

Tennessee Medical Laboratory Board
October 18, 2018
Minutes

Meeting Date: October 18, 2018

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
Keisha Burnett, S.A.-Cytotechnologist
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Stephanie Dolsen, MT Supervisor
Kathleen Kenwright, Ed.D MT- Med. Technologist,
Educator
Gaye G. Jolly, MT-Hospital Administrator
James A. Vaughn, MD-Pathologist Educator

Members Absent:

Mark A. Calarco, DO, Independent Lab Manager/Adm.
Michael Johnson, MT-Medical Technologist Generalist
Board Vice-chair
Jason S. Nolan, MD-Pathologist, Non-Educator
Jon Parham, DO Non-Pathologist Physician

Vacant Position: Citizen Representative

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 9:03 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 Board Member

James A. Vaughn, M.D. Knoxville, TN
Pathologist Educator
UT-Knoxville Medical Technologist Training Program

Quorum: Eight board members were present which constitute a quorum.

Approve Minutes

P & E Committee Meeting

A motion to approve the July 19, 2018 Personnel & Education Committee minutes was made by Ms. Cox.
Second: Ms. Dolsen.
Minutes: Approved.

Full Board Meeting

A motion to approve the July 20, 2018 Board minutes was made by Ms. Dolsen.
Second: Ms. Kenwright.
Board Minutes: Approved

Board Reports:

Ratification of Initial Determinations
P&E Committee Meeting:

Ms. Kenwright reported the actions of the Personnel & Education Committee meeting, October 17, 2018.
Motion to ratify Committee actions: Dr. Davis.
Second: Ms. Cox.
Report: Accepted as presented by Ms. Kenwright.

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):

Mr. Mike Harkreader, MS,RN,CARN
TNPAP Director

The statistical report for July 1, 2017-September30,
2018 was presented by Mr. Harkreader.

Two individuals were monitored during this time period
with no new personnel additions for services and no
non-regulatory issues involved with treatment.

Motion to accept the TNPAP report: Ms. Dolsen.
Second: Ms. Kenwright.
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

Ms. French gave the Fiscal Year Report to include
expenditures and projections for the fiscal year.

Those expenditures include those environments
associated with board expenditures for that year.

Those values are comparable with those of the 2017
year end data with little change from year to year.

Motion: Ms. Kenwright.
Second: Ms. Burnett.

Report accepted as given.

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

Investigations Report
Lori L. Leonard
Disciplinary Coordinator
July-October 2018

Ms. Leonard's investigative report included the following:

Monitored Practitioners: (2018)

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

Investigative Licensed Laboratory Personnel: (2018)

Three new complaints;
one for drug allegation.
one for unprofessional conduct.
one for malpractice.

Two complaints closed:
one sent on to OGC for CE violation.
one with letter of concern.

Investigative Licensed Facilities: (2018)

Two new complaints:
one for malpractice.
one unlicensed practice.

Motion To Accept Report: Ms. Jolly.
Second: Ms. Kenwright.

The investigations report was accepted as given.

Legislative Report
DOH Commissioner's Office

No Report Given During The Meeting

Discuss, review, take action,
if needed:

Aegis Sciences Corporation
365 Great Circle Road
Nashville, TN 37228
Joel T. Galanter
Chief Legal Officer

Mr. Galanter representing Aegis Scientific Corporation asked for clarification of TCA 68-29-138 (2) relative to the acceptance of ...”a state that has been determined to be exempt in accordance with Section §353(p) of the Public Health Services Act 42 U.S.C. §263a, as having enacted laboratory requirements that are equal to or more stringent than, the statutory and regulatory requirements of the Clinical Laboratory Improvement Amendments of 1988 CLIA)...be reviewed by board members pertaining to this statute.

During discussions it was determined two states are approved and meet the measures found in this statute: New York State and Washington State.

Previously this esoteric laboratory was accredited by the American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB) and presented the ASCLD certification upon biennial inspection to state surveyors.

The facility chose to utilize the New York State Department of Health Clinical Laboratory Permit (effective July 01, 2018-June 30, 2019) in lieu of continuing with the ASCLD certification.

After discussion board members agreed per this statute, the new permit was acceptable for compliance with Tennessee Rules and Regulations 1200-06-03.

No further action taken on this request per statute.

A second discussion concerned random urine creatinine testing performed on the Olympus analyzer strictly for specimen validation purposes with no intended clinical value to be utilized or derived from the numerical result.

If the creatinine result supports the specimen is valid, the actual process is completed on the mass-spectrophotometer.

Board members suggested a disclaimer be placed on the report stating the creatinine analysis is provided solely for urine specimen validation purposes.

Board members also noted with the appropriate disclaimer on the esoteric laboratory report, this action invalidates the necessity of an additional clinical license.

Motion to add disclaimer: Ms. Kenwright.
Second: Ms. Dolsen.

Motion for clarification approved.

Note: Should the facility determine a disclaimer cannot be added to the report representatives must present during the January 2019 meeting for additional review of the subject.

This directive would apply to ANY esoteric laboratory licensed as such by Tennessee, to alter their report to include creatinine testing for specimen validation only, if the test is performed on a non-esoteric instrument.

EZaccess MD
Rochester, NY 14623
Chris Dool, RT(R)
Chief Technologist

Clarification: x-ray Mobile Unit/Lab Testing Home Arena

Mr. Dool requested the item be withdrawn from the agenda: request honored.

Charles R. Handorf, M.D.
Medical Laboratory Director
Licensed Memphis Labs

Clarification of 1200-06-01-.21 (2) 1-3
Duties & Responsibilities of Medical Laboratory
Supervisor.

Dr. Handorf ask for clarification of this regulation for the purposes of surveyor presence on site during working hours and availability at other times.
His specific email questions concerned the preanalytical and postanalytical testing periods during regular workday activities.

Does a laboratory supervisor need to be on-site during: specimen receipt, data entry, and preparation for clinical testing procedures?

Also is an on-site supervisor needed on site when the laboratory results are reported when a licensed individual reviews the results prior to the release of the patient information?

Any activity per regulations that requires licensed personnel also requires a supervisor on site during the test procedure.

After review of the email from Dr. Handorf board members responded with:

No supervisor required to be onsite for:

Specimen Accession

Specimen Aliquoting

Specimen Collection

Specimen Preparation (Preservation)

Centrifuge/Separation/Specimen Storage

1-refrigeration

2-freezing

Supervisor must be available via phone, fax, etc., per Rule/Regulation 1200-06-01-.21(2)(a)1

Motion: Ms. Dolsen

Second: Dr. Davis

Motion Approved.

Point of Care Exemptions

1200-06-03-.16(1)

1. East Tennessee Children's Hospital
2018 Clinch Avenue
Knoxville, TN 37916
Holly L. Brown, MLS (ASCP)^{cm}
Point of Care Coordinator
Shelia Ware, RRT
Respiratory Care Director

The first request was to permit Licensed Respiratory Therapists to perform and report blood gas analyses throughout the hospital utilizing the i-STAT system.

Motion: Ms. Jolly.

Second: Ms. Kenwright

The exemption request was approved.

A second request was to permit Licensed Respiratory Therapists to perform and report blood gas analyses during transport of neonatal and pediatric cases via ambulance service to the hospital utilizing the i-STAT instrument.

Motion: Ms. Jolly.
Second: Ms. Cox.
Exemption Request Approved.

2. Methodist Med. Center of Oak Ridge
990 Oak Ridge Turnpike
Amanda Sutton, MT(ASCP)
POCT Technical Specialist

This point of care exemption request was to permit Nurse Anesthetist to perform and report pH, pCO₂, pO₂, sodium, potassium, glucose, Ca⁺, and hematocrit results in the operating rooms throughout the facility utilizing the i-STAT CG8+ cartridge.

Motion: Ms. Dolsen.
Second: Ms. Burnett.
Exemption granted.

Abstain: Ms. Jolly.

3. TriStar Centennial Medical Center
2300 Patterson Street
Nashville, TN 37230
Mollie Wynn, MT
Point of Care Coordinator

These three exemption requests were tentatively* approved with further instruction for a return board visit in January 2019 for further evaluation of “best practices” technique by non-laboratory personnel utilizing Isothermal technology on the Alere-i.

The first request was to permit Licensed Registered Nurses & EMT Paramedics to perform and report Influenza A&B test results in the Pediatric ER.

Motion to approve: Dr. Davis.
Second: Ms. Dolsen.
Exemption Approved.*

Oppose: Ms. Kenwright.

The second exemption request was to permit Licensed Registered Nurses & EMT Paramedics to perform and report Strep A test results in the Pediatric ER. No culture required on negative results.

Motion: Dr. Davis.
Second: Ms. Jolly.
Exemption Approved.*

Oppose: Ms. Kenwright.

The third request was to permit Licensed Registered Nurses & EMT Paramedics to perform and report RSV Test results in the Pediatric ER.

Motion: Dr. Davis
Second: Dr. Vaughn
Exemption Approved.*

Oppose: Ms. Kenwright.

Direct 3+ Labs
1200-06-03-.13(5)

No requests presented during the October meeting.

Reports/Requests
Board Director's Report
Lynda S. England BS 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: Ms. Kenwright.
Second: Ms. Jolly

Report accepted as given.

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

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 but should soon be forwarded to the Board Director's office for her review.

Those rules will be held for additions post Task Force meeting November 1, 2018 for additional personnel revisions to be processed and become effective at the same time as the entire rules packet.

Motion to accept report as given: Ms. Jolly.
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 during this meeting.

Licensure of Medical Laboratory Director

Cherilyn Garner, Ph.D.
Olive Branch, MS 38654

Dr. Garner received her BS degree in biology from Rhodes College, Memphis in 1999 and her Ph.D. in microbiology and infectious diseases from Cornell University of Veterinary Medicine in Ithaca, NY in 2010. She obtained her CLS certificate from Tarleton State University in Stephenville, TX in 2001 as a Medical Technologist-Generalist (ASCP) since 2002 with no expiration date on the license.

Dr. Garner is certified by the American Society for Medical Microbiology (ABMM) 2017 through 2020. Her post-doctoral training was completed at the University of Texas Southwestern Department of Cell Biology from 2004-2009 in Cell Biology, Molecular Biology and Biochemistry.

Dr. Garner is seeking licensure as a Director of Clinical Microbiology.

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

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

ETRO Report
Taylor Carpenter, MT
Consultant/Surveyor

East TN Regional Office: July 01-September 30, 2018
Complaint Investigations: One (in process)
Unsuccessful Proficiency Testing: Zero

MTRO Report
Richard Carroll, MT
Consultant/Surveyor

Middle TN Regional Office: July 01-September 30, 2018
Complaint Investigations: Zero
Unsuccessful Proficiency Testing: Eight
(Four Facilities Submitted Acceptable Plans of Correction; Four others are still pending)

WTRO Report
Debbie Haggard, MT
Consultant/Surveyor

West TN Regional Office: July 01-September 30, 2018
Complaint Investigations: Zero
Unsuccessful Proficiency Testing : Zero

Motion to accept regional surveyor reports:
Ms. Kenwright.
Second: Dr. Davis.

Surveyor reports accepted as presented.

Board Ratifications
Initial Facility Applications

Aegis Sciences Corporation
Clinical Laboratory License
365 Great Circle Road
Nashville, TN 37228

Specialties: Clinical Chemistry

Laboratory Director: Philip A. Poston, Ph.D. (ABCC)
Toxicological Chemist
TN License #23800
Director: Chemistry/Toxicology

Surveyor: Susan Wilson, MT Consultant I/MTRO

Motion: Ms. Jolly
Second: Dr. Davis
License Approved.

Statement of Next Meeting:

The next meeting will be January 18, 2019.

The beginning time is scheduled for 9 AM CST 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 11:55 am CDT.

Motion to adjourn: Ms. Kenwright.
Second: Ms. Jolly.

Patti Walton, MT
Board Chair

Date