Board of Clinical Laboratory Personnel  
The Law, Rules & Regulations related to Histology  
2014 Update

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 an outline form, that are designed to fill in the details of the broad concepts mandated by the legislature in statutes.
The Florida Statutes are updated annually and after the conclusion of a regular legislative session and is typically published in July/August.

**Summaries:**

**§§ 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.

Clinical laboratories provide essential services to practitioners of the healing arts by furnishing vital information that is essential to a determination of the nature, cause, and extent of the condition involved. Unreliable and inaccurate reports may cause unnecessary anxiety, suffering, and financial burdens and may even contribute directly to death.

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

The Legislature finds that laboratory testing technology continues to advance rapidly. The Legislature also finds that a hospital training program under the direction of the hospital clinical laboratory director offers an opportunity for individuals already trained in health care professions to expand the scope of their careers.

The Legislature further finds that there is an immediate need for properly trained personnel to ensure patient access to testing. Therefore, the Legislature recognizes the patient-focused benefits of hospital-based training for laboratory and non-laboratory personnel for testing within hospitals and commercial laboratories and recognizes the benefits of a training program approved by the Board of Clinical Laboratory Personnel under the direction of the hospital clinical laboratory director.

**What are the exemption?**

The declaration of Policy and Statement of Purpose under §§ 483.800 is linked to clinical laboratory personnel. However, there are a few exemptions of personnel included under this statute.

**§§ 483.801 - Exemptions**

This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

1) Clinical laboratories operated by the United States Government.
   Examples: Veteran’s Affair Hospitals, Military hospitals

2) Laboratories operated and maintained exclusively for research and teaching purposes, involving no patient or public health service whatsoever.
   Research & Animals laboratories

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.

§§ 483.803 Definitions

1. Board = Board of Clinical Laboratory Personnel.
2. Clinical laboratory means a clinical laboratory as defined in § 483.041, where there is a physical location offering or providing services such as diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition.
   a. Clinical Laboratory – offer examinations of fluids or other materials taken from the human body.
   b. Anatomical Laboratories – offer the examinations of tissue taken from the human body.
   c. Cytology Laboratories – offer examinations of cells from individual tissues or fluid taken from the human body.
3. Clinical laboratory examination means a clinical laboratory examination as defined in s. 483.041.

Procedure performed to deliver the services defined in subsection (2), including the oversight or interpretation thereof.

§ 483.041 subsection (2)

   a. Clinical Laboratory – offer examinations of fluids or other materials taken from the human body.
   b. Anatomical Laboratories – offer the examinations of tissue taken from the human body.
   c. Cytology Laboratories – offer examinations of cells from individual tissues or fluid taken from the human body.

4. Clinical laboratory personnel includes:
   a. Director
   b. Supervisor
   c. Technologist
   d. Blood gas analyst
   e. Technician

Does not include:

   a. Trainees
   b. persons who perform screening for blood banks or plasmapheresis centers
   c. phlebotomists
   d. persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities
   e. persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

§ 483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation

Subsection (1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments.
of 1988 and the federal regulations adopted thereunder.

Subsection (2) Subsection (1) does not apply to a clinical laboratory operated by one or more practitioners who hold the facilities of the laboratory out as available for the performance of diagnostic tests for other practitioners or their patients. All provisions of this part apply to a clinical laboratory that receives any referred work or performs any work for patients referred by another practitioner.

5. Clinical laboratory trainee means any person having qualifying education who is enrolled in a clinical laboratory training program approved by the Board of Clinical Laboratory Personnel, who is seeking experience required to meet minimum qualifications for licensing in the State of Florida.

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

6. Department or DOH means the Department of Health.

Other definitions included under this statute includes:

   a. Licensed practitioner of the healing arts
   b. Public health laboratory scientist

§§ 483.805- Board of Clinical Laboratory Personnel

The Board of Clinical Laboratory Personnel is created within the Department of Health composed of seven members that are appointed by the Governor and confirmed by the Florida Senate.

Five members of the board shall be persons licensed as follows:
1. At least one member shall be a practicing clinical laboratory director.
2. At least two members shall be practicing clinical laboratory supervisors.
3. Two members shall be practicing clinical laboratory personnel.

Two members of the board shall be citizens of the state who have never been licensed as health care practitioners and who are not, and have never been licensed as clinical laboratory personnel and who are in no way connected with the practice of such profession.

The Governors must appoint two members for a two-year term, two members for a three-years and three members for a four-year term. All terms are to expire on October 31 of their appointed term.

As terms of the initial members expire, the Governor shall appoint successors for terms of 4 years and such terms shall expire on October 31.

A member whose term has expired shall continue to serve on the board until such time as a replacement is appointed. No member shall serve for more than the remaining portion of a previous member’s unexpired term, plus two consecutive 4-year terms of the member’s own appointment thereafter.

The board shall maintain its official headquarters in Tallahassee.

§§ 483.807- Fees; Establishment; Disposition

As a licensed practitioner or person seeking licensure sometimes wonder how are fees for application and renewal are assessed. The Board of Clinical Laboratory Personnel MUST stay within the limits included in the Florida Statutes.

(1) The board, by rule, shall establish fees to be paid for application, examination, reexamination, licensing and renewal, registration, laboratory training program application, reinstatement, and record making and recordkeeping. The board may also establish, by rule, a delinquency fee. The board shall establish fees that are
adequate to ensure the continued operation of the board and to fund the proportionate expenses incurred by the department in carrying out its licensure and other related responsibilities under this part. Fees shall be based on departmental estimates of the revenue required to implement this part and the provisions of law with respect to the regulation of clinical laboratory personnel.

(2) Licensure application fee may not exceed $200 and it is nonrefundable.

(3) The examination fee shall be in an amount which covers the costs of obtaining and administering the examination and shall be refunded if the applicant is found ineligible to sit for the examination. The combined fees for initial application and examination may not exceed $200 plus the actual per applicant cost to the department for developing, administering, or procuring the licensure examination. The Board of Clinical Laboratory Personnel stopped offering its own professional examination in January 2002.

| Fees may not exceed the following amounts: |

(4) The initial license fee may not exceed $100.

(5) The fee for licensure by endorsement may not exceed $100.

(6) The biennial renewal fee may not exceed $150.

(7) The fee for application for an inactive status license or for reactivation of an inactive status license may not exceed $50.

(8) The initial application fee for registration of a trainee shall not exceed $20.

(9) The initial application and renewal fee for approval as a laboratory training program may not exceed $300. The fee for late filing of a renewal application shall be $50.

(10) All fees shall be established, collected, and deposited in accordance with §§. 456.025.

§§. 483.809 - Licensure; examinations; registration of Trainees; Approval of Curricula

(1) LICENSING
   a) The department shall provide biennial licensure of all clinical laboratory personnel who the board certifies have met the requirements.
   b) 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 §§. 483.819.

(2) EXAMINATIONS
   a) The department shall conduct examinations required by board rules to determine in part the qualification of clinical laboratory personnel for licensure (Not currently available for Clinical Laboratory Personnel).
   b) 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 (Currently the ASCP is the accepted examination for histology)

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

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

§§. 483.811 – Approval of Laboratory Personnel Training Programs
This statute refers to the approval of Programs to train laboratory personnel. The responsibility of the board is to:

1. approve training programs that satisfactory can provide evidence that the laboratory is appropriately staffed by qualified licensed personnel and that the laboratory can provide the adequate training needed to train individuals meeting the requirements of licensure for the specialty.

2. Adopt rules for training programs, including, but not limited to, rules relating to curriculum, educational objectives, evaluation procedures, personnel licensure requirements, pre-entry educational requirements, and length of clinical training.
   a) A clinical laboratory operated by one or more practitioners who hold the facilities of the laboratory out as available for the performance of diagnostic tests for other practitioners or their patients is subject to the provisions of this part.

3. Approve training programs for laboratory technicians in a hospital or clinical laboratory which programs are under the supervision of a clinical laboratory director. The training must be accepted in lieu of educational requirements for licensure, but a trainee must have a high school diploma or its equivalent. Any person who completes a training program must pass, before licensure, an examination given by the department.

4. To allow the department to inspect laboratory personnel training programs.

5. To allow the department to rescind the approval of any training program that no longer meets the required standards for a training program.

§§ 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 §§ 483.035 (1) or exempt from regulation under §§ 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. (Currently a temporary license may be requested in writing and the applicant MUST have a recorded date to take any examination associated with the specialty).

§§. 483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation

Subsection (1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

§§. 483.031 Application of part; exemptions

Subsection (2) A clinical laboratory that performs only waived tests.

§§. 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. (It is the applicant’s responsibility to make
sure that the most recent posted application is being used).

§§ 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. (This is now verified by CE Broker)

(2) The board shall adopt rules establishing a procedure for the biennial renewal of clinical laboratory personnel licenses. (All continued education credits MUST be reported to CE Broker)

§§ 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. (We recommend that if a licensee will not be using their license for a while, to request that their license be placed in an inactive status).

(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. (Keep in mind that reactivating the license from an inactive status may require 15 contact hours for every year that the license has been placed in an inactive status).

§§ 483.821 - Periodic Demonstration of Competency; Continuing Education or reexamination

Summary:

License MUST be renewed every two years by the deadline established in your renewal notice. The continued education requirement may range from 10 to 30 hours. All continued education must be approved by the board. Currently anyone holding a license in the specialty of histology MUST have 24 hours of continued education, to include 1 hour in the specialty of histology, 2 hours in Medical Errors, 1 Hour in HIV/AIDS and 1 Hour in Florida Rules & Regulations.

Competency may be demonstrated by reexamining in the specified specialty instead of completing the required continued education. The board may ask an applicant to complete the required continued education or retrain in their area of specialty, if the licensee fails an examination two or more times.

§§ 483.823 - Qualification of Clinical Laboratory Personnel

(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.

§§ 483.824 - Qualifications of Clinical Laboratory Director

A clinical laboratory director must have 4 years of clinical laboratory experience with 2 years of experience in the specialty to be directed or be nationally board certified in the specialty to be directed, and must meet one of the following requirements:

(1) Be a physician licensed under chapter 458 or chapter 459;

(2) Hold an earned doctoral degree in a chemical, physical, or biological science from a regionally accredited institution and maintain national certification requirements equal to those required by the federal Health Care Financing Administration; or
§§ 483.825 - Grounds for Disciplinary Actions

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in §§ 456.072 (2):

| (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 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 State Surgeon General 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. |
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.

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.

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.

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

Improperly interfering with an investigation or any disciplinary proceeding.

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, and instructor/student relationships for personal gain, sexual gratification, or advantage.

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

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).

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.

§§ 483.828 - Penalties for Violations

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

Chapter 64B3

BOARD OF CLINICAL LABORATORY PERSONNEL

This section will focus mainly on the rules and regulations of the Board of Clinical Laboratory personnel
related to the field of histotechnology. To read on the entire rules and regulations for all disciplines please visit: http://floridasclinicallabs.gov/resources/

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CHAPTER 64B3-1 ORGANIZATION

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

Each person holding a license issued pursuant to Chapter 483, Part III, F.S., must maintain on file with the Department the current mailing address and primary practice location at which any notice required by law may be served by the Department or its agent. Within 60 days of changing either address, whether or not within this state, the licensee shall notify the Department in writing or via electronic methods of the new address and designate at which address the licensee may be served with notices or other documents. (Failure to do so will result in penalties established by the board).

CHAPTER 64B3-1.008 - Board Meetings

(1) For purposes of Board member compensation pursuant to Section 456.011(4), Florida Statutes, “other business involving the Board” is defined to include:
   (a) Board meetings;
   (b) Meetings of committees of the Board;
   (c) Board meetings or Board committee meetings held via teleconference that last four (4) hours or more.
   (d) Meetings of a Board member with staff at the request of the Board or the Department;
   (e) Probable cause panel meetings;
   (f) Attendance at legislative workshops or committee meetings at the request of the Board or Department;
(g) Attendance at meetings of National Associations as an authorized representative of the Board;

(h) Attendance at continuing education programs for the purpose of auditing a Board-approved provider when such attendance has been approved by the Board;

(i) Attendance at any function authorized by the Board or Department.

(2)(a) Board members shall attend all regularly scheduled Board meetings unless prevented from doing so by reason of court order, subpoena, business with a court which has the sole prerogative of setting the date of such business, death of a family member, illness of the Board member, or hospitalization of the member’s immediate family.

(b) No Board member shall be absent from three consecutive regularly scheduled Board meetings unless the absence is excused for one of the reasons stated in paragraph (a) of this rule. An absence for any reason other than the reasons stated in paragraph (a) constitutes an unexcused absence for the purpose of declaring a vacancy on the Board. An otherwise excused absence is not excused if the Board member fails to notify the Board office of the impending absence prior to the regularly scheduled Board meeting at which the absence will occur or unless the failure to notify the Board office is the result of circumstances surrounding the reason for the absence which the Board itself excuses after the absence has occurred.

(c) “Family” consists of immediate family, nieces, nephews, cousins, and in-laws.

(d) “Immediate family” consists of spouse, child, parents, parents-in-law, siblings, grandchildren, and grandparents.

CHAPTER 64B3.0085 – Public Comment (Added 12-25-2013)

64B3-1.0085 Public Comment.

The Board of Clinical Laboratory Personnel invites and encourages all members of the public to provide comment on matters or propositions before the Board or a committee of the Board. The opportunity to provide comment shall be subject to the following:

(1) Members of the public will be given an opportunity to provide comment on subject matters before the Board after an agenda item is introduced at a properly noticed board meeting.

(2) Members of the public shall be limited to five (5) minutes to provide comment. This time shall not include time spent by the presenter responding to questions posed by Board members, staff or board counsel. The chair of the Board may extend the time to provide comment if time permits.

(3) A member of the public shall notify board staff in writing of his or her interest to be heard on a proposition or matter before the Board. The notification shall identify the person or entity, indicate support, opposition, or neutrality, and identify who will speak on behalf of a group or faction of persons consisting of five (5) or more persons. Any person or entity appearing before the Board may use a pseudonym if he or she does not wish to be identified.

CHAPTER 64B3-1.015 - Probable Cause Determinations

(1) The determination as to whether probable cause exists that a violation of the provisions of Chapters 456 and 483, Part III, Florida Statutes, and the rules promulgated thereto has occurred shall be made by a majority vote of a probable cause panel of the Board.

(2) There shall be one probable cause panel of the Board, which shall meet the requirements set forth in Section 456.073, Florida Statutes. The probable cause panel shall be composed of two members, one of whom may be a past Board member.
(3) The probable cause panel members shall be selected by the Chair of the Board, one of whom shall be designated by the Chair of the Board as the presiding officer of the panel.

(4) The probable cause panel shall meet at such times as called by the presiding officer of the panel or by two members of the panel.

CHAPTER 64B3-2 DEFINITIONS

CHAPTER 64B3-2.002 - Clinical Laboratory Personnel

(1) Director means a 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.

(2) Supervisor means a 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.

(3) Technologist means a person licensed pursuant to the Board’s rules who represents the first level of independent practice and under general supervision, fulfills the responsibilities specified in Rule 64B3-13.003, F.A.C.

(4) Technician means a 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 as published on October 1, 2007, 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 as published on October 1, 2007, incorporated by reference herein, and the requirements contained in Rule 64B3-5.004, F.A.C., and fulfills the responsibilities specified in Rule 64B3-13.004, F.A.C.

(5) General supervision means supervision by a director or supervisor who is available on a regular basis and who is responsible for the overall performance of laboratory testing.

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

CHAPTER 64B3-2.003 - Definitions

(1) Accredited means accredited by a regional accrediting agency for colleges and universities recognized by the U.S. Department of Education.

(2) Approved laboratory means a clinical laboratory licensed under Section 483.091, Florida Statutes, or federal or out-of-state laboratories which have standards equivalent to those prescribed in Chapter 483, Part I, Florida Statutes, and the rules promulgated thereunder.

(3) Year means a calendar year of twelve months duration except in the phrase “one year of full time experience”.

(4) One year of full time experience means a minimum of 1500 hours amassed in not less than twelve months nor more than thirty-six months.

(5) Contact hour means a continuing education offering which is at least 50 continuous minutes in duration. Total number of hours cannot be added up and divided into 50 minute intervals.
(6) Academic science is a science course with a chemical or biological science prefix. Acceptable courses include general chemistry, organic chemistry, biochemistry, qualitative or quantitative analysis, general biology, zoology, physiology, comparative anatomy, bacteriology, parasitology, cell biology and immunology. For purposes of this rule, the courses of geology, astronomy, entomology, oceanography, marine biology, physics and physical science or remedial, preparatory or introductory science courses shall not be acceptable.

(7) Applied science is a physical, chemical or biological science course which is specific to a major and directly prepares the individual for performance in a specific profession. Examples of such courses are chemistry for health science majors or nurses, clinical chemistry, clinical microbiology, clinical hematology, advanced entomology, and oceanography.

(8) Pertinent clinical laboratory experience is experience in a clinical laboratory as defined in Section 483.041(2), Florida Statutes.

- If acquired in-state or in a state where licensure is required, experience must be accrued while licensed and working in a licensed laboratory unless otherwise authorized by the administrative rules of this Board.
- Experience acquired as a part of a training program may not be used as pertinent clinical laboratory experience.
- Exempt experience may not be utilized with the exception of experience in federal laboratories.
  - Experience in industrial laboratories is not considered pertinent clinical laboratory experience.
  - Experience in research laboratories is not considered pertinent clinical laboratory experience unless the research experience involved human subjects and used methodologies, quality control and quality assurance techniques comparable to those of clinical laboratories.

If all of these requirements are met the Board will review the research experience to determine if it is relevant experience. If research experience was acquired under an exemption clause, it may not be utilized as pertinent clinical laboratory experience. Experience acquired in an exclusive use laboratory environment, waived laboratory environment or alternate site testing environment is generally unacceptable unless specifically authorized by rules of this Board.

(9) Accredited program means a clinical laboratory personnel training program that is accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), Commission on Accreditation of Allied Health Education Programs (CAAHEP), or Accrediting Bureau of Health Education Schools (ABHES).

(10) Independent practice means the authority to perform clinical laboratory tests and release the results of such tests without direct supervision.

(11) Semester hour means one hour of credit in an accredited college or university, pursuant to subsection 64B3-2.003(1), F.A.C., or foreign education equated, pursuant to subsection 64B3-6.002(6), F.A.C. (changed 12/2013)

(12) Sexual misconduct is any direct or indirect physical contact by any clinical laboratory personnel and a patient which is intended to erotically stimulate either person or which is likely to cause such stimulation. Sexual misconduct includes sexual intercourse, fellatio, cunnilingus, masturbation or anal intercourse. Sexual misconduct also includes: making suggestive, lewd or lascivious remarks to a patient or performing such acts in the presence of a patient and intentionally touching a patient’s breast(s) or sexual organs for non-laboratory related purposes regardless of whether the patient is clothed.

(13) High complexity testing is clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.25, which are incorporated by reference.

(14) Moderate complexity testing is clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.20, which
(15) Waived testing is clinical laboratory testing as defined in 42 CFR 493.5 and 42 CFR 493.15, which are hereby incorporated by reference.

(16) Board approved program is a training program or a continuing education program approved by the Board pursuant to this chapter.

(17) Screening for Blood Banks or Plasmapheresis Centers means interviewing prospective donors in a blood bank or plasmapheresis center during which a hemoglobin test using a method classified as waived, a spun hematocrit or a total protein by the refractometer method may be performed.

(18) Manual Pretesting procedures means collecting and labeling specimens; initially separating specimens by centrifugation prior to testing; receiving specimens and requisitions, processing, sorting, accessioning, prior to testing and delivering specimens to the appropriate testing sites; specimen processing for storage and shipping to a reference laboratory; routine hematology and microbiology slide preparation from a primary sample; loading automated stainers; loading specimens onto automated sampling or processing systems; cytopreparatory staining; measuring and aliquoting specimens; and direct primary inoculation of microbiology cultures. Placement of specimens onto an automated instrument or system is considered a manual pretesting duty, provided it does not include any activity that initiates the analytic process.

CHAPTER 64B3-3 APPROVAL OF CLINICAL LABORATORY PERSONNEL TRAINING PROGRAMS

CHAPTER 6463-3.001 - General Requirements of Clinical Laboratory Personnel Training Programs

(1) Each clinical laboratory personnel training program, hereinafter referred to as program, shall apply to the board on Form #DH-MQA 3007 (03/13) “Application for Clinical Laboratory Training Program”, http://www.flrules.org/Gateway/reference.asp?No=Ref-02475, which is incorporated by reference herein and pay the fee set forth in subsection 64B3-9.001(3), F.A.C.

(2) Each program and program affiliate shall be in compliance with the provisions of Chapter 483, Part I, F.S., and Chapter 59A-7, F.A.C.

(3)(a) Programs shall submit a self study at the time of the initial application and shall update the self study within six (6) months of any major change in curriculum, sponsorship, faculty, student enrollment or clinical sites. The self study document shall be prepared on a form provided by the Department entitled “Clinical Laboratory Training Program Self Study Document,” DH1261 10/98, effective 1-11-99, which is hereby incorporated by reference and may be obtained from the Board office. If the program is 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), proof of accreditation may be substituted in lieu of the self study document.

(b) Programs that are nationally accredited or pending national accreditation shall only be required to submit proof of accreditation status with the application.

(4) All trainee’s names shall be reported to the Board upon acceptance into the clinical laboratory personnel training program and at the time of the program’s biennial renewal. The program director shall notify the Board when a trainee withdraws.

(5) Each training program shall:

(a) Designate space and laboratory equipment for proper training of students.

(b) Maintain copies of inspection and approval by the fire department or the state fire marshal’s office and
provide them for inspection upon request.

(c) Maintain a file on each student which shall contain a completed application, evidence of high school graduation or completion of college courses, if applicable, attendance records, grades, instructor evaluations of laboratory practice, the trainee's registration, and a copy of the student's certificate of completion or official transcript.

(d) Maintain current examinations and laboratory evaluation instruments utilized by the program.

(e) Provide the student with a certificate or letter of graduation or a transcript indicating the degree granted. Certificates and letters of graduation shall include the program's license number and be signed by the program director.

(f) Include instruction in human immunodeficiency virus and acquired immunodeficiency syndrome.

(g) Include instruction on the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety.

(h) Upon initial application provide the names, addresses, license numbers, personnel rosters and latest licensure or certification survey reports of all affiliates which provide clinical training for the trainees enrolled in the program. If laboratory based, provide the same information initially and at each biennial renewal.

(i) Include course objectives, course descriptions, course outlines, assessment of outcomes, student evaluations and graduate evaluations in the curriculum.

(j) Utilize state of the art instructional aides and methodologies for teaching the affective, cognitive, and psychomotor domains.

(k) Employ systematic procedures for assessing learning outcomes in the affective, cognitive, and psychomotor domains.

(l) Have a practicum in a clinical laboratory where current laboratory procedures, instrumentation and diversity of specimens are available for a variety of analyses and are in sufficient quantity to provide competent training for the student.

(m) In the combined categories of clinical chemistry, hematology, immunohematology, microbiology, and serology/immunology, provide a minimum of one (1) year of integrated instruction covering all categories. For any one of the single categories listed in this subparagraph, a minimum of three months of instruction is required.

(n) In the category of histology, provide one (1) year of instruction.

(o) In the categories of cytogenetics, radioassay, blood gas analysis and cytology, which shall be established at the technologist level only, provide a minimum of one (1) year of instruction.

(p) In the category of andrology or embryology, a minimum of six months of instruction.

(q) In the category of molecular pathology, a minimum of six months of instruction.

(r) Ensure that each student receives a copy of Chapter 483, Parts I and III, F.S., Chapter 456, F.S., and Chapters 59A-7 and 64B3, F.A.C.

(6) A clinical laboratory personnel training program which is not in compliance with Chapter 64B3-3, F.A.C., shall be denied approval or a prior approval shall be rescinded.
CHAPTER 64B3-3.002 - Personnel of Clinical Laboratory Personnel Training Programs

(1) A clinical laboratory personnel training program shall have a program director who holds national certification from any Board listed in subsection 64B3-5.002(2), F.A.C., and:

(a) Holds an earned doctoral or master’s degree in a chemical, biological or clinical laboratory science and has three (3) years of experience in clinical laboratory science education; or

(b) Holds a baccalaureate degree in a chemical, biological or clinical laboratory science and has five (5) years of experience in clinical laboratory science education.

(2) Instructors of clinical laboratory science courses in each program shall teach only in areas in which they have pertinent clinical laboratory or teaching experience and shall either:

(a) Be licensed as a technologist, supervisor or director; or

(b) Have a minimum of three (3) years of pertinent clinical laboratory experience or experience in clinical laboratory science education.

(3) There shall be at least one licensed technologist or supervisor on duty for each trainee during the trainee’s scheduled practicum. If the training program provides an instructor whose sole responsibility is trainee instruction, the ratio shall be one instructor for three trainees.

(4) Trainee Requirements. Trainees shall:

(a) Not be substituted for licensed clinical laboratory personnel.

(b) Be registered when enrolled in the practicum portion of the training program.

(c) Not report clinical laboratory test results.

(d) 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 - Curriculum Requirements for Clinical Laboratory Personnel Training Programs

(1) All programs shall provide instruction in laboratory practice covering specimen collection, handling and storage, including collection of venous, capillary and arterial specimens (when practical), laboratory mathematics, statistical applications, general instrumentation, reagent preparation and storage, quality control, instrument maintenance and calibrations, reporting results, documentation techniques, laws, 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.

(2) 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:
(a) For the categories of clinical chemistry, hematology, immunohematology, microbiology, and serology/immunology, the associate degree medical laboratory technology program standards or the certificate medical laboratory technology program standards.

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

(3) For the category of cytogenetics, technologist level programs shall as a minimum include instructions in the following competencies:

   (a) Appropriate culture techniques for submitted specimens.
   (b) Principles and techniques for harvesting specimens or cell cultures.
   (c) Principles and techniques of chromosome banding and staining.
   (d) Maintenance and use of microscopes and photographic and computer generated imaging techniques and equipment.
   (e) Chromosome analysis.

(4) For the category of histocompatibility, technologist level programs shall at a minimum include instruction in the following competencies:

   (a) Specimen collection, processing, handling and preservation as it relates to histocompatibility testing.
   (b) Principles and techniques of blood typing, HLA typing, HLA antibody screening, and testing for infectious disease makers.
   (c) CDC or flow cytometry crossmatching, HLA antibody identification, lymphocyte immunophenotyping, mixed lymphocyte culture, stem cell culture and immunosuppressive drug analysis.
   (d) Allogenic and autologous bone marrow processing and storage.
   (e) Maintenance and use of instrumentation utilized in the category of histocompatibility testing.
   (f) Immunological principles to perform, assess, and interpret histocompatibility data.

(5) For the category of cytology, technologist level programs shall at a minimum include instruction in the following competencies:

   (a) Specimen preparation, staining and cover slipping.
   (b) Quality control and follow-up.
   (c) Specimen adequacy.
   (d) Review of gynecological and non-gynecological specimens in order to delineate data regarding human cytopathological disease.
   (e) Reporting of results using appropriate diagnostic terminology.

(6) For the category of blood banking, technologist level programs shall adopt the curriculum standards defined in paragraph 64B3-3.003(2)(a), F.A.C., for immunohematology, as well as provide instruction in the following competencies:

   (a) Serology instrumentation and serological principles associated with blood product testing and processing.
   (b) Clinical chemistry instrumentation and chemistry principles associated with blood product testing and processing.
   (c) Hematology instrumentation and hematological principles associated with blood product testing and processing.

(7) For the category of embryology, technician or technologist level programs shall at a minimum include instruction in the following competencies:

   (a) Maintenance and use of instrumentation utilized in the embryology laboratory.
   (b) Principles and techniques for isolating specimens.
(c) Appropriate culture techniques of specimens including principles of culture techniques.
(d) Appropriate handling of specimens.
(e) Quality control and quality assurance.

(8) For the category of andrology, technician or technologist level programs shall at a minimum include instruction in the following competencies:
   (a) Maintenance and use of instrumentation utilized in the category of andrology testing.
   (b) Principles and techniques for isolation specimens.
   (c) Appropriate culture techniques of specimens including principles of culture techniques.
   (d) Appropriate handling of specimens.
   (e) Quality control and quality assurance.

(9) For the category of molecular pathology, technologist level program shall at a minimum include instructions in the following competencies:
   (a) Applies knowledge of basic and special laboratory procedures, sources of error, fundamental characteristics of molecular theory, molecular biology, and molecular genetics.
   (b) Selects appropriate courses of actions for method and test requested.
   (c) Selects and prepares appropriate methods, instruments, reagents, controls and appropriate procedures to verify test results.
   (d) Calculates results and assesses test results by correlating laboratory data with clinical data, quality control data, and physiological process to validate results and procedures.
   (e) Evaluates laboratory data to recognize health and disease states, make identifications, verify test results, resolve inconsistent results and sources of error, take corrective actions, and recognize the need for additional testing.

(10) Technologist level programs shall include administration and supervision instruction which for purposes of this rule shall include:
   (a) General administrative management (planning, supervision, evaluation),
   (b) Personnel management (position specification, personnel practices, recruitment, workload assessment, staffing, employment, evaluation, discipline),
   (c) Financial management,
   (d) Critical management abilities (problem solving, test reporting and review),
   (e) Quality assurance/quality control (reference material/standards, error, statistics, method selection and evaluation, instrumentation, corrective action, and proficiency testing),
   (f) Federal and state laws and regulations,
   (g) Risk management.

(11) Technologist level programs shall additionally cover all pertinent topics listed in the following competencies:
   (a) Evaluate the systems and procedures for controlling, verifying, and correcting laboratory performance for optimum efficiency and minimum cost.
   (b) Evaluate new procedures and instruments.
   (c) Implement and monitor laboratory safety protocols.
   (d) Implement patient and specimen identification and control procedures fulfilling applicable policies and regulations including medico-legal custodial responsibilities.
   (e) Demonstrate knowledge of the principles of curriculum development, instructional methodologies and evaluation strategies.
   (f) Demonstrate knowledge concerning State and Federal regulations, licensure, inspection, liability, and the Patient’s Bill of Rights.
   (g) Demonstrate written communication skills and skills necessary to read and comprehend scientific journals, papers and reports.
CHAPTER 64B3-4 – TRAINEE REGISTRATION

(1) All trainee applicants shall be enrolled in a clinical laboratory training program approved according to Chapter 64B3-3, F.A.C.

(2) An applicant for trainee registration shall apply to the Department Form #DH-MQA 3005 (07/12) “Clinical Laboratory Personnel Trainee” which is incorporated by reference herein copies of which, can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-02066 or the Board office at 4052 Bald Cypress Way, Bin #C07, Tallahassee, Florida 32399-3257 or from the web http://www.doh.state.fl.us/mqa/ClinLab/index.html.

(3) Upon graduation from a Board approved training program, a student who intends to work in a laboratory licensed under Chapter 483, Part I, F.S., shall apply for licensure.

(4) Individuals enrolled in a Board-approved histology program shall be issued a two-year trainee registration.

(5) All trainee applicants shall submit either a certified copy of a high school diploma or its equivalent, or an official transcript from a training program as described in subsection (1) above, sent directly to the Department.

(6) If the trainee is unable to complete the training by the date indicated on the application for initial registration due to the reasons set forth in subsection (7), then the program director is responsible for ensuring that Form #DH-MQA 1165 (10/11) “Request to Extend Trainee Registration”, which is incorporated by reference herein is submitted to the Board. Copies of the form can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-00949 or 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.

(7) Trainee registration may not be extended beyond its expiration date except upon recommendation of the program director and approval by the Board based upon one of the following circumstances:
   (a) Approved training program failed to commence on the date indicated in the training program’s application for approval.
   (b) Trainee withdrew from approved training program and reentered the same or another approved training program at a later date.
   (c) Training program ceases to operate after trainee’s registration.
   (d) Trainee is unable to complete the approved program requirements prior to the expiration date of the trainee’s registration because of extenuating circumstances.

CHAPTER 64B3-5 QUALIFICATION FOR LICENSURE

CHAPTER 6483-5.011 - Definitions

(1) “AAB” means The American Association of Bioanalysts.
(2) “ABB” means The American Board of Bioanalysis.
(3) “ABCC” means American Board of Clinical Chemistry.
(4) “ABD” means American Board of Dermatology.
(5) “ABHES” means The Accrediting Bureau of Health Education Schools.
(6) “ABHI” means The American Board of Histocompatibility and Immunogenetics.
(7) “ABIM” means American Board of Internal Medicine.
(8) “ABMG” means American Board of Medical Genetics.
(9) “ABMLI” means American Board of Medical Laboratory Immunology.
(10) “ABMM” means American Board of Medical Microbiology.
(11) “ABNM” means American Board of Nuclear Medicine.
(12) “ABOP” means American Board of Oral Pathology.
(13) “ABP” means American Board of Pathology.
(14) “AMT” means American Medical Technologists.
(15) “AOBD” means American Osteopathic Board of Dermatology.
(16) “AOBIM” means American Osteopathic Board of Internal Medicine.
(17) “AOBNM” means American Osteopathic Board of Nuclear Medicine.
(18) “AOBP” means American Osteopathic Board of Pathology.
(19) “ASCP” means The American Society for Clinical Pathology.
(20) “BB” means Blood Banking.
(21) “BOC” means ASCP Board of Certification.
(22) “CAAHEP” means The Commission on Accreditation of Allied Health Education Programs.
(23) “CG” means Cytogenetics.
(24) “CHS” means Certified Histocompatibility Specialist.
(25) “CHT” means Certified Histocompatibility Technologist.
(26) “CT” means Cytotechnologist.
(27) “DLM” means Diplomat Laboratory Management.
(28) “ELD” means Embryology Laboratory Director.
(29) “HCLD” means High Complexity Laboratory Director.
(30) “HT” means Histotechnician.
(31) “HTL” means Histotechnologist.
(32) “MB” means Microbiology.
(33) “MLT” means Medical Laboratory Technician.
(34) “MLS” means Medical Laboratory Scientist.
(35) “MP” means Molecular Pathology.
(36) “MT” means Medical Technologist.
(37) “NAACLS” means The National Accrediting Agency for Clinical Laboratory Science.
(38) “NRCC” means the National Registry of Certified Chemists.
(39) “QIHC” means Qualification in Immunohistochemistry.
(40) “SBB” means Specialist in Blood Banking.
(41) “SC” means Specialist in Chemistry.
(42) “SCT” means Specialist in Cytotechnology.
(43) “SH” means Specialist in Hematology.
(44) “SM” means Specialist in Microbiology.
(45) “TS” means Technical Supervisor.
(46) “Academic Science” means college level courses in the areas of chemistry, biology, physiology, anatomy, microbiology, immunology, medical sciences, genetics, and molecular biology, pursuant to subsection 64B3-2.003(6), F.A.C.
(47) “Bachelor’s Degree” means a four year baccalaureate degree from a regionally accredited college or university.
(48) “Bachelor’s Degree in Medical Technology” means a four year baccalaureate degree earned at an accredited program, pursuant to subsection 64B3-2.003(9), F.A.C.
(49) “Medical Technology Training Program” means an ABHES, CAAHEP, NAACLS, board approved training program for clinical/medical laboratory scientists or medical technologists, pursuant to subsections 64B3-2.003(9) and (16), F.A.C., or Department of Defense programs that are equivalent to a board approved training program.
(50) “Semester Hour” means one hour of credit in an accredited college or university, pursuant to subsection 64B3-2.003(1), F.A.C., or foreign education equated, pursuant to subsection 64B3-6.002(6), F.A.C.

CHAPTER 64B3-5.002 - Supervisor - Qualifications and Responsibilities

(1) Qualification. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university or by foreign education equated pursuant to subsection 64B3-6.002(6), F.A.C.

(2) To be licensed as a supervisor, an applicant: shall be licensed or meet the requirements for licensure as a technologist; have a Board approved 2-hour course relating to the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, patient safety; complete a one-hour educational
course acceptable to the Department on human immunodeficiency virus and acquired immune deficiency syndrome; and meet the requirements of one of the options set forth in subsection (3) below:

(3)(c) Histology

**Education: As required by the certifying body**

**Option: 1a**

**Training/Experience:**
- 5 years of pertinent clinical laboratory experience in histology, and
- 25 hours of Board-approved continuing education in supervision and administration within the previous 5 years

**Certification:** HTL (ASCP)

**Option: 1b**

**Training/Experience:**
- 5 years of pertinent clinical laboratory experience post-certification, and
- 48 hours of Board-approved continuing education in supervision and administration within the previous 5 years

**Certification:** HT (ASCP)

**Option: 1c**

**Training/Experience:**
- 5 years of pertinent clinical laboratory experience, and
- 48 hours of Board-approved continuing education in supervision and administration within the previous 5 years, and Florida licensure as a technologist in the specialty of histology

**Certification:** Not Required

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**CHAPTER 64B3-5.003 – Technologist - Qualifications and Responsibilities**

(1) Technologist Qualifications. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university or, if foreign education, equated pursuant to subsection 64B3-6.002(6), F.A.C. Applicants for technologist licensure in the categories of microbiology, serology/immunology, chemistry, hematology, immunohematology, histocompatibility, blood banking, cytology, cytogenticics, histology, molecular pathology, andrology and embryology shall have a Board approved 2-hour course relating to the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety, and such applicants shall complete a one hour educational course acceptable to the Department on human immunodeficiency virus and acquired immune deficiency syndrome.

(2) All applicants for a Technologist license must satisfy the requirements for High Complexity Testing under CLIA Amendments, 42 CFR 493.1489.

(3) In addition, at least one of the following requirements must be met for specific areas of licensure. In some cases there are multiple options for meeting the requirement.

(3)(g) Histology

**Education:** Associate Degree (or higher)

**Option: 1**
Training/Experience: NAACLS-approved Histotechnology Program
Certification: HT(ASCP)

Education: As required by the certifying body
Option: 2a
Training/Experience: as required by the certifying body
Certification: HTL(ASCP) or HT(ASCP)QIHC

(A new proposal was introduced in May 2014 awaiting public comment for final approval):

Education: 60 semester hours 12 hours chemical/biological science
Option: 2b
Training/Experience: board approved training program
Certification: HT(ASCP)

Education: As required by the certifying body
Option: 2b
Training/Experience: as required by the certifying body, 3 years of pertinent experience
Certification: HTL(ASCP) or HT(ASCP)QIHC

CHAPTER 64B3-5.004 – Technician - Qualifications and Responsibilities

(1) General Qualifications. Degrees or semester hours of academic credit required in this section shall be obtained at a regionally accredited college or university, or by foreign education equated pursuant to subsection 64B3-6.002(6), F.A.C. In order to be licensed as a laboratory technician, which includes the categories of microbiology, serology/immunology, chemistry, hematology, immunohematology, histology, molecular pathology, andrology and embryology, an applicant shall have a Board approved 2-hour course relating to the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety. The applicant shall complete a one hour educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome.

(2) All applicants for a Technician license must satisfy the requirements for Moderate Complexity Testing under
(3) In addition, at least one of the following requirements must be met for specific areas of licensure. In some cases there are multiple options for meeting the requirement.

(3)(b) Histology

**Education:** As required by the certifying body  
Option: 1  
**Training/Experience:** As required by the certifying body  
**Certification:** HT(ASCP)

### CHAPTER 64B3-5.007 – Director; Limitations and Qualifications

(1) All applicants for a Director license must have the qualifications for a High Complexity Laboratory Director, listed in 42 CFR 493.1443 as published on October 1, 2007, and complete a Board-approved 2-hour course relating to the prevention of medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety. Such applicants shall also complete a one hour educational course acceptable to the Department on human immunodeficiency virus and acquired immune deficiency syndrome.

(2) In addition, at least one of the following requirements must be met for specific areas of licensure. In some cases, there are multiple options for meeting the requirements.

**a) All Specialties**

<table>
<thead>
<tr>
<th>Education</th>
<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida Licensed physician (does not require a separate laboratory director license)</td>
<td>1a</td>
<td>as required by the certifying body</td>
<td>Certification in Clinical Pathology by the ABP or AOBP</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>as required by the certifying body</td>
<td>Certification in the pertinent laboratory specialty by ABIM, AOBIM, ABMM, ABCC, ABNM, AOBNM, ABMG, ABB, ABMLI, ABHI</td>
</tr>
<tr>
<td></td>
<td>1c</td>
<td>Four years of pertinent clinical laboratory experience (post-graduate), with two years’ experience in the specialty to be directed</td>
<td>Not required</td>
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</table>

**b) Histology, Cytology**

<table>
<thead>
<tr>
<th>Education</th>
<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
</table>
Florida Licensed physician (does not require a separate laboratory director license) & Certification in Anatomical Pathology or Cytopathology by ABP or AOBP. For dermatopathology only, certification in Dermatopathology by the ABD or AOBD

(c) Oral Pathology Laboratories

<table>
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<tr>
<th>Education</th>
<th>Option</th>
<th>Training/Experience</th>
<th>Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida Licensed physician or dentist (does not require a separate laboratory director license)</td>
<td>1</td>
<td>as required by the certifying body</td>
<td>Certification in Anatomical Pathology by ABOP, ABP, or AOBP</td>
</tr>
</tbody>
</table>

**CHAPTER 64B3-6.001 - Manner of Application**


2. After one year from the date of the original submission of an application, a new application and fee shall be required from any applicant who desires to be considered for licensure.
With regard to persons who have been issued a social security number by the Federal Government, disclosure of a social security number is mandatory pursuant to Section 456.013(1)(a), F.S., and social security numbers are 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

The following is a list of acceptable documents, which shall be submitted to the Board as appropriate for the type of license sought to show eligibility for the license:

1. Official transcript sent directly from the institution.
2. A civil notarized copy of high school diploma.
3. Certified copy of a diploma, training certificate or Department of Defense form DD-214 or any other document, which verifies pertinent education and experience.
4. A civil notarized copy of certificate of attendance or documentation of training required pursuant to Chapters 64B3-3 and 64B3-4, F.A.C., and continuing education required pursuant to Chapter 64B3-11, F.A.C., including one (1) hour HIV/AIDS continuing education, and the 2-hour course on medical error prevention.
5. Civil notarized copies of documents of foreign education and translation, if appropriate.
6. Foreign credentials evaluation which includes a breakdown of all college level courses by credit hours and subject sent directly to the board office by one of the following evaluators:
   - A regionally accredited U.S. college or university.
   - American Society for Clinical Pathology Board of Certification.
   - National Accrediting Agency for Clinical Laboratory Sciences.
   - Center for Applied Research, Evaluation & Education, Inc.
   - Foundation for International Services, Inc.
   - Educational Credential Evaluators, Inc.
   - National Consultants of Delaware, Inc.
   - Education Evaluators International, Inc.
   - International Education Research Foundation, Inc.
   - Education International.
   - Foreign Academic Credentials Services, Inc.
   - World Education Services, Inc.
7. Individuals with a baccalaureate degree in accredited medical technology programs from accredited institutions in the Philippines need only submit official transcripts sent directly by the institution to the Board office. No foreign credentials evaluation is necessary.
8. Applicants with a degree from a regionally accredited U.S. college or university whose major is not a chemical or biological science may submit an evaluation of the applicant’s academic record from the chairperson of a chemical or biological science department of a regionally accredited U.S. college or university to demonstrate that the applicant’s education is equivalent to a U.S. degree in the chemical or biological sciences.
CHAPTER 64B3-6.003 - Personnel Licensure – Temporary License

(1) The Department shall issue a temporary license to an applicant who has applied and satisfied all Department application requirements for licensure and has been accepted to take a Board approved national examination for a period not to exceed one year.

(2) An applicant who fails an examination shall no longer be permitted to work and shall not receive a second temporary license to be employed at that licensure level.

(3) An applicant who does not appear to take an examination shall not receive a second temporary license to be employed and the temporary license currently held shall be invalid as of that date.

CHAPTER 64B3-7.005 - Security and Monitoring Procedures for Licensure Examination

Repealed. The state of Florida no longer offers their own examination for any of the clinical laboratory personnel licensure. All licensure are granted based on national certifying bodies and board rules.

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

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 of Inactive Clinical Laboratory Personnel License.

(1) A clinical laboratory personnel licensee may elect at any time to place the license into an inactive status by filing with the Board a complete application for inactive status and paying the inactive status fee of Rule 64B3-9.006, F.A.C. For the purpose of this section, a complete application shall be a renewal form provided by the Department on which the licensee affirmatively elects inactive status.

(2) An inactive status licensee may change to active status at any time provided the licensee meets the following continuing education. For licenses that have been inactive for one (1) year or less, the licensee must obtain twelve (12) hours of board approved continuing education. For licenses that have been inactive for one (1) year and (1) day or longer, the licensee shall obtain twenty-four (24) hours of board approved continuing education. The licensee shall be requested to provide copies of all continuing education hours; and
   (a) Pay the active status fee of Rule 64B3-9.004, F.A.C.; and
   (b) Pay the reactivation fee of Rule 64B3-9.005, F.A.C.; and
   (c) Pay, if applicable, the change of status fee of Rule 64B3-9.010, F.A.C.

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

(1) An approved training program shall renew biennially.

(2) The training program shall submit a renewal application and renewal fee to the Department.

(3) The training program renewal application shall include the following:
   (a) Names of the program director and all instructors, and if applicable the license number of the director and instructors, and submit a resumé, if the director has changed.
   (b) Name, address, license number, personnel roster, and most current licensure or certification survey report of the laboratory sponsoring the training program, if applicable, and all clinical affiliates.
CHAPTER 64B3-8.004 - Renewal of Clinical Laboratory Personnel Continuing Education Provider License

(1) The provider shall submit a biennial renewal application and renewal fee to the Department.

(2) The provider shall indicate any changes in the contact person and course offerings.

CHAPTER 64B3-8.005 - Delinquent License.

(1) The failure of a 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 either the active status fee of Rule 64B3-9.004, F.A.C., or the inactive status license fee of Rule 64B3-9.006, F.A.C., the delinquent license fee of Rule 64B3-9.011, F.A.C., and, if applicable, the change of status fee of Rule 64B3-9.010, F.A.C.; and
   (b) Demonstrate compliance with the continuing education requirements of Rules 64B3-11.001 and 64B3-8.002, F.A.C.

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 requirement for that biennium.
### CHAPTER 64B3-9.001 - Application Fees

<table>
<thead>
<tr>
<th>Permit/Application</th>
<th>Fee</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>Clinical Laboratory Personnel Training Program</td>
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<tr>
<td>Continued Education Provider</td>
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<tr>
<td>Public Health Science Technician</td>
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### CHAPTER 64B3-9.002 - Initial Licensure Fees.

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### CHAPTER 64B3-9.0035 - Additional Specialty Fee

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### CHAPTER 64B3-9.004 - Active Status Renewal Licensure Fee

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### CHAPTER 64B3-9.005 - Reactivation Fee

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### CHAPTER 64B3-9.0051 - Retired Status Fee

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### CHAPTER 64B3-9.006 - Fee for Inactive Status

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### CHAPTER 64B3-9.008 - Request to Extend Trainee Registration

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<tr>
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</table>
**CHAPTER 64B3-9.009 - Duplicate License Fee**

| Duplicate License Fee | $25.00 |

**CHAPTER 64B3-9.010 - Change of Status**

| Change of Status Fee | $50.00 |

* A licensee shall pay a change of status fee when the licensee applies for a change in licensure status at any time other than during licensure renewal.

**CHAPTER 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.

**CHAPTER 64B3-9.012 - Unlicensed Activity Fee**

| Unlicensed Activity Fee | $5.00 |

* An unlicensed activity fee shall be assessed on behalf of the Department, as part of initial licensure and each subsequent renewal, in addition to the current licensure and renewal fees.

**CHAPTER 64B3-10 Scope of Practice for Clinical Laboratory Personnel**

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

The following rules are not intended to prevent collection and storage of specimens or the performance of manual pretesting procedures by persons who are exempt by statute or statutorily authorized within their scope of practice. Clinical laboratory personnel qualified as a physician director, a licensed director, supervisor, technologist or technician in the specialty or specialties indicated can perform testing identified as being within the specialty. Tests, which are not yet classified shall be assigned by the Board upon review.

(11) 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. This 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.

**CHAPTER 64B3-11 CONTINUING EDUCATION**

**CHAPTER 64B3-11.001 - Continuing Education (Amended 3-18-2014)**

(1) In order to renew a clinical laboratory personnel license, a minimum of 24 contact hours of continuing education shall be earned during each biennium including a minimum of one contact hour for each of the categories in which the individual is licensed, and one contact hour of continuing education on HIV/AIDS. Also, as a part of the 24 continuing education hours, each licensee shall take a Board approved 2-hour course relating to the prevention of
medical errors, which shall include root-cause analysis, error reduction and prevention, and patient safety, as it relates to the practice of clinical laboratory personnel. Directors and supervisors are required to obtain one contact hour of continuing education in administration and supervision. As part of the minimum of 24 contact hours of continuing education, each licensee shall be required to take a one hour course on Florida laws and rules governing clinical laboratory personnel or attend a public meeting of the full Board at which disciplinary actions are addressed. A telephone conference call meeting of the Board will not satisfy this requirement.

(2) A licensee may choose to surrender 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 continuing education certificates of attendance received from approved providers for a minimum of four years.

(4) Applicants initially licensed (first time ever) are exempt from the continuing education 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 required 1 contact hour of continuing education in that category.

(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 areas specified in subsection 64B3-11.002(1), F.A.C.

(d) One semester hour equals 15 contact hours and one quarter hour equals 10 contact hours.

(7) A random sample of licensees shall be audited by the Department to determine compliance with the continuing education requirement. Within 30 calendar days of notification of selection, licensees selected for audit shall submit to the Department a certified copy of each certificate of attendance provided to the licensee under subsection 64B3-11.003(5), F.A.C., since the date of the last license 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.

**CHAPTER 64B3-11.002 - Standards for Continuing Education Courses**

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

(1) Provide subject matter from one or more of the following:

(a) Clinical laboratory sciences practice areas.

(b) Legal aspects of clinical laboratory sciences practice, state and federal regulation 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 that completed for current licensure.
(e) HIV/AIDS which shall include the minimum course content set forth in Rule 64B3-11.005, F.A.C.
(f) Latest developments in clinical laboratory methods, instrumentation, information systems and discoveries in biology, chemistry and medicine as 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 scheduled 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 at 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

Programs seeking Board approval shall meet the following requirements:

(1) All educational courses conducted within the program shall meet the standards for continuing education courses as outlined in Rule 64B3-11.002, F.A.C.

(2) Programs shall receive a program number upon approval and shall use this number on all correspondence with the Board and the Department.

(3) Providers shall initially designate and subsequently update as appropriate a person to assume responsibility for continuing education courses for clinical laboratory personnel.

(4) A system of record keeping shall be maintained which provides for storage of individual course information for a period of at least 3 years.

(5) Each participant shall be provided with an authenticated certificate or letter of attendance which shall include the participant’s name, license number, course title, number of contact hours earned by specialty area, dates of attendance, program provider’s name, approval number, and the signature of the provider.

CHAPTER 64B3-11.004 - Procedures for Approval of Provider Programs.

The provider seeking approval:

(1) Shall apply to the Department using Form DH 1052, (7/97), incorporated by reference herein and available by request to the Board, and submit the application fee set forth in Rule 64B3-9.001, F.A.C., prior to the first course being offered.

(2) Shall be granted initial approval for the biennium in which the application is submitted.

(3) Shall be subject to periodic review. Approval may be withdrawn if the Board determines that adherence to standards outlined in Rule Chapter 64B3-11, F.A.C., is not maintained or if information submitted to the Board by
the provider is found to be a material misrepresentation of fact.

(4) Shall use the program approval numbers, if applicable.

(5) Shall be granted authority to give continuing education courses without additional Board approval once they are offered by a program with approval status.

(6) Shall demonstrate continued compliance with the requirements of Rules 64B3-11.002 and 64B3-11.003, F.A.C., through periodic review and random audits of continuing education offerings. Audits shall be conducted for cause and randomly during renewal of the continuing education program.

CHAPTER 64B3-11.005 - Mandatory HIV/AIDS Education for Initial Licensure and Renewal

Applicants for initial licensure and renewal shall complete a one hour HIV/AIDS continuing education course pursuant to Section 381.0034, F.S., which shall be offered by an approved provider in accordance with Rule 64B3-11.004, F.A.C., or be an approved provider of any Board within the Department's Division of Medical Quality Assurance. (Changed 3-18-14)

CHAPTER 64B3-12 DISCIPLINE

Disciplines are sanctioned by the board following the established rules under Chapter 483, Part III of the Florida Statutes. Fines are given according to the established fees by the statutes.

64B3-12.001 Disciplinary Guidelines.

(1) Purpose. The Board provides within this rule disciplinary guidelines, which shall be imposed upon applicants, registrants or licensees whom it regulates under Chapter 483, Part III, F.S. The purpose of this rule is to notify applicants, registrants and licensees of the ranges of penalties which will routinely be imposed unless the Board finds it necessary to deviate from the guidelines for the stated reasons given within this rule. The ranges of penalties provided below are based upon a single count violation of each provision listed and also are provided for repeat violations; multiple counts of the violated provisions or a combination of the violations may result in a higher penalty than that for a single, isolated violation. Each range includes the lowest and highest penalty and all penalties falling between. The purposes of the imposition of discipline are to punish the applicants, registrants or licensees for violations and to deter them from future violations; to offer opportunities for rehabilitation, when appropriate; and to deter other applicants, registrants or licensees from violations.

(2) Violations and Range of Penalties. For applicants, all violations are sufficient for refusal to certify an application for licensure. For registrants or licensees, the imposition of probation as a penalty shall ordinarily require compliance with conditions such as restitution, continuing education and/or training, indirect or direct supervision by a Board-approved monitor, restrictions on practice, submission of reports, appearances before the Board, and/or hours of community service. As appropriate, such conditions of probation also shall be required following any period of suspension. In addition to any other discipline imposed, the Board shall assess the actual costs related to the investigation and prosecution of a case. In imposing discipline pursuant to Sections 120.57(1) and (2), F.S., the Board shall act in accordance with the following disciplinary guidelines and shall impose a penalty as authorized by Section 456.072(2), F.S., within the range corresponding to the violations set forth below. Offense identifications are descriptive only; the full language of each statutory provision must be considered in order to determine the conduct included.

(a) Section 483.825(1)(a) or 456.072(1)(h), F.S.: Attempting to obtain, obtaining, or renewing a license or registration under this part by bribery – from a minimum fine of $500 and/or up to two years of probation to a maximum of permanent revocation. After the first offense, from a minimum fine of $5,000 up to a
maximum fine of $10,000 and/or permanent revocation.
1. Fraudulent misrepresentation – from six months probation and a fine of $10,000 to a maximum of permanent revocation and a fine of $10,000. For a second offense, a fine of $10,000 and permanent revocation.
2. Error of the Department or the Board – from a minimum letter of concern and/or a $500 fine up to a maximum of suspension for one year followed by two years of probation and a fine of $5,000. For a second offense, from a minimum fine of $3,000 to permanent revocation of license. After the second offense, up to a maximum fine of $10,000 and/or permanent revocation.

(b) Section 483.825(1)(b), F.S.: Engaging in or attempting to engage in, or representing oneself as entitled to perform, any clinical laboratory procedure or category of procedures not authorized pursuant to the license – from a minimum fine of $300 and/or one year of probation to a maximum fine of $5,000 and/or two years of probation. After the first offense, from a minimum fine of $1,000 and/or two years of probation to a maximum fine of $10,000 and/or permanent revocation, however, regardless of whether it is an initial or repeat occurrence, if the violation is for fraud or knowingly making a false or fraudulent representation, the fine portion of the discipline imposed shall be $10,000 per count or offense.

(c) Section 483.825(1)(c), F.S.: Demonstrating incompetence or making consistent errors in the performance of clinical laboratory examinations or procedures or erroneous reporting – from a minimum fine of $300 and/or two years probation to a maximum fine of $5,000 and/or six months suspension. For a second offense, from a minimum fine of $750 and one year of probation to a maximum fine of $5,000 and/or permanent revocation. After the second offense, up to a maximum fine of $10,000 and/or permanent revocation.

(d) Section 483.825(1)(d), F.S.: Performing a test and rendering a report thereon to a person not authorized by law to receive such services – from a minimum fine of $500 and/or six months of probation to a maximum fine of $1,500 and one year of suspension. For a second offense, from a minimum fine of $750 and six months of probation to a maximum fine of $5,000 and/or up to three years suspension. After the second offense, up to a maximum fine of $10,000 and/or permanent revocation.

(e) Section 483.825(1)(e) or 456.072(1)(c), F.S.: Having been convicted of a crime relating to the practice or ability to practice or involving moral turpitude – from a minimum fine of $500 and/or one year of probation to a maximum fine of $6,000 and/or permanent revocation. After the first offense, from a minimum fine of $1,000 and/or two years of probation to a maximum fine of $10,000 and/or permanent revocation.

(f) Section 483.825(1)(f), F.S.: Having been adjudged mentally or physically incompetent from a minimum of supervised probation to a maximum of indefinite suspension until the licensee is 1) able to demonstrate ability to practice with reasonable skill and safety and 2) has completed appropriate remedial education based on the length of time that the licensee has been unable to practice.

(g) Section 483.825(1)(g), 483.825(1)(w), 456.072(1)(b) or 456.072(1)(dd), F.S.
1. Violating or aiding and abetting in the violation of any provision of Chapter 456 or Chapter 483, Part III, F.S., or the rules adopted thereunder – from a minimum fine of $500 and/or a reprimand to a maximum fine of up to $8,000 and/or permanent revocation. For a second offense, from a minimum fine of $1,000 and/or six months of probation to a maximum fine of $10,000 and/or permanent revocation. After the second offense, from a minimum fine of $1,500 and/or one year of probation to a maximum fine of $10,000 and/or permanent revocation.
2. Section 456.072(1)(e) or 456.072(1)(s), F.S.: In the case of noncompliance with a continuing education or HIV/AIDS or domestic violence course requirement, which is not a citation offense.
under Section 456.072(3), F.S., – from a minimum of suspension until the required continuing education hours are earned and/or a fine of $500 up to a maximum fine of $5,000 and/or permanent revocation.

(h) Section 483.825(1)(h), F.S.: Reporting a test result when no laboratory test was performed on a clinical specimen – fine of $10,000 and/or permanent revocation.

(i) Section 483.825(1)(i) or 456.072(1)(m), F.S.: Knowingly advertising false services or credentials or making fraudulent misrepresentations or employing a trick or scheme – from six months of probation and a fine of $10,000 per count or offense up to a maximum of one year suspension followed by two years of probation. After the first offense, from a minimum of two years of probation with a fine of $10,000 per count or offense up to a maximum of permanent revocation and a $10,000 fine per count or offense.

(j) Section 483.825(1)(j) or 456.072(1)(f), F.S.: Having a license revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of another jurisdiction – Imposition of discipline comparable to the discipline which would have been imposed if the substantive violation had occurred in Florida. After the first offense, action consistent with the disciplinary guidelines for a repeat offense had the violation occurred in Florida.

(k) Section 483.825(1)(k), 456.072(1)(w) or 456.072(1)(x), F.S.: Failing to report to the Board in writing within 30 days of conviction, adjudication of incompetency, or if disciplinary action has been taken against one’s license as clinical laboratory personnel in another state, territory or country – from a minimum fine of $750 and/or a letter of concern up to a maximum fine of $5,000 and/or three months suspension followed by probation. After the first offense, from a minimum fine of $3,000 up to a maximum fine of $10,000 and/or permanent revocation.

(l) Section 483.825(1)(l), 456.072(1)(aa) or 456.072(1)(z), F.S.: Being unable to perform or report clinical laboratory examination 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 or testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer-ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the drug – from a minimum referral for a PRN evaluation up to permanent revocation for non-compliance. After the first offense, from a minimum referral for a PRN evaluation up to maximum of permanent revocation and/or a $3,000 fine.

(m) Section 483.825(1)(m), 456.072(1)(j) or 456.072(1)(p), F.S.: 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 or aiding unlicensed person to practice – from a minimum fine of $800 and/or six months of probation up to a maximum fine of $5,000 and three years suspension of license followed by up to 2 years probation. For a second offense, from a minimum fine of $1,000 and one year of probation up to a maximum fine of $7,500 and/or permanent revocation. After the second offense, from a minimum fine of $2,000 and/or six months suspension followed by probation up to a maximum of permanent revocation and/or a fine of $10,000.

(n) Section 483.825(1)(n) or 456.072(1)(q), F.S.: Violating an order or failing to comply with subpoena – from a minimum fine of $500 and a reprimand up to a maximum fine of $5,000 and/or three years suspension of license followed by a term of probation. For a second offense, from a minimum fine of $1,500 and/or two years of probation up to a maximum fine of $10,000 and/or permanent revocation of license. After the second offense, from a minimum fine of $5,000 and/or six months of suspension.
followed by probation up to a maximum fine of $10,000 and/or permanent revocation of license.

(o) Section 483.825(1)(o) or 456.072(1)(i), F.S.: Failing to report a person in violation of Part III of Chapter 483, Chapter 456, F.S., or the applicable rules – from a minimum fine of $800 and a letter of concern up to a maximum fine of $2,000 and/or six months suspension followed by probation. After the second offense, from a minimum of six months probation and/or a fine of $1,000 up to a maximum fine of $10,000 and/or permanent revocation.

(p) Section 483.825(1)(p) or 456.072(1)(l), F.S.: Negligent filing of false report – from a minimum fine of $500 and a letter of concern up to a maximum fine $3,000 fine and/or up to three years of probation. For a second offense, from a minimum fine of $1,500 and a reprimand to a maximum fine of $10,000 and/or two years suspension followed by probation. After the second offense, up to a maximum fine of $10,000 and/or permanent revocation.

(q) Section 483.825(1)(p), 456.072(1)(g), or 456.072(1)(l), F.S.: Willful filing of false report, impeding, or inducing another to file a false report – from a minimum fine of $2,000 and/or suspension of license for three months followed by six months of probation up to a maximum fine of $8,000 and/or permanent revocation of license. After the first offense, up to a maximum fine of $10,000 and/or permanent revocation; however, regardless of whether it is an initial or repeat occurrence, if the violation is for fraud or knowingly making a false or fraudulent representation, the fine portion of the discipline imposed shall be $10,000 per count or offense.

(r) Section 483.825(1)(q), F.S.: Paying or receiving a kickback, bonus, or split fee arrangement – from a minimum fine of $1,000 and/or one year probation up to a maximum fine of $10,000 and/or permanent revocation. After the first offense, from a minimum fine of $1,500 and two years of probation up to a maximum fine of $10,000 and/or permanent revocation.

(s) Section 483.825(1)(r) or 456.072(1)(n), F.S.: Exercising influence or exploitation for financial gain – from a minimum fine of $1,000 and/or restitution of improper gains and six months of probation to a maximum fine of $10,000 and/or permanent revocation. After the first offense, up to a maximum fine of $10,000 and/or permanent revocation.

(t) Section 483.825(1)(s) or 456.072(1)(o), F.S.: Practicing or offering to practice beyond the scope permitted or competent to perform – from a minimum fine of $1,000 and/or one year of probation up to a maximum fine of $10,000 and/or permanent revocation. After the first offense, up to a maximum fine of $10,000 and/or permanent revocation.

(u) Section 483.825(1)(t) or 456.072(1)(a), F.S.: Misrepresenting or concealing a material fact or fraudulent representations – from a minimum of six months of probation and a fine of $10,000 per count or offense up to a maximum of permanent revocation and a fine of $10,000 per count or offense. After the first offense, from a fine of $10,000 per count or offense as well as a minimum of one year of suspension followed by probation up to a maximum of permanent revocation.

(v) Section 483.825(1)(u) or 456.072(1)(r), F.S.: Improperly interfering with an investigation or disciplinary proceeding – from a minimum fine of $1,000 and/or one year of probation up to a maximum fine of $10,000 and/or permanent revocation. After the first offense, from a minimum fine of $2,000 and two years of probation up to a maximum fine of $10,000 and/or permanent revocation.

(w) Section 483.825(1)(v) or 456.072(1)(v), F.S.: Engaging or attempting to engage in sexual misconduct
– from a minimum reprimand and/or referral for PRN evaluation up to a maximum fine of $10,000 and/or permanent revocation. After the first offense, from a minimum year of probation and fine of $1,500 to a maximum fine of $10,000 and/or permanent revocation.

(x) Section 456.072(1)(k), F.S.: Failing to perform any legal obligation – from a minimum fine of $500 and/or a reprimand to a maximum fine of up to $8,000 and/or permanent revocation. After the first offense, from a minimum fine of $1,000 and/or one year of probation to a maximum fine of $10,000 and/or permanent revocation.

(y) Section 456.072(1)(hh), F.S.: Being terminated from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant, as described in Section 456.076, F.S., for failure to comply without good cause, with the terms of the monitoring or treatment contract entered into by the licensee, or for not successfully completing any drug-treatment or alcohol treatment program – from a minimum fine of $500 to $1000 and suspension until compliant up to permanent revocation.

(z) Section 456.072(1)(ii), F.S. for being convicted of or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to Medicaid program-from a minimum of permanent revocation and a fine of $10,000, or in the case of application for licensure, denial of license.

(aa) Section 456.072(1)(jj), F.S., for failing to remit the sum owed to state for an overpayment from Medicaid program pursuant to a final order, judgment, or stipulation or settlement – from a minimum of a letter of concern to probation and a fine of $500 to a maximum of a reprimand to permanent revocation and fine of $2,500 for a first offense. After the first offense, from a minimum of suspension and $5,000 fine to maximum of permanent revocation and $10,000 fine.

(bb) Section 456.072(1)(kk), F.S., for being terminated from the state Medicaid program pursuant to Section 409.913, F.S., any other state Medicaid program, or the federal Medicare program, unless eligibility to participate in the program from which the practitioner was terminated has been restored – from a minimum of letter of concern and $1,000 fine to maximum of reprimand to permanent revocation and $5,000 fine. After the first offense, from a minimum of suspension and $5,000 fine to maximum of permanent revocation and $10,000 fine.

(cc) Section 456.072(1)(ll), F.S., for being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud – permanent revocation or denial of license (minimum and maximum same).

(3) Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. If the Board finds aggravating factors, the Board shall impose a more severe action against the license and a higher administrative fine. If the Board finds mitigating factors, the Board shall impose a less severe action against the license and a lower administrative fine. The Board shall consider as aggravating or mitigating factors the following:

(a) The positive or negative intentions or motivations surrounding the Respondent’s actions or failure to act.
(b) The severity of the actual or potential harm;
(c) The extent to which the provisions of Chapter 483, F.S., were violated;
(d) Actions taken by the licensee to correct the violation or to remedy complaints;
(e) Any previous discipline imposed for violation of a different guideline by the licensee;
(f) The financial benefit to the licensee of committing or continuing the violation.
(g) Any other relevant mitigating or aggravating factors.

(4) Stipulations or Settlements. The provisions of this rule are not intended and shall not be construed to limit the ability of the Board to dispose informally of disciplinary action by stipulation, agreed settlement, or consent order pursuant to Section 120.57(4), F.S.

(5) Letters of Guidance. The provisions of this rule cannot and shall not be construed to limit the authority of the probable cause panel of the Board to direct the Department to send a letter of guidance pursuant to Section 456.073(4), F.S., in any case for which it finds such action appropriate.

(6) Other Action. The provisions of this rule are not intended to and shall not be construed to limit the ability of the Board to pursue or recommend that the Department pursue collateral civil or criminal actions when appropriate.

CHAPTER 64B3-12.002 - Citations.

(1) “Citation” means an instrument which meets the requirements set forth in Section 456.077, F.S., 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 the subject correct the violation, if remediable, within a specified period of time not to exceed 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) In lieu of the disciplinary procedures contained in Section 456.073, F.S., the Department may issue a citation to the subject within six months after the filing of the complaint which is the basis for the citation.

(3) The Board designates the following offenses as citation violations, which shall result in a penalty of $250:
   (a) Failure to pay one of the licensure renewal fees set forth in Rule 64B3-9.004, F.A.C., during which time the person continues to practice for up to 60 days.
   (b) Attempting to pay any of the fees set forth in Chapter 64B3-9, F.A.C., by tendering a check payable to the Board of Clinical Laboratory Personnel or to the Department of Health that is dishonored by the institution upon which it is drawn.
   (c) Failure to notify the Department of a change of address within 60 days as required by Rule 64B3-1.006, F.A.C.
   (d) Failure to respond to a continuing education audit as required by subsection 64B3-11.001(7).
   (e) Failure to pay any of the fees set forth in Chapter 64B3-9, F.A.C.
   (f) 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 as required by Section 456.072(1)(x), F.S.
   (g) 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.
   (h) Failure to comply with a portion of a Final Order of the Board due to negligence pursuant to Section 483.825(1)(n), F.S.

(4) Failure to comply with and document continuing education requirements shall result in a fine of $50.00 per hour missing or incomplete.

(5) In addition to the penalties established in this rule, the Department shall recover the costs of investigation. The penalty specified in the citation shall be the sum of the penalty established by this rule plus the Department’s cost of investigation.
(6) If the subject disputes any matter contained in the citation, within thirty days after service, the Department shall follow the procedure set forth in Section 456.073, F.S. Otherwise, the citation shall become a final order of the Board.

(7) The Department shall report to the Board regarding the number of citations issued and the nature of the offenses for which they were issued.

**CHAPTER 64B3-12.003 - Terms of Probation.**

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

1. Probationer’s license is suspended for a period of time set by the Board, said suspension to be stayed so long as the licensee complies with the terms of probation set forth below.

2. The licensee is placed on probation for a period of time set by the Board. Any deviation from the requirements of the probation without prior written consent of the Board shall constitute a violation of this probation. Upon a finding of probable cause that a violation of this probation has occurred, the licensee’s license shall be subject to immediate and automatic suspension upon the recommendation of the Probable Cause Panel pending the licensee’s appearance before the next Board meeting. The licensee will be given notice of the hearing and an opportunity to defend. The probationary period shall automatically terminate at the end of a prescribed time, but only if all terms and conditions have been met. Otherwise, the probation shall be terminated only by order of the Board upon proper petition of the licensee, supported by evidence of compliance with the Final Order.

3. The licensee’s probation shall be subject to the following terms and conditions:
   a. Probationer shall comply with all state statutes and rules pertaining to clinical laboratory personnel in Chapters 456 and 483, Part III, F.S., and the rules of the Board.
   b. Probationer shall appear before the Board at the first meeting after said 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 Probationer leaves the State of Florida for a period of thirty days or more, or otherwise does not engage in practice in Florida, Probationer’s probation shall be tolled and shall remain in a tolled status until Probationer returns to active practice in the State of Florida, at which time the probationary status shall resume. Probationer must keep current residence and business addresses on file with the Board. Probationer shall notify the Board within ten (10) days of any changes of said addresses.
   d. Probationer shall practice only under the supervision of a clinical laboratory person licensed under Chapter 483, Part III, F.S., to be approved by the Board or its designee. Probationer shall have the supervising person with the Probationer at the Probationer’s first probation appearance before the Board. Prior to approval of the supervising person by the Board or its designee, the Probationer shall provide to the supervising person a copy of the administrative complaint filed in this case. A failure of the Probationer or the supervising person to appear at the scheduled Board meeting shall constitute a violation of the Board’s Final Order. Prior to the approval of the supervising person by the Board or its designee, Probationer shall submit to the Board or its designee a current curriculum vitae and description of the current practice from the proposed supervising person. Said materials shall be received in the Board office no later than 14 days before Probationer’s first scheduled probation appearance. Probationer shall be responsible for ensuring that the supervising person submits the required reports.

   **The responsibilities of the supervising person shall include:**
   1. Submit quarterly reports, which shall include:
a. Brief statement 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.
e. Detail any problems which may have arisen with Probationer.

2. Review a percentage of records which reflect the Probationer’s practice and performance which may include but not be limited to patient reports, proficiency testing, quality control records, calibration, preventive maintenance and any other pertinent records.

3. Consult with Probationer’s immediate superior at work regarding Probationer’s performance.

4. Review Probationer’s use of pharmaceutical agents.


(e) Probationer shall submit quarterly reports to the Board. The reports shall include:
   1. Brief statement of why Probationer is on probation.
   2. Practice location.
   3. Description of current practice stating type and composition.
   5. Description of relationship with the supervising person.
   6. Description of any problems.
   7. Notarized copies of a number of records which reflect the practice and performance of the Probationer within the previous 30 days with all identification of patient suitably obliterated, if appropriate.

(f) Probationer shall obtain a number of Continuing Education credits in specific areas, within a number of months/year(s), in addition to those hours required for renewal of licensure.

(g) Probationer shall see a psychiatrist, psychologist or psychotherapist approved by the Board or its designee at least the specified number of visits for evaluation and treatment.

(h) Probationer shall not consume, inject or ingest any controlled substance unless prescribed or administered by a practitioner authorized by law to prescribe or dispense controlled substances. However, the drugs shall only be consumed, injected or ingested for a medically justifiable purpose.

(i) Probationer shall not consume alcohol.

(j) Probationer shall attend AA or NA meetings on a frequency of at least one meeting per week.

(k) Probationer shall submit to random blood and/or urine testing for the purpose of ascertaining Probationer’s compliance with probation.

(l) Probationer shall pay all reasonable costs of obtaining random urine and/or blood screens.

(4) Probationer shall pay an administrative fine in the amount set by the Board and comply with Rule 64B3-12.006, F.A.C.

**CHAPTER 64B3-12.004 - Mediation Offenses**

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 456.078, F.S., as these violations are economic in nature or can be remedied by the licensee:

(1) Failure of the licensee to comply with Rule 64B3-12.006, F.A.C., or with a Final Order with regard to the time limitation for the payment of fines or costs under Section 483.825(1)(n), F.S.
(2) Failure of the licensee to timely respond to a continuing education audit as required by subsection 64B3-11.001(7), F.A.C.

(3) Attempting to pay any of the fees set forth in Chapter 64B3-9, F.A.C., by tendering a check payable to the Board of Clinical Laboratory Personnel or to the Department of Health that is dishonored by the institution upon which it is drawn.

(4) Failure to notify the Department of a change of address within 60 days as required by Rule 64B3-1.006, F.A.C.

(5) Failure to complete continuing education in a specialty area solely because the subject contends that he or she was unaware that according to the Board’s records 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, as required by Rule 64B3-11.001, F.A.C.

**CHAPTER 64B3-12.005 - Notice of Noncompliance.**

(1) In accordance with Section 456.073(3), F.S., and Section 120.695, F.S., when a complaint is received, 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 the 15 days after notice may result in either the issuance of a citation when appropriate or the institution of regular disciplinary proceedings. “Minor violations” as used in Section 456.073(3), F.S., and Section 120.695, F.S., are defined as follows:

(2) Failure to notify of a change of address within 60 days as required by Rule 64B3-1.006, F.A.C.

(3) Attempting to pay any of the fees set forth in Chapter 64B3-9, F.A.C., by tendering a check payable to the Board of Clinical Laboratory Personnel or to the Department of Health that is dishonored by the institution upon which it is drawn.

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

In cases where the Board of Clinical Laboratory Personnel imposes an administrative fine and/or costs, the fine and/or costs shall be paid within thirty (30) days from the date 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.

**CHAPTER 64B3-13 RESPONSIBILITIES OF CLINICAL LABORATORY PERSONNEL**

**CHAPTER 64B3-13.001 - Responsibilities of Directors.**

(1) The director is the responsible head of the clinical laboratory and is responsible for the overall operation and administration of the clinical laboratory, including the employment of personnel who are competent to perform the procedures or tasks assigned to them, and also including the prompt, accurate and proficient performance, recording and reporting of test results, and is responsible for assuring compliance with all applicable state and federal laws, rules, and regulations.

(2) The director, if qualified or licensed as applicable under Rule Chapter 64B3-5, F.A.C., may perform the duties of a supervisor or technologist in the specialty(ies) for which they are qualified or licensed or delegate these responsibilities to personnel licensed according to Rule Chapter 64B3-5, F.A.C.
(3) A director not certified by the American Board of Pathology in clinical pathology or by the American Board of Oral Pathology, the American Board of Pathology, or the American Osteopathic Board of Pathology who is directing a clinical laboratory performing highly complex testing, shall ensure a co-director certified by the American Board of Pathology in clinical pathology or by the American Board of Oral Pathology, the American Board of Pathology, or the American Osteopathic Board of Pathology is available to provide clinical consultation and technical supervision consistent with the scope and volume of highly complex testing being performed as defined in 42 C.F.R. 493.5 as published on October 1, 2007 and 42 C.F.R. 493.17 as published on October 1, 2007 which are incorporated by reference. Directors certified by the American Board of Oral Pathology, the American Board of Pathology, or the American Osteopathic Board of Pathology shall provide clinical consultation only in the specialty area(s) for which they are board certified or have 4 years of pertinent clinical laboratory experience.

(4) Each director shall not direct more than 5 clinical laboratories.

(5) The director can delegate performance of responsibilities to licensed supervisors, with the exception of the approval, signing and dating of procedures. However, the director remains responsible for ensuring that all duties are properly performed. The delegation of responsibilities must be written and specific.

(6) The laboratory director shall:

(a) Be accessible to the clinical laboratory to provide on-site, telephone or electronic consultation as needed. This responsibility may not be delegated except to a clinical laboratory director.

(b) Ensure that testing systems developed and used for each of the tests performed in the clinical laboratory provide for quality clinical laboratory services for all aspects of test performance which includes the preanalytic, analytic and postanalytic phases of testing.

(c) Ensure that the physical plant and environmental conditions of the clinical laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical and biological hazards.

(d) Ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

(e) Ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent characteristics of the method.

(f) Ensure that clinical laboratory personnel are performing the test methods as defined in the clinical laboratory’s policies and procedures for accurate and reliable results.

(g) Ensure that the clinical laboratory successfully participates in a proficiency testing program for the testing performed which meets the requirements of Rule Chapter 59A-7, F.A.C.

(h) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the clinical laboratory’s performance and to identify any problems that require corrective action.

(i) Ensure that an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

(j) Ensure that quality control and quality assurance programs are established and maintained to assure the quality of clinical laboratory services provided and to identify and correct failures in quality as they occur.

(k) Ensure that acceptable levels of analytical performance for each test system are established.

(l) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the clinical laboratory’s established performance characteristics are identified and that patient test results shall not be reported until the system is functioning properly.

(m) Ensure that reports of test results include pertinent information required for interpretation.

(n) Ensure that consultation is available to the clinical laboratory’s clients on matters relating to the quality of test results reported, the methodology used, and their interpretation concerning specific patient conditions.
(o) Ensure that supervision is provided as specified in Rule Chapter 59A-7, F.A.C., by a supervisor or supervisors licensed pursuant to Rule 64B3-5.002, F.A.C.

(p) Assess laboratory staffing needs and advise management when insufficient clinical laboratory personnel are employed to provide appropriate consultation, supervision, and accurate performance of tests and reporting of test results in accordance with the standards of practice and responsibilities for clinical laboratory personnel defined in Rule Chapters 64B3-10 and 64B3-13, F.A.C.

(q) Ensure that licensed clinical laboratory personnel can perform all testing operations reliably in order to provide and report accurate test results.

(r) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical and postanalytical phases of testing to assure that they are competent and maintain their competency and, whenever necessary, identify needs for corrective action including remedial training or continuing education.

(s) Ensure that a procedure manual approved, signed, and dated by the clinical laboratory director both initially and biennially thereafter is available to all personnel responsible for any aspect of the testing process.

(t) Identify in writing which examinations and procedures each individual is authorized to perform including whether supervision is required for specimen processing, test performance or result reporting and whether supervisor or director review is required prior to reporting patient test results.

(u) Select the clinical laboratory's test menu and methods, the schedule of testing, the criteria for specimen collection and rejection and the methods for reporting results.

(v) Identify weaknesses in performance and take necessary action to ensure minimum acceptable performance.

(w) Establish and maintain a patient identification system.

(x) Design a system for obtaining and managing financial resources for the clinical laboratory and ensure accurate billing practices are maintained.

(y) In the specialty of cytology, in addition to the above responsibilities, the Director shall:
   1. Establish the workload limit for each individual examining slides.
   2. Reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.
   3. Ensure that each individual examining gynecologic preparations participates in a proficiency testing program approved as specified in Rule Chapter 59A-7, F.A.C., and achieves a passing score as specified in Rule Chapter 59A-7, F.A.C.
   4. Ensure that no individual examines more slides than that established pursuant to Rule Chapter 59A-7, F.A.C., regardless of the location of testing.

(7) Only a clinical laboratory director qualified pursuant to Chapter 483, Part III, F.S., may use the term “Clinical Laboratory Director” in his or her job title.

CHAPTER 64B3-13.002 - Responsibilities of Supervisors

(1) The supervisor is responsible for fulfilling the responsibilities of the director as assigned and for monitoring compliance with all applicable regulations of the board and of the Department.

(2) In addition, the supervisor shall fulfill the following responsibilities:
   (a) Performs the duties of a technologist in the specialty or specialties in which licensure is held, as needed.
   (b) Assigns, if needed, performance of his or her direct supervision responsibilities to licensed technologists, however, the supervisor remains responsible for ensuring that direct supervision is properly performed. The assignment of responsibilities from the supervisor to the technologist must be written and specific.
   (c) Evaluates the competency of technologists and technicians and assures that the staff maintain their
competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff shall include:

1. Direct observation of routine test performance including patient preparation, if applicable, and specimen handling, processing and testing.
2. Monitoring the recording and reporting of test results.
3. Reviewing the intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
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.

(d) Evaluates and documents the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes have occurred, in which case, prior to reporting patient test results, the individuals performance must be reevaluated and documented to include the use of the new test methodology or instrumentation.

(e) Is accessible to clinical laboratory personnel at all times testing is performed and provides on-site telephone or electronic consultation to resolve technical problems in accordance with approved polices and procedures of the clinical laboratory.

(f) Provides day-to-day supervision of test performance by technologists and technicians.

(g) Ensures on-site direct supervision when testing is being performed by those technicians who are required to work under direct supervision.

(h) Monitors test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(i) Assures that all remedial actions are taken whenever test systems deviate from the clinical laboratory’s established performance specifications.

(j) Ensures that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.

(k) Provides orientation to all testing personnel.

(l) Identifies weakness in performance and takes necessary action to ensure minimal acceptable performance.

(m) Establishes and maintains systems for the accession, identification, transport, storage and disposal of specimens adhering to internal and external policies and regulations including medico-legal custodial responsibilities.

(n) Determines the need for, selects, utilizes and evaluates referral services as appropriate to laboratory resources and/or priorities.

(o) Establishes protocols for performance of confirmatory and additional procedures as indicated.

(p) Establishes a system for providing patients with blood and blood products in accordance with internal and external policies and regulations.

(q) Devises a plan for management and scheduling of clinical laboratory personnel.

(r) Establishes and communicates short term goals and objectives for delivery of clinical laboratory services.

(s) Monitors compliance with institutional policies and regulations and standards of external agencies.

(t) Designs and/or implements a quality assurance program to monitor variables which affect the quality of clinical laboratory services.

(u) Prepares and periodically updates policy and procedure manuals.

(v) Establishes and evaluates the preventive maintenance program for instrumentation and equipment.

(w) Establishes and periodically evaluates safety measures in accordance with internal and external regulations.

(x) Evaluates and selects chemicals, biologicals and radionucleotides for clinical use and establishes
monitoring systems for handling, processing, and storing these supplies and reagents.

(y) Designs a plan for administration of education programs in the clinical laboratory sciences for a variety of settings including academic, clinical, alternate site, exclusive use, in-service, and continuing education.

(2) Designs research in the clinical laboratory sciences by obtaining and utilizing resources and by reporting results as appropriate.

(aa) In the specialty of Cytology, in addition to the above responsibilities, the supervisor shall, if responsible for screening cytology slide preparations, document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24 hour period to screening of cytology slides, as indicated in Rule Chapter 59A-7, F.A.C. The supervisor shall be responsible for and be required to provide this information to any laboratory for which the individual screens slides.

**CHAPTER 64B3-13.003 Responsibilities of Technologists**

(1) The technologist is responsible for fulfilling the responsibilities of the supervisor, as assigned. The assignment of responsibilities must be written and specific.

(2) In addition the technologist shall fulfill the following responsibilities.

(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 test results.

(c) Maintains records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.

(d) Adheres to the clinical laboratory’s quality control policies, documents all quality control activities, instrument and procedural calibrations and maintenance performed in accordance with the clinical laboratory’s approval policies and procedures.

(e) Follows the clinical laboratory’s established policies and procedures whenever test systems are not within the clinical laboratory’s defined acceptable levels of performance.

(f) Is capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify a supervisor or director.

(g) Documents all corrective action taken when test systems deviate from the laboratory’s established performance specifications.

(h) Exercises professional judgment in evaluation, specimen integrity, result accuracy and inter-result validity and takes corrective action as necessary. Such corrective action shall include specimen rejection, recollection, and/or retesting using the same or alternate methods and/or utilizes other skills associated with the practice of clinical laboratory science to ensure validity and accuracy of testing at all times taking care not to compromise patient care with excessive rejections, recollections or delays. If in their judgment a specimen is compromised, the technologist shall include an appropriate disclaimer statement in the report indicating the potential compromised nature of the result and why, in accordance with Rule Chapter 59A-7, F.A.C.

(i) Participate in proficiency testing samples and ensure that these samples are tested in the same manner as patient specimens.

(j) In the specialty of Cytology, in addition to the above responsibilities, the technologist shall:

1. Document slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed as specified in Rule Chapter 59A-7, F.A.C., and the clinical laboratory’s policies and procedure.

2. Document for each 24 hour period the total number of slides examined or reviewed.

3. Document the number of hours spent examining slides in each 24 hour period.
CHAPTER 64B3-13.004 - Responsibilities of Technicians

The technician shall:
(1) Perform tests classified as highly complex pursuant to 42 CFR 493.17 as published on October 1, 2007, incorporated by reference herein, only when under the direct supervision of a licensed technologist, supervisor, or director unless the technician meets the minimum qualifications set forth in 42 CFR 493.1489 as published on October 1, 2007, incorporated by reference herein and the requirement contained in Rule 64B3-5.004, F.A.C.

(2) Perform only those tests authorized by the director.

(3) Follow the clinical laboratory’s procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test 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 and ensure that these samples are tested in the same manner as patient specimens.

(6) Adhere to the clinical laboratory’s quality control policies and document quality control activities, instrument and procedural calibrations and maintenance performed.

(7) Be capable of identifying problems that may adversely affect test performance or reporting of test results and immediately notify a licensed technologist or supervisor.

(8) Document all corrective actions taken when test systems deviate from the clinical laboratory’s established performance specifications.

(9) Follow the directives of directors, supervisors or technologists while exercising their duties and responsibilities.

References: