

**Tennessee Medical Laboratory Board
July 19, 2019**

Minutes

Meeting Date: July 19, 2019

Time: 9:00 AM CDT

Location: Tennessee Department of Health
Division of Health Licensure and Regulations
Metro Center Complex, Iris Room, Ground Floor
665 Mainstream Drive
Nashville, TN 37243

Members Present:

Patti J. Walton, MT-Hospital/Lab Mgr./Adm. Dir., Chair
Tereyo M. Cox, MT-Medical-Technologist, General
Danielle Gibson, M.D., Pathologist Non-educator
Gaye G. Jolly, MT-Hospital Administrator
Michael Johnson, MT-Medical Technologist General
Jon Parham, DO Non-Pathologist Physician
James A. Vaughn, MD-Pathologist Educator

Members Absent:

Carla M. Davis, MD-Pathologist
Stephanie Dolsen, MT Supervisor
LeeAnne Briggs MT- Medical Technologist Educator,
Board Vice-chair
Mark A. Calarco, DO, Independent Lab Manager/Adm.
Lynn Stewart, Citizen Representative
Keisha Burnett, S.A.-Cytotechnologist

Vacant Position: No vacant positions

Staff Present:

Nina V. Smith, MT Consultant, Director
Kyonzte Hughes-Toombs, Deputy General OGC
Fowlen Anders, MT Consultant/Surveyor ETRO
Taylor Carpenter, MT Consultant/Surveyor ETRO
Richard Carroll, MT Consultant/Surveyor MTRO
Susan Wilson, MT Consultant/Surveyor MTRO
Karon Hathcoat, MT Consultant/Surveyor WTRO
Debbie Haggard, MT Consultant/Surveyor WTRO

Staff Absent: Board Consultant position vacant

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer:

Patti Walton, MT, Chair

Call To Order:

The meeting was called to order at 9:03 am CDT by Board Chair Patti J. Walton.

Introduction of Board Members/Staff:

Board members and staff made their introductions to the audience and for the record.

Introduction: New Surveyor

Fowlen Anders, MT (ASCP) Surveyor of ETRO

Quorum:

Seven board members were present which constitutes a quorum.

Approve Minutes

P & E Committee Meeting

A motion to approve the April 17, 2019 Personnel & Education Committee minutes was made by Dr. Gibson.
Second: Dr. Cox
Minutes: Approved

Full Board Meeting

A motion to approve the April 18, 2019 Board minutes was made by Mr. Johnson.
Second: Ms. Jolly
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations
P&E Committee Meeting:

Mr. Johnson reported the actions of the Personnel & Education Committee meeting, July 18, 2019.
Motion to ratify Committee actions: Dr. Vaughan
Second: Dr. Parham
Report was accepted as presented by Mr. Johnson.

**Consent, Agreed
Compliance Orders
Letters of Reprimand**

Consent Orders

No consent orders presented.

Agreed Orders

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand presented.

Presentations to the Board:

**Tennessee Professional Peer Assistance
Program
(TNPAP):**

Mike Harkreader, MS, RN, CARN
TNPAP Director

The statistical report for July 1, 2018-June 30, 2019 was presented by Mr. Harkreader.

Two individuals were monitored during this time period, both with non-regulatory issues, both were reported by their employer.

One individual was referred following an arrest conviction issue while the other was referred because of an impairment and UDS workplace issue.

Two cases were closed because individuals declined recommendations for TNPAP assistance.

Motion to accept the TNPAP report: Mr. Johnson
Second: Ms. Cox
The TNPAP Report was accepted as given.

Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits.

A certificate of completion documenting review of these materials can be completed at the end of the session. Internet site: www.TNPAP.org

Financial Report

Noranda M. French
Presentation/Discussion

No report was given this quarter

Investigations Report

Lori L. Leonard
Disciplinary Coordinator
April-July 2019

Ms. Leonard's investigative report included the following:

Monitored Practitioners: (2019)

Four suspensions, two probation, one currently under board order.

Investigative Licensed Laboratory Personnel: (2019)

Two new complaints:
Both complaints were for drug use.

One complaint closed:
For insufficient evidence
Three complaints currently open.

Investigative Licensed Facilities: (2019)

No new complaints.

One complaint currently open.

Motion To Accept Report: Ms. Jolly

Second: Dr. Gibson

The Investigations Report was accepted as given.

The following Legislative update was presented by Sara C. Warner, Esq., Legislative Liaison:

**Legislative Report
DOH Commissioner's Office**

Public Chapter 61

This act states that an entity responsible for an AED program is immune from civil liability for personal injury caused by maintenance or use of an AED if such conduct does not rise to the level of willful or wanton misconduct or gross negligence. This act took effect on March 28, 2019.

Public Chapter 144

This act amends the Prevention of Youth Access to Tobacco and Vapor Products Act by limiting the places in which one may use vapor products. The act defines vapor products and prohibits the use of such products in a number of locations including child care centers, group care homes, healthcare facilities (excluding nursing homes), residential treatment facilities, school grounds, and several other areas. Several locations have specific exceptions set forth in the statute. This act took effect on April 17, 2019.

Public Chapter 195

The majority of this act pertains to boards governed by the Department of Commerce and Insurance. One small section applies to the health related boards. Currently, the health related boards have an expedited licensure process for military members and their spouses. Previously, a spouse of an active military member had to leave active employment to

be eligible for this expedited process. This act removes that requirement. This section applies to all health related boards. The Commissioner of Health is permitted to promulgate rules, but rules are not needed to implement the act.

This act takes effect July 1, 2019.

Public Chapter 243

This act mandates that an agency that requires a person applying for a license to engage in an occupation, trade, or profession in this state to take an examination must provide appropriate accommodations in accordance with the Americans with Disabilities Act (ADA). Any state agency that administers a required examination for licensure (except for examinations required by federal law) shall promulgate rules in regard to eligibility criteria. This legislation was introduced to assist individuals with dyslexia.

This act took effect May 2, 2019 for the purpose of promulgating rules, and for all other purposes, takes effect July 1, 2020.

Public Chapter 447

This act permits law enforcement agencies to subpoena materials and documents pertaining to an investigation conducted by the Department of Health prior to formal disciplinary charges being filed against the provider. This bill was brought by the Tennessee Bureau of Investigation.

This act went into effect May 22, 2019.

The motion to accept this report was offered by Ms. Jolly

Second: Dr. Parham

The Legislative Report was accepted as given.

Point of Care Exemptions

1200-06-03-.16(1)

1. Fort Sanders Regional Medical Center
1901 Clinch Ave
Knoxville, TN 37919

Kristi Parker, MT, ASCP
Point of Care Coordinator

The following exemption request was granted: to permit perfusionists and anesthesia staff including certified registered nurse anesthetists, anesthesia technicians, and physicians to perform and report ABGs, Na, K, iCa, Hct, and Glucose determinations utilizing the i-STAT CG8+ cartridges.

The results of this testing will be performed and reported from the surgical department's holding area, operating rooms, and recovery area.

Motion: Mr. Johnson

Second: Dr. Vaughan
Abstain: Ms. Jolly
The exemption request was approved.

2. Mid-South Transplant Foundation
8001 Centerview Parkway Suite 302
Cordova, TN 38018
James M. Mason, PhD

POSTPONED UNTIL OCTOBER BOARD MEETING

3. Saint Thomas Midtown Hospital
2000 Church Street
Nashville, TN 37236

Sue Ann Allen, MT(ASCP)^{CM}
Lead, Point of Care & Supervisor

The following exemption request was granted: to permit Licensed Registered Nurses in the Medical ICU to perform and report sodium, potassium, chloride, BUN, glucose, creatinine, ionized calcium, hematocrit, hemoglobin*, anion gap* TCO₂, pH, PCO₂, PO₂, HCO₃, BE, and sO₂* utilizing the Abbott i-STAT instrument and methodology. (*calculated)

This request was for an addition of a location in the hospital for Registered Nurses to use the i-Stat and for the addition of Registered Nurses to perform the ABG analytes, to the previous point of care exemptions given January 2002, April 2010, and July 2012.

Motion: Mr. Johnson
Second: Dr. Gibson
The exemption request was approved.

4. University of Tennessee Medical Center
1924 Alcoa Highway
Knoxville, TN 37920

Pattie Cole, MT (ASCP)
Point of Care Coordinator/Quality Analyst

The following exemption request was granted: to permit Emergency Medical Technicians-Paramedics in the Emergency Department to perform sodium, potassium, chloride, ionized calcium, glucose, BUN, creatinine, lactate, hematocrit, hemoglobin, and troponin determinations utilizing the i-STAT analyzer.

This request is for an addition of personnel to previous point of care exemptions for Registered Nurses performing the same testing using the same analyzers at the same location.

Motion: Ms. Jolly
Second: Mr. Johnson
Abstain: Drs. Vaughan and Parham
The exemption request was approved

5. Vanderbilt University Medical Center
Nashville, TN 37232

Judy Davis, MA, MLS(ASCP), DLM, QLC
Director, Quality Management/Compliance/POCT

The following exemption request was granted: to permit state Licensed RNs and LPNs, Licensed Certified Perfusionists, Licensed Respiratory Therapists, Radiology Technologists and Technicians, Licensed Paramedics, Certified Anesthesia Technicians, Clinical Trials

Nephrology Coordinator and Research Assistant to perform Activated Clotting Time (ACT) testing utilizing the Hemochron Elite analyzer throughout the Vanderbilt University Hospital (VUH) and the Vanderbilt Children’s Hospital (VCH).

This request represents the consolidation of multiple POC ACT exemptions, encompassing multiple locations, testing personnel, and dates into one comprehensive exemption request for both medical center hospitals.

Motion: Mr. Johnson
Second: Dr. Vaughan
The exemption request was approved

**Direct More than Three (3) Labs:
1200-06-03-.13(5)**

No requests presented during the July meeting.

**Discuss, review, take action,
if needed:**

Proposed changes for Point of Care
Rule 1200-06-01-03-. 16 (1)(b)

The Board Chair, Ms. Walton proposed reinterpreting the current rules to eliminate the necessity of Point of Care exemption requestors from having to appear before the Board in person, since some facility representatives have to travel from regions several hours from Nashville. According to counsel, Kyonzte Hughes-Toombs, the word “appear” in Rule 1200-06-01-03-. 16 (1)(b) could be accomplished via telephone. Exemptions allowed by the telephone would be for previous approved personnel, instruments and methodologies.

The motion was made by Ms. Jolly to allow the use of the phone option for previously approved Point of Care personnel and instrument exemptions until the Rule 1200-06-01-03-. 16 (1) (b) could be rewritten.

Second: Mr. Johnson
Motion approved

After discussion the board members decided that after the Rule 1200-06-01-03-. 16 (1)(b) is rewritten, a board appearance (either in person or via telephone) will not be necessary if the following conditions are met:

1. The instrument or methodology has been previously approved by the Board in any facility in Tennessee.
2. The personnel using the instrument have been previously approved by the Board in any facility in Tennessee.

The only conditions that would require an appearance before the Board would be the addition of new personnel, a new instrument or a new methodology not previously approved by the Board.

Motion: Mr. Johnson

Second: Ms. Jolly

Motion approved

**Review Licensure of Medical
Laboratory Director:**

1. Evan S. Holzberg, PhD
Lawrenceville, NJ 08648
Director: Chemistry

Dr. Holzberg received a BS degree in Chemistry from State University of New York, New York in 1975. He received a M.S. from North Dakota State Univ., Fargo, ND in Pharmacology and Toxicology in 1977. He received a M.S. from Cleveland State Univ., Cleveland, OH in Chemistry in 1980. He received a Ph.D. from Cleveland State Univ., Cleveland, OH in Clinical Chemistry in 1990.

His Clinical Chemistry internship was at the Cleveland Clinical Foundation, Department of Biochemistry, Cleveland, Ohio from 1978 to 1979.

Dr. Holzberg is certified by the American Board of Clinical Chemistry with an expiration date of December 31, 2020.

Dr. Holzberg is seeking licensure as a Director of Chemistry.

Motion: Dr. Vaughan

Second: Dr. Gibson

License Approved

2. Samir Aleryani, PhD
Spring Hill, TN 37174
Director: Chemistry

Dr. Aleryani received a B.S. from Sanaa University, Yemen in Biochemistry in 1988. He received a M.S. from Northeastern University, Boston, MA in Medical Laboratory Sciences in 1994. He received a Ph.D. from Cleveland State Univ., Cleveland, OH in Clinical-Bioanalytical Chemistry in 1999.

His Clinical Chemistry Post-Doctoral Fellowship was at Massachusetts General Hospital, Pathology Department, Laboratory Medicine Division from 2003 to 2005.

Dr. Aleryani is certified by the National Registry of Certified Chemists (NRCC) with an expiration date of December 31, 2019.

Dr. Aleryani is seeking licensure as a Director of Chemistry.

Motion: Mr. Johnson
Second: Dr. Parham
License Approved

3. Jeehong Kyhm, PhD
Lubbock, TX 79423
Director: Molecular Diagnostics

Dr. Kyhm was unable to attend due to unforeseen circumstances in Texas. The Board still reviewed his application for Medical Laboratory Director.

Dr. Kyhm received a B.S. from Daegu University, South Korea in Molecular Biology in 1999. He received a M.S. from Hanyang University, Seoul, South Korea in Medical Genetics in 2002. He received a Ph.D. from Hanyang University, Seoul, South Korea in Medical Genetics in 2005.

His Clinical Molecular Genetics Fellowship, was at the Center for Human Genetics at Boston University, Cambridge, MA from 2006 to 2008.

Dr. Kyhm is certified by the American Board of Bioanalysis (ABB) in Molecular Diagnostics with an expiration date of 12-31-2019.

Dr. Aleryani is seeking licensure as a Director of Molecular Diagnostics.

Motion: Dr. Vaughan
Second: Dr. Gibson
License Approved

**Reports or Requests from the Board
Director:**

Board Director's Report
Nina V. Smith, BA MT(ASCP)

The report included statistical data concerning the licensure of laboratory personnel, facilities, training programs licensure and health fair/health screening events.

Motion to approve report as given: Mr. Johnson
Second: Ms. Jolly

The Director's Report was accepted as given.

A copy of this report is kept on file in the administrative office.

Reinstatement of License:

No licenses were presented for reinstatement this quarter.

**Additions/Deletions
Board's Waived Test List:**

No requests for additions or deletions presented during this meeting.

**Reports or requests from the
Office of General Counsel:**

Board Attorney Report
Kyonzté Hughes-Toombs
Deputy General Counsel

Counsel Hughes-Toombs gave her report for the past quarter:

One open case is currently in the Office of General Counsel.

The re-write of the Rules Governing Medical Laboratory Personnel 1200-06-01 are still under internal review.

Motion to accept report as given: Dr. Vaughan
Second: Dr. Parham
The OGC Report was accepted as given.

**Regional Surveyors Reports:
Complaint Investigations
Proficiency Testing Events
Regional Offices:
East, Middle, West Tennessee**

ETRO Report
Taylor Carpenter, MT
Consultant II/Surveyor

East TN Regional Office: April 1 –June 30, 2019
Complaint Investigations: One (in process)
Unsuccessful Proficiency Testing 1st Occurrence for
Compatibility Testing: One
Plan of Correction was received and found acceptable.
Unsuccessful Proficiency Testing 2nd Occurrence : Zero

MTRO Report
Richard Carroll, MT
Consultant II/Surveyor

Middle TN Regional Office: April 1 –June 30, 2019
Complaint Investigations: One
Unsuccessful Proficiency Testing 1st Occurrence : Zero
Unsuccessful Proficiency Testing 2nd Occurrence : Zero

WTRO Report
Debbie Haggard, MT
Consultant I/Surveyor

West TN Regional Office: April 1 –June 30, 2019
Complaint Investigations: Zero
Unsuccessful Proficiency Testing 1st Occurrence : Two
Unsuccessful Proficiency Testing 2nd Occurrence : Zero

Motion to accept regional surveyor reports:
Mr. Johnson

Second: Ms. Cox

Surveyor reports accepted as presented

Board Ratifications

Initial Facility Applications:

1. Pathology Consultants of America
(PCA) Southwest
100 North Crest Drive
Springfield, TN 37172

Specialties: Histopathology, Oral Pathology,
Cytopathology (Gyn and non-Gyn)

Medical Laboratory Director:
John R. Olsen, M.D.
ABP/Anatomic-Clinical Pathology

Surveyor: Susan Wilson, MT-Consultant/Surveyor/MTRO

Motion: Mr. Johnson
Second: Dr. Vaughan
License Approved.

2. Quest Diagnostics-Jackson
768 W. Forest Ave.
Jackson, TN 38301

Specialty: Collection Station

Medical Laboratory Director:
Andrew N. Young, M.D., PhD
ABP/Anatomic-Clinical Pathology

Surveyor: Karon Hathcoat,
MT-Consultant/Surveyor/WTRO

Motion: Dr. Gibson
Second: Dr. Parham
License Approved.

Other Business/Discussion :

The next meeting will be October 17, 2019.

The beginning time is scheduled for 9 AM CDT in the
Iris Conference Room, Ground Floor, Metro Center
Complex 665 Mainstream Drive Nashville, TN.

Adjournment:

With no further business to discuss, the meeting
adjourned at 11:00 AM CDT.

Motion to adjourn: Mr. Johnson
Second: Ms. Cox