

Florida Histology Licensure: The Rules & Regulations

Biennium 2008-2010

This course meets the Rules & Law continuing education requirement for healthcare providers in the state of Florida.

Objectives:

- Define the difference between Statutes, Rules & Regulations
 - Review the Florida Statutes F.S. Chapter 483
 - Review the Florida Board of Clinical Laboratory Personnel Rules 64B3
 - Review the Rules directed to the Histotechnology field
 - Review and clarify rule updates
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Statutes vs. Rules & Regulations

Statute

- A law established by an act of the legislature.
- Under the U.S. and state constitutions, statutes are considered the primary source of law in the U.S. -- that is, legislatures make the law (statutes) and courts interpret the law (cases).

Rules

- To control the will and actions of
- To exercise authority or dominion over
- To govern
- To manage

Regulations

- Regulations are rules, written in outline form, that are designed to fill in the details of the broad concepts mandated by the legislature in statutes.

Florida Statutes

Chapter 483

PART III

CLINICAL LABORATORY PERSONNEL

(SS. 483.800 - 483.828)

Chapter 483.800 - Declaration of Policy and Statement of Purpose

The purpose of this part is to protect the public health, safety, and welfare of the people of this state from the hazards of improper performance by clinical laboratory personnel.

The protection of public and individual health requires the licensure of clinical laboratory personnel who meet minimum requirements for safe practice.

Chapter 483.801 - Exemptions

- (1) Clinical laboratories operated by the United States Government.
- (2) Laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health service whatsoever.
- (3) Persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).
- (4) Respiratory therapists and respiratory care practitioners certified or registered under part V of chapter 468.
- (5) Advanced registered nurse practitioners licensed under part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in an exclusive-use laboratory setting.

Chapter 483.803 - Definitions

"Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures.

DO NOT include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities, or persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

"Clinical laboratory trainee" means any person having qualifying education who is enrolled in a clinical laboratory training program approved pursuant to s. 483.811 and who is seeking experience required to meet minimum qualifications for licensing in this state.

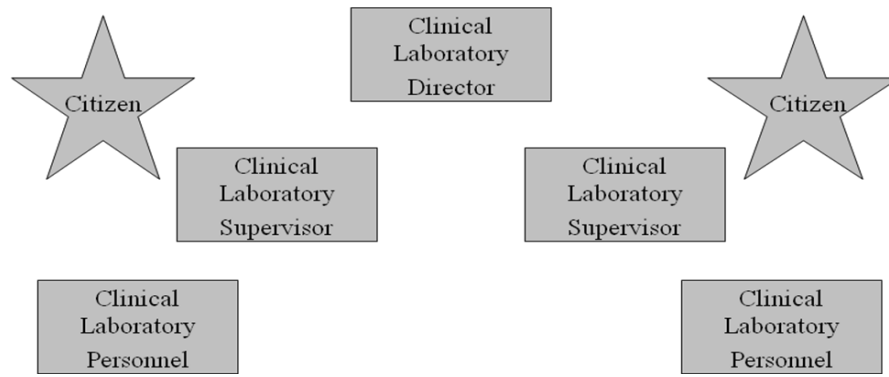
Trainees may perform procedures under direct and responsible supervision of duly licensed clinical laboratory personnel, but they may not report test results.

Chapter 483.805 - Board of Clinical Laboratory Personnel

There is created within the department the Board of Clinical Laboratory Personnel, composed of seven members appointed by the Governor and confirmed by the Senate.

* Five Members should be licensed

* Two members should be state citizens never licensed and not attached to the clinical professions.



Chapter 483.807 - Fees; Establishment; Disposition

Non Refundable Application Fee not to exceed:	\$200.00
Initial Licensure Fee may not exceed:	\$100.00
Licensure by Endorsement not to exceed:	\$100.00
Biennial renewal fee may not exceed:	\$150.00
Inactive status or reactivation may not exceed:	\$50.00
Training Initial application shall not exceed:	\$20.00
Training Program may not exceed:	\$300.00

Chapter 483.809 - Licensure; examination; registration of Trainees; Approval of Curriculum

(1) LICENSING.--The department shall provide biennial licensure of all clinical laboratory personnel who the board certifies have met the requirements of this part. The license of any person who fails to pay a required fee or otherwise fails to qualify within 60 days after the date of expiration of such license shall be automatically canceled without notice or further proceedings unless the individual has made application for inactive status pursuant to s. 483.819.

(2) EXAMINATIONS.--The department shall conduct examinations required by board rules to determine in part the qualification of clinical laboratory personnel for licensure. The board by rule may designate a national certification examination that may be accepted in lieu of state examination for clinical laboratory personnel or public health scientists.

(3) REGISTRATION OF TRAINEES.--The department shall provide for registration of clinical laboratory trainees who are enrolled in a training program approved pursuant to s. 483.811, which registration may not be renewed except upon special authorization of the board.

(4) APPROVAL OF CURRICULUM IN SCHOOLS AND COLLEGES.--The board may approve the curriculum in schools and colleges offering education and training leading toward qualification for licensure under this part.

Chapter 483.811 - Approval of Laboratory Personnel Training Programs

1. The Board will approve clinical laboratories for training programs
2. Adopt rules for the training programs, including curriculum, educational objectives, evaluation procedures, personnel licensure requirements, pre-entry requirements and length of clinical training.
3. The Board shall approve training programs for laboratory technicians in a hospital or clinical laboratory under the supervision of a Clinical Laboratory Director. Any person who completes a training program must pass, before licensure, an examination given by the department. (For Histology is the ASCP).
4. The Department may inspect Laboratory Personnel training programs and may terminate a program that no longer meets their criteria's.

Chapter 483.812 - Public Health Laboratory Scientists

Chapter 483.813 - Clinical Laboratory Personnel License

A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures.

However, this provision does not apply to any practitioner of the healing arts authorized to practice in this state or to persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

The department may grant a temporary license to any candidate it deems properly qualified, for a period not to exceed 1 year.

Chapter 483.815 - Application for Clinical Laboratory Personnel License

An application for a clinical laboratory personnel license shall be made under oath on forms provided by the department and shall be accompanied by payment of fees as provided by this part.

A license may be issued authorizing the performance of procedures of one or more categories.

Chapter 483.817 - Renewal of Clinical Laboratory Personnel License

(1) The department shall renew a license upon receipt of a renewal application and fee and upon certification by the board that the licensee has demonstrated her or his competence.

(2) The board shall adopt rules establishing a procedure for the biennial renewal of clinical laboratory personnel licenses.

Chapter 483.819 - Inactive Status

- (1) A licensee may request that her or his license be placed in an inactive status by making application to the department and paying a fee in an amount set by the board.
- (2) A license that has been inactive for more than 1 year may be reactivated upon application to the department. The board shall prescribe, by rule, continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license may not exceed 15 classroom hours for each year the license was inactive and in no event may exceed 65 classroom hours for all years in which the license was inactive.

Chapter 483.823 - Periodic Demonstration of Competency; Continuing Education or Re-examination

- (1) The board shall prescribe minimal qualifications for clinical laboratory personnel and shall issue a license to any person who meets the minimum qualifications and who demonstrates that she or he possesses the character, training, and ability to qualify in those areas for which the license is sought.
- (2) Personnel qualifications may require appropriate education, training, or experience or the passing of an examination in appropriate subjects or any combination of these, but no practitioner of the healing arts licensed to practice in this state is required to obtain any license under this part or to pay any fee hereunder except the fee required for clinical laboratory licensure.

Chapter 483.825 - Grounds for Disciplinary Actions

- (a) Attempting to obtain, obtaining, or renewing a license or registration under this part by bribery, by fraudulent misrepresentation, or through an error of the department or the board.
- (b) Engaging in or attempting to engage in, or representing herself or himself as entitled to perform, any clinical laboratory procedure or category of procedures not authorized pursuant to her or his license.
- (c) Demonstrating incompetence or making consistent errors in the performance of clinical laboratory examinations or procedures or erroneous reporting.
- (d) Performing a test and rendering a report thereon to a person not authorized by law to receive such services.
- (e) Has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the activities of clinical laboratory personnel or involves moral turpitude or fraudulent or dishonest dealing. The record of a conviction certified or authenticated in such form as to be admissible in evidence under the laws of the state shall be admissible as prima facie evidence of such guilt.
- (f) Having been adjudged mentally or physically incompetent.
- (g) Aiding and abetting in the violation of any provision of this part or the rules adopted hereunder.
- (h) Reporting a test result when no laboratory test was performed on a clinical specimen.
- (i) Knowingly advertising false services or credentials.
- (j) Having a license revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another jurisdiction. The licensing authority's acceptance of a relinquishment of a license,

stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of administrative charges against the licensee, shall be construed as action against the licensee.

(k) Failing to report to the board, in writing, within 30 days that an action under paragraph (e), paragraph (f), or paragraph (j) has been taken against the licensee or one's license to practice as clinical laboratory personnel in another state, territory, country, or other jurisdiction.

(l) Being unable to perform or report clinical laboratory examinations with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department shall have, upon a finding of the secretary or his or her designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department. If the licensee refuses to comply with such order, the department's order directing such examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business.

The department shall be entitled to the summary procedure provided in s. 51.011. A licensee affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that he or she can resume competent practice with reasonable skill and safety to patients.

(m) Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows, or has reason to know, that such person is not qualified by training, experience, or licensure to perform them.

(n) Violating a previous order of the board entered in a disciplinary proceeding.

(o) Failing to report to the department a person or other licensee who the licensee knows is in violation of this chapter or the rules of the department or board adopted hereunder.

(p) 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, willfully impeding or obstructing such filing or inducing another person to do so, including, but not limited to, impeding an agent of the state from obtaining a report or record for investigative purposes. Such reports or records shall include only those generated in the capacity as a licensed clinical laboratory personnel.

(q) Paying or receiving any commission, bonus, kickback, or rebate, or engaging in any split-fee arrangement in any form whatsoever with a physician, organization, agency, or person, either directly or indirectly for patients referred to providers of health care goods and services including, but not limited to, hospitals, nursing homes, clinical laboratories, ambulatory surgical centers, or pharmacies. The provisions of this paragraph shall not be construed to prevent a clinical laboratory professional from receiving a fee for professional consultation services.

(r) Exercising influence on a patient or client in such a manner as to exploit the patient or client for the financial gain of the licensee or other third party, which shall include, but not be limited to, the promoting, selling, or withholding of services, goods, appliances, referrals, or drugs.

(s) Practicing or offering to practice beyond the scope permitted by law or rule, or accepting or performing professional services or responsibilities which the licensee knows or has reason to know that he or she is not competent to perform.

(t) Misrepresenting or concealing a material fact at any time during any phase of the licensing, investigative, or disciplinary process, procedure, or proceeding.

(u) Improperly interfering with an investigation or any disciplinary proceeding.

(v) Engaging in or attempting to engage in sexual misconduct, causing undue embarrassment or using disparaging language or language of a sexual nature towards a patient, exploiting superior/subordinate, professional/patient, instructor/student relationships for personal gain, sexual gratification, or advantage.

(w) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

(3) In determining the amount of the fine to be levied for a violation, as provided in subsection (1), the following factors shall be considered:

(a) The severity of the violation, including the probability that death or serious harm to the health or safety of any person will result or has resulted, the severity of the actual or potential harm, and the extent to which the provisions of this part were violated.

(b) Actions taken by the licensee to correct the violation or to remedy complaints.

(c) Any previous violation by the licensee.

(d) The financial benefit to the licensee of committing or continuing the violation.

Chapter 483.828 - Penalties for Violations

1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) Practicing as clinical laboratory personnel without an active license.

(b) Using or attempting to use a license to practice as clinical laboratory personnel which is suspended or revoked.

(c) Attempting to obtain or obtaining a license to practice as clinical laboratory personnel by knowing misrepresentation.

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Knowingly concealing information relating to violations of this part.

(b) Making any willfully false oath or affirmation whenever an oath or affirmation is required by this part.

(c) Leading the public to believe that one is licensed as clinical laboratory personnel, or is engaged in licensed practice as clinical laboratory personnel, without holding a valid, active license.

Florida Rules & Regulations

64B3

BOARD OF CLINICAL LABORATORY PERSONNEL CHAPTER 64B3-1 ORGANIZATION

CHAPTER 64B3-1.006 - Notices, Current Address of Licensees

If you hold a Professional Licensure you should maintain with the department:

1. a current mailing address
2. a current primary practice location
3. Must be done within 60 days, regardless if in or out of state.

CHAPTER 64B3-1.008 - Board Meetings

1. applies to Board Members
2. can obtain 1 hour ceu for attending a board meeting

CHAPTER 64B3-1.015 - Probable Cause Determinations

- A panel determines if there is probable cause violating one of the provisions of the statutes.
- The probable cause panel is selected by the Chair of the Board.
- They meet accordingly to discuss the probable cause.

64B3-2 DEFINITIONS

CHAPTER 64B3-2.002 - Clinical Laboratory Personnel

Director = Clinical Laboratory Director qualified or licensed pursuant to the Board's rules who is responsible for and assures the overall operation and administration of the clinical laboratory and fulfills the responsibilities specified in Rule 64B3-13.001 F.A.C.

Supervisor = person licensed pursuant to the Board's rules who is responsible for the day to day supervision and oversight of technical and scientific operations in a clinical laboratory and fulfills the responsibilities specified in Rule 64B3-13.002, F.A.C.

Technologist = person licensed pursuant to the Board's rules who represents the first level of independence practice and under general supervision, fulfills the responsibilities specified in Rule 64B3-13.003, F.A.C.

Technician = person licensed pursuant to the Board's rules who practices the profession and may perform tests classified as highly complex pursuant to 42 CFR 493.17 (September 17, 1999), incorporated by reference herein, only when under direct supervision of a licensed technologist, supervisor, or director unless the technician meets the minimum qualifications contained in 42 CFR 493.1489 (September 7, 1999), incorporated by reference herein, and the requirements contained in subsection 64B3-5.004(5), F.A.C, and fulfills the responsibilities specified in Rule 64B3-13.004, F.A.C.

General Supervision - supervision by a director, or supervisor who is available on a regular basis and who is responsible for the overall performance of laboratory testing.

Direct Supervision - supervision by a director, supervisor, or technologist who is on the premises or is available to the laboratory when test procedures are being performed and is responsible for the oversight of testing and reporting results.

Accredited - Regional Accrediting agency for colleges/Universities recognized by the U.S. Department of Education

Approval Laboratory - Laboratory approved to operate under F.S. 483.091 or equivalent to Chapter 483, Part I, F.S.

Year - 12 months calendar year, except "one year full time experience"

One year FT experience - 1500 hours not less than 12 months not more than 36 months

Contact hours - CE offering at least 50 minutes in duration.

Academic science - Classes with a chemical or biological prefix

Applied science - physical, chemical or biological courses specific to a major.

Pertinent clinical laboratory experience - experience defined in Section 483.041, F.S., Experienced may occur while licensed if in-state or state with licensure.

Not Acceptable Experience:

- Industrial laboratories
- Research laboratories, unless they involve human tissue and follow QA/QC procedure comparable to those in the clinical lab.

CHAPTER 64B3-2.003 - Definitions - Accredited program - Programs accredited by:

1. CAHEA - Committee on Allied Health Education and Accreditation
2. NAACLS - National Accrediting Agency for Clinical Laboratory Sciences
3. CAAHEP - Council on Accreditation of Allied Health Education Programs
4. ABHES - Accrediting Bureau of Health Education Schools

Independent practice authority to perform clinical laboratory testing and release of results without direct supervision

Semester hours - one semester hour or 1.5 quarter hour of academic credit

Sexual misconduct - direct or indirect physical contact by any CLP and a patient which is intended to be erotic, etc.

High complexity testing - clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.25

Moderate complexity testing - clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.20

Waived testing - clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.15

Board approved programs - training program or a continuing education program approved by the Board.

64B3-3

APPROVAL OF CLINICAL LABORATORY PERSONNEL TRAINING PROGRAMS

CHAPTER 64B3-3.001 - General Requirements of Clinical Laboratory Personnel Training Programs

1. Approved by the Board and pay the fees in section 64B3-9.001
2. Program should be in compliance with F.S. Chapter 483, Part I
3. Submit a self study at application time, updated every 6 months if any changes in curriculum, faculty, enrollment, etc. Not required of National Accreditations, just present certificate.
4. All trainee's name shall be reported to the Board.

Program Requirements:

- Lab Space and equipment for training
- Maintain copies of inspections and fire marshall's office
- Maintain file on each student
- Maintain examinations and laboratory evaluations instruments utilized by the program
- Provide the student with a certificate or letter of graduation, including license number and Directors signature

Curriculum Requirements:

- HIV and AIDS
- Prevention of Medical Errors
- Course objectives, descriptions, outlines assessment of outcomes, student evaluations and graduate evaluations in the curriculum
- Teach the affective, cognitive and psychomotor domains
- Practicum included with instrumentation and specimens for evaluations
- One year in Histology instruction
- Copies of the Chapter 483, Parts I & III, Chapter 456, F.S., and Chapters 59A-7 and 654B3, F.A.C.

CHAPTER 64B3-3.002 - General Requirements of Clinical Laboratory Personnel Training Programs

Personnel:

- Director with a national certification
- Instructor in their specialty only
 - Licensed as a supervisor, technologist or director
 - Three years of experience
- A licensed technologist or supervisor should be on duty during training practicum hours.

Trainee:

- Shall not be used to substitute a licensed clinical personnel
- Be registered when enrolled in the practicum portion of the training program
- Cannot report clinical laboratory results
- Perform tests only when a director, supervisor or technologist is in the immediate bench area where the trainee is performing tests

CHAPTER 64B3-3.003 - General Requirements of Clinical Laboratory Personnel Training Programs

Curriculum Requirements (Histology):

- All programs shall include
 - Specimen collection, handling and storage
 - Laboratory Mathematics
 - Statistical applications
 - General instrumentation
 - Reagent preparation and storage
 - Quality control
 - Instrument maintenance and Calibrations
 - Documentation Techniques
 - Laws and Regulations
 - monitoring systems for results and errors
 - ethics, communication skills
 - interpersonal skills
 - computer skills
 - correlation of laboratory data with common physiological conditions for the purpose of assessing validity of the results and laboratory safety
 - Histologic technology standards
- All programs not accredited by the National Accrediting Agency for Clinical Laboratory Science (NAACLS), the Council on Accreditation of Allied Health Education Programs (CAAHEP), or the Accrediting Bureau of Health Education Schools (ABHES) except for those in the categories of cytology, cytogenetics, histocompatibility, embryology or andrology shall adopt the 2008-09 curriculum frameworks for Health Science Education set forth by the Florida Department of Education at http://www.fldoe.org/workforce/dwdframe/he_cluster-frame08.asp for the categories in which training occurs as follows:

(b) For the category of histology, the histologic technology standards.

64B3-4 TRAINEES

CHAPTER 64B3-4.001 - Trainee Registration

All trainee should be enrolled in a CL training program approved according to chapter 64B3-3 F.A.C.

Apply to the Department of Health

Trainee registration may not be extended beyond its expiration date, except upon recommendation of the program director and approval of the Board for:

- Program failed to start on time
- Trainee withdrew and started at another time
- Training program cancellation
- Trainee unable to complete the program on time
- Trainee shall apply for licensure once program is completed
- Trainee in histology Board approved programs should be granted a two year trainee license
- Trainee should submit a certified copy of a high school diploma or transcript to the DOH

64B3-5 QUALIFICATION FOR LICENSURE

CHAPTER 64B3-5.002 - Supervisor

(1) Qualification

- Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university.
- Be licensed or meet the requirements for the technologist licensure.
- Complete a Board approved examination or 25 hours of Board approved continuing education in Administration and Supervision which includes an examination and not older than five years.
- One (1) hour of HIV/AIDS
- Two (2) Hours of Medical Errors & Patient safety
- And one of the following:

(f) Category of Histology:

1. ASCP at the HTL level and five years of pertinent experience.
2. ASCP at the technician level, five years of pertinent experience post-certification, and an additional 23 hours of continuing education in administration and supervision within five years prior to application for licensure.
3. Florida licensure or meeting the requirements for licensure as a histology technologist, five years of pertinent clinical laboratory experience, and an additional 23 hours of continuing education in administration and supervision within five years prior to application for licensure

CHAPTER 64B3-5.003 - Technologist

(1) Qualification

- Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university. All associate degrees used to qualify shall include, at a minimum, 60 semester hours of academic credit including a total of 16 semester hours of biological or chemical sciences.
- One (1) hour of HIV/AIDS
- Two (2) Hours of Medical Errors & Patient safety
- And one of the following:

(g) Category of Histology:

- Option 1: Certified by ASCP at the HTL level or ASCP at the technician (HT) level and Qualification in Immunohistochemistry (QIHC)

- Option 2: Graduation from a NAACLS approved associate degree histotechnology program and Board certification gained by examination through ASCP at the Histotechnician (HT) level.
- Option 3: Certified by ASCP at the technician level (HT), five years of pertinent experience, and 48 contact hours of continuing education in immunohistochemistry/advanced histologic techniques.
- Option 4: Florida licensure as a histology technician, 48 contact hours of continuing education in immunohistochemistry/advanced histologic techniques and five years of pertinent clinical laboratory experience.

CHAPTER 64B3-5.004 - Technician

(1) Qualification

- Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university. All associate degrees used to qualify shall include, at a minimum, 60 semester hours of academic credit including a total of 16 semester hours of biological or chemical sciences.
- One (1) hour of HIV/AIDS
- Two (2) Hours of Medical Errors & Patient safety
- And one of the following:

(b) Qualification for Histology Technician:

Option 1: Certification by ASCP at the Histotechnician (HT) level.

CHAPTER 64B3-6.001 – Application

1. Apply to the Department of Health on form #DH-MQA 3000 (11/08), copies of which can be obtained from the Board office at 4052 Bald Cypress Way, Bin #C07, Tallahassee, Florida 32399-3257 or from its website at <http://www.doh.state.fl.us/mqa/ClinLab/index.html>. The application must be accompanied by the appropriate application fee required by Rule 64B3-9.001, F.A.C.
2. Application and fee good for one (1) year.
3. Social security number is mandatory, used to allow efficient screening of applicants and licensees by a Title IV-D child support agency to assure compliance with child support obligations.

CHAPTER 64B3-6.002 - Documentation for Licensure

1. Official transcript from institution.
2. Notarized copy of high school diploma.
3. Certified copy of a diploma, training certificate or Dept.of Defense.
4. Notarized copy of attendance of training, HIV/AIDS and Medical Errors.
5. Certified copies of foreign education and translation.
6. Foreign credential evaluation which includes a breakdown of all college level courses by credit hours and subject sent directly to the Board office by an evaluator.

CHAPTER 64B3-6.003 - Personnel Licensure - Temporary Permit

1. The Department shall issue one temporary license to an applicant who has met the qualifications requirements for initial examination for a period not to exceed one year.
2. Failure to pass the examination, the applicant shall no longer be permitted to work and shall not receive a second temporary license to be employed at that licensure level.
3. Failure to present the examination, temporary license shall be invalid as of that date. A second temporary license will not be issued. However applicant can retake the test by reapplying and requalifying

CHAPTER 64B3-8.001 - Renewal of Clinical Laboratory Personnel License

1. The department shall renew a license upon receipt of the renewal fee provided that the Board has not withdrawn its certification of competency for an active status licensee.

CHAPTER 64B3-8.002 - Inactive Status and Reactivation

1. A clinical laboratory personnel may elect at any time to place the license into in inactive status by filing with the Board a complete application for inactive status and paying the inactive status fee.
2. An inactive license may change to active status at any time provided the licensee meets the continuing education requirements. The licensee shall be requested to provide copies of all continuing education hours; and requirements:
 - a) Pay the active status fee
 - b) Pay the reactivation fee
 - c) Pay, if applicable, the change of status fee

CHAPTER 64B3-8.003 - Renewal of Clinical Laboratory Training Program License

1. An approved training program shall renew biennially.
2. Submit a renewal application with the applicable fee to the Department.
3. The renewal application shall include the following:
 - a) Name of the program director and all instructors
 - b) License number of the director and instructors
 - c) Submit a resumé if the Director has changed
 - d) Name, address, Lic #, personnel roster, and most current licensure or certification survey report of the laboratory sponsoring the training program, and affiliates.

CHAPTER 64B3-8.004 - Renewal of Clinical Laboratory Personnel Continuing Education Provider License

1. Submit a biennial renewal application and renewal fee to the Department.
2. Shall indicate any changes in the contact person and course offerings.

CHAPTER 64B3-8.005 - Delinquent License

1. Failure of the licensee to elect active or inactive status before the license expires shall cause the license to become delinquent.
2. The delinquent licensee must affirmatively apply for active or inactive status during the biennium in which the license becomes delinquent. Failure by the delinquent licensee to cause the license to become active or inactive before the expiration of the biennium in which the license became delinquent shall render the license null and void without further action by the Board or the Department.

3. The delinquent licensee who applies for active or inactive license status shall:
 - a) Pay the active or inactive fee
 - b) Demonstrate compliance with the continuing education requirements of Rules 64B3-11.001 & 64B3-8.002

CHAPTER 64B3-8.006 - Exemption of Spouses of Members of Armed Forces from Licensure Renewal Provisions
 A licensee who is the spouse of a member of the Armed Forces of the United States shall be exempt from all licensure renewal provisions for any period of time which the licensee is absent from the State of Florida due to the spouse's duties with the Armed Forces.

The licensee must document the absence and the spouse's military status to the Board. The licensee is required to notify the Board of a change in status within six months of the licensee's return to the State of Florida or the spouse's discharge from active duty.

If the change of status occurs within the second half of the biennium, the licensee is exempt from the continuing education requirements for that biennium.

64B3-9 FEES

64B3-9.001 Application Fees

Category	Fee
Trainee	\$20.00
Licensure Application:	
Director	\$90.00 (Effective 4-27-2010)
Supervisor	\$70.00 (Effective 4-27-2010)
Technologist	\$50.00 (Effective 4-27-2010)
Technician	\$25.00 (Effective 4-27-2010)
Clinical Laboratory Personnel Training Program	\$200.00
CEU Provider	\$250.00
Public Health Science Technician	\$100.00

64B3-9.002 Initial Licensure Fees

Category	Fee
Director	\$65.00 (Effective 4-27-2010)
Supervisor	\$55.00 (Effective 4-27-2010)
Technologist	\$45.00 (Effective 4-27-2010)
Technician	\$25.00 (Effective 4-27-2010)
All Clinical Laboratory Personnel	\$100.00
Clinical Laboratory Personnel Training Program	\$200.00
Clinical Laboratory Personnel Trainees	\$20.00

64B3-9.004 Active Status Renewal Licensure Fee

Category	Fee
Director	\$130.00
Supervisor	\$110.00
Technologist	\$90.00
Technician	\$50.00
Clinical Laboratory Personnel Training Program	\$300.00
CEU Provider	\$250.00

64B3-9.005 Reactivation Fee

Reactivation \$ 50.00

64B3-9.006 Inactive Status Fee

Inactive Status \$ 50.00

Renewal of Inactive Status \$ 50.00

64B3-9.009 Duplicate License Fee

Duplicate License \$ 25.00

64B3-9.010 Change of Status Fee

Change of Status \$ 50.00

64B3-9.011 Delinquency Fee

The fee for a delinquent licensee applying for active or inactive status shall be equal to the renewal fee set forth in Rule 64B3-9.004, F.A.C. (Changed 6/17/2009)

64B3-9.012 Unlicensed Activity Fee

Unlicensed Activity \$ 5.00

64B3-9.0035 Additional Specialty Fee \$ 25.00

64B3-10

SCOPE OF PRACTICE

CHAPTER 64B3-10.005 - Scope of Practice Relative to Specialty of Licensure

- (1) The scope of practice for licensed clinical laboratory personnel includes specimen collecting, processing, storing, shipping and performing manual pretesting procedures.

- (2) The scope of practice for licensed clinical laboratory technologists, supervisors and directors includes interpretation of clinical laboratory test results.

(11) Histology

The purpose of the specialty of histology is to process cellular and tissue components through methods of fixation, dehydration, embedding, microtomy, frozen sectioning, staining, and other related procedures and techniques employed in the preparation of smears, slides, and tissues.

The specialty also encompasses methods for antigen detection and other molecular hybridization testing methods where the purpose is analysis and/or quantification of cellular and tissue components for interpretation by a qualified physician.

Technicians licensed in histology are limited to the performance of specimen processing, embedding, cutting, routine and special histologic staining, frozen sectioning and mounting of preparations under the general supervision of a director, supervisor, or technologist.

64B3-11

CONTINUING EDUCATION

CHAPTER 64B3-11.001 - Continuing Education

- 1) In order to renew a Clinical Laboratory Personnel license the following should be met:
 - a) 24 Hours of Continuing education to include:
 - 1) One (1) hour of HIV/ADIS
 - 2) Two (2) hours of Medical Errors
 - 3) One (1) hour of Florida Laws and Rules Governing CLP
 - 4) One (1) hour for each specialty
 - b) Directors and Supervisors must include One (1) hour of Supervision and Administration
- 2) A licensee may choose to surrender his/her licensure in a given category by submitting a written request to the Board at the time of renewal.
- 3) The licensee shall retain the original CEU certificates of attendance received from approved providers for a minimum of four years.
- 4) First time applicants are exempt from ceu requirements for that biennium with the exception of completing any statutorily mandated courses. Licensees adding a category to an existing license are exempt from the one (1) contact hour in that specialty.
- 5) A licensee intending to use a course offered by a state or federal government agency or a regionally accredited educational institution is responsible for maintaining documentation to verify the date, location, attendance, and subject matter of such course.
- 6) In order to count for continuing education credit, courses taken at a regionally accredited college or university must be:
 - a) Documented by an official transcript.
 - b) Successfully completed.
 - c) In the subject matter area specified in subsection 64B3-11.002
 - d) One semester hour equals 15 contact hours and one quarter hour equals 10 contact hours.
- 7) A random sample of licensee shall be audited by the Department to determine compliance with the CEU's requirements. Within 30 days of notification of selection, licensee shall submit an original or certified copy of each certificate of attendance since the date of last renewal.
- 8) Licensed clinical laboratory personnel who teach Board approved continuing education may claim three hours of continuing education credit for each hour of prepared lecture. These hours, however may be

claimed only once per biennium during which the person teaches the program. Continuing education credit shall not be claimed by school faculty for regular teaching assignments.

- 9) In addition to the continuing education credits authorized herein, former Board members will receive eight hours of credit per biennium for annual service on a Probable Cause Panel. (New 6/17/2009)

CHAPTER 64B3-11.002 - Standards for Continuing Education Courses

Continuing education courses approved by the Board shall meet the following standards:

- 1) Provide subject matters from one or more of the following standards:
 - a) Clinical laboratory sciences practice areas.
 - b) Legal aspects of Clinical Laboratory sciences, state and federal regulations and accreditation standards.
 - c) Management or Administration of a clinical laboratory.
 - d) Subjects relating to laboratory practice which are required as part of an approved laboratory training program advanced beyond the completed for current licensure.
 - e) HIV/AIDS which shall include the minimum course content set forth in Rule 64B3-11.005.
 - f) Latest developments in clinical laboratory methods, instrumentation, information systems and discoveries in biology, chemistry and medicine applied to clinical laboratory practice.
- 2) Provide faculty qualified by experience in the area of instruction or experience sufficient to achieve the course objectives. Faculty qualifications shall be presented to the Board upon request.
- 3) Provide learning experiences and utilize teaching methods which are appropriate to achieve the course objectives.
- 4) Ensure that time schedules for each activity is sufficient for the learner to meet the learner objectives.
- 5) Provide participants an opportunity to evaluate learning experiences, course objectives, instructional methods, facilities and faculty.
- 6) Provide offerings which are least 50 minutes in duration for 1 contact hour. In calculating the number of contact hours for offerings which are longer than one hour, the time used for breaks, lunches and other activities not directly part of the instructional experience shall be subtracted from the total number of hours in the offering.

CHAPTER 64B3-11.003 - Requirements for Continuing Education Programs

- 1) Meet the standards of 64B3-11.002
- 2) Receive a program number upon approval.
- 3) Providers to update current information of the person responsible for the ceu's of their facility.
- 4) Record keeping and storage of such reports for three years.
- 5) Each participant shall receive a certificate of attendance to include: Participant name, lic #, course title, number of contact hours earned by specialty, dates of attendance, program provider's name, approval number, and signature of the provider.

64B3-12 DISCIPLINE

64B3-12.001- Disciplinary Guideline

Offense	Fine
Obtain License by Bribery	st 1 Offense: \$500.00/2 years probation
	nd 2 Offense: \$5K- 10K
Fraudulent misrepresentation	\$10K/6 months probation

Error of the Department or the Board	Letter of concern to \$500.00 up to suspension for 1 year followed by 2 years probation & \$5K fine. 2 nd Offense: \$3K, 3 rd Offense: \$10K
Representing itself as entitled to perform testing	\$300/ 1 YR Probation; \$5K/ 2YR Probation 2 nd Offense: \$1K - \$10K/Probation
Delegating knowingly not licensed to perform the task	Min: \$800/6 months Probation Max: \$5K/3 Yrs Suspension 2 nd Offense: Min: \$1K/1 YR Probation Max: \$7,500.00/Revocation After 2 nd Offense: Min: \$2K/6 months suspension followed by probation Max: \$10K/Revocation of license

64B3-12.002 Citations

1. Definition: instrument which meets the requirements set forth in Section 456.077, and which is served upon a licensee for the purpose of assessing a penalty in an amount established by this rule. All citations will include a requirement that if it can be corrected it must be done within 60 days, and impose whatever obligations will remedy the offense, except that up to six months shall be permitted with regard to the completion of continuing education credit hours.
2. The Department may issue a citation to the subject within 6 months after the filing of the complaint which is the basis for the citation.
3. The Board designates the following offenses citations violations, which shall result in a penalty of \$250.00

Offense
<ul style="list-style-type: none"> a) Failure to renew license during which time the person continues to practice up to 60 days in violation of Rule 64B3-8.001 b) Issuing a bad check. c) Failure to notify of change of address within 60 days. d) Failure to respond to a continuing education audit. e) Failure to pay required fees and fines in a timely manner. f) Failure to comply with continuing education requirements. g) Failure to report to the Board in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. h) Failure to report to the Board in writing within 30 days of action taken against a license to practice by another jurisdiction as required by section 483.825(1)(k), F.S. i) Failure to comply with a portion of a Final Order of the Board due to negligence.

Probations
<ol style="list-style-type: none"> 1) License suspended for a period of time set by the Board. 2) The licensee is placed on probation for a period of time set by the Board. 3) The licensee's probation shall be subject to the following terms & conditions: <ol style="list-style-type: none"> a) Probationer shall comply with all state statutes and rules pertaining to Clinical Laboratory Personnel. b) Probationer shall appear before the Board at the first meeting after said such probation commences, at the last meeting of the Board preceding termination of probation, and at such other times as requested by the Board. c) In the event of leaving the State of Florida for period of 30 days or more, probation shall be tolled and remain in such status until the return back to the State of Florida which time the probation status shall resume. Shall notify Board of any change of address residential or commercial within ten days which must be kept on file. d) Shall practice under the supervision of a licensed clinical laboratory personnel. This person shall appear to the first meeting with the probationer. Failing to do so constitute a violation to a Board's Final Rule
Probations
<p>The responsibilities of the supervising person shall include:</p> <ol style="list-style-type: none"> 1) Submit quarterly reports, which shall include: <ol style="list-style-type: none"> a) Brief statements of why probationer is on probation. b) Description of Probationer's practice. c) Brief statement of Probationer compliance with terms of probation. d) Brief statement of Probationer's relationship with supervising person. 2) Detail any problem which may have arisen with Probationer. 3) Review a percentage of records which reflects the Probationer's practice and performance which may include but not be limited to patient reports, proficiency testing, QC records, calibrations, PM and any other pertinent records. 4) Consultation with Probationer's immediate supervisor regarding Probationer's performance. 5) Review Probationer's use of pharmaceutical agents.

Any licensee determined to have violated the provisions of Chapter 483, F.S., and the rules adopted hereunder may be ordered to serve probationary terms including any or all of the following:

Probations

- 1) Report to the Board any violations by the Probationer of Chapters 456 & 483, Part III, F.S.
 - e) Probationer shall submit quarterly report to the Board and shall include:
 1. Brief statements of why probationer is on probation.
 2. Practice location.
 3. Description of current practice stating type and composition.
 4. Brief statement of compliance with probationary terms.
 5. Description of relationship with the supervising person.
 6. Description of any problems.
 7. Notarized copies of a number of records.
 - f) Probationer shall obtain a number of CEU's in specific areas, within a # of months/years, in addition to those required for renewal.
 - g) Probationer shall see a psychiatrist, psychologist or psychotherapist approved by the Board.
 - e) Probationer shall not consume, inject or ingest any controlled substances unless prescribed or administered by a practitioner authorized by law to prescribe or dispense controlled substances.
 - f) Probationer shall not consume alcohol.
 - g) Probationer shall attend AA or NA meetings at least once a week.
 - h) Probationer shall submit to random blood and/or urine testing for the purpose of ascertaining Probationer's compliance with probation.
 - i) Probationer shall pay all reasonable costs of obtaining random urine and/or blood screens.
 - j) Probationer shall pay an administrative fine in the amount set by the Board and comply with Rule 64B3-12.006

64B3-12.004 - Mediation Offenses

Mediations
<p>The Board designates the following violations of its practice act as being appropriate for mediation where the subject has an explanation and a differing view from the complainant as to the nature or extent of the violation as provided in Section 4546.078, F.S., as these violations are economic in nature or can be remedied by the licensee:</p> <ol style="list-style-type: none">1. Failure to comply with Rule 64B3-12.006 or with a Final Order with regards to the time limitation for the payment of fines or costs.2. Timely response to CEU audit.3. Issuing a bad check to the Department.4. Failure to notify the Department of Change of Address within 60 days.5. Failure to complete CE in a specialty area solely because the subjects contends the he or she was unaware that according to the Board's record the subject is still licensed in that specialty area, provided that the subject has not been actively practicing in that specialty area during the biennium.

64B3-12.005 - Notice of Noncompliance

Noncompliance
<ol style="list-style-type: none">1) The department shall issue a notice of noncompliance as a first response to a minor violation of a rule. Failure of a licensee to take action in correcting the violation within 15 days may result in an issuance of a citation or disciplinary proceedings.2) Failure to notify a change of address with 60 days.3) Issuing a bad check to the department.

64B3-12.006 - Time Limitation for Payment of Administrative Fine or Costs

Cases where the Board impose an Administrative Fine or cost this shall be paid within 30 days from the date of the Final Order of the Board is filed with the Clerk of the department unless a different time frame is set forth in the final order.

64B3-13
RESPONSIBILITIES OF
CLINICAL LABORATORY PERSONNEL

64B3-13.001 - Responsibilities of Directors

Directors Responsibilities
<ol style="list-style-type: none">1) Responsible head of the Clinical Laboratory and overall operation and administration of the Clinical laboratory.2) May perform or delegate duties of the Supervisor or technologist if licensed in that specialty.3) Not qualified shall have a co-director that meets the licensure qualifications.4) Shall not direct more than five labs.5) Can delegate performance of responsibilities to licensed supervisors, however, the director remains responsible for ensuring that all duties are properly performed. Must be written and specific.6) The laboratory director shall:<ol style="list-style-type: none">a) Shall be accessible (on-site, by phone or electronic consultation as needed).

64B3-13.002 - Responsibilities of Supervisors

Supervisors Responsibilities
<ol style="list-style-type: none">1) Fulfill the responsibilities of the director as assigned and monitor compliance with all applicable regulations of the Board and the Department.2) In addition shall:<ol style="list-style-type: none">a) Perform the duties of a technologist as needed in specialties where is licensed.b) Assign as needed performance of his or her direct supervision responsibilities to licensed technologists, however they are still responsible.c) Evaluates competency of the technologists and technicians and assures staff maintain their competency to perform test procedures. This shall include:<ol style="list-style-type: none">1) Direct observation of routine test performance.2) Monitoring and reporting of test results3) Review of QC records, proficiency testing results and preventive maintenance.4) Direct observation of Instrument maintenance and function checks.5) Assessment of test performance through testing previously analyzed specimens, through internal blind testing samples or through external proficiency testing samples.

- 6) Assessment of problem solving skills.
- 7) Evaluates and documents the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens. After that shall be annually.
- 8) Accessible through on-site, phone or electronic to resolve technical issues.
- 9) Provide day to day supervision of test performance by technologists and technicians.
- 10) Ensure on-site direct supervision when testing is being performed by those technicians who are required to work under direct supervision.

64B3-13.003 - Responsibilities of Technologists

Technologist Responsibilities
<ol style="list-style-type: none"> 1) Responsible for fulfilling the responsibilities of the supervisor, as assigned. 2) In addition the technologist shall fulfill the following responsibilities: <ol style="list-style-type: none"> a) Performs only those tests authorized by the director. b) Follows the clinical laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient results. c) Maintain record that demonstrates proficiency testing samples are tested in the same manner. d) Adhere to the QC policies, document all QC activities, instruments and procedures. e) Follow policies and procedures when tests do not meet expectations. f) Able to identify the problem and correct or report the problem to the immediate supervisor. g) Document all corrective action taken when test systems deviate from the laboratory's established performance specifications.

Technicians Responsibilities

- 1) Perform tests classified as highly complex pursuant to 42 CFR 493.17 (September 7, 1999), only when under the direct supervision of a licensed technologist, supervisor, or director unless the technician meets minimum qualifications set forth in 42 CFR 493.1489 (September 7, 1999).
- 2) Perform only those test authorized by the Director.
- 3) Follow the Clinical Laboratory procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient tests results.
- 4) Notify a licensed technologist or supervisor whenever test systems are not within the Clinical Laboratory's defined acceptable levels of performance.
- 5) Participate in proficiency testing samples.
- 6) Adhere to the QC policies, document all QC activities, instruments and procedures.
- 7) Able to identify the problem and immediately report the problem to a licensed technologist or supervisor.
- 8) Document all corrective action taken when test systems deviate from the laboratory's established performance specifications.
- 9) Follow the directives of directors, supervisors or technologists while exercising their duties and responsibilities.

References:

Florida Department of Health. Division 64B3 Board of Clinical Laboratory Personnel. Retrieved, March 25, 2010 from <https://www.flrules.org/gateway/Organization.asp?OrgNo=64b3>.

TEST

1. The Chapter number for the Clinical Laboratory Professional for regulations is::
 - a) Chapter 483
 - b) Chapter 64B3
 - c) Chapter 446B1
 - d) Chapter 66B4
2. Grounds for Disciplinary actions may include performing and reporting a test to a person not authorized by law to receive such services:
 - a) True
 - b) False
3. In order to obtain a license at the histology technology level one should:
 - a) Certified by the ASCP at HTL level
 - b) Certified by the ASCP at the HT level with a certification in Immunohistochemistry by ASCP
 - c) Florida HT licensure, 5 years of experience and 48 hrs of advance histologic techniques
 - d) all of the above
4. The penalty for representing yourself as entitled to perform testing is:
 - a) A fine of \$300 and 1 year probation
 - b) A fine of \$5,000 and 2 years probation
 - c) A fine of \$20,000 and 2 years of probation
 - d) a & b
 - e) all of the above
5. The renewal of licensure requires 1 hour of continued education for each specialty that you are licensed:
 - a) True
 - b) False
6. All trainee should be enrolled in clinical lab training program approved by:
 - a) The Department of Health
 - b) American Society for Clinical Pathologist
 - c) College of American Pathologist
 - d) The Florida Society for Histotechnology
7. Technicians licensed in histology are limited to the performance of processing, embedding, cutting, routine, special stains, frozen sections and mounting of specimens.
 - a) True
 - b) False
8. The Department shall consider a notice of noncompliance when:
 - a) License is suspended for a period of time.
 - b) Unable to receive approval for a program number
 - c) A failure to notify a change of address within 60 days
 - d) Not completing an approved program.
9. A random sample of license shall be audited by the Department of Health to determine compliance of the CEU's requirements.
 - a) True
 - b) False
10. Technicians are responsible for::
 - a) Participating in proficiency testing samples
 - b) Performing only test authorized by the Director
 - c) Adhere to the qc policies
 - d) All of the above

Answer Sheet

Title: **Florida Histology Licensure: The Rules & Regulations**

Name: _____

Address: _____

E-mail Address: _____

FL Licensure #: (TC, TN, SU) _____

.....
Note: Circle the correct answer.

- | | | | | |
|------------|----------|----------|----------|----------|
| 1. | A | B | C | D |
| 2. | A | B | C | D |
| 3. | A | B | C | D |
| 4. | A | B | C | D |
| 5. | A | B | C | D |
| 6. | A | B | C | D |
| 7. | A | B | C | D |
| 8. | A | B | C | D |
| 9. | A | B | C | D |
| 10. | A | B | C | D |

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