

Tennessee Medical Laboratory Board
January 17, 2019
Minutes

Meeting Date: January 17, 2019

Time: 9:00 AM CST

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
LeeAnne Briggs, MT Program Director UT/MT Program
Keisha Burnett, S.A.-Cytotechnologist
Mark A. Calarco, DO, Independent Lab Manager/Adm.
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Stephanie Dolsen, MT Supervisor
Michael Johnson, MT-Medical Technologist Generalist
Board Vice-chair
Jon Parham, DO Non-Pathologist Physician
Lynn Stewart, Citizen Representative
James D. Vaughan, M.D. Pathologist Educator

Members Absent:

Staff Present:

Lynda S. England, MT Consultant, Director
Nina V. Smith, MT Consultant Administrative Office
Kyonzte Hughes-Toombs, Deputy General OGC
Julia Daniels, 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:

Mary Hamblen, MT Consultant/Surveyor

CLIA Manager/Representative:

Sandra Bogard, MT CLIA Manager

Presiding Officer:

Patti Walton, MT, Chair

Call To Order:

The meeting was called to order at 9:00 am CST 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.

Two new board members were welcomed by the chair and
members:

LeeAnne Briggs, MT
Program Educator
Program Director UT/MT Knoxville

Lynn Stewart
Citizen Representative
Nashville, TN

Dr. Jon Parham was reappointed to serve a second term
as the non-pathologist physician representative.

Quorum:

Eleven board members were present which constitute a quorum.

Approve Minutes

P & E Committee Meeting

A motion to approve the October 17, 2018
Personnel & Education Committee minutes was made by
Mr. Johnson.
Second: Ms. Dolsen.
Minutes: Approved.

Full Board Meeting

A motion to approve the October 18, 2018 board minutes
was made by Ms. Dolsen.
Second: Dr. Davis.
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations
P & E Committee Meeting:

Ms. Walton reported the actions of the Personnel & Education
Committee meeting, January 16, 2019 serving as interim chair
until 2019 calendar year board elections were held at the
end of the meeting.

During this presentation the gavel was passed to board
vice-chair: Michael Johnson.

Motion to ratify Committee actions: Dr. Calarco.
Second: Dr. Vaughan.

Report: Accepted as presented by Ms. Walton.
Gavel returned to board chair, Ms. Walton.

Contested Case

Stephanie Renee Miller
Adamsville, TN 38310
Medical Laboratory Technician
License # 21222
Docket Number 17.08.154527A

Administrative Law Judge, The Honorable Steve Darnell, presided over the proceedings.

Ms. Miller appeared before board members, without Counsel, to clarify a violation of the Medical Laboratory Practice Act by providing professional services while mentally incompetent, or under the influence of alcohol, a narcotic, or other controlled dangerous substance that is in excess of therapeutic amounts or without valid medical indication and also violating or aiding and abetting the violation of any provisions of this chapter or the rules or regulations promulgated under this chapter. (Tennessee Code Annotated §68-29-127)

After a lengthy discussion, board members established the following Findings of Fact:

Respondent was granted a medical laboratory technician license, license #21222 on April 20, 2004. The license expired on October 21, 2018.

While working in a licensed clinical laboratory, Ms. Miller agreed to a "for cause" specimen toxicology screen with a positive alcohol result.

Ms. Miller received two DUI citations in 2014 and 2016 and failed to appropriately notify the Department of either citation when applying for the renewal of her license as asked on the renewal invoice for her medical laboratory technician license.

Ms. Miller agreed with the investigator's complaint findings.

Board members agreed with these Findings of Fact on a motion presented by Dr. Calarco.
Second: Mr. Johnson.

After further deliberations board members determined the following disciplinary actions:

- 1-The license is currently suspended: evaluation by TNPAP agency for necessity of program attendance. If result of evaluation recommends a return to practice with monitoring, Ms. Smith may sign a TNPAP advocacy agreement.
- 2-With receipt of TNPAP notification advocacy has been established plus recommendation of return to practice, the suspension shall be lifted and the license shall be placed on probation with the following terms applicable.
- 3-Probation period to run concurrent to monitoring agreement with TNPAP, with no less than three (3) years. If TNPAP monitoring agreement is extended the probationary period shall be extended too.

4-Failure to maintain 100% compliance with terms of monitoring agreement and advocacy of TNPAP until completion of the agreement and any amendments will be a violation of probation and a violation of the Order.

5-Respondent shall remain clean and sober.

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4-Failure to maintain 100% compliance with terms of monitoring agreement and advocacy of TNPAP until completion of the agreement and any amendments will be a violation of probation and a violation of the Order.

5-Respondent shall remain clean and sober.

6-Ms. Miller shall notify Board staff of any current criminal proceedings pending or that may occur in the future.

7-Compliance must be met with all Board laws, rules and regulations.

8-Ms. Miller is required to report to the Board annually.

9-Should TNPAP report an evaluation that recommends a return to practice, but does not recommend a monitoring agreement, the suspension shall be immediately lifted and the license shall be placed on probation for a period of three (3) years from the date of the receipt of the notification from TNPAP per the evaluation results.

Compliance with all Order items is mandatory.

To have the probation lifted, an appearance before the Board with a petition for an Order of Compliance is mandatory.

Should the Board approve, the license shall be returned to the unencumbered status.

Ms. Miller's license is currently in an expired status and should she decide to reinstate the license to an active status, normal procedure for reinstatement, including, but not limited to, payment of past due renewal, and late fees, plus the completion of any outstanding continuing education hours.

An appearance before the Board is necessary before the license can be reinstated.

Reinstatement only returns the license to active status.

The suspension or probation is NOT removed.

Ms. Miller is responsible for payment of the actual and reasonable cost of prosecuting this case with the amount not to exceed \$1000.00.

Adoption of Disciplinary Actions:

Motion: Dr. Davis

Second: Dr. Parham

Motion Approved.

Board members then adopted a policy statement which recommends these disciplinary actions in fulfillment of their duties pertinent to the health, welfare and safety for the citizens of Tennessee.

Adoption Policy Statement:

Motion: Dr. Calarco

Second: Mr. Johnson

Conclusion: Board members approved the Finding of Facts, Conclusions of Law, and The Order, within their Policy Statement.

*TNPAP-TN Professional Peer Assistance Program
Advocacy Program for Impaired Professionals

Consent Orders

No Consent Orders presented.

Agreed Order

No Agreed Orders presented.

Compliance Orders

No Compliance Orders presented.

Letters of Reprimand

No Letters of Reprimand presented.

Presentations to the Board:

TN Professional Peer Assistance Program

Teresa Phillips, RN

Elaine Eaton
TNPAP Representative

The statistical report for July 1, 2018-December 31, 2018 was presented by Ms. Phillips.

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

One case was closed because individual declined recommendation for TNPAP assistance.

Motion to accept the TNPAP report: Mr. Johnson.
Second: Ms. Cox.
Report 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 however a report will be given by Ms. French during the April 2019 meeting.

No board action taken on this matter.

Investigative Report
Lori L. Leonard
Disciplinary Coordinator
October 2017 – December 2017

Ms. Leonard's investigative report included the following:

Monitored Practitioners:
Three new complaints were opened in November with a total of six complaints for 2018.

One complaint was closed and one complaint was closed with a letter of concern.

Licensed Laboratory Personnel-Allegation:

One complaint was for drugs, one complaint was for malpractice/negligence, one complaint was for unlicensed practice, two complaints were for unprofessional conduct, and one complaint for failure to supervise.

Investigative Licensed Facilities:
No complaints on facilities this quarter.

Motion To Accept Report: Mr. Johnson.
Second: Ms. Burnett.

The investigation report was accepted as given.

Legislative Report
DOH Commissioner's Office
Legislative Liaison/Legislative Affairs

No legislative report this time.
Convened 2019 Legislative Session January 8, 2019

Discuss, review, take action, if needed:

Zendesk Group
Oral Report
Lynda England BSMT(ASCP)
Board Director

Ms. England gave a brief report on the installation of a new program to aid with the many program-staff inquiries concerning licensure in Tennessee.

The medical labs program area joined with other program areas in Health Related Boards with the implementation of the Zendesk program to monitor the receipt and response of telephone calls and email questions concerning state licensure.

In essence, this program represents call center capability to record, capture, and monitor written responses between board staff, applicants pertaining to licensure, renewals, and general information for compliance with statutes, rules and regulations to practice laboratory medicine in Tennessee.

These requests are captured on screen via email and/or voice recording whichever choice is made by the caller utilizing a phone menu. Staff responses are delivered via email and include general information, state web sites with links to all information and documents applicable to the licensure process.

This program went live on December 20, 2018.
No board action taken.

Mobile Images Acquisition
6111 Heritage Park Drive

Building A Suite 400
Chattanooga, TN 37416
Rick Merchant, CEO

Mr. Merchant requested board members give guidance for a proposal to the operations of his company, Mobile Images, which provides testing to individuals in their home via a mobile van service for X-ray and ultrasound.

Included with the operational procedures a request could be submitted from a Tennessee license physician for the mobile unit to go into the home and provide selective laboratory services to the individual to include the following tests:

- 1-Influenza A&B (Virology).
- 2-Streptococcus Group A (Bacteriology).
- 3-Urine dipstick analysis to include: bilirubin, blood leukocytes, ketone, nitrite, pH, protein, specific gravity, and blood glucose.

Currently this company maintains locations in Knoxville, Chattanooga, and Kingsport, Tennessee.

After discussion board members determined mobile, in home testing events, were not a part of the statute or laboratory rules and regulations.

The fixed location where laboratory supplies for Mobile Image operations are kept for future use in a warehouse.

No laboratory tests are performed in this storage area.

This operation provides per laboratory rules and regulations, no physical location for a Tennessee laboratory license as all follow-up biennial surveys are unannounced.

This business operation and also personnel hold a current License and or certification by the Tennessee Department of Radiological Health.

After further discussion members agreed to differ to the Federal Guidelines per CLIA* Waived Exemption 1-Temporary Testing Sites and Mobile Units-CFR 493.35(b) (1) and CFR 493.43(b) (1), and also CFR 493.55(b) (1).

*Clinical Laboratory Improvements Act.

Several documents were requested to be kept on file in the board's administrative office from Mobile Images:

- 1-TNMLB Waived Test Form.
- 2-Copy of CLIA certificate for Waived Testing.
- 3-copy of state license/certificate issued by the Board of Radiological Health, and
- 4-a copy of the medical director's license issued by the TN Board of Medical Examiners.

Motion: Dr. Calarco.
Second: Dr. Vaughan.

Motion to defer to CLIA Guidelines and State Waived Test Guidelines as a mobile imaging unit performing those tests that do not require a license.

Approved.

Point of Care Exemptions
1200-06-03-016(1)

1. Centennial Medical Center
2300 Patterson Street
Nashville, TN
Mollie Wynn, MT
POCT Coordinator

Ms. Wynn appeared before the board in October 2018 to request an exemption for hospital staff to perform and report lab tests utilizing instrument and methodology not previously approved by the board.

After discussion board member requested a second review of the implementation of this instrument per "best practices" and to return to the January meeting with subsequent data.

Documentation received in the program area's office in December stated the start-up date for this point of care event had been postponed.

No Board Action Taken.

2. Baptist Memorial Hospital
Department of Pathology
6019 Walnut Grove Road
Memphis, TN 38120

Karen S. Clark, BSMT(ASCP)
POC Supervisor

This point of care exemption request was granted to permit Registered Nurses, Practical Nurses, Paramedics and Emergency Medical Technicians to perform and report troponin analyses in the Emergency Department utilizing the i-STAT instrument and methodology.

Motion: Mr. Johnson.
Second: Dr. Calarco.
Exemption granted.

1200-06-03-.13(5)

Thomas Watkins, D.O. , Ph.D., FCAP
Medical Laboratory Director
Medic, Inc.
Crossville, TN 38555

Dr. Watkins appeared before the board to request approval to direct a fifth laboratory.

Dr. Watkins, currently serves as medical laboratory director for the following Tennessee licensed facilities:

- 1-Medic Inc. 1601 Ailor Avenue, Knoxville 37921.
- 2-Medic Inc. Kingston Pike, Farragut, TN 37934.
- 3-CSL Plasma, Inc., 1001 Corridor Pk. Knoxville, TN 37932.
- 4-Medic Inc. 79 S. Main Street Crossville, TN 38555.
(Initial App. Review Today)
- 5-Medic Inc. 213 E. Washington Ave. Athens, TN 37303.
(Application Pending)

Motion: Ms. Dolsen.
Second: Dr. Vaughan.

Directorship of 5th laboratory approved.

Reports/Requests

Director's Report

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: Dr. Calarco.
Second: Ms. Briggs.
Report accepted as given.

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

OGC Report

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

One open case is currently the Office of General Counsel.

Motion to accept report as given: Dr. Vaughan.
Second: Ms. Cox.
Report accepted as given.

Board Attorney Report
Kyonzté Hughes-Toombs
Deputy General Counsel

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

One open case is currently the Office of General Counsel.

Motion to accept report as given: Dr. Vaughan.
Second: Ms. Cox.
Report accepted as given.

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.

Licensure of Medical Laboratory Director

Manoj Tyagi, Ph.D.
Charlotte, NC 28277

Dr. Tyagi received his BS degree in biotechnology from the Chaudhary Charan Singh University India. In 1997; he obtained a MS degree from Guru Ghasidas University India: in 2005 Biotechnology, and his Ph.D. from the University of Delhi, India in 2007 in Medical Biochemistry.

He holds certification as a clinical chemist from the National Registry of Certified Chemists with an expiration date of December 31, 2019.

Dr. Tyagi is seeking licensure as Director Clinical Chemistry.

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

Xiaowei Rose Fu, Ph.D.

Dr. Fu obtain her physician's license from China Medical University in 1989 in Pediatric Medicine.

Her Ph.D. was granted in 2001 from the Shimane Medical University in Japan in Metabolism.

She is certified by the America Board of Medical Genetics and Genomics in Clinical Biochemical Genetics and Genomics, obtaining certification in 2007.

The expiration date of this certification is December 31, 2028.

*Pending receipt in the administrative office of her transcript Evaluation from Professional Examination Services. (Transcript evaluation received 02/19) Motion: Mr. Johnson.
Second: Ms. Dolsen.

Director: Clinical Biochemical Genetics and Genomics

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

ETRO Report
Taylor Carpenter, MT
Consultant/Surveyor

East TN Regional Office: October 01-December 31, 2018
Complaint Investigations: One (in process)
Unsuccessful Proficiency Testing: One; Acceptable POC.

MTRO Report
Richard Carroll, MT
Consultant/Surveyor

Middle TN Regional Office:
October 01-December 31, 2018
Complaint Investigations: Zero
Unsuccessful Proficiency Testing: Three
(One Provided Acceptable POC; two are pending)

WTRO Report
Debbie Haggard, MT
Consultant/Surveyor

West TN Regional Office: April 01-June 30, 2018
Complaint Investigations: Zero
Unsuccessful Proficiency Testing : One (Acceptable POC)

Motion to accept reports: Mr. Johnson
Second: Dr. Parham
Reports accepted as given.

**Board Ratifications
Initial Facility Applications**

1- Medic, Inc.
79 South /Main Street
Crossville, TN 38555

Specialties: Hemoglobin (Blood Donor Center)

Laboratory Director: Thomas Watkins, DO PhD, FCAP
ABP Clinical Pathology
ABP Blood Bank
ABP Transfusion Medicine

Surveyor: Richard Carroll, MT Consultant 2/MTRO

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

2-Quest diagnostics
2075 Exeter Road Suite 20
Germantown, TN 381138

Specialties: Collection Station

Laboratory Director: Janice Hessling, MD
Anatomic Pathology

Surveyor: Debbie Haggard, MT Consultant 1/WTRO

Motion: Ms. Dolsen.
Second: Ms. Briggs.
License: Approved

3- Lab. Corporation of America
2017 South College Street Suite
Trenton, TN 38382

Specialties: Hematology, Routine Clinical Chemistry, Urinalysis,
HCG Pregnancy Test, KOH,
Strep A Antigen Screen, Wet Prep

Laboratory Director: Cynthia Carruth, MD
ABP Anatomic/Clinical Pathology

Surveyor: Karon Hathcoat, MT Consultant 2/WTRO

Motion: Mr. Johnson.
Second: Ms. Burnett.

License: Approved

**Board Review and Approval of
Task Force Recommendations
Review, Discuss & Revise:**

Rules and Regulations Governing
Medical Laboratory Personnel
1200-06-01

Board members reviewed these rule and regulation rewrites on a line by line basis, making sure the changes were in context with the practice of laboratory medicine and Board's intent, and Tennessee statute.

After a lengthy discussion the decision was made to send the document on for legal review and in time on to public hearing.

Motion: Dr. Vaughan.
Second: Ms. Briggs.
Rules revision sent to OGC* review.
*Office of General Counsel

Rules and Regulations Governing
Medical Laboratory Training Programs
1200-06-02

Board members reviewed and applied the changes to the personnel rules in those areas where training program guidelines are applicable.

Training program rules were sent to OGC for review and will also be part of the public rulemaking hearing in time,

Motion: Dr. Parham.
Second: Ms. Dolsen.

Rules sent to OGC* for review.

*Office of General Counsel

Task force Reinterpretation
Rule 1200-06-01-.22(1)(a)(2)(i)

On November 01, 2018 a Board requested task force meeting convened with representatives from the laboratory board, state education institutions for training of medical laboratory personnel, staff and the board's advisory attorney.

Their specific charge was to review the process of initial licensure for those applicants seeking licensure in Tennessee as a medical laboratory technologist.

After board member review and discussion the participants determined:

A reinterpretation was in order for:
Rule 1200-06-01-.22(1)(a)(2)(i)
Rules and Regulations Governing Medical Laboratory Personnel.

Reinterpretation of medical Laboratory
Technologist Qualifications

After board member review and discussion the participants determined:

Rule 1200-06-01-.22(1)(a)(2)(i)

Rules and Regulations Governing Medical Laboratory Personnel.

Reinterpretation:

If an applicant:

- 1-has obtained a baccalaureate degree and
- 2-has completed a NACCALS accredited program and
- 3-has passed a board approved national certification examination.

The requirements are met for licensure as a medical laboratory Technologist in Tennessee.

Motion for approval: Mr. Johnson.

Second: Ms. Briggs.

Reinterpretation Does **NOT** Apply

NOTE: Rules Reinterpretation

DOES NOT APPLY TO THE FOLLOWING CATEGORIES:

1-Medical Laboratory Technician (MLT) upgrade to Medical Laboratory Technologist (MT) that has not attended an MT training program.

2-Medical Laboratory Technician (MLT) with military training upgrade to Medical Laboratory Technologist (MT) that has not attended a MT training program.

3-Applicant with no training program (MLT, MT) but has 5 years of work experience and a baccalaureate degree.

Requirements for items 1-3 require full compliance with the: 16:16:3 hour and subject qualifications for licensure. (chemistry, biology, math)

After review, board members agreed the reinterpretation was in order.

Motion: Mr. Johnson.

Second: Ms. Briggs.

Approved.

Pathology Report/Necessity of Facility License

A regional surveyor presented a question pertaining to the necessity of a state license in pathology for a location

in a hospital where the pathologist was reading slides for the outpatients of the hospital.

Slides were processed (grossing & staining) by the pathologist's histology group, and then read in the hospital's laboratory facility.

Board member discussion determined no additional state license is necessary; laboratory report as presented was acceptable with no additional action as both sites were included on the final laboratory report.

No action taken on this matter.

Board Request: Change in Receiving Board Meeting Documents

Board members collectively requested change to receiving their pre-board individual information from disc to the Cloud. Many members are unable to receive the information because their computers no longer have disc drives. Ms. England said she would look into the revision of the process as requested.

Election of Officers for 2019 Calendar Year

Personnel & Education Committee Chair
Michael Johnson, MT Supervisor

Nomination By: Ms. Walton.

Motion: Ms. Dolsen.
Second: Dr. Davis.
Approved by acclamation.

Board Chair
Patti Walton, MT Supervisor

Nominated by: Dr. Calarco.
Second: Mr. Johnson.
Approved by acclamation.

Board Vice-chair
LeeAnne Briggs, MT Supervisor

Motion: Dr. Calarco.
Second: Ms. Dolsen.
Approved by acclamation.

Adjourn Meeting

With no further business to discuss, the meeting adjourned 2:30 pm CST.

The next meeting will be April 18, 2019.

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

Motion to adjourn: Dr. Calarco.
Second: Ms. Davis.

Approved.