

**Tennessee Medical Laboratory Board Meeting
April 2016
Minutes**

Date: April 21, 2016

Time 09:00 AM CDT

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

Members Present: Cheryl Arnott, S.A.-Cytotechnologist, Board Chair
Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir, Vice-Chair
Kathleen Kenwright, MT- Medical Technologist, Educator
Jason S. Nolan, MD-Pathologist, Non-Educator
Tereyo M. Cox, MT-Medical-Technologist, General
Mark A. Calarco, DO, Independent Lab Manager/Administrator
Stephanie Dolsen, MT- Medical Technologist Supervisor
Michael Johnson, MT-Medical Technologist Generalist
Michael J. Wright-Citizen Representative

Members Absent: Carla M. Davis, MD-Pathologist
Royce Joyner, MD-Pathologist Educator
Gaye G. Jolly, MT-Hospital Administrator Representative

Vacant Position: Non-Pathologist Physician

Staff Present: Lynda S. England, Medical Technologist Consultant, Director
Nina V. Smith, Medical Technologist Consultant
Andrea Huddleston, Deputy General, Office of General Counsel
Julia Daniels, Medical Technologist Consultant/ Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor, East Tennessee Regional Office
Richard Carroll, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Angie Sneed, Medical Technologist Consultant/Surveyor, Middle Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor, West Tennessee Regional Office

Staff Absent: Mary Hamblen, Medical Technologist Consultant/Surveyor, West Tennessee Regional Office

CLIA Manager/Representative: No Representative Present

Presiding Officer: Cheryl Arnott, S.A.-Cytotechnologist, Chairman

Call To Order: The meeting was called to order at 9:05 am CDT by Board Chair Cheryl Arnott.

Introductions of Board Members: Board members and staff made their introductions to the record. New Advisory Attorney: Andrea Huddleston

Introductions of Staff:
Quorum: Nine members of the Board were present which constituted a quorum.

Approve Minutes:

P & E Committee Meeting A motion to approve the January 20, 2016 Personnel & Education Committee minutes was made by: Dr. Nolan
Second: Mr. Johnson
Committee Minutes: Approved.

Full Board Meeting A motion to approve the January 21, 2016 Board meeting minutes was made by: Dr. Calarco
Second: Dr. Nolan
Board Minutes: Approved.

Board Reports:
Ratification of Initial Determinations of the P&E Committee Meeting: Ms. Kenwright reported the actions of the Board's Personnel & Education Committee meeting, April 20, 2016.
Motion to ratify Committee actions: Ms. Walton
Second: Ms. Dolsen
Report ratified as presented.

Contested Cases
William L. Hatfield
Nashville, TN
Medical Laboratory Technician
TN License 18079

Honorable Administrative Law Judge: Mary Collier
Chief Deputy General Counsel: Andrea Huddleston TDOH
Docket No: 17.08-134961A

This case was presented to board members as a matter of default to the continuing education audit for the calendar years of 2012-2013 per Rules for Medical Laboratory Personnel 1200-06-01-.12 which require twenty-four (24) hours of continuing education for the two (2) calendar years preceding the renewal of any medical laboratory professional's license. Attempts to reach Mr. Hatfield via regular and certified mail on numerous attempts were returned with no forwarding address noted by the United States Postal Service. After board review of the Findings of Fact, and Conclusions of Law with the presented violation of the Tennessee Code Annotated §68-129-127 (8) members unanimously found the respondent in default of the afore mentioned statute and regulations.

Board members voted to have Mr. Hatfield's license suspended effective as of the date of the order.

The suspension may be lifted automatically (with no Order of Compliance) upon providing proof of compliance with the Disciplinary Coordinator for the Department of Health's Office of Investigations, Department of Health Licensing and Regulation and completion of all required continuing education hours and civil penalty fees.

The Tennessee Medical Laboratory Board takes this action in order to protect the health, safety and welfare of the citizens of Tennessee.

Motion: Ms. Walton
Second: Dr. Calarco
Vote: Aye All Members

Consent, Agreed, Compliance Orders & Letters of Reprimand

Consent Orders	No consent orders were presented.
Agreed Orders	No Agreed Orders were presented
Compliance Orders	No Compliance Orders were presented
Letters of Reprimand	No Letters of Reprimand were presented

Presentations to the Board:

Tennessee Professional Peer Assistance Program (TNPAP):

Ms. Elaine Eaton gave the TNPAP report.
The statistical report for July 2, 2015 March 31, 2016 was presented to board members with zero (0) individuals being monitored. There were zero (0) referrals.
No activity of record was noted on this report during the past three months.

Motion to accept the TN PAP report: Ms. Kenwright
Second: Ms. Walton
Report accepted as presented.

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 Internet session. Internet site: www.TNPAP.org

Financial Report

The financial report was given by Ms. Vanessa Crutcher, Fiscal Officer.

Motion: Ms. Dolsen

Second: Mr. Johnson

Report accepted as presented with no changes.

(Copy of report on file in administrative office)

Investigations Report Nichelle Dorroh Presentation/Discussion

The investigations report was accepted as presented by Ms. Dorroh. There were no new complaints opened and currently four (4) complaint remain open with two (2) concerning facilities and two (2) concerning personnel.

There were no questions or requests concerning the information as presented.

Motion To Accept Report: Ms. Walton

Second: Dr. Nolan

Report accepted as given.

Compliance Orders

There was no compliance orders from the Bureau of Investigations submitted for discussion during the meeting.

Discuss, review, take action, if needed, regarding but not limited to:

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Consider Rule Making for 1200-06-01-.1(22) and 1200-06-03-.08(d) (5) relative to pathologists reading slides/location of diagnosis.

This topic was tabled pending the formulation of an advisory task force at a later date.

Motion: Ms. Walton

Second: Ms. Kenwright

Tabled until August Meeting

Discuss QC Measures 1200-06-03-.09 in regards to CLIA IQCP January 01, 2016 implementation

Per previous board discussion the review of CLIA/IQCP was tabled until the August 18, 2016 meeting.

Motion: Ms. Walton

Second: Ms. Kenwright

Discuss Laboratory Developed Tests (LDT's)

**Charles R. Handorf, MD, Ph.D.
Medical Laboratory Director
Oxford Laboratories
Memphis, TN 38141**

Dr. Handorf made a presentation of this facilities laboratory developed tests (LDT's), and the information that could/should be submitted to the surveyor and administrative office considering the implementation of these processes. Manufactured/developed tests utilized and produced within that laboratory.

Many of these tests are currently being performed within the laboratory community.

Approval may be granted after submission of protocol and validation studies. Proficiency tests may present a problem with the LDT's and can be performed with blind testing analyses and by other methods. Dr. Handorf wanted to know what regulatory oversight the board considered necessary to comply with Tennessee's regulatory process for facility licensure.

After discussion it was determined the regional surveyor review the documented QA and QC plan of each LDT platform on the first survey post implementation of the LDT event in contest with the current regulatory oversight as promulgated by the Tennessee Medical Laboratory Act.

A possibility the state surveyors would begin to gather information LDT's on all subsequent surveys for follow-up during biennial survey review to capture on the survey form.

Resolution/Motion: Board does nothing at this time waiting on ultimate response on LDT's issues from FDA, Congress and other regulatory authorities.

Motion: Ms. Walton

Second: Dr. Calarco

Approved

Discuss exemption of all laboratory personnel working in Dept. of Health Laboratory Services Divisions

**Representatives: Dr. Richard Steece,
Lab Director
TDH Lab Services**

**Dr. David Reagan,
Chief Medical Officer,
TDH**

During the January 2016 meeting, Dr. Steece and Dr. Reagan presented and discussed a possible reclassification proposal for the Division of Laboratory Services to enhance the public's awareness of employment possibilities with the laboratory service. The Department of Human Resources is currently reviewing the proposal with future decisions to be published.

Request to table until future notification from Dr. Steece.

Motion: Ms. Walton

Second: Mr. Johnson

Tabled until August Meeting.

Discuss bedside testing procedures in long term facilities; mobile testing personnel and ultimately sending referral samples to a laboratory in North Carolina.

**Representative: William DePond, MD
Pathologist
Sky Laboratory
North Carolina**

Dr. DePond appeared before the board to discuss the possibility of performing laboratory testing procedures in long term facilities, (acute care, SNFF, etc.) utilizing mobile diagnostics to provide access to these patients.

If a stat procedure is ordered, an i-STAT would be utilized to perform the test on site and if further laboratory information is necessary, specimens would be referred to facility in North Carolina.

Phlebotomists would perform venous draws; tests to be performed: would utilize all i-STAT cartridges.

Long term facility would contract with Sky Laboratory to perform testing procedures.

Issue #1-If specimens are sent directly to North Carolina a collection station license would be in order.

Issue #2-Testing in the long-term facility.

After discussion, board members determined each long term care facility would need to have a license issued by the Board to perform point of care testing procedures. Each licensed facility would need to have a director, supervisor and qualified personnel performing these testing procedures.

No motion was made as this discussion was for information on part of the presenter.

**Michael Twilbeck
Tennessee Toxicology/
ISSAC Pain & Joint Institute
Nashville, TN**

Mr. Twilbeck appeared before the board to discuss the plausibility of the joint operation of a LC/MS in conjunction with the Pain & Joint Institute on a shared basis. The instrument is located within the clinic. Per board member discussion the instrument and all methodologies associated with instrument operations (calibration and verification), collection/accession of patient specimens, reporting of patient results and all aspects of patient testing would comply with the Rules and Regulations Governing Medical Laboratories (1200-06-03) and Medical Laboratory Personnel (1200-06-01). The laboratory setting would be performed in a separate location (suite) from the pain clinic. The only thing that would be shared would be the instrument which would be operational for Tennessee Toxicology on designated alternate days with complete separation of activities, to include personnel, reagents, specimen storage, etc.

Maintenance of the LC/MS would be provided by a 3rd party vendor. After discussion, board members agreed that with full compliance with CLIA certification, Tennessee licensure requirements plus surveyor recommendation they would consider initial license review as a reference laboratory in the specialty of toxicology. No further action was taken on this matter.

Dual Licensure for Regular and Esoteric Laboratories

Ms. England asked for clarification if dual licenses were in order for clinical laboratories performing esoteric testing procedures. Board members reiterated per their policy, a second license is necessary to distinguish those testers that are not licensed medical laboratory professionals who perform esoteric tests. No further discussion was necessary; no motion was made.

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Exemptions for point of care testing procedures (POCT) in a licensed Facility

**1: North Knoxville Medical Center
7565 Dannaher Drive
Powell, TN 37849**

This request was for Licensed Registered Nurses (RN's) to perform and report oxyhemoglobin testing procedures in the Cath Lab utilizing the AvoxiMeter instrument and methodology.

Motion: Ms. Walton
Second: Dr. Nolan
Request: **Approved.**

**2: LeBonheur Children's Hospital
50 North Dunlap
Memphis, TN**

The request permits Certified Registered Nurse Anesthetists, Perfusionists, Registered Nurses, Registered Respiratory Therapists, Certified Respiratory Therapists, and Registered Radiology Technologists to perform and report activated clotting time (ACT's) in the Critical Care Cardiac Service, and Surgical Settings utilizing the Hemochron Elite Analyzer.

Motion to approve exemption: Ms. Walton
Second: Mr. Johnson
Request Approved:

Abstain: Ms. Kenwright
Note. Dr. Joyner was absent from the meeting.

**3. Saint Frances Hospital-
Bartlett
2986 Kate Bond Road
Bartlett, TN 38133**

Permits Licensed Paramedics and Licensed EMT-IV Technicians to perform and report troponin levels in the Emergency Department utilizing the i-STAT instrument and methodology.

Motion: Mr. Johnson
Second: Ms. Dolsen
Request: **Approved.**

4. **Region One Health Medical Center**
877 Jefferson Avenue
Memphis, TN 38103

Region One requests board exemption approval to permit Certified Registered Nurse Anesthetists (CRNA's) to perform activated clotting time (ACT's) in the Labor & Delivery OR utilizing the i-STAT instrument and methodology .

Motion to approve: Dr. Calarco

Second: Dr. Nolan

Request: **Approved.**

5. **Methodist University Hospital**
1265 Union Avenue
Memphis, TN
38104

Request approval for Licensed CRNA's and Licensed Perfusionists to perform and report delta thromboelastometry in the Perioperative Department utilizing the Rotem *delta* instrument and methodologies.

Motion to approve: Ms. Kenwright

Second: Ms. Dolsen

Request: **Approved.**

6. **Parkridge East Hospital**
941 Spring Creek Road
Chattanooga, TN 37404

This facility presented two exemption requests:

1-To permit Registered Respiratory Therapists to perform and report blood gas and electrolytes (pH, PCO₂, HCO₃, BE, SO₂, Na, K, CA+, glucose and hematocrit) on the i-STAT analyzer in the NICU

Motion to approve: Ms. Walton

Second: Mr. Johnson

Exemption: **Approved**

2- To permit Registered Respiratory Therapists to perform and report blood gas and electrolytes (pH, PCO₂, HCO₃, BE, SO₂, Na, K, CA+, glucose and hematocrit) on the i-STAT analyzer and for ground transport to the facility in conjunction with the NICU Unit.

Motion to approve: Ms. Dolsen

Second: Ms. Kenwright

Request: **Approved**

Direct more than three (3)
Laboratories

No requests were made during the past quarter.

RECEIVE REPORTS AND /OR
REQUESTS:

Board Director's Report

Ms. England gave the board director's report for the quarter January 01, 2016 thru March 31, 2016. The report included a statistical report of activities of licensure for personnel and laboratory facilities.

Motion to accept Director's report: Ms. Walton

Second: Dr. Calarco

Report accepted.

(Copy of report is on file in the Administrative Office)

REINSTATEMENT OF LICENSES

No licenses to reinstate this quarter.

ADDITIONS/DELETIONS TO THE BOARD'S WAIVED TEST LIST

LEGISLATIVE UPDATE

Public notice information from the 2016 legislative session was included in the report by Andrea Huddleston, Board Council.

Office of General Counsel's Report:

As of April 01, 2016 there are two (2) disciplinary complaints against two (2) respondents pending in the Office of General Counsel. The Personnel & Education Committee's rules re-write are currently undergoing internal review.

Litigation: HB1800

As introduced, permits certain persons with masters or bachelor's degrees to serve as a medical laboratory director for hospitals with 30 beds or fewer. The bill was amended to provide that, for hospitals licensed for 30 beds or fewer, any physician licensed to practice medicine in Tennessee shall qualify to be a medical laboratory director (if determined otherwise qualified by the Med Lab Board) with a restricted license. Permits the director to delegate day-to-day operations to the medical laboratory supervisor.

For these same hospitals, an individual with at least a 3-year undergraduate degree plus 1 year of training in medical laboratory science (and otherwise qualified as determined by the Board) shall be qualified to be a medical laboratory supervisor with a restricted license.

The bill was signed by the Governor on April 6, 2016 and is now law. Amends Tennessee Code Annotated Title 68 Chapter 29

Motion: Ms. Walton

Second: Mr. Johnson

Report: Accepted As Presented.

**Review/Discuss Approval
Licensure of Medical Laboratory
Director**

**Scott R. Wheeler, Ph.D.
Nashville, TN 37211
Director: Molecular Diagnostics**

Dr. Wheeler appeared before the board seeking licensure as a director of a laboratory performing molecular diagnostic technique. Dr. Wheeler has a PhD from Washington University- St. Louis in Biology/BioMed Science, with Fellow Designation from Vanderbilt University Medical Center in Molecular Diagnostics. He is boarded by the American Board of Medical Genetics and Genomics (ABMGG) and his boarding is current.

**Motion: Dr. Calarco
Second: Dr. Nolan
Directorship Approved**

**Phillip R. Gibbs, Ph.D.
Atlanta, GA 30327
Director: Toxicology**

Dr. Gibbs holds a BS degree from Massachusetts Institute of Technology (1991) in Chemical Engineering and a PhD from the University of Houston in Biomedical Engineering (2000), and Fellow Designation with the Georgia Institute of Technology School of Engineering.

Dr. Gibbs holds current certification with the National Registry of Certified Chemists (NRCC) as a Toxicological Chemist, expiration date 12/31/2016.

**Motion: Ms. Dolsen
Second: Ms. Walton
Directorship: Approved**

**Greg L. Christensen, Ph.D.
Crestwood, KY 40014
Director: Andrology and Embryology**

Dr. Christensen holds a BS degree from Brigham Young University in Animal Science (1996) and a PhD from the University of Utah (2006) in Physiology. His training was at the University of Utah School of Medicine and IVF Laboratories (1998-2006)

Dr. Christensen is currently boarded by the American Board of Bioanalysis (AABB)-HCLD level in Andrology, Embryology and General Knowledge. Exp. 12/31/2016.

**Motion: Ms. Walton
Second: Dr. Calarco
Directorship Approved**

Regional Surveyors Reports

Complaint Investigations and proficiency testing (East, West and Middle TN)

ETRO Report
Julia Daniels
Taylor Carpenter

East TN Regional Office: Taylor Carpenter for the first quarter of 2016, (January-March, 2016).

Unsatisfactory/ Unsuccessful Proficiency Testing: Two (2)
1-Analyte: T4 Compatibility Testing; Acceptable plan of correction submitted to surveyor, and
2-Analyte: Compatibility Testing; Acceptable plan of correction
Complaint Investigations: Zero (0)

MTRO Report
Richard Carroll

Middle TN Regional Office: First quarter of 2016, (January-March, 2016).

Unsatisfactory/Unsuccessful Proficiency Testing: Zero (0)

Zero (0) Complaint Investigations: Zero (0)

WTRO Report
Karon Hathcoat

West TN Regional Office: First quarter of 2016, (January-March, 2016).

Unsatisfactory/Unsuccessful Proficiency Testing: One (1)

Complaint Investigations: Zero (0)

Move to accept reports : Mr. Johnson

Second: Ms. Walton

All Reports accepted as presented

Board Ratification of Laboratory Initial License:

Advanced Lab Services, Inc.
165 Payne Road
Mosheim, TN 37818

Application withdrawn prior to board meeting.

Advanced Lab Services, Inc.
988 W. Hwy 25/70
Newport, TN 37821

Application withdrawn prior to board meeting.

TriStar Natchez ER
107 Natchez Park Drive
Dickson, TN 37055

Medical Laboratory Director:

Venk Mani, MD
Anatomic/Clinical Pathology

Specialties:

Hematology, Clinical Chemistry, Urinalysis, Toxicology, Endocrinology, pH and Blood Gas, Mono Screen, HCG Serum Pregnancy, Strep A Screen , Wet Prep

Aegis Sciences Corporation
345 Hill Avenue Road
Nashville, TN 37228

Surveyor: Angie Sneed, MT
Consultant 1/Surveyor MTRO

Motion: Dr. Calarco
Second: Ms. Walton
License Approved.

Medical Laboratory Director: Timothy A. Robert, PhD
Director: Toxicology

Specialties: Toxicology

Surveyor: Angie Sneed, MT
Consultant 1/MTRO
ESOTERIC LABORATORY

Motion: Ms. Walton
Second: Dr. Nolan
License Approved

Quest MMC RRL
205 Hospital Drive Suite Q
McKenzie, TN 38201

Medical Laboratory Director Kelly O. Montoya, MD
Anatomic/Clinical Pathology

Specialties: Hematology, Clinical Chemistry,
Urinalysis, Toxicology, Influenza
Screen, KOH, Wet Prep, Strep
Antigen Screen, UCG

Surveyor: Karon Hathcoat, MT
Consultant II/WTRO

Motion: Mr. Johnson
Second: Ms. Walton
License Approved

Bluff City Laboratory Services
8110 Cordova Road Suite 113A
Cordova, TN 38016

Medical Laboratory Director: Blazej Zybek, MD
Anatomic/Clinical Pathology
Dermatopathology

Specialties: Toxicology

Surveyor: Karon Hathcoat, MT
Consultant II/WTRO

Motion: Ms. Walton
Second: Mr. Johnson
License Approved

Blood Assurance-Columbia Donor Center
1412 Trotwood Avenue Suite 69
Columbia, TN

Medical Laboratory Director:

Elizabeth Culler, MD
Clinical Pathology
Transfusion Medicine

Specialties:

Hemoglobin (Hemocue)

Surveyor:

Richard Carroll, MT
Consultant II/Surveyor MTRO

Motion: Ms. Kenwright

Second: Dr. Nolan

License Approved

Bio-Reference Laboratories @ Jan L. Crean, M.D.

Medical Laboratory Director

Rajendra Persad, M.D.
Anatomic/Clinical Pathology

Specialties:

Collection Station

Surveyor:

Richard Carroll, MT
Consultant II/Surveyor MTRO

Motion: Ms. Walton

Second: Ms. Dolsen

License Approved

OTHER BUSINESS:

Item 1

Per Surveyor/Director Request for Board Review

Board clarification of items relating to operation of administrative office technicalities:

A. Continuing Education

Board members addressed the necessity of completion of the requirements for continuing education in that the continuing education events, must be within the two (2) years preceding the renewal event to be acceptable per 1200-06-01-.12 (1) for compliance with the audit process.

Discussion only.

B. Electronic Crossmatch

Surveyor Karon Hathcoat, West TN Regional Office, asked members if they were comfortable or their facility utilized electronic crossmatch processes. Board members responded there seemed to be no problems with this crossmatch procedure in their facility. Administrative staff has had no reported issues with electronic crossmatch procedures.

Discussion only.

Record of Adjournment

With no further business to discuss, the meeting adjourned at 2:45 PM CDT.

Motion: Ms. Walton

Second: Mr. Johnson

Motion and Second Properly Presented: Meeting Adjourned