, and license amendments shall be filed with the department ~~in triplicate~~ on Application for Radioactive Materials License Non-Human Use, D~~O~~H Form 1054 12/09 ~~Dec. 86~~ or Application for Radioactive Materials Human Use, D~~O~~H Form 1322 12/09 ~~Oct. 92, in accordance with Regulatory Guide 1.30 dated October 1992~~, which are herein incorporated by reference.

(2) through (4) No change.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (9), (10), (11), 404.061(2), 404.141 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 5-15-96, Formerly 10D-91.307, Amended _____.

64E-5.210 Special Requirements for a Specific License to Manufacture, Assemble, Repair or Distribute Commodities, Products or Devices Which Contain Radioactive Material.

(1) through (9) No change.

(10) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part VI for the uses listed in Rules 64E-5.626, 64E-5.627, ~~and~~ 64E-5.630 and 64E-5.664, F.A.C., will be approved if:

(a) through (b) No change.

1. through 3. No change.

(c) through (e) No change.

(11) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to Part VI for the uses listed in Rule 64E-5.627 or 64E-5.664, F.A.C., will be approved if:

(a) through (e) No change.

(12) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part VI for use as a calibration, transmission or reference source or for the uses listed in Rule 64E-5.631, 64E-5.634, 64E-5.664 or 64E-5.632, F.A.C., will be approved if:

(a) through (c) No change.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051, 404.061, 404.081, 404.141 FS. History–New 7-17-85, Amended 8-25-91, 5-12-93, 1-1-94, 5-15-96, Formerly 10D-91.311, Amended 8-6-01, 9-28-06, 8-16-07, 2-28-08, _____.

64E-5.213 Specific Terms and Conditions of License.

(1) through (4) No change.

(5) A separate license is required for the following:

(a) No change.

(b) Facilities for which one or more of the following applies:

1. through 3. No change.

4. Temporary jobsites lasting more than two years.

(c) through (d) No change.

(6) A separate license is not required for temporary job sites lasting less than two years or for each facility that is authorized under a broad scope license.

(7) through (8) No change.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.141 FS. Law Implemented 404.051(1), (4), 404.061(2), (3), 404.081(1), 404.141 FS. History–New 7-17-85, Amended 4-4-89, 5-12-93, 8-29-94, Formerly 10D-91.314, Amended 5-18-98., 9-28-06, _____.

Subpart D
Reciprocity

64E-5.216 Reciprocal Recognition of Licenses for Byproduct, Source, Naturally Occurring and Accelerator Produced Radioactive Material, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

(1) Subject to these regulations, any person who holds a specific license from the NRC, or an Agreement state and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, will be granted a general license by the Department to conduct the activities authorized in such licensing document within the State of Florida, except for areas of exclusive federal jurisdiction, for a period not in excess of 180 ~~365~~ consecutive days provided that:

(a) through (d) No change.

(e) Any licensee using or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the department with the information listed in paragraph 64E-5.216(1)(b), F.A.C., prior to exceeding the 180 days. ~~Shall not possess or use radioactive materials or engage in activities authorized in subsection 64E-5.216(1), F.A.C., above for more than a period in excess of 180 days in any calendar year. (Pursuant to Section 120.54(6), F.S., paragraph 64E-5.216(1)(e), F.A.C., is substantively identical to 10 CFR 150.20(b)(4) published on 01/01/2007.)~~

1. through 2. No change.

(2) In addition to ~~Notwithstanding~~ the provisions of (1), above, any person who holds a specific license issued by the NRC ~~U.S. Nuclear Regulatory Commission~~, an agreement state, or a licensing state authorizing the holder to manufacture, transfer, install or service a device described in paragraph 64E-5.206(4)(a), F.A.C., within areas subject to the jurisdiction of the licensing body may be granted a general license by the Department to install, transfer, demonstrate or service such a device in this State provided that:

(a) through (d) No change.

(3) No change.

Rulemaking ~~Specific~~ Authority 404.051(4), (11), 404.061(2), 404.081(1), 404.141 FS. Law Implemented 404.051(1), (2), (4), (6), (11), 404.061(2), 404.081(1) FS. History–New 7-17-85, Amended 4-4-89, Formerly 10D-91.321, Amended 10-8-00, 2-28-08, _____.

PART III
STANDARDS FOR PROTECTION AGAINST RADIATION
SUBPART D
RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

64E-5.312 Dose Limits for Individual Members of the Public.

(1) through (4) No change.

(5) A licensee or applicant for a license may permit visitors to an individual who cannot be released under Rule 64E-5.622, F.A.C., to receive a radiation dose greater than 0.1 rem (1 millisievert) provided the following are satisfied:

(a) The radiation dose received does not exceed 0.5 rem (5 millisievert);

(b) The authorized user, as defined in Rule 64E-5.6011, F.A.C., has determined before the visit that it is appropriate.

Rulemaking ~~Specific~~ Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Amended 5-15-96, Formerly 10D-91.443, Amended 10-8-00, _____.

SUBPART J
WASTE MANAGEMENT

64E-5.331 Disposal of Specific Wastes.

(1) A licensee can dispose of the following licensed material without regard to its radioactivity:

(a) through (b) No change.

(c) Any radioactive material which is not a sealed source with a physical half-life of less than 120 ~~90~~ days if all of the following are met:

1. through 5. No change.

(2) through (3) No change.

Rulemaking ~~Specific~~ Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.465, Amended _____.

SUBPART L
REPORTS

64E-5.344 Notification of Incidents.

(1) through (6) No change.

(7) Twenty-four hour report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material:

(a) through (d) No change.

(e) Dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user as defined in Rule 64E-5.6011, F.A.C.

(f) Dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that meets one of the following:

1. Greater than 50 mSv (5 rem) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(8) No change.

Rulemaking ~~Specific~~ Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Amended 5-15-98, Formerly 10D-91.481, Amended 10-8-00, _____.

64E-5.345 Reports of Exposures, Radiation Levels, Concentrations of Radioactive Material Exceeding the Constraints or Limits, Medical Events and Dose to an Embryo/Fetus or a Nursing Child ~~and Misadministrations~~.

(1) through (3) No change.

(4) Reports of Medical Events ~~Misadministrations~~.

(a) The licensee or registrant shall notify the department by telephone no later than the next calendar day after the discovery of the medical event ~~misadministration~~. The licensee or registrant shall also notify the referring physician of the affected individual and the individual's or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he will inform the individual or believes, based on medical judgment, that telling the individual or the individual's responsible relative or guardian would be harmful to either. These notifications shall be made within 24 hours after the licensee or registrant discovers the medical event ~~misadministration~~. If the referring physician, individual or the individual's responsible relative or guardian cannot be reached within 24 hours, the licensee or registrant shall notify them as soon as practicable. The licensee is not required to notify the individual or the individual's responsible relative or guardian without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the individual because of this. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(b) Written Report. Within 15 days after the medical event ~~misadministration~~ report to the department, the licensee or registrant shall report in writing to the department and to the referring physician and furnish a copy of the report to the individual or the individual's responsible relative or guardian if either was previously notified by the licensee or registrant as specified in paragraph (4)(a), above, or a brief description of both event and consequences as they affect the individual or the individual's responsible relative or guardian if a statement is included that the report submitted to the department can be obtained from the licensee or registrant. The written report shall include the licensee's or registrant's name; the prescribing physician's name; the referring physician's name; a brief description of the event; why the event occurred; the effect on the individual; the action taken to prevent recurrence; whether the licensee or registrant informed the individual or the individual's responsible relative or guardian and what information was provided to the individual or individual's responsible relative or guardian, and if not, a written medical justification. The report shall not include the individual's name or other information that could lead to identification of the individual.

(5) Records of medical event ~~misadministration~~. Each licensee or registrant shall retain a record of each medical event ~~misadministration~~ for 20 years. The record shall contain the names of all individuals involved in the event, including the prescribing physician, the allied health personnel, the individual, and the individual's referring physician, the individual's identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken, if any, to prevent recurrence.

(6) No change.

(7) Reports of a dose to an embryo/fetus or a nursing child.

(a) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event,

because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(b) Written Report.

1. Within 15 days after the discovery of an event that would require reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the licensee or registrant shall report in writing as described below, to the department and to the referring physician.

2. Within 15 days after the discovery of an event that would require reporting under paragraph 64E-5.344(7)(e) or (f), F.A.C., the licensee or registrant shall also furnish a copy of the report or a brief description of both the event and the consequences of the event as they affect the embryo/fetus or nursing child, to the mother, or the mother or child's responsible relative or guardian if either was previously notified by the licensee or registrant as specified in paragraph (7)(a), above. If a brief description of both the event and consequences of the event is provided in lieu of the report, such description shall include a statement that the report submitted to the department can be obtained from the licensee or registrant.

3. The written report shall include the licensee's or registrant's name; the prescribing physician's name; the referring physician's name; a brief description of the event; why the event occurred; the effect on the embryo/fetus or nursing child; the action taken to prevent recurrence; whether the licensee or registrant informed the pregnant individual or mother or the mother's or child's responsible relative or guardian and what information was provided to the individual or individual's responsible relative or guardian, and if not, a written medical justification. The report shall not include the individual's or child's name or other information that could lead to identification of the individual or child.

(8) Records of reports of dose to an embryo/fetus or a nursing child. Each licensee or registrant shall retain a record of each report of dose to an embryo/fetus or a nursing child for 20 years. The record shall contain the names of all individuals involved in the event, including the prescribing physician, the allied health personnel, mother or the nursing child's name, and the mother or nursing child's referring physician, the social security number of the mother, the nursing child's social security number or identification number if either has been assigned, a brief description of the event, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken, if any, to prevent recurrence.

Rulemaking ~~Specific~~ Authority 404.051, 404.081 FS. Law Implemented 404.022, 404.051(1), (4), 404.081 FS. History–New 1-1-94, Formerly 10D-91.482, Amended 10-8-00, _____.

PART VI

USE OF RADIONUCLIDES IN THE HEALING ARTS

64E-5.601 License Required.

(1) Radioactive materials shall not be manufactured, produced, acquired, received, possessed, prepared, used, or transferred for medical use except as provided in a specific license.

(2) No change.

(3)(a) Unless prohibited by license condition, a physician~~, dentist, or podiatrist~~ in training may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in subsections ~~Rule~~ 64E-5.608(1) and 64E-5.608(3), F.A.C.

(b) Current and active certified radiologic technologists as authorized in Part IV Chapter 468, F.S., may receive, possess, acquire, prepare, use, or transfer radioactive materials as provided in these regulations under the supervision of an authorized user as provided in paragraph 64E-5.607(3)(e) and subsection 64E-5.608(3), F.A.C.

(c) Unless prohibited by license condition, a medical physicist in training may receive, acquire, prepare, use, possess, or transfer radioactive materials as provided in these regulations under the supervision of an authorized medical physicist as provided in subsections 64E-5.608(2) and 64E-5.608(3), F.A.C.

(4) Unless authorized by the department, no individual shall manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive materials for medical use unless:

(a) That individual is listed on the licensee's specific license as an authorized user, authorized medical physicist, or an authorized nuclear pharmacist;

(b) through (c) No change.

(d) That individual is in training, a~~A~~uthorized by subsection 64E-5.601(3), F.A.C., and subpart I of Part VI.

(5) Provisions for the protection of human research subjects are:

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by another federal agency that has implemented the "Federal Policy for the Protection of Human Subjects (Federal Policy)", the licensee shall, before conducting research:

1. Obtain review and approval of the research from an "Institutional Review Board (IRB)," as defined and described in the Federal Policy; and

2. Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its radioactive materials medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

1. Obtain review and approval of the research from an IRB as defined and described in the Federal Policy; and

2. Obtain "informed consent", as defined and described in the Federal Policy, from the human research subject.

(d) Nothing in this section relieves licensees from complying with the other requirements in this part.

(6) Authorized nuclear pharmacists must be actively licensed as a nuclear pharmacist by the Department of Health, Division of Medical Quality Assurance as specified in Rule 64B16-28.903, F.A.C., and authorized medical physicists must have an active medical physicist license, in the area they are practicing, issued by the Department of Health, Division of Medical Quality Assurance.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.707, Amended 8-6-01, _____.

64E-5.6011 Definitions.

(1) "Authorized medical physicist" means an individual who meets the requirements:

(a) Specified in subsection 64E-5.656(1) and Rule 64E-5.658, F.A.C. ; or

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

1. A specific medical use license issued by the NRC or an agreement state;

2. A medical use permit issued by a NRC master material licensee;

3. A permit issued by a NRC or agreement state broad scope medical use licensee; or

4. A permit issued by a NRC master material license broad scope medical use permittee.

(2) "Authorized user" means:

(a) A physician who meets the requirements in Rule 64E-5.658 and subsections 64E-5.549(1), 64E-5.550(1), 64E-5.660(1), 64E-5.661(1), 64E-5.662(1), 64E-5.652(1), 64E-5.654(1), or 64E-5.655(1), F.A.C.; or

(b) An individual identified for medical use of radioactive materials on:

1. A NRC or agreement state license that authorizes the medical use of radioactive material;

2. A permit issued by a NRC master material licensee that is authorized to permit the medical use of radioactive material;

3. A permit issued by a NRC or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

4. A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

(3) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose by surface, intracavitary, intralumimnal or interstitial application.

(4) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(5) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method by which the licensee shall perform diagnostic clinical procedures, and provides other instructions and precautions related thereto. Each diagnostic clinical procedure shall be approved by the authorized user and shall include the radiopharmaceutical, dosage, and route of administration.

(6) "High dose-rate remote afterloader," as used in this part, 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.

(7) "Low dose-rate remote afterloader," as used in this part, 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.

(8) "Manual brachytherapy," as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually delivered.

(9) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation there from, to patients or human~~s~~ research subjects under the supervision of an authorized user.

(10) "Medium dose-rate remote afterloader," as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(11) "Mobile medical service" means the ability to transport and use radioactive materials for medical use at the client's address.

(12) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(13) "Preceptor" means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user under Chapter 64E-5,

Part VI, F.A.C., an authorized medical physicist, an authorized nuclear pharmacist or a RSO under Chapter 64E-5, Part VI, F.A.C.

(14) "Pulsed dose-rate remote afterloader," as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, provided that the source is:

(a) Approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

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

(15) "Radiation Safety Officer or RSO" means an individual who:

(a) Meets the requirements in subsection 64E-5.648(1) or paragraph 64E-5.648(3)(a) and Rule 64E-5.658, F.A.C.; or

(b) Is identified as a RSO on a specific medical use license issued by the NRC or an agreement state or a medical use permit issued by a NRC master material licensee.

(16) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a department license.

(17) "Therapeutic dosage" means a dosage of unsealed radioactive materials that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(18) "Therapeutic dose" means a radiation dose delivered from a source containing radioactive materials to a patient or human research subject for palliative or curative treatment.

(19) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(20) "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Rulemaking Authority 404.051, 404.061 FS. Law Implemented 404.031, 404.061(2), 404.20, 404.22, 404.30 FS. History–New _____.

64E-5.602 License Amendments.

A licensee shall apply for and receive a license amendment or departmental approval:

(1) No change.

(2) Before permitting anyone, except a visiting authorized user, visiting authorized medical physicist, or visiting authorized nuclear pharmacist described in Rule 64E-5.609, F.A.C., to work as an authorized user,~~:~~ authorized nuclear pharmacist, or authorized medical physicist.

(3) Before changing a RSO ~~radiation safety officer~~ or authorized medical ~~teletherapy~~ physicist;

(4) Before ordering or receiving radioactive material in excess of the amount, in a different form, or receiving a different radionuclide than is authorized on the license;

(5) through (6) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1) (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.708, Amended _____.

64E-5.603 Notification.

A licensee shall notify the department in writing within 30 days when the licensee changes its mailing address or when an authorized user, RSO, authorized nuclear pharmacist, or authorized medical physicist permanently discontinues performance of their duties under the licensee. ~~A licensee shall notify the department in writing within 30 days when an authorized user, radiation safety officer, authorized nuclear pharmacist, or teletherapy physicist permanently discontinues performance of these duties for the licensee.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.709, Amended 8-6-01, _____

PART VI
USE OF RADIONUCLIDES IN THE HEALING ARTS
SUBPART A
GENERAL ADMINISTRATIVE REQUIREMENTS

64E-5.604 ALARA Program.

(1) through (2) No change.

(3) For licensees that are not required to have a radiation safety committee, medical institutions, management and all authorized users shall participate in the program as required by the RSO ~~radiation safety officer~~.

(4) The ALARA program shall include an annual review by the radiation safety committee for medical ~~institution~~ licensees required to have a radiation safety committee, or by management and the RSO ~~radiation safety officer~~ for licensees that are not required to have a radiation safety committee ~~medical institutions~~. The review shall include summaries of the types, amounts and purposes of radioactive material used; occupational dose reports; and continuing education and training of all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology and the cost of improvements in relation to benefits.

(5) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1,) (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.710, Amended _____.

64E-5.605 Radiation Safety Officer.

(1) A licensee shall appoint a RSO who agrees in writing to be ~~radiation safety officer~~ responsible for implementing the radiation safety program. The licensee, through the RSO ~~radiation safety officer~~, shall ensure that radiation safety activities are performed with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive materials program.

(2) through (5) No change.

(6) The RSO ~~radiation safety officer~~ shall review, sign and date, at least every 3 months, the occupational radiation exposure records of all personnel working with radioactive material.

(7) The licensee shall retain a copy of both authority, duties, and responsibilities of the RSO and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program for the duration of the license. The records must include the signature of the RSO and licensee management.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.711, Amended _____.

64E-5.606 Radiation Safety Committee.

~~Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.~~

(1) Each license listed below shall establish a radiation safety committee to oversee the use of radioactive materials; ~~Membership of the radiation safety committee shall consist of at least four individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, a representative of management who is neither an authorized user nor a radiation safety officer, and a person experienced in the assay of radioactive material and protection against radiation, such as a radiological physicist or a nuclear medicine technologist employed by or working under contract with the institution. Other members may be included as appropriate.~~

(a) Medical institutions as defined in Rule 64E-5.101, F.A.C.; or

(b) Other licenses authorized for any of the following medical uses:

1. Subsection 64E-5.627(2), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

2. Subsection 64E-5.627(3), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

3. Subsection 64E-5.627(4), F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

4. Any subsection of Rule 64E-5.630, F.A.C., and any subsection of Rule 64E-5.632 or 64E-5.634, F.A.C.;

5. Subsections 64E-5.634(1) and 64E-5.634(2), F.A.C.;

6. Subsections 64E-5.634(1) and 64E-5.634(3), F.A.C.; or

7. Subsections 64E-5.634(2) and 64E-5.634(3), F.A.C.

(2) Membership of the radiation safety committee shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. Other members who are experienced in the assay of radioactive material and protection against radiation, such as an authorized medical physicist or a nuclear medicine technologist employed by or working under contract with the institution may be included as appropriate.

(3)~~(2)~~ The committee shall meet at least every 6 months. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the RSO, or designee ~~radiation safety officer~~ and the management representative, or designee.

(4)~~(3)~~ The minutes of each radiation safety committee meeting shall include:

(a) through (f) No change.

(5)~~(4)~~ The committee shall provide each member with a copy of the meeting minutes and shall retain a copy for 5 years or until the department authorizes its disposition.

(6)~~(5)~~ The committee shall be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable.

(7)~~(6)~~ The committee shall review and approve any individual to be an authorized user, an authorized nuclear pharmacist, the RSO ~~radiation safety officer~~, or an authorized medical ~~teletherapy~~ physicist based on safety and the training and experience standards of this part before sending a license application or request for amendment or renewal.

(8)~~(7)~~ The committee shall review and approve each proposed method of use of radioactive material based on safety.

(9)~~(8)~~ The committee shall review and approve procedures and radiation safety program changes based on safety and with the advice of the RSO ~~radiation safety officer~~ and the management representative prior to sending to the department for licensing action.

(10)~~(9)~~ The committee shall review occupational radiation exposure records of all personnel working with radioactive material and all incidents involving radioactive material at least every 6 months, with the assistance of the RSO ~~radiation safety officer~~, to determine cause and review subsequent actions taken.

(11)~~(10)~~ The committee shall review the radioactive materials program at least every 12 months with the assistance of the RSO ~~radiation safety officer~~ as described in subsection 64E-5.604(4), F.A.C.

(12)~~(11)~~ The committee shall establish levels for occupational dose that will result in investigations and considerations of action by the RSO ~~radiation safety officer~~ when exceeded.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.712, Amended 8-6-01, _____.

64E-5.607 Authority and Responsibilities.

(1) through (2) No change.

(3) Authorized users shall have the following special responsibilities:

(a) For written directives; ~~Review personally the patient's case or develop and implement adequate written procedures to assure that the diagnostic radiation procedure is appropriate;~~

1. A written directive must be dated and signed by an authorized user before the administration of I-131 as sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries ([micro]Ci)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from material; or

2. Due to the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable provided:

a. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record; and

b. A written directive must be prepared within 48 hours of the oral directive.

3. The written directive must contain the patient or human research subject's name and the following information:

a. For any administration of quantities greater than 1.11 MBq (30 [micro]Ci) of sodium iodide I-131: the dosage;

b. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;

c. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

d. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

e. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

f. For all other brachytherapy; and

(I) Before implantation: treatment site, the radionuclide, and dose; and

(II) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

4. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed radioactive material, the brachytherapy dose, high dose remote afterloader dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose; or

5. Due to the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable provided:

a. The information contained in the oral directive must be documented as soon as possible in the patient's record; and

b. A written directive must be prepared within 48 hours of the oral directive.

(b) No change.

(c) Review personally the patient's case or develop and implement adequate written procedures to assure that the diagnostic radiation procedure is appropriate. ~~For therapy procedures or diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 123, iodine 125 or iodine 131 as sodium iodide, prepare a written directive;~~

(d) Prior to administration, the authorized user must document deviations from the diagnostic clinical procedures manual for each patient. ~~For all other diagnostic procedures, prepare a written directive or assure that the procedure is in accordance with a diagnostic clinical procedures manual;~~

(e) through (g) No change.

(4) The licensee shall retain a copy of the written directives specified in paragraph 64E-5.607(3)(a), F.A.C., for three years.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.713, Amended _____.

64E-5.608 Supervision.

(1) Supervision of a physician in training to become an authorized user: ~~A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by Rule 64E-5.601, F.A.C., shall:~~

(a) A licensee who permits the receipt, acquisition, possession, use, preparation, or transfer of radioactive material by a physician in training under the supervision of an authorized user as allowed by paragraph 64E-5.601(3)(a), F.A.C., shall: ~~Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program~~;

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

3. Require the preparation of radioactive materials use only under the supervision of an authorized user or authorized nuclear pharmacist;

4. Require the authorized user to be immediately available to communicate with the supervised individual; and

5. Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.

(b) A licensee shall require the supervised individual receiving, possessing, acquiring, preparing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(a), F.A.C., to: ~~Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;~~

1. Follow the instructions of the supervising authorized user;

2. Follow the written radiation and quality management program procedures established by the licensee; and

3. Comply with these regulations and the license conditions regarding the use of radioactive material.

(c) The licensees' management or radiation safety committee shall provide written training approval prior to any training of a physician to receive, acquire, prepare, possess or use radioactive material under the supervision of an authorized user. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify physicians currently in training and the physicians who have completed training for 7 years after the last date training was received; and ~~Require the authorized user to be immediately available to communicate with the supervised individual;~~

~~(d) Require the authorized user to be able to be physically present and available to the supervised individual within 1 hour; and~~

~~(e) Require that only those individuals specifically designated by the authorized user be permitted to administer radionuclides or radiation to patients.~~

(2) Supervision of an individual in training to become an authorized medical physicist: ~~A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material specified in Rule 64E-5.601, F.A.C., to:~~

(a) A licensee who permits the receipt, preparation, acquisition, possession, use, or transfer of radioactive material to an individual in training under the supervision of an authorized medical physicist as allowed by paragraph 64E-5.601(3)(c), F.A.C., shall: ~~Follow the instructions of the supervising authorized user;~~

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

2. Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use; and

3. Require the authorized medical physicist to be immediately available to communicate with the supervised individual.

(b) A licensee shall require the supervised individual receiving, acquiring or preparing, possessing, using or transferring radioactive material specified in paragraph 64E-5.601(3)(c), F.A.C., to: ~~Follow the written radiation and quality management program procedures established by the licensee; and~~

1. Follow the instructions of the supervising authorized medical physicist;

2. Follow the written radiation and quality management program procedures established by the licensee; and

3. Comply with these regulations and the license conditions regarding the use of radioactive material.

(c) The licensee's management or radiation safety committee shall provide written training approval prior to any individual to receive, possess or use radioactive material under the supervision of an authorized medical physicist. After the training has been completed, the licensee shall provide documentation to the supervised individual that the individual received the training and experience required by this section. The licensee shall maintain records that identify individuals currently in training and the individuals who have completed training for 7 years after the last date training was received. ~~Comply with these regulations and the license conditions regarding the use of radioactive material.~~

(3) A licensee that permits any supervised activities regarding the use of radioactive materials or radiation from radioactive materials is responsible for the acts and omissions of the supervised individual.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.714, Amended _____.

64E-5.609 Visiting Authorized User, Visiting Authorized Medical Physicist, or Visiting RSO.

(1) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

~~(a) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of a medical institution, the institution's radiation safety committee;~~

(a)~~(b)~~ The licensee has a copy of a license issued by the department, the NRC ~~U.S. Nuclear Regulatory Commission~~, or an agreement state ~~or a licensing state~~ that identifies the visiting authorized user by name as an authorized user for medical use; and

(b)~~(c)~~ No change.

(2) For up to 60 days each year, a licensee may permit an authorized medical physicist or an individual qualified under Rules 64E-5.656 and 64E-5.658, F.A.C., to function as a visiting authorized medical physicist as authorized by the license. ~~A license amendment is not needed to permit a visiting authorized user to use licensed materials as described in subsection 64E-5.609(1), F.A.C.~~

(3) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a RSO, under Rules 64E-5.648 and 64E-5.658, F.A.C., to function as a visiting RSO and to perform the functions of a RSO, as provided in Rule 64E-5.605 and subsection 64E-5.607(1), F.A.C. ~~A licensee shall retain copies of the records specified in subsection 64E-5.609(1), F.A.C., for 5 years after the last visit.~~

(4) A license amendment is not needed to permit a visiting authorized user, visiting authorized medical physicist, or visiting RSO to use licensed material or perform functions in accordance with this section.

(5) The visiting authorized user, visiting authorized medical physicist, or visiting RSO shall have the prior written permission of the licensee's management and, if the use or function occurs on behalf of a medical institution, the institution's radiation safety committee.

(6) Licensee records shall include a copy of the record described in Rule 64E-5.657, F.A.C., or some other form of documentation that verifies the individual has met the perspective training and experience requirements listed in Subpart I. A licensee shall retain copies of the records specified in Rule 64E-5.609, F.A.C., for 3 years after the last visit.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.715, Amended _____.

64E-5.610 Mobile Medical ~~Nuclear Medicine~~ Service Requirements.

The department shall license mobile medical ~~nuclear medicine~~ services or clients of such services. The mobile medical ~~nuclear medicine~~ service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical ~~nuclear medicine~~ service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical ~~nuclear medicine~~ service.

(1) The mobile medical licensee shall obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive materials at the client's address and clearly delineates the authority and responsibility of the licensee and the client. A licensee providing mobile medical services shall retain this letter for 3 years after the provision of service. ~~Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.~~

(2) Mobile medical ~~nuclear medicine~~ service licensees shall secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use.

(3) The mobile medical licensee shall check instruments used to measure the activity of unsealed or sealed radioactive materials for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check ~~Mobile nuclear medicine service licensees shall check dose calibrators as required by Rule 64E-5.614, F.A.C.,~~ and shall perform all daily ~~required gamma camera~~ quality control tests on all equipment used to obtain images or information from radionuclide studies before medical use at each location of use.

(4) Before leaving a client location, m~~M~~obile medical ~~nuclear medicine~~ service licensees shall perform a survey of all areas where radioactive materials are used ~~of radiopharmaceutical use~~ with a radiation survey instrument in order to ensure that they have complied with the requirements in Rule 64E-5.621, F.A.C., that radiation dose rates are at background levels, and that removable contamination is below 2000 disintegrations per minute per 100 square centimeters sampled ~~before leaving a client location~~. A licensee shall check each survey instrument for proper operation with a dedicated check source before each use at each location. The licensee is not required to keep records of these dedicated source survey instrument checks.

(5) Mobile medical ~~nuclear medicine~~ service licensees shall retain a record of each survey required ~~above~~ for 3 years. The record must include the date of the survey, a diagram ~~plan~~ of each area that was surveyed, the measured dose rate at several points in each area of use in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

(6) A physician shall be on site at each client's address at the time radioactive materials ~~radiopharmaceuticals~~ are administered. An authorized user shall be immediately

available to communicate with the supervised individuals or individuals under their direction ~~able to be physically present and available within 1 hour~~.

(7) Radioactive material will be received at the permanent location of the mobile medical service or delivered directly to an authorized individual in the vehicle at a place of use. A mobile medical service may not have radioactive materials delivered from the manufacturer or the distributor to the client unless the client has a radioactive materials license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license. ~~Radioactive material shall not be stored in the mobile vehicle overnight when vehicle is located at its permanent location. The vehicle shall be monitored for contamination after all sources of radiation have been removed.~~

(8) Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material. ~~Radioactive material will be received at the permanent location of the mobile nuclear medicine service or delivered directly to an authorized individual in the vehicle at a place of use.~~

(9) Radioactive gases or aerosols shall not be used by mobile medical service licenses. ~~All use of radioactive material shall be in the mobile vehicle unless there is written documentation by the attending physician that the use of radioactive materials within the facility is in the best interest of the patient. All radioactive waste generated shall be stored on the vehicle for subsequent removal at the permanent location of the mobile nuclear medicine service.~~

(10) Prior to administration, the mobile medical service licensee shall assure that individuals or human research subjects meet the patient release criteria specified in Rule 64E-5.622, F.A.C. ~~Restrooms contained in mobile vehicles shall not routinely be used by patients who have been administered radioactive material. If the patient's condition requires the use of the restroom, the sewage holding tank of the vehicle shall be emptied and thoroughly rinsed into a sanitary sewer system at the permanent location of the mobile nuclear medicine service.~~

(11) A licensee authorized to use mobile remote afterloaders for medical use shall follow the requirements specified in Rule 64E-5.6423, F.A.C. ~~Radioactive gases shall not be used in mobile vehicles~~.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.716, Amended _____.

64E-5.611 Quality Management Program and Notifications, Records and Reports of Medical Events ~~Misadministrations~~.

(1) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide a high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following objectives:

(a) Except where a delay to provide a written directive would jeopardize the patient's health as specified in paragraphs (b) and (c) of this section, a written directive is prepared prior to administration for the following:

1. through 3. No change.

4. Any administration of ~~iodine 123, iodine 125 or~~ iodine 131 as sodium iodide in quantities greater than 30 microcuries (1.11 megabecquerels); ~~or~~

5. Any therapeutic administration of a radiopharmaceutical other than ~~iodine 123, iodine 125, or~~ iodine 131 as sodium iodide; or

6. Any high dose rate remote afterloader radiation dose.

(b) An oral directive is 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 48 ~~24~~ hours of the oral directive.

(c) No change.

(d) A written directive which changes an existing written directive can be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, high dose rate remote afterloader dose, the teletherapy dose, or the next ~~teletherapy~~ fractional dose.

(e) The patient's or human research subject's identity is verified by more than one method as the individual named in the written directive prior to administration;

(f) The final plans of treatment and related dose calculations, manually or computer generated, for brachytherapy, teletherapy, high dose rate remote afterloader, and gamma stereotactic radiosurgery agree with the respective written directives:

(g) Verify that any computer-generated calculations are correctly transferred into the consoles of therapeutic medical units authorized by Rule 64E-5.634, F.A.C.; ~~Each administration agrees with the written directive; and~~

(h) Each administration agrees with the written directive; and ~~Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.~~

(i) Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

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

(a) through (b) No change.

(c) All medical events ~~misadministrations~~ within the review period to verify compliance with all aspects of the quality management program.

(3) through (6) No change.

~~(7) The licensee may make modifications to the quality management program to increase the program's efficiency if the program's effectiveness is not decreased. The licensee is required to submit the modifications to the department within 30 days after the modifications have been made.~~

(7)~~(8)~~ Each applicant for a new license shall submit to the department a quality management program as part of the application for a license and implement the program upon issuance of the license by the department.

(8)~~(9)~~ Each licensee shall maintain copies of the quality management program for the duration of the license. ~~Each existing licensee shall submit to the department by July 1, 1994, a copy of their quality management program with a written certification that the quality management program has been implemented.~~

(9)~~(10)~~ Each licensee shall submit and maintain records and reports of medical events ~~misadministrations~~ as required by subsections 64E-5.345(4) and (5), F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6,)(8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.717, Amended _____.

64E-5.612 Suppliers.

A licensee shall use for medical use only:

(1) through (2) No change.

(3) Teletherapy sources manufactured and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the NRC ~~U.S. Nuclear Regulatory Commission; or~~.

(4) Sealed sources or devices containing radioactive materials that are either;

(a) Manufactured, labeled, packaged, and distributed as specified in a license issued by the department or by another agreement state, a licensing state or the NRC; or

(b) Noncommercially transferred from a medical use licensee authorized by Chapter 64E-5, Part VI, F.A.C., or equivalent medical use license issued by another agreement state or the NRC.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.718, Amended _____.

SUBPART B
GENERAL TECHNICAL REQUIREMENTS

64E-5.614 Possession, Use, Calibration, and Check of Dose Calibrators in the Use of Unsealed Radiopharmaceuticals.

(1) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

(2) A licensee shall check each dose calibrator before use each day of use, or during an assigned shift for facilities operating continuously, for constancy with a dedicated check source. The check shall be performed on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium 226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days. A record shall be made of each check, which shall include:

(a) through (g) No change.

(3) The licensee shall test each dose calibrator for accuracy at the time of installation and at least every 12 months. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or by the manufacturer who has compared their source to a source calibrated by the NIST ~~National Institute of Standards and Technology~~. The sources shall have a minimum activity of 10 microcuries (370 kBq) for radium 226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 kiloelectron volts and 500 kiloelectron volts. A record shall be made of each test, which shall include:

(a) through (e) No change.

(f) The name of the individual performing this test ~~signature of the radiation safety officer~~.

(4) The licensee shall test each dose calibrator for linearity at the time of installation and at least every 3 months over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered. A record shall be made of each test, which shall include:

(a) through (d) No change.

(e) The name of the individual performing this test ~~signature of the radiation safety officer~~.

(5) The licensee shall test each dose calibrator for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator. A record shall be made of each test, which shall include:

(a) through (d) No change.

(e) The name of the individual performing this test ~~signature of the radiation safety officer~~.

(6) through (8) No change.

(9) A licensee may calibrate instrumentation used in Rule 64E-5.614, F.A.C., using nationally recognized standards or the manufacturer's instructions. The standards or instructions used by the licensee must be available for inspection by the department.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.720, Amended _____.

64E-5.615 Use, Calibration and Check of Survey Instruments.

A licensee shall ensure that the survey instruments used to comply with this part have been calibrated before first use, at least every 12 months, and after repair.

(1) ~~A licensee shall ensure that the survey instruments used to comply with this part have been calibrated before first use, at least every 12 months, and after repair.~~ A record shall be made of each calibration, which shall include:

(a) through (d) No change.

(e) The name ~~signature~~ of the individual who performed the calibration; ~~and~~

(f) The date of calibration;~~.~~

(g) The model number and serial number of the instrument being calibrated; and

(h) The results of the calibration.

(2) The licensee shall:

(a) No change.

(b) Calibrate each linear scale instrument at two points located approximately 1/3 and 2/3 of full-scale, calibrate each logarithmic scale instrument at midrange of each decade and at two points of at least one decade, and calibrate each digital instrument at appropriate points; and

(c) Conspicuously note on the instrument the date of calibration;

(3) through (6) No change.

(7) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies or sealed sources for diagnostic purposes shall possess a portable radiation survey instrument with a range from 0.1 millirem (1.0 μSv) per hour to at least 1,000 millirem (10 mSv) per hour ~~50 millirem (500 μSv) per hour~~.

(8) A licensee authorized to use radioactive material for imaging and localization studies, radiopharmaceutical therapy or implant therapy shall possess portable radiation survey instruments with a range from 0.1 millirem (1.0 μSv) per hour to at least 1,000 millirem (10 mSv) per hour.

(9) A licensee authorized to use radioactive material in Rule 64E-5.634, F.A.C., ~~a teletherapy unit~~ shall possess a radiation survey instrument as described in subsection (7) or (8), above.

(10) The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(11) A licensee may calibrate instrumentation used in Rule 64E-5.615, F.A.C., using nationally recognized standards or the manufacturer's instructions. The standards or instructions used by the licensee must be available for inspection by the department.

Rulemaking ~~Specific~~ Authority 404.051, 404.061 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-15-96, Formerly 10D-91.721, Amended _____.

64E-5.616 Determination of Dosages of Unsealed Radioactive Material for Medical Use ~~Assay of Radiopharmaceutical Dosages~~.

(1) The licensee shall determine by assay or direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made which shall include: ~~A licensee shall assay within 30 minutes before use the activity of each photon-emitting radiopharmaceutical dosage, a record of the assay shall be made, which shall include:~~

(a) The generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number; expiration date; and the radionuclide;

(b) The patient's or human research subject's name or ~~and~~ identification number if one has been assigned;

(c) The prescribed dosage and activity of the dosage at the time of assay or a notation that the total activity assayed is less than 10 microcuries (370 kBq),

(d) The date and time of the assay and administration; and

(e) The name ~~initials~~ of the individual who performed the assay.

(2) Unless directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. ~~A licensee shall retain a record of the assays required by subsection 64E-5.616(1), F.A.C., for 3 years.~~

(3) A licensee shall retain a record of the assays listed in Rule 64E-5.616, F.A.C., for 3 years.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.722, Amended _____.

64E-5.617 Authorization for Calibration, Transmission and Reference Sources.

Any person authorized by Rule 64E-5.601, F.A.C., for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission and reference use:

(1) Sealed sources that: ~~manufactured and distributed by persons specifically licensed by the department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that do not exceed 15 millicuries (555 MBq) each;~~

(a) Do not exceed 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed by the department, the NRC, an agreement state; or

(b) Do not exceed 1.11 GBq (30 mCi) each, which are redistributed by a licensee that is authorized to redistribute sealed sources that are manufactured and distributed by a person licensed by the department, the NRC, or an agreement state, provided the redistributed sealed sources are in the original packaging and shielding, and are accompanied by the manufacturer's approved instructions;

(2) ~~Samarium 153 and~~ Aany radioactive material ~~listed in Rule 64E-5.626 or 64E-5.627, F.A.C.,~~ with a half-life of 120 ~~100~~ days or less in individual amounts not to exceed 15 millicuries (555 MBq) each;

(3) Any radioactive material ~~listed in Rule 64E-5.626 or 64E-5.627, F.A.C.,~~ with a half-life greater than 120 ~~100~~ days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

(4) Unless approved by the department, the maximum possession limit of radioactive materials described in subsections 64E-5.617(1), (2) and (3), F.A.C., above, shall not exceed a combined activity of 1 curie (37 GBq), This includes radioactive materials as waste in storage. ~~Technetium 99m in individual amounts not to exceed 00 millicuries (3.7 GBq) each.~~

(5) Unless approved by the department, the maximum possession limit for Technetium 99m in individual amounts shall not exceed 300 millicuries (11.1 GBq) each and a combined activity of 900 millicuries (33.3 GBq).

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.141 FS. Law Implemented 404.051(1), (4), (6), (10), 404.061(2), 404.141 FS. History–New 8-25-91, Formerly 10D-91.723, Amended 5-18-98, Amended _____.

64E-5.618 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(1) through (2) No change.

(3) A licensee shall retain leak test records for 3 years. The records shall contain the model number and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), the date of the test, and the name of the individual who performed the test analysis ~~signature of the radiation safety officer~~.

(4) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(a) No change.

(b) File a written report with the department within 5 days of receiving the leak test results describing the equipment involved, the test results, ~~and~~ the action taken, the model number and serial number or the leaking source if assigned, the radioisotope and its estimated activity, and the date of the test.

(5) through (7) No change.

(8) A licensee who possesses sealed sources or brachytherapy sources, except gamma stereotactic radiosurgery sources, ~~or teletherapy sources~~ shall conduct a physical inventory of all such sources at intervals not to exceed six ~~least every 3~~ months. ~~A licensee who possesses other sealed sources shall conduct a physical inventory of all such sources at least every 6 months.~~ The licensee shall retain each inventory record for 3 years. The inventory records shall contain the model number of each source and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, the date of the inventory, and the name of the individual who performed the inventory ~~signature of the radiation safety officer~~.

(9) No change.

(10) A licensee shall retain a record of each survey required in subsection 64E-5.618(9), F.A.C., for 3 years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the name of the individual who performed the survey ~~signature of the radiation safety officer~~.

(11) Sealed sources designated as radioactive waste and held for decay in storage as in Rule 64E-5.624, F.A.C., are not required to be leak tested or inventoried as required by this section.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.724, Amended _____.

64E-5.621 Surveys for Contamination and Ambient Radiation Dose Rate.

(1) A licensee shall survey with a radiation survey instrument at the end of each day of use, or during an assigned shift for facilities operating continuously, all areas where radiopharmaceuticals are routinely prepared for use or administered.

(2) through (7) No change.

(8) A licensee shall retain a record of each survey required by subsections 64E-5.621(1), (2), and (5), F.A.C., for 3 years. The record shall include:

(a) No change.

(b) A diagram ~~sketch~~ of each area surveyed;

(c) through (e) No change.

(f) The name ~~initials~~ of the person who performed the survey.

(9) The licensee does not need to perform the radiation surveys in subsections 64E-5.621(1) or (2), F.A.C., in areas where patients or human research subjects are currently confined when such patients or subjects cannot be released under Rule 64E-5.622, F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 04.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.729, Amended _____.

64E-5.622 Release of Patients or Human Research Subjects Treated With ~~Containing~~ Radiopharmaceuticals, ~~or Permanent~~ Implants or Remote Afterloader Units.

(1) through (3) No change.

(4) Licensees and license applicants whose proposed procedures to release individuals who have been administered radiopharmaceuticals or permanent implants containing radioactive material from the control of licensees differ from those specified in (1) and (2), above, must submit their proposed procedures to the department for approval. The procedures must:

(a) No change.

(b) Contain a copy of the instructions including written instructions to be given to the released individual, or the individual's parent or guardian, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to another individual is likely to exceed 100 millirem (1 μSv). If the dose to a breast-feeding infant or child could exceed 100 millirem (1 μSv) if there were no interruption of breast-feeding, the instructions also shall include:

1. through 2. No change.

(c) No change.

(5) A licensee shall maintain a record of patient surveys which demonstrates compliance with subsections 64E-5.622(3) and (6), F.A.C., for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient, and the initials of the individual who performed ~~made~~ the survey.

(6) Before releasing a patient or human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-15-96, Formerly 10D-91.730, Amended 10-8-00, _____.

64E-5.624 Decay In Storage.

(1) A licensee shall hold radioactive material with a physical half life of less than 120 ~~90~~ days for decay in storage before disposal as ordinary trash. A licensee is exempt from the requirements of paragraph 64E-5.331(1)(c) ~~Rule 64E-5.328~~, F.A.C., of these regulations if:

(a) through (d) No change.

(2) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.732, Amended _____.

64E-5.625 Safety Instructions and Precautions for Liquid Iodine, Radiopharmaceutical Therapy, Manual Brachytherapy, Remote Afterloader Units, ~~and~~ Teletherapy Units, and Gamma Stereotactic Radiosurgery.

(1) A licensee shall provide oral and written radiation safety instructions to all personnel caring for patients or human research subjects, who cannot be released under Rule 64E-5.622, F.A.C., undergoing radiopharmaceutical therapy or manual brachytherapy ~~and to personnel who operate a teletherapy unit~~. This training shall be provided initially prior to caring for patients and r~~R~~efresher training shall be provided at least every 12 months. The instruction shall describe the licensee's procedures for notification of the RSO and an ~~radiation safety officer or~~ authorized user in case of the patient's death or medical emergency.

(2) The instruction for radiopharmaceutical therapy shall be commensurate with the duties of the personnel and describe the procedures for:

(a) Patient or human research subject control;

(b) Visitor control, including;

1. Routine visitation to hospitalized individuals in accordance with paragraph 64E-5.312(1)(a), F.A.C.; and

2. Visitation authorized in accordance with subsection 63E-5.312(5), F.A.C.

(c) through (d) No change.

(3) The instruction for manual brachytherapy shall be commensurate with the duties of the personnel and describe:

(a) No change.

(b) Safe handling and shielding instructions ~~in case of a dislodged source~~;

(c) Procedures for patient or human research subject control; and

(d) Procedures for visitor control, including:

1. Routine visitation to hospitalized individuals in accordance with paragraph 64E-5.312(1)(a), F.A.C.; and

2. Visitation authorized in accordance with paragraph 64E-5.312(5), F.A.C.

(4) A licensee shall provide instruction for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as described in Rule 64E-5.636, F.A.C. ~~and post conspicuously written instructions at the teletherapy unit console. These instructions shall inform the operator of:~~

~~(a) The procedure to be followed to ensure that only the patient is in the treatment room before turning on the primary beam of radiation or after a door interlock interruption;~~

~~(b) The procedure to be followed if the operator is unable to turn off the primary beam of radiation with controls outside the treatment room or any other abnormal operation occurs; and~~

~~(c) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.~~

(5) A licensee shall keep a record of individuals receiving instruction required by (1), (2), ~~and~~ (3), and (4) above, which includes a list of topics covered ~~description of the instruction~~, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the department for 3 years.

(6) A licensee shall take the following safety precautions for each patient or human research subject receiving manual brachytherapy or radiopharmaceutical therapy who cannot be released under Rule 64E-5.622, F.A.C. ~~and hospitalized.~~

(a) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room.

~~(b) Authorize visits by individuals under 18 years of age only with the approval of the authorized user after consultation with the radiation safety officer.~~

(b)~~(c)~~ Measure promptly, after administration of the dosage, the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Rule 64E-5.312, F.A.C. Retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(c)~~(d)~~ Provide the patient with radiation safety guidance before authorizing release of the patient that will help to keep radiation dose to household members and the public as low as reasonably achievable.

(d)~~(e)~~ Notify the RSO and an ~~radiation safety officer or the~~ authorized user immediately if the patient dies or has a medical emergency.

(7) Individuals receiving radiopharmaceutical therapy shall be provided a private room with a private sanitary facility or a room with another individual who is receiving unsealed radioactive materials who cannot be released under Rule 64E-5.622, F.A.C. Individuals receiving manual brachytherapy shall be provided a private room or a room with another individual who is receiving manual brachytherapy and cannot be released under Rule 64E-5.622, F.A.C. ~~A licensee shall provide a private room with a private sanitary facility for a radiopharmaceutical therapy patient.~~ The licensee shall not place an individual receiving manual brachytherapy ~~patient~~ in the same room with a patient who is not receiving manual brachytherapy ~~radiation therapy unless the licensee can demonstrate compliance with the requirements of paragraph 64E-5.312(1)(c), F.A.C., at a distance of 1 meter from the implant~~.

(8) A licensee shall take these additional safety precautions for radiopharmaceutical therapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C. ~~who are hospitalized~~:

(a) Monitor material and items removed from the patient's or human research subject's room to determine that any contamination 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 these materials and items as radioactive waste.

(b) No change.

~~(c) Establish a bioassay program to measure the thyroid burden of each individual who helped prepare or administer a dosage of liquid iodine 131 within 3 days after administering the dosage, and retain for the period required by subsection 64E-5.339(5), F.A.C., a record of each thyroid burden measurement, the date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Action levels and corresponding actions will be in accordance with the U.S. Nuclear Regulatory Commission's Regulatory Guide 8.20, Revision 1, September, 1979.~~

(9) For manual brachytherapy patients or human research subjects who cannot be released by Rule 64E-5.622, F.A.C., the licensee shall have the applicable emergency response equipment available near each treatment room to respond to the following:

(a) A source that is dislodged from the patient or human research subject; and

(b) A sealed source lodged within the patient following removal of the source applicators.

(10) The licensee shall establish a bioassay program to measure the thyroid burden of each individual who helps prepare, prepares or administers a dosage of unsealed iodine 131 or iodine 125 in accordance with Rule 64E-5.1320, F.A.C.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS. History–New 5-15-96, Formerly 10D-91.7321, Amended _____.

64E-5.6251 Therapy Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) The 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; and

(4) The accuracy of the software used to determine sealed source positions from radiographic images.

The licensee shall maintain records of this acceptance testing and protocols used in performing these tests for inspection by the department.

Rulemaking Authority 404.051, 404.061, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), (11), 404.061(2), (3), 404.081, 404.141 FS. History–New _____.

SUBPART C
UPTAKE, DILUTION, AND EXCRETION

64E-5.626 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for medical use under the following conditions ~~that is either~~:

(1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following: ~~Obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations; or~~

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or a Notice of Claimed Investigational Exemption for a New Drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.649 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following: ~~Prepared by an authorized nuclear pharmacist as specified in Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user~~.

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is 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 IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662, or 64E-5.663, F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.733, Amended 8-6-01, _____.

SUBPART D
IMAGING AND LOCALIZATION

64E-5.627 Use of Unsealed Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, or any generator, or reagent kit, for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use under the following conditions:

(1) When a written directive is not required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following: ~~A licensee is allowed to use any radioactive material in a diagnostic radiopharmaceutical, except in an aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for medical use that is either:~~

(a) No change.

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or ~~Prepared by an authorized nuclear pharmacist as specified in Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user.~~

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. Except for sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rules 64E-5.650, 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.650 or 64E-5.657, F.A.C.

(2) When a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following: ~~A licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department and the requirements of Rule 64E-5.629, F.A.C., are met.~~

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is 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 IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq) a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the applicable training and experience specified in Rules 64E-5.657, 64E-5.660, 64E-5.661, 64E-5.662, or 64E-5.663, F.A.C.

(3) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) and when a written directive is required by subsection 64E-5.607(3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by a NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. For sodium iodide I-131 in quantities greater than 30 microcuries (1.11 MBq), a physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.657, 64E-5.660 or 64E-5.661, F.A.C.

(4) A licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the department and the requirements of Rule 64E-5.629, F.A.C., are met.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.735, Amended 8-6-01, _____.

64E-5.628 Generators ~~Permissible Molybdenum 99 Concentration~~.

(1) Permissible Molybdenum/Technetium Concentration. ~~A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m (5.55 kilo becquerel of molybdenum 99 per 37 megabecquerel of technetium 99m).~~

(a) A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum 99 per millicurie of technetium 99m (5.55 kilo-becquerel of molybdenum 99 per 37 megabecquerel of technetium 99m).

(b) A licensee preparing technetium 99m radiopharmaceuticals from molybdenum 99/technetium 99m generators shall measure the molybdenum 99 concentration in each eluate or extract.

(c) A licensee who is required to measure molybdenum concentrations shall retain a record of each measurement for 3 years. The record shall include for each elution or extraction of technetium 99m:

1. The measured activity of the technetium expressed in millicuries (megabecquerels);

2. The measured activity of molybdenum expressed in microcuries (kilobecquerels);

3. The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);

4. The date of the test; and

5. The initials of the individual who performed the test.

(d) A licensee shall report immediately to the department each occurrence of molybdenum 99 concentration exceeding the limits specified in subsection 64E-5.628(1), F.A.C.

(2) Permissible Strontium/Rubidium Concentration. ~~A licensee preparing technetium 99m radiopharmaceuticals from molybdenum 99/technetium 99m generators shall measure the molybdenum 99 concentration in each eluate or extract.~~

(a) A licensee shall not administer a radiopharmaceutical containing more than 0.02 microcurie of strontium 82 per millicurie of rubidium 82 (0.74 kilobecquerel of strontium 82 per 37 megabecquerel of rubidium 82) or more than 0.2 microcurie of strontium 85 per millicurie of rubidium 82 (7.4 kilobecquerel of strontium 85 per 37 megabecquerel of rubidium 82).

(b) A licensee preparing rubidium 82 radiopharmaceuticals from strontium 82/rubidium 82 generators shall measure and calculate the strontium 82 and strontium 85 concentration on each day of use prior to the use of rubidium chloride for injection.

(c) A licensee who is required to measure strontium 82 and strontium 85 concentrations shall retain a record of each measurement for 3 years. The record shall include for each day of use assay:

1. The measured activity of the rubidium 82 expressed in millicuries (megabecquerels);

2. The measured activity of strontium 82 expressed in microcuries (kilobecquerels);

3. The calculated activity of strontium 85 expressed in microcuries (kilobecquerels);

4. The ratio of the measures expressed as microcuries of strontium 82 per millicurie of rubidium 82 (kilobecquerels of strontium 82 per megabecquerel of rubidium 82) and the ratio of the measures expressed as microcuries of strontium 85 per millicurie of rubidium 82 (kilobecquerels of strontium 85 per megabecquerel of rubidium 82);

5. The date of the test; and

6. The initials of the individual who performed the test.

(d) A licensee shall report immediately to the department each occurrence of strontium 82 or strontium 85 concentrations exceeding the limits specified in subsection 64E-5.628(2), F.A.C.

(3) Other Permissible Parent/Daughter Concentration. ~~A licensee who is required to measure molybdenum concentrations shall retain a record of each measurement for 3 years. The record shall include for each elution or extraction of technetium 99m:~~

(a) If a licensee seeks to utilize a Parent/Daughter concentration other that those listed in subsection (1) or (2) above, the licensee must submit a license amendment to the department for review and approval of the maximum parent isotope or other contaminate concentrations breakthrough per daughter isotope concentration allowed for administration to patients or human research subjects, and the instrumentation and procedures used in determining parent isotope or other contaminate breakthrough concentrations; ~~The measured activity of the technetium expressed in millicuries (megabecquerels);~~

(b) Each license must perform the determination listed in paragraph (3)(a), above, on each day of use prior to the administration to patients or human research subjects; ~~The measured activity of molybdenum expressed in microcuries (kilobecquerels);~~

(c) Retain a record of each measurement for 3 years. The record shall include for each day of use assay: ~~The ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium);~~

1. The measured activity of the daughter isotope expressed in millicuries (megabecquerels);

2. The measured activity of parent isotope(s) and other contaminates expressed in microcuries (kilobecquerels);

3. The calculated activity of parent isotope(s) and other contaminates expressed in microcuries (kilobecquerels) as applicable;

4. The ratio of the measures expressed as microcuries of parent isotope(s) and other contaminates per millicurie of daughter isotope (kilobecquerels of parent isotope(s) per megabecquerel of daughter isotope);

5. The date of the test; and

6. The initials of the individual who performed the test.

(d) A licensee shall report immediately to the department each occurrence of parent isotope(s) or other contaminates concentrations exceeding the limits specified in paragraph 64E-5.628(3)(a), F.A.C. ~~The date of the test; and~~

~~(e) The initials of the individual who performed the test.~~

~~(4) A licensee shall report immediately to the department each occurrence of molybdenum-99 concentration exceeding the limits specified in subsection 64E-5.628(1), F.A.C.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.736, Amended _____.

64E-5.629 Control of Aerosols and Gases.

(1) through (5) No change.

(6) A licensee shall check the operation of collection systems prior to use each month of use ~~monthly~~ and measure the ventilation rates in areas of use every 6 months. Records of these checks and measurements shall be maintained for 3 years.

(7) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1, (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.737, Amended _____.

SUBPART E

RADIOPHARMACEUTICALS FOR THERAPY

64E-5.630 Use of Radiopharmaceuticals for Therapy.

A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met ~~that is either~~:

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following: ~~Obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent U.S. Nuclear Regulatory Commission or Agreement State regulations; or~~

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is 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 IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or.

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 54E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following: ~~Prepared by an authorized nuclear pharmacist as specified in Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user.~~

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2, A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

(3) Only for oral administration of sodium iodide I-131 in quantities greater than 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is 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 IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2, A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C, or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

(4) Only parenteral use of radioactive materials the licensee must satisfy the following: ~~Rule 64B16-28.903, F.A.C., or by a physician who is an authorized user~~.

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is 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 IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2, A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e), or subsection 64E-5.608(1), F.A.C., or;

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.663, or 64E-5.657, F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, _____.

SUBPART F
SEALED SOURCES FOR DIAGNOSIS

64E-5.631 Use of Sealed Sources for Diagnosis.

The licensee is allowed to use the sealed sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met. ~~A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for diagnosis:~~

(1) through (2) No change.

(3) Gadolinium 153 as a sealed source in a device for bone mineral analysis; ~~and~~

(4) Americium 241 as a sealed source in a device for bone mineral analysis; or~~.~~

(5) For isotopes or uses not listed in subsections 64E-5.631(1) through (4), F.A.C., above, the licensee must amend their radioactive materials license.

In order to use isotopes in accordance this Rule, an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.654 or 64E-5.657, F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.743, Amended _____.

SUBPART G
SOURCES FOR BRACHYTHERAPY

64E-5.632 Use of Sources for Manual Brachytherapy.

The licensee is allowed to use the brachytherapy sources listed below, provided they are approved by and used as specified in, the Sealed Source and Device Registry, for diagnostic medical uses, or in research in accordance with an active IDE application accepted by the FDA and the requirements of Rule 64E-5.612, F.A.C., are met. ~~A licensee shall follow the manufacturer's radiation safety and handling instructions and use only the following sealed sources for brachytherapy:~~

(1) through (7) No change.

(8) Radon 222 as seeds for interstitial treatment of cancer; ~~and~~

(9) Radium 226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;.

(10) Cesium 131 as a sealed source in seeds for interstitial treatment of cancer; or

(11) For isotopes or uses not listed in subsections 64E-5.632(1) through (10), F.A.C., above, the licensee must amend their radioactive materials license.

In order to use isotopes in accordance with Rule 64E-5.632, F.A.C., an authorized user must satisfy the training and experience requirements specified in Rule 64E-5.652, or 64E-5.657, F.A.C. An authorized user of only Strontium 90 as a sealed source in an applicator for treatment of superficial eye conditions listed in subsection 64E-5.632(2), F.A.C., above must satisfy the training and experience specified in Rule 64E-5.652, 64E-5.653, or 64E-5.657, F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.745, Amended _____.

64E-5.633 Manual Brachytherapy Sources Inventory and Surveys.

(1) The licensee shall maintain accountability at all times for all manual brachytherapy sources in storage or use. As soon as possible e~~E~~ach time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

(2) A licensee shall make a record of the use of manual brachytherapy sources which includes:

(a) For temporary implants; ~~The names of the individuals permitted to handle the sources;~~

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage; and

2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage.

(b) For permanent implants; ~~The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and~~

1. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date the sources were removed from storage, the number and activity of sources in storage after the removal, and the name of the individual who removed the sources from storage;

2. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date the sources were returned to storage, the number and activity of sources in storage after the return, and the name of the individual who returned the sources to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

~~(c) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.~~

(3) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey. This record shall contain the date and results of the survey, the survey instrument used and the name of the individual who performed the survey.

(4) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.748, Amended _____.

64E-5.6331 Calibration Measurements of Manual Brachytherapy Sources.

(1) Before the first medical use of a brachytherapy source, the licensee shall, using published protocols currently accepted by nationally recognized bodies, determine the following:

(a) Source output or activity using a dosimetry system that meets the requirements of subsection 64E-5.640(1), F.A.C., and

(b) Source positioning accuracy within applicators;

(2) Instead of a licensee making its own measurements as required in subsection 64E-5.6331(1), F.A.C., the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM) that are made in accordance with subsection 64E-5.6331(1), F.A.C.

(3) A licensee shall mathematically correct the outputs or activities determined in subsection 64E-5.6331(1), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

(4) For each brachytherapy source the licensee shall retain the following records for three years after the last use of the source:

(a) The date of calibration;

(b) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(c) The source output or activity;

(d) The source positioning accuracy within the applicators; and

(e) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.6332 Decay of Strontium-90 Sources for Ophthalmic Treatments.

(1) Only an authorized medical physicist or authorized user qualified to perform procedures described in subsection 64E-5.632(2), F.A.C., shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Rule 64E-5.6331, F.A.C.

(2) For each Strontium 90 source the licensee shall retain the following records for the life of the source:

(a) The date and activity of the source as determined under Rule 64E-5.6331, F.A.C.; and

(b) For each decay calculation, the date and the source activity as determined under Rule 64E-5.6332, F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

SUBPART H

PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS.

64E-5.634 Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit ~~Use of Sealed Source in a Teletherapy Unit~~. ~~A licensee shall follow the manufacturer's radiation safety and operating instructions and use only cobalt 60 or cesium 137 as a sealed source in a teletherapy unit for medical use.~~

(1) A licensee shall use sealed sources in photon emitting gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

(2) A licensee shall use sealed sources in photon emitting remote afterloader units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

(3) A licensee shall use sealed sources in photon emitting teletherapy units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the FDA provided the requirements of Rule 64E-5.612, F.A.C., are met.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.751, Amended _____.

64E-5.635 Installation, Adjustment, Maintenance and Repair Restrictions.

~~Only a person specifically licensed by the department, the U.S. Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source. Only such a person shall maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.~~

(1) Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(4) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery

units for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.752, Amended _____.

64E-5.636 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units ~~Amendments~~.

~~In addition to the requirements specified in Rule 64E-5.602, F.A.C., a licensee shall apply for and receive a license amendment or departmental approval before:~~

(1) Listed below are the safety and instruction requirements for a licensee: ~~Making any change in the treatment room shielding~~;

(a) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(b) Permit only individuals approved by the authorized user, RSO, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include the following:

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 RSO to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by paragraph 64E-5.636(1)(d), F.A.C., of this section must be physically located at the unit console. ~~Making any change in the location of the teletherapy unit within the treatment room~~;

(3) A licensee shall post instructions at the unit console to inform the operator of the following: ~~Using the teletherapy unit in a manner that could increase radiation levels in areas outside the teletherapy treatment room~~;

(a) The location of the procedures required by paragraph (4)(a) of this section; and

(b) The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally.

(4) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the following: ~~Relocating the teletherapy unit; or~~

(a) The procedures identified in paragraph 64E-5.636(1)(d), F.A.C., of this section; and

(b) The operating procedures for the unit.

(5) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. ~~Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist~~.

(6) A licensee shall retain a record of individuals receiving instruction required by paragraph 64E-5.636(4), F.A.C., of this section. These records shall be maintained for 3 years and must include the list of topics covered, the date of the instruction, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

(7) A licensee shall retain a copy of the procedures required by paragraphs 64E-5.636(1)(d) and 64E-5.636(4)(b), F.A.C., until the licensee no longer possesses the remote afterloader, teletherapy unit or gamma stereotactic radiosurgery unit.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.753, Amended _____.

64E-5.637 Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units ~~Doors, Interlocks, and Warning Systems~~.

(1) A licensee shall control access to the treatment ~~teletherapy~~ room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment ~~teletherapy~~ room with an electrical interlock system that shall:

(a) Prevent the operator from initiating the treatment cycle ~~turning on the primary beam of radiation~~ unless each treatment room entrance door is closed;

(b) Cause the source(s) to be shielded when an entrance door is opened; ~~Turn off the beam of radiation immediately when an entrance door is opened;~~ and;

(c) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console. ~~Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.~~

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to

ambient levels. ~~A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.~~

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in paragraphs 64E-5.637(1) through (5), F.A.C., of this section, a licensee shall:

(a) For medium dose-rate and pulsed dose-rate remote afterloader units, require:

1. An authorized medical physicist and either, an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either, an authorized user or an individual under, the supervision of an authorized user, who have been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(b) For high dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either, an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(c) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(d) Notify the RSO, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room in order to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.755, Amended _____.

64E-5.638 Radiation Monitoring Devices.

(1) A licensee shall have a permanent radiation monitor in each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room capable of continuously monitoring radiation levels.

(2) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room.

(3) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit. This backup power supply may be a battery system.

(4) Each radiation monitor shall be checked daily with a dedicated check source for proper operation before the teletherapy unit, medium or high dose rate remote afterloader unit, or gamma stereotactic radiosurgery unit is used.

(5) No change.

(6) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to use a radiation survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The radiation survey instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in subsection 64E-5.638(5), F.A.C.

(7) No change.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.757, Amended _____.

64E-5.639 Viewing Systems.

A licensee shall construct or equip each teletherapy, medium or high dose rate remote afterloader, or gamma stereotactic radiosurgery room to permit continuous observation of the patient, or human research subject from the teletherapy unit console during irradiation.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.758, Amended_____.

64E-5.640 Dosimetry Equipment Used With Remote Afterloading Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units.

(1) Except for low dose-rate remote afterloader source output or where the activity is determined by the manufacturer, a~~A~~ licensee shall have a dosimetry system available for use calibrated by (a) or (b) below.

(a) The system must have been calibrated using a system or source traceable to the NIST and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the AAPM. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration. ~~The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine within the previous 2 years and after any servicing that may have affected the system calibration~~.

(b) The system shall have been calibrated within the previous 4 years and shall have been intercompared 18 to 30 months after the calibration at an intercomparison meeting with another dosimetry system that has been calibrated within the previous 2 years by the NIST ~~National Institute of Standards and Technology~~ or by a calibration laboratory accredited by the AAPM ~~American Association of Physicists in Medicine~~. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM ~~American Association of Physicists in Medicine~~. The calibration factor of the licensee's system shall not have changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility. ~~When intercomparing dosimetry systems to be used for calibrating cobalt 60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt 60 source. When intercomparing dosimetry systems to be used for calibrating cesium 137 teletherapy units, the licensee shall use a teletherapy unit with a cesium 137 source.~~

(2) The licensee shall have available for use a dosimetry system for spot-check measurements. The spot-check system shall be the same system used to meet the requirement in subsection 64E-5.640(1), F.A.C., or shall be a system that has been compared with a system that has been calibrated as provided in subsection 64E-5.640(1), F.A.C. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration.

(3) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include:

(a) The date, the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 64E-5.640(1) and (2), F.A.C.;

(b) through (c) No change.

~~(d) Evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.759, Amended_____.

64E-5.641 Full Calibration Measurements on Teletherapy Units.

(1) through (3) No change.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.641(1), F.A.C., using the manufactures published protocols, published protocols as accepted by nationally recognized bodies ~~either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, which is herein incorporated by reference effective 5-12-93; or procedures recommended by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213, which is herein incorporated by reference effective 5-12-93;~~ or equivalent procedures that have been submitted to ~~approved by~~ the department.

(5) No change.

(6) Full calibration measurements required by subsection 64E-5.641(1), F.A.C., and physical decay corrections required by subsection 64E-5.641(5), F.A.C., shall be performed by the authorized medical ~~teletherapy~~ physicist ~~named on the licensee's license~~.

(7) A licensee shall maintain a record of each calibration of each teletherapy unit for three years ~~the duration of the license~~. The record shall include:

(a) through (c) No change.

(d) The results and an assessment of the full calibration to include the following: ~~The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;~~

1. The tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy;

2. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The measured timer accuracy for a typical treatment time;

4. The calculated on-off error;

5. The estimated accuracy of each distance measuring or localization device; and

6. The signature of the authorized medical physicist.

~~(e) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;~~

~~(f) The measured timer accuracy for a typical treatment time;~~

~~(g) The calculated on-off error;~~

~~(h) The estimated accuracy of each distance measuring or localization device; and~~

~~(i) The signature of the teletherapy physicist.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.760, Amended _____.

64E-5.6411 Full Calibration Measurements on Remote Afterloader Units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each remote afterloader unit:

(a) Before the first medical use of the unit;

(b)1. Before medical use following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

2. Before medical use following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(d) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(2) Full calibration measurements of remote afterloader unit shall include the determination of:

(a) The output within 5 percent;

(b) Source positioning accuracy to within 1 millimeter;

(c) Source retraction with backup battery upon power failure;

(d) Timer constancy and linearity over the range of use;

(e) Length of the source transfer tubes;

(f) Length of the applicators; and

(g) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.6411(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.6411(1), F.A.C., in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.641(2)(a), F.A.C., for physical decay at intervals consistent with 1 percent physical decay.

(6) Full calibration measurements required by subsection 64E-5.6411(1), F.A.C., and physical decay corrections required by subsection 64E-5.641(5), F.A.C., shall be performed by the authorized medical physicist.

(7) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection 64E-5.6411(2), F.A.C., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(8) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsections 64E-5.6411(1)-(5), F.A.C.

(9) A licensee shall maintain a record of each remote afterloader unit calibration for three years. The record shall include the following:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for both the remote afterloader unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the remote afterloader unit;

(d) The results and an assessment of the full calibrations.

(e) The results of the audiograph required for low dose-rate remote afterloaders; and

(f) The signature of the authorized medical physicist.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.6412 Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each gamma stereotactic radiosurgery:

(a) Before the first medical use of the unit;

(b)1. Before medical use whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Before medical use following replacement of the source or following reinstallation of the gamma stereotactic radiosurgery unit in a new location;

3. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

(c) At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) Full calibration measurements of the gamma stereotactic radiosurgery unit shall include the determination of:

(a) The output within 3 percent;

(b) Relative helmet factors;

(c) Isocenter coincidence;

(d) Timer constancy and linearity over the range of use;

(e) On-off timers;

(f) Trunnion centricity;

(g) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(h) Helmet microswitches;

(i) Emergency timing circuits; and

(j) Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in Rule 64E-5.640, F.A.C., to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph 64E-5.6412(2)(a), F.A.C., may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by subsection 64E-5.6412(1), F.A.C., in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall correct mathematically the outputs determined in paragraph 64E-5.6412(2)(a), F.A.C., at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by subsection 64E-5.6412(1), F.A.C., and physical decay corrections required by subsection 64E-5.6412(5), F.A.C., shall be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each gamma stereotactic radiosurgery unit calibration for three years. The record shall include:

(a) The date of the calibration;

(b) The manufacturer's name, model number, and serial number for both the gamma stereotactic radiosurgery unit and the source;

(c) The model numbers and serial numbers of the instruments used to calibrate the gamma stereotactic radiosurgery unit;

(d) The results and an assessment of the full calibrations; and

(e) The signature of the authorized medical physicist.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.642 Periodic Spot-Checks of Teletherapy Units.

(1) through (3) No change.

(4) A licensee shall perform spot-checks required by subsection 64E-5.642(1), F.A.C., following procedures established by the authorized medical ~~teletherapy~~ physicist.

(5) A licensee shall have the authorized medical ~~teletherapy~~ physicist review the results of each output spot-check within 15 days and promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 3 years.

(6) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility monthly and after each source installation.

(7) Safety spot-checks shall assure proper operation of:

(a) through (b) No change.

(c) Source exposure ~~Beam condition~~ indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) Viewing and intercom systems;

(e) through (f) No change.

(8) If the results of the checks required in subsection 64E-5.642(7), F.A.C., of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit. ~~A licensee shall lock the control console in the off position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the department.~~

(9) No change.

(10) A licensee shall maintain a record of each spot-check required by subsections 64E-5.642(1) and (6), F.A.C., for 3 years and a copy of the procedures required by subsection 64E-5.641(4), F.A.C., until the licensee no longer possesses the teletherapy unit. The record shall include:

(a) through (i) No change.

(j) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot check. ~~The signature of the individual who performed the periodic spot-check.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2,)(3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.761, Amended _____.

64E-5.6421 Periodic Spot-Checks for Remote Afterloader Units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform the following spot-checks:

(a) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

(b) Before each patient treatment with a low dose-rate remote afterloader unit; and

(c) After each source installation.

(2) Spot-checks shall include the determination of:

(a) Electrical interlocks at each remote afterloader unit room entrance;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(d) Emergency response equipment;

(e) Radiation monitors used to indicate the source position;

(f) Timer accuracy;

(g) Clock (date and time) in the unit's computer; and

(h) Decayed source(s) activity in the unit's computer.

(3) If the results of the checks required in subsection 64E-5.6421(2), F.A.C., of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(4) A licensee shall perform spot-checks required by subsection 64E-5.6421(2), F.A.C., following procedures established by the authorized medical physicist.

(5) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years.

(6) A licensee shall retain a copy of the procedures required by subsection 64E-5.6421(4), F.A.C., until the licensee no longer possesses the remote afterloader unit.

(7) A licensee shall maintain a record of each spot-check required by subsection 64E-5.6421(2), F.A.C., for 3 years and a copy of the procedures required by subsections 64E-5.6421(4) and (5), F.A.C., until the licensee no longer possesses the remote afterloader unit. The record shall include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for both the remote afterloader unit and source;

(c) An assessment of timer accuracy;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

(e) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.6422 Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform the following spot-checks:

(a) Monthly:

(b) Before the first use of the unit on a given day; and

(c) After each source installation.

(2) Spot-checks shall include the determination of:

(a) Assure the proper operation of the:

1. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

2. Helmet microswitches;

3. Emergency timing circuits; and

4. Stereotactic frames and localizing devices (trunnions).

(b) Determine the following elements:

1. The output for one typical set of operating conditions measured with the dosimetry system described in subsection 64E-5.640(2), F.A.C.;

2. The difference between the measurement made in subparagraph 64E-5.6422(2)(b)1., F.A.C., and the anticipated output, expressed as a percentage of the anticipated output value obtained at last full calibration corrected mathematically for physical decay;

3. Source output against computer calculation;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. Trunnion centricity.

(3) A licensee shall perform spot-checks required by subsection 64E-5.6422(1), F.A.C., following procedures established by the authorized medical physicist.

(4) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days and promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for 3 years.

(5) To satisfy the requirements of paragraphs 64E-5.6422(1)(b) and (c), F.A.C., the licensee's spot-checks must assure proper operation of the following:

(a) Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Timer termination;

(e) Radiation monitors used to indicate room exposures; and

(f) Emergency off buttons.

(6) If the results of the checks required in subsection 64E-5.6422(5), F.A.C., of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall arrange for the repair of any system identified in subsection 64E-5.6422(2), F.A.C., that is not operating properly as soon as possible.

(8) A licensee shall maintain a record of each spot-check required by subsections 64E-5.6422(2) and (5), F.A.C., for 3 years and a copy of the procedures required in subsections 64E-5.5422(2) and (3), F.A.C., until the licensee no longer possesses the gamma stereotactic radiosurgery unit. The record shall include:

(a) The date of the spot-check;

(b) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit;

(c) The manufacturer's name, model number and serial number of the instrument used to measure the output of the gamma stereotactic radiosurgery unit;

(d) The timer linearity and constancy;

(e) The calculated on-off error;

(f) A determination of trunnion centricity;

(g) The difference between the anticipated output and the measured output;

(h) An assessment of source output against computer calculations;

(i) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

(j) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.6423 Additional Technical Requirements for Mobile Remote Afterloader Units.

(1) A licensee providing mobile remote afterloader service for medical use shall perform the following:

(a) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) Account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by Rule 64E-5.6421, F.A.C., a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of the following:

(a) Electrical interlocks on treatment area access points;

(b) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) Viewing and intercom systems;

(d) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(e) Radiation monitors used to indicate room exposures;

(f) Source positioning (accuracy); and

(g) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in subsection 64E-5.6423(2), F.A.C., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in subsection 64E-5.6423(2), F.A.C., indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(5) The licensee shall keep a copy of each check for mobile remote afterloader unit required by subsection 64E-5.6423(2), F.A.C., for three years. The records shall include:

(a) The date of the check;

(b) The manufacturer's name, model number, and serial number of the remote afterloader unit;

(c) Notations accounting for all sources before the licensee departs from a facility;

(d) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and

(e) The signature of the individual who performed the check.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10),)(11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.643 Radiation Surveys for Teletherapy Facilities.

(1) through (2) No change.

(3) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include:

(a) through (g) No change.

(h) The signature of the RSO authorized medical ~~radiation safety officer~~ or the ~~teletherapy~~ physicist.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.762, Amended 10-8-00, _____..

64E-5.644 Radiation Surveys for Remote Afterloader and Gamma Stereotactic Radiosurgery Facilities ~~Safety Spot Checks for Teletherapy Facilities~~.

(1) The licensee shall perform radiation surveys with an operable radiation survey instrument calibrated as provided in Rule 64E-5.615, F.A.C., to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry. ~~A licensee shall promptly spot-check all systems listed in subsection 64E-5.642(7), F.A.C., for proper functioning after each installation of a teletherapy source and after making any change for which an amendment is required by Rule 64E-5.636, F.A.C.~~

(2) The licensee shall make the survey specified in subsection 64E-5.644(1), F.A.C., at the installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). ~~If the results of the safety spot-checks required in subsection 64E-5.644(1), F.A.C., indicate the malfunction of any system specified in Rule 64E-5.642, F.A.C., the licensee shall lock the control console in the off position and not use the unit except to repair, replace, or check the malfunctioning system.~~

(3) A licensee shall retain a record of the radiation surveys required by subsection 64E-5.644(1), F.A.C., for the duration of the license. These records shall include: ~~A licensee shall maintain a record of the facility spot-checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer or the teletherapy physicist.~~

(a) The date of the measurements;

(b) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

(c) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) The signature of the RSO or authorized medical physicist who performed the test.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.763, Amended _____.

64E-5.645 Therapy-Related Computer Systems ~~Modification of Teletherapy Unit or Room Before Beginning a Treatment Program~~.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of the following: ~~If the survey required by Rule 64E-5.643, F.A.C., indicates that any individual member of the public is likely to receive a dose in excess of those specified in paragraph 64E-5.312(1)(c), F.A.C., before beginning the treatment program the licensee shall comply with (1) or (2) below:~~

(1) The source-specific input parameters required by the dose calculation algorithm; ~~Equip the unit with stops or add additional radiation shielding to ensure compliance with paragraph 64E-5.312(1)(c), F.A.C.; perform the survey required by Rule 64E-5.643, F.A.C., again; and include in the report required by Rule 64E-5.646, F.A.C., the results of the initial survey, a description of the modification made to comply with subsection 64E-5.645(1), F.A.C., and the results of the second survey.~~

(2) The accuracy of dose, dwell time, and treatment time calculations at representative points; ~~Request and receive a license amendment as provided in subsection 64E-5.312(3), F.A.C., that authorizes radiation levels in unrestricted areas greater than those permitted by paragraph 64E-5.312(1)(c), F.A.C.~~

(3) The accuracy of isodose plots and graphic displays;

(4) The accuracy of the software used to determine sealed source positions from radiographic images; and

(5) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 1-1-94, Formerly 10D-91.764, Amended 10-8-00, _____.

64E-5.647 Five Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during ~~teletherapy~~ source replacement or at least every 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(2) No change.

(3) A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain:

(a) No change

(b) The inspector's radioactive materials license number;

(c) No change.

(d) The manufacturer's name and model number and serial number for both the treatment ~~teletherapy~~ unit and source;

(e) through (h) No change

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.766, Amended _____.

Subpart I

Training and Experience Requirements

64E-5.648 Radiation Safety Officer.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the RSO as provided in Rule 64E-5.605, F.A.C., to be an individual who: ~~radiation safety officer to be certified as specified in (1) below or to complete 200 hours of classroom and laboratory training as specified in (2) below or to be an authorized user identified on the licensee's license.~~

(1) Is certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in subsections 64E-5.648(4) and (5), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be by:~~

(a)1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and

3. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or ~~American Board of Health Physics in Comprehensive Health Physics:~~

(b)1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics either:

a. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state; or

b. In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in Rule 64E-5.657, 64E-4.650 or 64E-5.660, F.A.C.;

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or ~~American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics;~~

~~(c) American Board of Nuclear Medicine;~~

~~(d) American Board of Science in Nuclear Medicine; or~~

~~(e) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science.~~

(2) Have completed a structured educational program consisting of both: ~~Classroom and laboratory training shall consist of the following:~~

(a) 200 hours of classroom and laboratory training in the following areas: ~~One hundred hours of radiation physics and instrumentation;~~

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology;

5. Radiation dosimetry; and

(b) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a NRC or agreement state license or permit issued by a NRC

master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following: ~~Thirty hours of radiation protection;~~

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

6. Using emergency procedures to control radioactive material; and

7. Disposing of radioactive material; or

~~(c) Twenty hours of mathematics pertaining to the use and measurement of radioactivity;~~

~~(d) Twenty hours of radiation biology;~~

~~(e) Thirty hours of radiopharmaceutical chemistry; and~~

~~(f) 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 on a department, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.~~

(3)(a) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC or an agreement state under subsection 64E-5.656(1), F.A.C., and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in subsections 64E-5-648(4) and (5), F.A.C., of this section; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and,

(4) Have obtained written attestation, signed by a preceptor RSO, or residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category as designated by the applicant seeking authorized status) who meets the requirements in paragraph (e) and in sub-paragraphs 64E-5-648(1)(a)1., and 64E-5-648(1)(a)2., or 64E-5-648(1)(b)1., and 64E-5-648(1)(b)2., or subsection 64E-5.648(2) or paragraph 64E-5.648(3)(a), F.A.C., of this section, and has demonstrated the ability to function independently as a RSO to fulfill the radiation safety related duties for a medical use licensee; and

(5) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.767, Amended _____.

64E-5.649 Training for Uptake, Dilution, or Excretion Studies.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a radiopharmaceutical listed in subsection ~~Rule~~ 64E-5.626(1), F.A.C., to: ~~be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.~~

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.649(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be in:~~

(a) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraph 64E-5.649(3)(a) and sub-paragraph 64E-5.649(3)(a)2., F.A.C., of this section; and ~~Nuclear medicine by the American Board of Nuclear Medicine;~~

(b) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or ~~Diagnostic radiology by the American Board of Radiology;~~

~~(c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or~~

~~(d) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine.~~

(2) Be an authorized user under Rules 64E-5.650 and 64E-5.660, F.A.C., or equivalent agreement state requirements; or ~~Training and experience shall be as follows:~~

~~(a) Forty hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, including:~~

~~1. Fifteen hours of radiation physics and instrumentation;~~

~~2. Ten hours of radiation protection;~~

~~3. Five hours of mathematics pertaining to the use and measurement of radioactivity;~~

~~4. Five hours of radiation biology; and~~

~~5. Five hours of radiopharmaceutical chemistry.~~

~~(b) Twenty hours of training under the supervision of an authorized user including:~~

~~1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~3. Administering dosages to patients and using syringe radiation shields;~~

~~4. Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~5. Patient follow-up.~~

(3) ~~Training shall be a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 64E-5.649(2), F.A.C.~~

(a) Have completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include the following:

1. Classroom and laboratory training in the following areas:

b. Radiation protection;a. Radiation physics and instrumentation;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.649, 64E-5.650 and 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

f. Administering dosages of radioactive drugs to patients or human research subjects; and

(b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.649, 64E-5.650 and 64E-5.660, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.649(1)(a) or 64E-5.649(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsection 64E-5.626(1), F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.769, Amended _____.

64E-5.650 Training for Imaging and Localization Studies for Which a Written Directive Is Not Required.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user ~~of a radiopharmaceutical, generator, or reagent kit~~ specified in subsection ~~Rule~~ 64E-5.627(1), F.A.C., to: ~~be certified as specified in (1) below or to complete training and experience as specified in (2) below or to complete training as specified in (3) below.~~

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.650(3)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be in:~~

(a) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes the topics listed in sub-paragraphs 64E-5.650(3)(a)1., and 64E-5.650(3)(a)2., F.A.C., of this section; and ~~Nuclear medicine by the American Board of Nuclear Medicine;~~

(b) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or ~~Diagnostic radiology by the American Board of Radiology;~~

~~(c) Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or~~

~~(d) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine.~~

(2) Be an authorized user under Rule 64E-5.660, F.A.C., and meet the requirements in sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state requirements; or paragraph 64E-5.650(3)(a), F.A.C.; or ~~Training and experience shall be as follows:~~

~~(a) Two hundred hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, including:~~

~~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 radioactivity;~~

~~4. Thirty hours of radiopharmaceutical chemistry; and~~

~~5. Twenty hours of radiation biology.~~

~~(b) Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:~~

~~1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;~~

~~3. Calculating and safely preparing patient dosages;~~

~~4. Using administrative controls to prevent the misadministration of radioactive material;~~

~~5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and~~

~~6. Eluting technetium 99m from generator systems, assaying and testing the eluate for molybdenum 99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium 99m labeled radiopharmaceuticals.~~

~~(c) Five hundred hours of clinical experience under the supervision of an authorized user at a medical institution including:~~

~~1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;~~

~~2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;~~

~~3. Administering dosages to patients and using syringe radiation shields;~~

~~4. Collaborating with the authorized user in the interpretation of radionuclide test results; and~~

~~5. Patient follow-up.~~

~~(d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.~~

(3) ~~Training shall be a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and shall include classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 64E-5.650(2), F.A.C.~~

(a) Have completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use;

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657, 64E-5.650 or sub-subparagraph 64E-5.650(3)(a)2.g., and Rule 64E-5.660, F.A.C., or equivalent agreement state requirements, involving the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

f. Administering dosages of radioactive drugs to patients or human research subjects; and

g. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the

requirements in Rules 64E-5.657, 64E-5.650, 64E-5.660, and sub-subparagraph 64E-5.650(3)(a)2.g., F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.650(1)(a) or 64E-5.650(3)(a) or 64E-5.650(3)(a), F.A.C., of this section and has demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses authorized under subsections 64E-5.626(1) and 64E-5.627(1), F.A.C.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.770, Amended _____.

64E-5.651 Training for Therapeutic Use of Radiopharmaceuticals.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.771, Repealed _____.

64E-5.652 Training for ~~Therapeutic~~ Use of Manual Brachytherapy Sources.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a brachytherapy source specified in Rule 64E-5.632, F.A.C., to ~~be:~~ ~~in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.~~

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.652(2)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be in:~~

(a) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and ~~Radiology, radiation oncology or therapeutic radiology by the American Board of Radiology;~~

(b) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or ~~Radiation oncology by the American Osteopathic Board of Radiology;~~

~~(c) Radiology, with a 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.~~

(2) ~~Training and experience shall be as follows:~~

(a) Have completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes. ~~Two hundred hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources including~~:

1. 200 hours of classroom and laboratory training in the following areas: ~~One hundred and ten hours of radiation physics and instrumentation;~~

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.652, F.A.C., or equivalent agreement state requirements at a medical institution, clinic, or private practice facility, involving the following: ~~Forty hours of radiation protection;~~

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Checking survey meters for proper operation;

c. Preparing, implanting, and removing brachytherapy sources;

d. Maintaining running inventories of material on hand;

e. Using administrative controls to prevent a medical event involving the use of radioactive material;

f. Using emergency procedures to control radioactive material; and

~~3. Twenty five hours of mathematics pertaining to the use and measurement of radioactivity; and~~

~~4. Twenty five hours of radiation biology.~~

(b) Have completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.652, F.A.C., or equivalent agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph

64E-5.652(2)(a)2., F.A.C., of this section; and ~~Five hundred hours of work experience under the supervision of an authorized user at a medical institution including:~~

~~1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;~~

~~2. Checking survey meters for proper operation;~~

~~3. Preparing, implanting, and removing sealed sources;~~

~~4. Using administrative controls to prevent the misadministration of radioactive material; and~~

~~5. Using emergency procedures to control radioactive material.~~

(c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657 and 64E-5.652, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraph 64E-5.652(1)(a), or 64E-5.652(2)(a) and 64E-5.652(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for medical uses of manual brachytherapy sources authorized under Rule 64E-5.632, F.A.C. ~~Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:~~

~~1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;~~

~~2. Selecting the proper brachytherapy source, dose, and method of administration;~~

~~3. Calculating the dose; and~~

~~4. Post administration follow up and review of case histories in collaboration with the authorized user.~~

~~(d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.772, Amended _____.

64E-5.653 Training for Ophthalmic Use of Strontium 90. Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of only strontium 90 for ophthalmic radiotherapy to: ~~be in the active practice of therapeutic radiology or ophthalmology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.~~

(1) Be authorized user under Rule 64E-5.652, F.A.C., or equivalent agreement state requirements; or ~~Certification shall be in radiology, radiation oncology or therapeutic radiology by the American Board of Radiology.~~

(2) ~~Training and experience shall be as follows:~~

(a) Have completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include the following: ~~Twenty four hours of instruction in basic radionuclide handling techniques applicable to the use of strontium 90 for ophthalmic radiotherapy, including:~~

1. ~~Six hours of~~ Rradiation physics and instrumentation:

2. ~~Six hours of~~ Rradiation protection;

3. ~~Four hours of~~ Mmathematics pertaining to the use and measurement of radioactivity; and

4. ~~Eight hours of~~ Rradiation biology; and

(b) Have supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve the following: ~~Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, including the use of strontium 90 for the ophthalmic treatment of five individuals that includes:~~

1. through 3. No change.

4. Follow up and review of each individual's case history~~.~~; and

(c) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.652, 64E-5.653, F.A.C., or equivalent agreement state requirements, that the individual has satisfactorily completed the requirements in paragraphs 64E-5.653(2)(a) and 64E-5.653(2)(b), F.A.C., of this section and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee-authorized for strontium-90 for ophthalmic use. ~~The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the~~

~~radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.~~

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.773, Amended _____.

64E-5.654 Training for Use of Sealed Sources for Diagnosis.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a sealed source in a device specified in Rule 64E-5.631, F.A.C., to: ~~to be a physician, dentist, or podiatrist who is certified as specified in (1) below or who has completed the training as specified in (2) below~~.

(1) Be certified by a specialty board whose certification process includes all of the requirements in subsections 64E-5.654(2) and (3), F.A.C., of this section and whose certification has been recognized by the NRC or an agreement state. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or ~~Certification shall be in:~~

~~(a) Radiology, diagnostic radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;~~

~~(b) Nuclear medicine by the American Board of Nuclear Medicine;~~

~~(c) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or~~

~~(d) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine.~~

(2) Have completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include the following: ~~Training shall be 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including:~~

(a) Radiation physics and instrumentation; ~~Three hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation~~

(b) Radiation protection; ~~Three hours of radiation biology; and~~

(c) Mathematics pertaining to the use and measurement of radioactivity; and ~~Two hours of radiation protection and training in the use of the device for the purposes authorized by the license.~~

(d) Radiation biology; and

(3) Have completed training in the use of the device for the uses requested.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.774, Amended _____.

64E-5.655 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units ~~Teletherapy~~.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of a sealed source specified in Rule 64E-5.634, F.A.C., to: ~~in a teletherapy unit to be in the active practice of therapeutic radiology. In addition, the individual shall be certified as specified in (1) below or shall complete training and experience as specified in (2) below.~~

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.655(2)(c) and subsection 64E-5.655(3), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be in:~~

(a) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and ~~Radiology, radiation oncology, or therapeutic radiology by the American Board of Radiology;~~

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or ~~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.~~

~~(2) Training and experience shall be as follows:~~

(a) Have completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes the following: ~~Two hundred hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, including:~~

1. 200 hours of classroom and laboratory training in the following areas: ~~One hundred and ten hours of radiation physics and instrumentation;~~

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.655, F.A.C., or equivalent agreement state requirements at a medical institution, clinic, or private practice facility, involving the following: ~~Forty hours of radiation protection;~~

a. Reviewing full calibration measurements and periodic spot-checks;

b. Preparing treatment plans and calculating treatment doses and times;

c. Using administrative controls to prevent a medical event involving the use of radioactive material;

d. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

e. Checking and using survey meters;

f. Selecting the proper dose and how it is to be administered; and

~~3. Twenty-five hours of mathematics pertaining to the use and measurement of radioactivity; and~~

~~4. Twenty-five hours of radiation biology.~~

(b) Have completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in Rules 64E-5.657 and 64E-5.655, F.A.C., or equivalent agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subparagraph 64E-5.655(2)(a)2., F.A.C., of this section; and ~~Five hundred hours of work experience under the supervision of an authorized user at a medical institution, including:~~

~~1. Review of the full calibration measurements and periodic spot checks;~~

~~2. Preparing treatment plans and calculating treatment times;~~

~~3. Using administrative controls to prevent misadministrations;~~

~~4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and~~

~~5. Checking and using survey meters.~~

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 64E-5.655(1)(a) or 64E-5.655(2)(a) and 64E-5.655(2)(b) and subsection 64E-5.655(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee for each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657 and 64E-5.655, F.A.C., or equivalent agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and ~~Three years of supervised clinical experience including 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution, including:~~

~~1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;~~

~~2. Selecting the proper dose and how it is to be administered;~~

~~3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patient's progress and consideration of the need to modify originally prescribed doses as warranted by patient's reaction to radiation; and~~

~~4. Post administration follow-up and review of case histories.~~

~~(d) The radiation safety committee shall approve in writing any training of a physician, dentist or podiatrist to receive, possess or use radioactive material under the supervision of an authorized user at a medical institution. After training has been completed, the radiation safety committee shall provide documentation to the supervised individual that he has received the training and experience required by this section.~~

(3) Have received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.775, Amended _____.

64E-5.656 Training for an Authorized Medical ~~Teletherapy~~ Physicist.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized medical physicist to: ~~The licensee shall require the teletherapy physicist to be certified as specified in (1) below or meet the requirements specified in (2) below.~~

(1) Be certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.656(2)(b) and subsection 64E-5.656(3), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to: ~~Certification shall be by the American Board of Radiology in:~~

(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; ~~Therapeutic radiological physics;~~

(b) Have 2 years of full-time practical training and/or supervised experience in medical physics; ~~Roentgen ray and gamma ray physics;~~

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in Rule 64E-5.657, 64E-5.652 or 64E-5.655, F.A.C.; and

(c) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or ~~X ray and radium physics; or~~

~~(d) Radiological physics.~~

(2)(a) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include: ~~Education and training shall be a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in Rules 64E-5.618, 64E-5.641, 64E-5.642, and 64E-5.643, F.A.C., under the supervision of a teletherapy physicist during the year of work experience.~~

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsection 64E-5.656(3) and paragraph 64E-5.656(1)(a) and (b), or 64E-5.656(2)(a) and 64E-5.656(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized medical physicist to fulfill the radiation safety related duties for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.656 or 64E-5.657, F.A.C., or equivalent agreement state requirements, for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(3) Have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2),(3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.776, Amended _____.

64E-5.657 Training for Experienced RSO, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist ~~Training for Experienced Authorized Users or Radiation Safety Officers.~~

~~Authorized users or radiation safety officers identified on a department, U.S. Nuclear Regulatory Commission, agreement state or licensing state license on 8-25-91 who perform only those methods of use for which they were authorized on that date need not comply with the applicable training requirements of Rules 64E-5.648 through 64E-5.658, F.A.C.~~

(1)(a) An individual identified as a RSO, a teletherapy or medical physicist, or a nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(b) An individual identified as a RSO, an authorized medical physicist, or an authorized nuclear pharmacist on a NRC or agreement state license or a permit issued by a NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope, need not comply with the training requirements of Rule 64E-5.648, 64E-5.656 or 64E-5.659, F.A.C., respectively.

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the NRC or agreement state, a permit issued by a NRC master material licensee, a permit issued by a NRC or agreement state broad scope licensee, or a permit issued by a NRC master material license broad scope permittee~~,~~ who perform only those medical uses for which they were authorized, need not comply with the training requirements of Rule 64E-5.649, 64E-5.650, 64E-5.660, 64E-5.661, 64E-5.662, 64E-5.663, 64E-5.652, 64E-5.653, 64E-5.654, or 64E-5.655, F.A.C.

(3) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on department radioactive materials licenses for the same uses for which these individuals are authorized.

Rulemaking ~~Specific~~ Authority 404.051, 404.061, 404.071 FS. Law Implemented 404.022, 404.051(1), (4), (10), (11), 404.061(2), (3), 404.071(3) 404.141 FS. History–New 8-25-91, Amended 5-15-96, Formerly 10D-91.777, Amended _____.

64E-5.658 Recentness of Training.

The training and experience specified in Rules 64E-5.648, 64E-5.649, 64E-5.650, 64E-5.652, 64E-5.653, 64E-5.654, 64E-5.655, 64E-5.656, 64E-5.657,64E-5.659, 64E-5.660, 64E-5.661, 64E-5.662 and 64E-5.663 ~~through 64E-5.656~~, F.A.C., shall have been obtained within the 7 ~~5~~ years preceding the date of application or the individual shall have had related continuing education or experience since the required training and experience was completed and within the 7 ~~5~~ years preceding the date of application.

Rulemaking ~~Specific~~ Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Formerly 10D-91.779, Amended _____.

64E-5.659 Training for an Authorized Nuclear Pharmacist.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized nuclear pharmacist to:

(1) Be certified by a specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.659(2)(b), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(b) Hold a current, active license to practice pharmacy;

(c) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

(d) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, that assess knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(2)(a) Have completed 700 hours in a structured educational program consisting of both:

1. 200 hours of classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Supervised practical experience in a nuclear pharmacy involving:

a. Shipping, receiving, and performing related radiation surveys;

b. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

c. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

d. Using administrative controls to avoid medical events in the administration of radioactive material; and

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(b) Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in paragraph 64E-5.659(1)(a), 64E-5.659(1)(b), and 64E-5.659(1)(c) or 64E-5.659(2)(a), F.A.C., of this section and have demonstrated the ability to function independently as an authorized nuclear pharmacist to fulfill the radiation safety related duties for a medical use licensee.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.660 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of unsealed radioactive materials specified in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., which require a written directive to:

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in sub-subparagraphs 64E-5.660(2)(a)2.g., and paragraph 64E-5.660(2)(b), F.A.C., of this section. (Specialty boards whose certification processes have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subparagraph 64E-5.660(2)(a)1. through sub-subparagraph 64E-5.660(2)(a)2.e., F.A.C., of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and,

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2)(a) Have completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657 and 64E-5.660, F.A.C., or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages in the same dosage category or categories (*i.e.*, sub-subparagraph 64E-5.660(2)(a)2.g., F.A.C.,) as the individual requesting authorized user status. The work experience must involve the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

f. Performing checks for proper operation of survey meters; and

g. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status as listed below:

(I) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required or sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;

(II) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(III) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(IV) Parenteral administration of any other radionuclide, for which a written directive is required; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs 64E-5.660(1)(a) and 64E-5.660(2)(a)2.g. and 64E-5.660(2)(a)2.g., or paragraph 64E-5.660(2)(a), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657 and 64E-5.660, F.A.C., or equivalent agreement state requirements. The preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must have experience in administering dosages in the same dosage category or categories specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., as the individual requesting authorized user status.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.661 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicuries).

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to:

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section and whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in paragraph 64E-5.661(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., or uses listed in sub-sub-subparagraphs64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), Rule 64E-5.662, F.A.C., or equivalent agreement state requirements; or

(3)(a) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.660, 64E-5.661 and 64E-5.662, F.A.C., or equivalent agreement state requirements. A supervising authorized user who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.661(3)(a) and 64E-5.661(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee that required a written directive under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized

individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.660, 64E-5.661 and 64E-5.662, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirement in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(I) or 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.662 Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicuries).

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to:

(1) Be certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and whose certification has been recognized by the NRC or an agreement state, and who meets the requirements in paragraph 64E-5.662(3)(c), F.A.C., of this section. (The names of board certifications which have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.); or

(2) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., or equivalent agreement state requirements; or

(3)(a) Have successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.660 and 64E-5.662, F.A.C., or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of radioactive material;

5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6 Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 64E-5.662(3)(a) and 64E-5.662(3)(b), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require written directives. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.660 and 64E-5.662, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

64E-5.663 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to:

(1) Be an authorized user under Rule 64E-5.660, F.A.C., for uses listed in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., or equivalent agreement state requirements; or

(2) Be an authorized user under Rules 64E-5.652, 64E-5.655, F.A.C., or equivalent agreement state requirements and who meets the requirements in subsection 64E-5.663(4), F.A.C. of this section; or

(3) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under Rules 64E-5.652 and 64E-5.655, F.A.C., and who meets the requirements in subsection 64E-5.663(4), F.A.C., of this section.

(4)(a) Have successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include the following:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

(b) Have work experience, under the supervision of an authorized user who meets the requirements in Rules 64E-5.657, 64E-5.660 and 65E-5.663, F.A.C., or equivalent agreement state requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in Rule 64E-5.660, F.A.C., or equivalent agreement state requirements, must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C., or equivalent agreement state requirements. The work experience must involve the following:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

3. Calculating, measuring, and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

5. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

6. Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

(c) Have obtained written attestation that the individual has satisfactorily completed the requirements in subsections 64E-5.663(2) or 64E-5.663(3), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized for the parenteral administration of unsealed radioactive material requiring a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rules 64E-5.657, 64E-5.660 and 65E-5.663, F.A.C., or equivalent agreement state requirements. A preceptor authorized user, who meets the requirements in Rule 64E-5.660, F.A.C., must have experience in administering dosages as specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(III) or 64E-5.660(2)(a)2.g.(IV), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

SUBPART J

64E-5.664 Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.

A licensee may use radioactive materials or a radiation source from radioactive materials approved for medical use which is not specifically addressed in Rules 64E-5.626, 64E-5.627, 64E-5.630, 64E-5.631, 64E-5.632 and 64E-5.634, F.A.C., provided the following are satisfied:

(1) The applicant or licensee has received written approval from the department in a license or license amendment and uses the material in accordance with the regulations and specific license conditions the department considers necessary for the medical use of the material;

(2) The applicant or licensee has submitted the information required by Rules 64E-5.207 and 64E-5.208, F.A.C.; and

(3) The licensee shall provide specific information on the following:

(a) Radiation safety precautions and instruction;

(b) Methodology for measuring dosages or doses to be administered to patients or human research subjects;

(c) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(d) Security of radioactive materials, training or experience of individuals involved in these uses or other information not specified in paragraph 64E-5.665(3)(a)(b) or (c), F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New _____.

PART XIII
RADIATION SAFETY REQUIREMENTS FOR POSSESSION AND USE OF SEALED OR UNSEALED SOURCES OF RADIOACTIVE MATERIALS

64E-5.1301 Sealed or Unsealed Sources of Radioactive Material.

The rules in this part establish radiation safety requirements for licensees possessing or using sealed or unsealed sources of radioactive materials not otherwise specified in a license or addressed in these rules. The requirements of this part are in addition to and not in substitution for other applicable requirements of these rules. Licenses of broad scope are exempt from the requirements of Rule 64E-5.1313, subsections 64E-5.1318(2), and 64E-5.1319(1), (2), (3) and (4), F.A.C. Except for Rule 64E-5.1320, F.A.C., t~~T~~he requirements of this part do not apply to persons licensed as specified in Parts IV, VI, and XI. General licensees as specified in subsections 64E-5.206(7) and (8), F.A.C., are exempt from the requirements of this part.

Rulemaking ~~Specific~~ Authority 404.051, 404.061 FS. Law Implemented 404.022, 404.051(1), (4), (6), (10), 404.061(2), (3), 404.081(1) FS. History–New 5-12-93, Amended 5-15-96, Formerly 10D-91.1401, Amended _____.

SUBPART D
REQUIREMENTS FOR POSSESSION AND USE OF UNSEALED SOURCES OF RADIOACTIVE MATERIALS

64E-5.1320 Bioassay Program.

The licensee shall establish and submit for department approval a bioassay program used to evaluate internal doses. At a minimum an acceptable program shall include the following action levels for organ uptakes, corresponding actions taken if these levels are exceeded, frequency of measurement and maintenance of records.

(1) Routine bioassay is required when an individual handles in open form unsealed quantities of radioactive iodine that exceed those shown in the table 1 below. The quantities shown apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over any 3-month period.

TABLE 1

I-125 or I-131 Activity Handled in Unsealed Form Requiring Bioassay

Type of Operation	Volatile or Dispersible	Bound to Nonvolatile Agent
Processes in open room or bench, with possible escape of iodine from process vessels	1.0 mCi (37 MBq)	1.0 mCi (37 MBq)
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, and performance reliability	1.0 mCi (37 MBq)	10.0 mCi (370 MBq)
Processed carried out within glove boxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	10.0 mCi (370 MBq)	100.0 mCi (3700 MBq)

(a) A bioassay shall be taken within 72 hours of initial use of radioiodine and every 2 weeks thereafter. When radioiodine use is on an infrequent basis (less than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

(b) If the thyroid burden at the time of measurement exceeds 0.12 microcurie (4.44 KBq) of iodine 125 or 0.04 microcurie (1.48 KBq) of iodine 131, the following actions shall be taken:

1. An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s);

2. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented;

3. A repeat bioassay shall be taken within 2 weeks of the previous measurement and shall be evaluated within 24 hours after the measurement in order to confirm the presence of internal radioiodines; and

4. Notification reports must be provided as required by Rules 64E-5.345, and 64E-5.347, F.A.C., or as required by conditions of the license; and

(c) A record of each bioassay shall be maintained for inspection by the department in an auditable form for 3 years and shall include the date of the bioassay, the name of the individual, and the thyroid burden at the time of the measurement.

(2) Routine bioassay is required when an individual handles in open form unsealed quantities of tritium that exceed those shown in table 2 below. The quantities shown apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over a 1-month period.

TABLE 2

Tritium Activity Handled in Levels or Concentrations Requiring

Type of Operation	HTO and Other Tritiated Compounds (Including Nucleotide Precursors)	Tritium (HT or T) Gas in Sealed Process Vessels
Processes in open room or bench with possible escape of tritium from process vessels	0.1 Ci (3.70 GBq)	100 Ci (3.7 TBq)
Processes with possible escape of tritium carried out within a fume hood of adequate design, face velocity, and performance reliability	1 Ci (37 GBq)	1,000 Ci (37 TBq)
Processes carried out within glove boxes that are ordinarily closed but with possible release of tritium from process vessels and occasional exposure to contaminated box and leakage	10 Ci (370 GBq)	10,000 Ci (370 TBq)

(a) A bioassay shall be taken within 72 hours of initial use of tritium and every 2 weeks thereafter. When work with tritium is on an infrequent basis (less frequent than every 2 weeks), a bioassay shall be taken within 10 days of the last day of use.

(b) If the urinary tritium concentration exceed 5 microcuries (185 KBq) per liter at the time of the measurement the following actions shall be taken:

1. An investigation of the operations involved, including air and other facility surveys, shall be carried out to determine the cause(s);

2. Corrective actions that will eliminate or lower the potential for further exposures shall be implemented;

3. A repeat bioassay shall be taken within 1 week of the previous measurement and shall be evaluated within 1 week after the measurement. Internal dose commitments shall be estimated using at least two bioassays and other survey data, including the probable times of intake of tritium; and

4. Notification reports must be provided as required by Rules 64E-5.345 and 64E-5.347, F.A.C., or as required by conditions of the license; and

(c) A record of each bioassay shall be maintained for inspection by the department in an auditable form for 3 years and shall include the date of the bioassay, the name of the patient, and the urinary tritium concentration at the time of the measurement.

Rulemaking Authority 404.022, 404.042, 404.051, 404.061, 404.071, 404.081 FS. Law Implemented 404.022, 404.042, 404.051(1), (4), (6), (9), (10), 404.061(2), (3), 404.071(1), 404.081(1) FS. History–New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: William A. Passetti

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ana Maria Viamonte Ros

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: September 18, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: October 3, 2008

DEPARTMENT OF FINANCIAL SERVICES

Division of Consumer Services

RULE NO.: RULE TITLE:
69J-123.002 Civil Remedy Notice

PURPOSE AND EFFECT: The proposed rule amendment resolves the problem of paper document processing by requiring all material filed with the Department relating to a Section 624.155, F.S. civil remedy action be filed electronically. The civil remedy notice is already required to be filed electronically. This amendment requires the insurer's report of disposition and other communications, which parties wish to submit, to likewise be filed electronically.

SUMMARY: Insurer reports of the disposition of a matter for which a civil remedy notice was filed pursuant to Section 624.155, F.S., and additional communications parties wish to include in the record must be filed electronically.

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.

RULEMAKING AUTHORITY: 624.308(1) FS.

LAW IMPLEMENTED: 624.307, 624.155(3)(b) 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: Wednesday, October 28, 2009, 10:00 a.m.

PLACE: 142 Larson Building, 200 East Gaines Street, Tallahassee, Florida

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 5 days before the workshop/meeting by contacting: Greg Thomas, (850)413-3130. 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 RULE IS: Greg Thomas, Chief of Education, Advocacy & Research, Division of Consumer Services, Department of Financial Services, 200 East Gaines Street, Tallahassee, FL 32399-0320; (850)413-3130

THE FULL TEXT OF THE PROPOSED RULE IS:

69J-123.002 Civil Remedy Notice ~~Procedure~~.

(1) The civil remedy notice required by Section 624.155, F.S., shall be electronically submitted on Form DFS-10-363, "Civil Remedy Notice of Insurer Violation," (Effective 10-14-08), which is hereby adopted and incorporated by reference. The form shall be submitted to the Department of Financial Services, Bureau of Consumer Assistance, through the website at https://apps.fldfs.com/civilremedy. No fee is required.

(2) Authorized insurer reports to the Department as required by Section 624.155(3)(e), F.S., regarding the disposition of the alleged violation shall be electronically added to the existing Form DFS-10-363 specific to the notice being addressed.

(3) Any written communications between the parties to the civil remedy notice, which are intended for inclusion in the Department's electronic record, shall be electronically added to the existing Form DFS-10-363 specific to the notice being addressed.

Rulemaking ~~Specific~~ Authority 624.308(1) FS. Law Implemented 624.307, 624.155(3)(b) FS. History–New 10-14-08, Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Greg Thomas, Chief of Education, Advocacy & Research, Division of Consumer Services, Department of Financial Services

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Tammy Teston, Deputy Chief Financial Officer, Division of Consumer Services, Department of Financial Services

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 14, 2009

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: June 5, 2009

Section III
Notices of Changes, Corrections and Withdrawals

DEPARTMENT OF EDUCATION

State Board of Education

RULE NO.: RULE TITLE:
6A-1.09981 Implementation of Florida's System of School Improvement and Accountability

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 35, No. 32, August 14, 2009 issue of the Florida Administrative Weekly.

The following changes were approved by the State Board of Education on September 15, 2009:

(3)(e) ~~The Commissioner will issue guidelines regarding which school types shall receive school performance grades.~~ The accountability contact person, as specified in subsection (9) of this rule, is responsible for verifying that each school is