provided by the DOH. The authorized user and the applicable licensing authority or agency shall notify the DOH, Bureau of Immunization Florida SHOTS personnel when an authorized user's license or registration has expired or has been suspended or revoked.

Specific Authority 381.0011(13), 381.003(1), (2), 381.005(2), 1003.22 FS. Law Implemented 381.0011(4), 381.003(1), 381.005(1)(i), 1003.22 FS. History–New 11-20-06, Amended 7-15-07, _____.

Editorial Note: Formerly 10D-3.88, 10D-3.088 and 64D-3.011.

NAME OF PERSON ORIGINATING PROPOSED RULE: Charles Alexander, Chief, Bureau of Immunization

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Russell W. Eggert, M.D., M.P.H., Director, Division of Disease Control

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: March 20, 2008

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAW: April 4, 2008

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. 34, No. 11, March 14, 2008 issue of the Florida Administrative Weekly.

Sub-Subparagraph (1)(a)3.b. is amended to read:

(1)(a)3.b. Schools demonstrate a five (5) percentage point improvement in the percent of such students making learning gains over the prior year, if the percent of such students making learning gains is below forty (40) percent in the current year.

If the minimum requirement for adequate progress in reading among the lowest twenty-five (25) percent of students in the school is not met, the School Advisory Council shall amend its School Improvement Plan to include a component for improving learning gains of the lowest performing students. If a school otherwise designated as Performance Grade "B" or "C" does not make adequate progress, as defined, in at least one (1) of two (2) consecutive years, the final Performance Grade designation shall be reduced by one (1) letter grade. ~~No school shall be designated as Performance Grade "A" unless the adequate progress criterion in reading, learning gains for at least half of the lowest performing students, is met each year.~~

DEPARTMENT OF EDUCATION

State Board of Education

RULE NO.:	RULE TITLE:
6A-6.053	K-12 Comprehensive Reading Plan Implementation

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. 34, No. 11, March 14, 2008 issue of the Florida Administrative Weekly.

Subsection (9) has been amended to read:

(9)(a) No change.

(b) A Comprehensive Core Reading Program (CCRP) must be implemented as the major instructional tool for reading instruction. Districts are provided a performance-based flexibility option which may exempt schools from the use of the CCRP. Districts implementing this flexibility must describe their plan for reading instruction, including the intervention for students reading below grade level in grades K-5 or K-6 as applicable. It is a district decision whether to implement the following performance-based flexibility option. ~~1.~~ Elementary schools meeting all of the following criteria are not required to implement a Comprehensive Core Reading Program:

1.~~a.~~ A current school grade of an A or B;

2.~~b.~~ Adequate Yearly Progress (AYP) in reading met for all subgroups;

3.~~c.~~ Ninety (90) percent of students meeting high standards in reading (an FCAT score of Level 3 or above).

(c) The second performance-based flexibility option may exempt elementary schools from the use of the CCRP as well as the ninety (90) minute reading block. Districts implementing this flexibility must report the reading instruction that will be provided, including the time allotted for reading instruction. It is a district decision whether to implement the following performance-based flexibility option: ~~1.~~ For students in grades four and five scoring Level 4 or 5 on FCAT reading, districts shall ~~should~~ offer enrichment programs steeped in content that continue to develop the child's reading skills. These students are not required to receive instruction from a Comprehensive Core Reading Program, nor are they required to receive ninety (90) minutes of reading instruction.

DEPARTMENT OF LAW ENFORCEMENT

Criminal Justice Standards and Training Commission

RULE NO.:	RULE TITLE:
11B-27.0011	Moral Character

NOTICE OF WITHDRAWAL

Notice pursuant to Section 120.54(3)(d), F.S., is hereby given that the proposed rule language in the above rule, subsection 11B-27.0011(5), F.A.C., as noticed on March 7, 2008, in Vol. 34, No. 10, issue of the Florida Administrative Weekly, has been withdrawn.

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."

EXECUTIVE OFFICE OF THE GOVERNOR

Office of Tourism, Trade and Economic Development

RULE NO.: RULE TITLE:
27M-3.003 Certification Decision and Allocation Policy

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. 34, No. 17, April 25, 2008 issue of the Florida Administrative Weekly.

The change is in response to concerns of the Joint Administrative Procedures Committee in a letter dated March 31, 2008, regarding the Rule 27M-3.003, F.A.C. The change is as follows:

The rule shall read as:

27M-3.003 Certification Decision and Allocation Policy.

(1) No change.

(2) Services provided under the Act are to be disbursed equitably throughout the state. For the purposes of this rule, disbursed equitably means the distribution of services shall contemplate the number of Eligible Applicants, the distribution of Florida's black population among Applicants' proposed service areas, and the information submitted in the Application for Certification as Eligible Recipient of Funds as set forth in form OTTED 7102-1.

(3) No change.

Specific Authority 288.7102(6)(a) FS. Law Implemented 288.7094(2), 288.7102 FS. History–New _____.

WATER MANAGEMENT DISTRICTS

Suwannee River Water Management District

RULE NO.: RULE TITLE:
40B-1.901 General

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. 34, No. 3, January 18, 2008 issue of the Florida Administrative Weekly.

CHAPTER 40B-1 General and Procedural Rules

40B-1.901 General.

(1) through (10) No change.

(11) Application for General Work of the District Development Permit, Effective _____ ~~January 29, 2001~~;

(12) through (17) No change.

Specific Authority 373.044, 373.113, 373.171 FS. Law Implemented 373.118, 373.413, 373.416, 373.426 FS. History–New 9-15-81, Amended 3-17-88, 12-21-88, 10-8-89, 6-17-93, 10-3-95, 1-3-96, 6-22-99, 1-29-01, 5-15-05, _____.

The form incorporated by reference in this rulemaking process has been changed to reflect comments from Joint Administrative Procedures Committee. Specifically, the following text has been removed from the form: "By signature of this application, property owner consents to any site visit on the property by agents or personnel from the Water Management District necessary for the review and inspection of the proposed project specified in this application and to monitor permitted work if a permit is granted." Also on the application, "Agent" has been replaced with "Owner." Copies of the form may be obtained by contacting Linda Welch, Administrative Assistant, SRWMD, 9225 CR 49, Live Oak, FL 32060, (386)362-1001.

WATER MANAGEMENT DISTRICTS

Southwest Florida Water Management District

RULE NO.: RULE TITLE:
40D-4.091 Publications and Agreements Incorporated by Reference

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. 34, No. 4, January 25, 2008 issue of the Florida Administrative Weekly.

The Environmental Resource Permitting Information Manual, Basis of Review, adopted by reference in Rule 40D-4.091, F.A.C., is amended as follows: Appendix 4, Section (6), Establishment of Mitigation Credits – The proposed new paragraph (g)3. is changed to read:

3. The District will consider, during its evaluation of the permit application pursuant to Section 373.4136, F.S., a request by the banker to require additional signatures on the documentation provided to the District by the banker asking that mitigation credits be withdrawn from the mitigation bank.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Electrical Contractors' Licensing Board

RULE NO.: RULE TITLE:
61G6-5.0061 Registration of Additional New Business Entity or Transfers

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. 33, No. 35, August 31, 2007 issue of the Florida Administrative Weekly.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee. The changes are as follows:

Subsection (2) shall now read as follows:

(2) The Application for registration is form number DBPR ECLB 4452-1, titled Application for Registered Electrical, Alarm System or Specialty Contractor, effective July +2007, which is hereby incorporated by reference, copies of which may be obtained from the Board office at: Division of Professions, Electrical Contractors' Licensing Board, 1940 North Monroe Street, Tallahassee, FL 32399; or via the internet at http://www.myflorida.com/dbpr/pro/elboard/forms.html. Applications must be completed and received thirty (30) calendar days prior to a meeting of the Board.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Anthony B. Spivey, Executive Director, Construction Industry Licensing Board, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Electrical Contractors' Licensing Board

RULE NO.:	RULE TITLE:
61G6-10.0015	Standards of Practice

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 33, No. 51, December 21, 2007 issue of the Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Electrical Contractors' Licensing Board

RULE NO.:	RULE TITLE:
61G6-10.0065	Reinstatement of Null and Void License Pursuant to Section 455.271(6)(b) of the Florida Statutes

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. 33, No. 35, August 31, 2007 issue of the Florida Administrative Weekly.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee. The changes are as follows:

1. Subsection (1) of the rule shall now read as follows:

(1) Submit a Florida DBPR Electrical Contractor application (DBPR form PRO 4951, effective April 2007, herein incorporated by reference, which can be obtained at: Division of Professions, Electrical Contractors' Licensing Board, 1940 North Monroe Street, Tallahassee, FL 32399; for reinstatement of a null and void electrical contractor's certification or registration in which the applicant shall:

2. Subsection (1)(b) of the rule shall now read as follows:

(b) Submit a written statement and any documentation of when the applicant's electrical contractor's certification or registration was last active and in good standing with the Board;

3. Subsection (1)(c) of the rule shall now read as follows:

(c) Submit a written statement and any documentation regarding whether or not the applicant has completed twelve (12) classroom hours of continuing education as set forth in Rule 61G6-9.001, F.A.C., prior to the applicant's submission of his or her application for reinstatement of a null and void electrical contractor's certification or registration;

4. Subsection (1)(d) of the rule shall now read as follows:

(d) Submit a written statement and any documentation evidencing whether or not the applicant has engaged in the practice of electrical contracting during the time period the applicant's electrical contractor's certification or registration was null and void;

5. Subsection (1)(e) of the rule shall now read as follows:

(e) Submit a written statement and any documentation evidencing the applicant's good faith effort to comply with Chapters 455 and 489 of the Florida Statutes and also the applicant's failure to comply due to illness or unusual hardship.

6. Subsection (1)(f) of the rule shall now read as follows:

(f) Submit a written statement and any documentation evidencing the applicant's illness or unusual hardship which prevented the applicant from renewing his or her electrical contractor's certification or registration;

7. Subsection (1)(h) of the rule shall be renumbered as (1)(g) and shall now read as follows:

(g) Submit a written time-line that chronologically documents when the applicant's electrical contractor's certification or registration was last active, when the applicant's electrical contractor's certification or registration became null and void, when the applicant suffered his or her illness, and/or when the applicant experienced an unusual hardship that prevented the renewal of the electrical contractor's certification or registration;

8. Subsection (1)(i) of the rule shall be renumbered as (1)(h) and shall now read as follows:

(h) Submit an application (DBPR form ECLB 4453, effective September 2007, herein incorporated by reference, which can be obtained at: Division of Professions, Electrical Contractors' Licensing Board, 1940 North Monroe Street, Tallahassee, FL 32399; or via the internet at

http://www.myflorida.com/dbpr/pro/elboard/forms.html), requesting active or inactive license status, as appropriate, along with all applicable documentation.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Anthony B. Spivey, Executive Director, Electrical Contractors' Licensing Board, 1940 North Monroe Street, Tallahassee, Florida 32399-0750

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 Nursing

RULE NO.:	RULE TITLE:
64B9-15.009	Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 34, No. 2, January 11, 2008 issue of the Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF HEALTH

Board of Orthotists and Prosthetists

RULE NOS.:	RULE TITLES:
64B14-4.001	Approved Examinations
64B14-4.110	Requirements for Orthotic Fitter, Orthotic Fitter Assistant and Pedorthic

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 34, No. 1, January 4, 2008 issue of the Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF HEALTH

Board of Orthotists and Prosthetists

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

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 34, No. 1, January 4, 2008 issue of the Florida Administrative Weekly has been withdrawn.

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.:	RULE TITLE:
64B16-27.797	Standards of Practice for Compounding Sterile Preparations (CSPs)

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. 33, No. 15, April 13, 2007 issue of the Florida Administrative Weekly.

The change is in response to written comments submitted by the staff of the Joint Administrative Procedures Committee. Substantial changes were made to the language of the rule. The rule shall now read as follows:

64B16-27.797 Standards of Practice for Compounding Sterile Preparations (CSPs).

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order, and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

(1) Definitions.

(a) "Anteroom" means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that airflows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

(b) "Antineoplastic" means a pharmaceutical agent that has the intent of causing cell death targeted to cancer cells, metastatic cells, or other cells involved in a severe inflammatory or autoimmune response.

(c) "Beyond-use-date" means the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

(d) "Biological safety cabinet" means a containment unit suitable for the preparation of low, moderate, and high risk agents where there is a need for protection of the product, personnel, and environment.

(e) "Bulk Compounding" means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

(f) "Buffer area" (Clean room) is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

(g) "Class 100 environment" means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

(h) "Compounding Aseptic Isolator" (CAI) – is a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it is first passed through a microbially retentive filter (HEPA minimum 0.2 microns).

(i) "High-Risk Level CSPs" – are products compounded under any of the following conditions are either non-sterile or at high risk to become non-sterile with infectious microorganisms.

1. Non-sterile ingredients, including manufactured products for routes of administration other than sterile parenteral administration are incorporated or a non-sterile device is employed before terminal sterilization.

2. Sterile contents of commercially manufactured products, CSP that lack effective antimicrobial preservatives, sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs are exposed to air quality worse than ISO Class 5 for more than one (1) hour.

3. Before sterilization, non-sterile procedures such as weighing and mixing are conducted in air quality worse than ISO Class 7 compounding personnel are improperly garbed and gloved, or water-containing preparations are stored for more than 6 hours.

4. For properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

5. Examples of high-risk compounding include: (1) dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be terminally sterilized; (2) exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 for more than one (1) hour; (3) measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed; (4) assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

6. All high risk category products must be rendered sterile by heat sterilization, gas sterilization, or filtration sterilization in order to become a CSP.

7. Quality assurance practices for high-risk level CSPs include all those for low-risk level CSPs. In addition, each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

(j) Immediate Use CSPs:

1. Requires only simple aseptic measuring and transfer manipulations are performed with not more than three (3) sterile non-hazardous drug or diagnostic radiopharmaceutical drug preparations, including an infusion or dilution solution.

2. The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

3. At no point during preparation and prior to administration are critical surfaces and ingredients of the CSP directly exposed to contact contamination such as human touch, cosmetic flakes or particulates, blood, human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.

4. Administration begins not later than one (1) hour following the start of preparing the CSP.

5. When the CSP is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the CSP container shall bear a label listing patient identification information (name, identification numbers), and the names and amounts of all active ingredients, and the name or identifiable initials of the person who prepared the CSP, and one (1) hour beyond-use time and date.

6. If administration has not begun within one (1) hour following the start of preparing the CSP, the CSP is promptly and safely discarded. Immediate use CSPs shall not be stored for later use.

(k) ISO Class 5 guidelines are met when particulate contamination is measured at "not more than 3,520 particles 0.5 micron size or larger per cubic meter of air for any lamiar airflow workbench (LAWF), BSC, or CAI. (Also referred to as a "Class 100 environment.")

(l) ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."

(m) ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."

(n) Low-Risk Level CSPs compounded under all of the following are at a low risk of contamination:

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (class 100) or better air quality using only sterile ingredients, products, components, and devices.

2. The compounding involves only transfer, measuring, and mixing manipulations using no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the CSP.

3. Manipulations are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers for storage and dispensing. The contents of ampules shall be passed through a sterile filter to remove any particles.

4. For low-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 48 hours at controlled room temperature, and for not more than 14 days at a cold temperature (2-8 degrees celcius) and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. Quality Assurance practices include, but are not limited to, the following: (1) routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality; (2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; (3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded; (4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and accuracy and thoroughness of labeling.

6. All compounding personnel are required to demonstrate competency by completing a media-filled test that represents low-level compounding annually. A media-filled test is a commercially available sterile fluid culture media that shall be able to promote exponential colonization of bacteria that are both likely to be transmitted to CSP from the compounding personnel and environment. Media filled vials are incubated at 25-35 degrees celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.

(o) Medium-Risk Level CSPs – When CSPs are compounded aseptically under Low-Risk Conditions, and one or more of the following conditions exist, such CSPs are at a medium risk of contamination:

1. CSPs containing more than three (3) commercial sterile drug products and those requiring complex manipulations and/or preparation methods.

2. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.

3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

4. For Medium-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 30 hours at controlled room temperature, and for not more than 9 days at a cold temperature and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. These include compounding of total parenteral nutrition (TPN) using either manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

6. Filling of reservoirs of injection and infusion devices with more than three (3) sterile drug products and evacuation of air from those reservoirs before the filled devices are dispensed.

7. Transfer of volumes from multiple ampules or vials into one or more final sterile containers.

8. Quality assurance practices for medium-risk level CSPs include all those for low-risk level CSPs.

9. Demonstrates competency by completing a media-filled test that represents medium-level compounding annually.

(p) Parenteral means a sterile preparation of drugs for injection through one or more layers of the skin.

(q) Risk level of the sterile preparation means the level assigned to a sterile product by a pharmacist that represents the probability that the sterile product will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals or other physical matter.

(r) Sterile preparation means any dosage form devoid of viable microorganisms, including but not limited to, parenterals, injectables, ophthalmics, and aqueous inhalant solutions for respiratory treatments.

(2) Compounded sterile preparations include, but are not limited, to the following:

(a) Total Parenteral Nutrition (TPN) solutions;

(b) Parenteral analgesic drugs;

(c) Parenteral antibiotics;

(d) Parenteral antineoplastic agents;

(e) Parenteral electrolytes;

(f) Parenteral vitamins;

(g) Irrigating fluids;

(h) Ophthalmic preparations; and

(i) Aqueous inhalant solutions for respiratory treatments.

(3) Sterile preparations shall not include commercially manufactured products that do not require compounding prior to dispensing.

(4) Policy & Procedure Manual.

A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, and delivery of sterile preparation prescriptions. The policy and procedure manual shall be available for inspection by the Department and include at a minimum:

(a) Use of single dose and multiple dose containers not to exceed United States Pharmacopeia 797 guidelines.

(b) Verification of compounding accuracy and sterility.

(c) Personnel training and evaluation in aseptic manipulation skills.

(d) Environmental quality and control:

1. Air particle monitoring for hoods (or Barrier Isolator), clean room and buffer area (or anteroom) when applicable.

2. Unidirectional airflow (pressure differential monitoring).

3. Cleaning and disinfecting the sterile compounding areas

4. Personnel cleansing and garbing

5. Environmental monitoring (air and surfaces)

(e) Personnel monitoring and validation.

(f) Finished product checks and tests.

(g) Method to identify and verify ingredients used in compounding.

(h) Labeling requirements for bulk compounded products:

1. Contents

2. Beyond-Use-Date

3. Storage requirements

(i) Packing, storage, and transportation conditions

(5) Physical Requirements

(a) The pharmacy shall have a designated area with entry restricted to designated personnel for preparing parenteral products. This area shall have a specified ante area and buffer area; in high risk compounding, this shall be separate rooms. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and interference with unidirectional airflow. It shall be used only for the preparation of these sterile preparations. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy compounding parenteral and sterile preparation shall have the following:

1. Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices must be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;

2. Appropriate disposal containers for used needles, syringes, and if applicable, for antineoplastic waste from the preparation of chemotherapy agents;

3. Appropriate environmental control including approved biohazard cabinetry when antineoplastic drug products are prepared;

4. Appropriate temperature and transport containers;

5. Infusion devices and equipment, if appropriate.

(c) The pharmacy shall maintain and use supplies adequate to preserve an environment suitable for the aseptic preparation of sterile preparations, such as:

1. Gloves, masks, shoe covers, head and facial hair covers, and non-shedding gowns.

2. Needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Hand washing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. “Spill kits” for antineoplastic agent spills.

(d) The pharmacy should have current reference material in hard copy or readily available on line:

1. USP Pharmacist Pharmacopeia (optional) or Handbook of Injectable Drugs by American Society of Hospital Pharmacists; or other nationally recognized standard reference; and

2. “Practice Guidelines for Personnel Dealing with Cytotoxic Drugs,” or other nationally recognized standard cytotoxic reference if applicable.

(e) Barrier isolator is exempt from all physical requirements subject to manufacturer guidelines for proper placement.

(6) Antineoplastic Drugs.

The following requirements are necessary for those pharmacies that prepare antineoplastic drugs to ensure the protection of the personnel involved:

(a) All antineoplastic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet placed in negative pressure room unless using barrier isolators. Other preparations shall not be compounded in this cabinet.

(b) Protective apparel shall be worn by personnel compounding antineoplastic drugs. This shall include at least gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding antineoplastic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of antineoplastic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of antineoplastic agents shall be developed and shall be included in the policy and procedure manual.

(f) Prepared doses of antineoplastic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Quality Assurance:

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and preparations. Appropriate samples of finished preparations shall be examined to assure that the pharmacy is capable of consistently preparing sterile preparations meeting specifications:

1. All clean rooms and laminar flow hoods shall be certified by an independent contractor or National Sanitation Foundation Standard 49, for operational efficiency at least semiannually for high risk CSPs and annually for low and medium risk CSPs or any time the hood is relocated or the structure is altered and records shall be maintained for two years.

2. There shall be written procedures developed requiring sampling if microbial contamination is suspected for batches greater than 25 units.

3. High risk greater than 25 units have antimicrobial testing prior to dispensing.

4. There shall be referenced written justification of the chosen beyond-use-dates for compounded products.

5. There shall be documentation of quality assurance audits at regular planned intervals, including infection control and sterile technique audits.

(b) Compounding personnel shall be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:

1. Demonstrate by observation or test a functional understanding of USP Chapter 797 and definitions, to include Risk Category assessment;

2. Understand the characteristics of touch contamination and airborne microbial contaminants;

3. Perform antiseptic hand cleaning and disinfections of non-sterile compounding surfaces;

4. Select and appropriately don protective garb;

5. Demonstrate aseptic techniques and requirements while handling medications;

6. Maintain and achieve sterility of CSPs in ISO Class 5 (Class 100) primary engineering devices and protect personnel and compounding environments from contamination by antineoplastic and chemotoxic or other hazardous drugs or substances;

7. Manipulate sterile products aseptically, sterilize high-risk level CSPs (where applicable) and quality inspect CSPs;

8. Identify, weigh and measure ingredients;

9. Prepare product labeling requirements and "beyond use" requirements of product expiration;

10. Prepare equipment and barrier requirement work requirements to maintain sterility;

11. Prepare end point testing and demonstrated competencies for relevant risk levels;

12. Prepare media fills to test aseptic technique.

Specific Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New .

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Rebecca Poston, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254

DEPARTMENT OF HEALTH

Board of Respiratory Care

RULE NO.:	RULE TITLE:
64B32-4.002	Reactivation of Retired Status License

NOTICE OF WITHDRAWAL

Notice is hereby given that the above rule, as noticed in Vol. 34, No. 10, March 7, 2008 issue of the Florida Administrative Weekly has been withdrawn.

Section IV
Emergency 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."

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."