

**Tennessee Medical Laboratory Board Meeting
April 20, 2017
Minutes**

ate: April 20, 2017

Time 09:15 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: Patti J. Walton, MT-Hospital/Lab Manager/Adm. Dir., Chair
Kathleen Kenwright, MT- Medical Technologist, Educator
Cheryl Arnott, S.A.-Cytotechnologist
Tereyo M. Cox, MT-Medical-Technologist, General
Carla M. Davis, MD-Pathologist
Michael Johnson, MT-Medical Technologist Generalist
Gaye G. Jolly, MT-Hospital Administrator
Jason S. Nolan, MD-Pathologist, Non-Educator

Members Absent: Mark A. Calarco, DO, Independent Lab
Manager/Administrator
Stephanie Dolsen, MT- Medical Technologist Supervisor Vice-
Chair
Royce Joyner, MD-Pathologist Educator
Jon Parham, DO, Non-pathologist Physician
Michael J. Wright-Citizen Representative

Vacant Position: All board positions filled.

Staff Present: Lynda S. England, Medical Technologist Consultant, Director
Nina V. Smith, Medical Technologist Consultant
Kyonzté Hughes-Toombs, 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
Karon Hathcoat, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office
Debbie Haggard, Medical Technologist Consultant/Surveyor,
West Tennessee

Staff Absent: All staff present for the meeting.

CLIA Manager/Representative: Sandra Bogard, MT CLIA Manager

Presiding Officer:	Patti Walton, MT, Chair
Call To Order:	The meeting was called to order at 9:15 am CDT by Board Chair Patti J. Walton.
Introductions of Board Members:	Board members and staff made their introductions to the record.
Introductions of Staff:	
Quorum:	Eight (8) board members were present which constituted a quorum.
Approve Minutes:	
P & E Committee Meeting	A motion to approve the January 26, 2017 Personnel & Education Committee minutes was made by: Ms. Arnott. Second: Mr. Johnson. Committee Minutes Approved.
Full Board Meeting	A motion to approve the April 20, 2016 board meeting minutes was made by: Ms. Arnott. 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 19, 2017. Motion to ratify Committee actions: Ms. Arnott, Second: Mr. Johnson. Report: Ratified as presented.
Contested Case	No contested cases were presented during this meeting.
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 were presented.

Presentations to the Board:

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

Mr. Mike Harkreader
TnPAP Director

The statistical report for July 1, 2016-December 31, 2016 was presented with one (1) individual being monitored during this period.

One referral was made by an employer for impairment and positive urine drug screen in the workplace.

One TnPAP evaluation was performed with one individual consenting to treatment.

Another individual declined the TnPAP Service and has been reported to the Department for further review.

Motion to accept the TnPAP report: Ms. Arnott,
Second: Dr. Davis.

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
Noranda M. French*
Presentation/Discussion**

No financial report was presented during this meeting.

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

**Investigations Report
Nichelle Dorroh*
Presentation/Discussion
December 2016-April 2017**

Personnel: BIV received a total of six (6) complaints concerning personnel issues, with two (2) complaints remaining from December 2016. One complaint was for unprofessional conduct with four (4) complaints for continuing education violations.

Facilities: One (1) complaint remains from December 2016 with four (4) complaints in January 2017: three (3) complaints for unprofessional conduct and one (1) complaint for care of services.

*Ms. England gave report.

Motion To Accept Report: Ms. Arnott.
Second: Dr. Nolan.
Investigations Report accepted as given.

**Legislative Report
DOH Commissioner's Office
Legislative Liaison
Lacey Blair
Legislative Liaison**

No report was presented during this meeting.

**Compliance Orders
Bureau of Investigations**

No compliance orders from the were submitted 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:

**Report of board request for
purchase of printer, case and ink
utilized in survey process.**

Ms. England notified board members the items requested for purchase (printers, cases and ink) during the January 2017 meeting had been purchased and the surveyors were oriented by the central division's IT staff this week.

No board action taken on this matter.

**Director Visit Requirements:
Licensed Blood Donor Centers,
Plasmapheresis Centers and
Ambulatory Surgical Care
Treatment Centers.**

Clarification of requirements for medical laboratory director visits to these licensed facilities was requested via on-site survey review. Rule 1200-06-03-.15(5)(c) pertaining to director visits at a minimum of once a month per facility inquiry should not be applied to these centers because they are not in the "main laboratory arena" per tests performed on a very limited basis.

After discussion board members agreed the above rule remains the minimum visits per month for all licensed facilities in Tennessee.

Any further questions pertaining to the rule must have board review.

A request must be made for an exemption to the addition on the board agenda and provide documentation for consideration at the next board meeting.

No additional action was taken on this matter.

**Revisit, review, additions to ASCP'
Policy for Categorical/Licensure
Approval
for National Certification**

Patricia A. Tanabe, Executive Director ASCP Board of Certification request a second review of the qualification examinations for those individuals taking the ASCP' exam and recognized by ASCP in equivalency to the examination administered in the United States. Board members created a policy during their meeting January 2017 and Ms. Tanabe requested members to consider additions to that policy based on specialty categories utilized in the practice of laboratory medicine.

The additional ASCP' categories include:

Medical Technologist-Blood Banking
Medical Technologist-Chemistry
Medical Technologist-Hematology
Medical Technologist-Microbiology
Medical Technologist-Cytogenetics
Specialist-Blood Banking
Specialist-Chemistry

Specialist-Hematology
Specialist-Microbiology

Board members agreed to accept the addition of these categories and include in the policy previously ratified during the January, 2017 meeting.

Motion to ratify policy: Mr. Johnson.
Second: Ms. Arnott.
Policy amended.

Note:
The ASCP_i examination may be taken in the United States and/or territories and any other physical location where this agency (ASCP) sponsors the exam.

This policy does not affect any other board approved examination agency.

**Tennessee Pharmacists
Association
Brian Cost, Pharm D
Hamilton Borden, Pharm D**

Clarification #1 Addition to Waived Test Menu

Doctors of pharmacy, Cost and Borden, presentation before board members concerning the addition of an instrument and methodology to the board's approved waived test list.

The instrument utilized in the performance of the clinical laboratory tests is the Cobas Liat analyzer performing PCR screening diagnosis testing for the diagnostic purposes related to influenza and Streptococcus A & B bacteria.

The analyzer is CLIA waived because specimens are directly presented for analysis during the screen event. The specimen is collected and put into the machine located in the pharmacy.

After discussion, board members expressed concern within having the instrument added to the waived test list for any pharmacy to perform and the concern of the adequacy of the oversight of the procedure presenting the possibility of inaccurate information disseminated to the patient.

Board members expressed concern about cross reactivity and possible contamination with other items located within the pharmacy arena.

This specific instrument can be either classified as waived or moderate complexity according to CLIA classification.

Board members reviewed their own definition of waived testing, Rules and Regulations Governing Medical Laboratories 1200-06-03-.17 and expressed concern about adding this instrument to the waived test list because of the varied populous that could perform this testing procedure.

After discussion, board members denied the addition of the Cobas Liat/PCR instrument/methodology to their approved waived test list based on the technology that did not, in the board's opinion, qualify for waived test status.

Motion: Ms. Kenwright.

Second: Ms. Arnott.

Motion Approved.

Clarification #2 Oversight of Waived Tests in Pharmacies

A second clarification pertained to the physician designated oversight responsibility for the waived test processes via the waived test list promulgated by the board.

The inquiry concerned a change of oversight/signature to doctors of pharmacy in lieu of having a physician responsible for the screening events.

After discussion, it was determined the medical director must be a physician licensed in Tennessee for the oversight of these event, screening, waived test notification form etc. The current rules and regulation indicate there are no substitutions for the physician oversight per board interpretation of Rule Governing Medical Laboratories 1200-06-03.

No board action was taken on this subject.

Clarification #3 Pharmacy /Collection Station

This discussion centered the necessity of licensure if a pharmacy location collects patient's samples.

**Bronchoscopy Tissue
Staining/Specimen Retrieval
Respiratory Therapist/Med
Technologist**

The Rules Governing Medical Laboratories 1200-06-03-.18 are applicable to this process: if specimens are submitted to in-state licensed laboratories for processing, no collection license is required. However, if a specimen is sent to a laboratory not physically located in Tennessee a collection station license is in order.

No board action taken on this discussion.

This agenda item included revisit of a previous inquiry by a point of care coordinator, discussed during the January 20, 2017 board meeting.

The request involved the staining of nodule tissue at the time of specimen retrieval during a bronchoscopy procedure by either a licensed respiratory therapist or a licensed medical technologist.

After board discussion during the January meeting, board members decided to have the Board of Respiratory Care determine if this procedure fell under the scope of practice for that profession.

Ms. Tracy Alcock, advisory attorney for that board discussed their review and response to the email/nodule-stain procedure with respiratory therapist participation.

Respiratory care board members determined there was to be no advisory opinion issued by this board because the subject in question did not come directly from the respirator care licensee.

Ms. Alcock responded to the inquirer via email stating such and included respiratory regulations pertaining to scope of practice with additional information concerning the concerning the email question.

After med lab board discussion, board members determined the original email did not contain complete information to entertain an evaluation of the questions pertaining to respiratory therapists and medical technologist.

A motion was made for those individuals seeking solution to the requested information (pulmonologist, point of care coordinator, respiratory care individual who would be making the smear, medical laboratory director (pathologist)) to make an appearance during the July 21, 2017 quarterly meeting.

Motion: Mr. Johnson.

Second: Dr. Davis.

Motion Approved.

Board Approval of Surveyor

Supplies

A follow-up report was given to board members stating the requested (6) printers, cases and ink were now in the possession of the surveyors and training was completed on April 19th.

No additional discussion taken on this subject.

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. **Tennova Healthcare
Physicians Reg. Med Center
Knoxville, TN 37917
Barry Noe, MT**

Facility decided to cancel appearance at this time because a separate instrument has been ordered for use in their Surgery Department.

No board action taken.

2. **Saint Francis Hospital
Bartlett, TN 38133
Doretha Franklin, MT
Administrative Lab Dir.**

The request permits Registered EMT's and Paramedics (hospital employees) to perform and report Chem 8+ cartridge procedures (BMP, Ca+, HCT, and –hemoglobin), troponin and creatinine in the Emergency Department. This request is an addition to a previously granted exemption for Registered Nurses (RN's) throughout the facility, granted January 2015.

Motion to approve exemption: Ms. Jolly,
Second: Ms. Arnott.

Exemption Request Approved.

3. **Baroness Erlanger Hospital
Chattanooga, TN 37403
Rita Stewart, MT
Laboratory Support Services
Coordinator**

This facility request was presented and approved for Registered Nurses (RN's) to perform and report malaria testing procedures in the Special Pathogens Unit utilizing the BinaxNOW test kit.

Motion: Mr. Johnson.
Second: Ms. Arnott.
Exemption Request Approved.

An additional question was raised concerning the practice of Nurse Practitioner to be included with exemptions granted to Registered Nurses. Board members agreed that because of the higher level of education, nurse practitioners are to be included to perform and report tests granted by the board.

After discussion board members agreed to allow advanced practice registered nurses (APRN's) (Nurse Practitioners) to perform and report tests granted to Registered Nurses in this facility.

Motion: Dr. Nolan.
Second: Ms. Arnott.

Exemption Request Approved.

Board members agreed to formulate a policy to include Advanced Registered Nurse Practitioners (NP's) in the POC practices previously granted to Registered Nurses.

Policy will be written for board review and approval during the July 21, 2017 meeting.

Note: Advanced Practice Registered Nurses (Nurse Practitioners) approved via the board policy for POCT events, does not automatically apply to Registered Nurses.

RN's performing point-of-care testing procedures still require board review on a case by case basis.

**4. Parkridge Medical Center
Chattanooga, TN 37404
Helen Richardson, MT
Laboratory Manager**

Two (2) request were presented to board members for approval:

Request #1 involved an instrument change from the Osmetech OPT1 to the Alere Epop analyzer.

In 2005, Licensed Perfusionists were give the exemption allowing the performing and reporting of electrolytes, arterial blood gases, tHgb, SO2 and glucose testing procedures plus the addition of Ca+, Hct, and lactate testing procedures; same location: Surgical Services Department during cardiopulmonary by-pass surgery.

Same personnel; same location; different methodology + addition of analytes.

Motion: Mr. Johnson
Second: Ms. Arnott

Request: Approved.

Request #2 represented an additional location, Special Procedures (Vascular Lab), to a previously approved (July 07) exemption for Respiratory Therapists (ABG-endorsed) and Radiology Technoloigsts to perform and report activated clotting times (ATC's) utilizing the Hemochron Signature Elite instrument and methodology.

Motion: Ms. Jolly.
Second: Ms. Arnott.

Request: Approved.

5. **Vanderbilt University
Medical Center
Nashville, TN 37232
Judy Davis, MA, MLS (ASCP)
DLM**

This exemption request was for Registered Nurses (RN's) to perform and report drugs of abuse in the Vanderbilt Psychiatric Hospital on campus utilizing the Rapid Drug Test Cup. The qualitatively tested analytes utilizing this methodology: marijuana, cocaine, opiates, methamphetamines, amphetamines, ecstasy, phencyclidine, propoxyphene, benzodiazepines, barbiturates, methadone, buprenorphine, tricyclic antidepressants and oxycodone.

Confirmation of testing results will be performed in the Vanderbilt clinical laboratory.

Motion: Mr. Johnson.
Second: Ms. Kenwright.

Exemption Request: Approved.

Abstain: Ms. Arnott

**Direct more than three (3)
Laboratories**

No requests for this meeting

RECEIVE REPORTS AND /OR REQUESTS:

Board Director's Report

Ms. England gave the board director's report for the quarter January 01, 2017 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. Arnott
Second: Mr. Johnson
Report approved as given.

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

**Board Attorney Report
Kyonté Hughes-Toombs
Deputy General Counsel**

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

No open cases

Personnel Rules (1200.06.01) are still in review but we are looking to a possible rule-making hearing in July or October this year.

Motion: Ms. Arnott.

Second: Dr. Davis.

Report approved as given,

REINSTATEMENT OF LICENSES

No licenses to reinstate this quarter,

**ADDITIONS/DELETIONS TO THE
BOARD'S WAIVED TEST LIST**

There were no additions or deletions to the board's approved waived test list.

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

Lekh N. Sharma, Ph.D.
Hixon, TN 37343
Director: Toxicology

Dr. Sharma was received his B.S. degree from the University of India, his M.S. from Tribhuvan University in India and his Ph.D. from Baylor University in Texas. All three degrees were in Chemistry.

Training: His training was from the University of Georgia in the Dept. of Microbiology and the Tennessee Valley Pain Management facility in Hixon, TN.

Certification: He holds a current certification from the National Registry of Certified Chemists (NRCC) as a toxicological chemist.

Motion: Ms. Arnott.
Second: Mr. Johnson.

License Approved.

Ana C. Dawsey, Ph.D.,
Rock Hill, SC 29732
Director: Toxicology

Dr. Dawsey obtained her B.S. degree from the College of Charleston in South Carolina and her Ph.D. degree from the University of Southern California. Both degrees were in Chemistry.

Training: Dr. Dawsey was trained in the AIT Laboratory (Physician's Choice Laboratory Services) in Rock Hill South Carolina.

Certification: Dr. Dawsey is currently certified by the National Registry of Certified Chemists (NRCC) as a toxicological chemist.

Motion: Ms. Arnott.
Second: Ms. Jolly.

License: Approved.

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

ETRO Report
Taylor Carpenter
MT-Consultant

East TN Regional Office: January 01-March 31, 2017
Unsuccessful Proficiency Testing:
One (1) first unsuccessful event for pO₂ with an acceptable plan of correction provided to the regional consultant.
Complaint Investigation: Zero.

MTRO Report
Richard Carroll
MT-Consultant

Middle TN Regional Office: January 01-March 31, 2017
Unsuccessful Proficiency Testing:
No proficiency testing reported for this quarter.
Complaint Investigation:
Two (2) complaint investigations during this quarter.

WTRO Report
Karon Hathcoat
MT-Consultant

West TN Regional Office: January 01-March 31, 2017
Unsuccessful Proficiency Testing:
One (1) for pO2 in January; with an acceptable plan of correction provided to the regional consultant.
Complaint Investigation: Zero.

Motion to accept regional surveyor reports: Mr. Johnson.
Second: Ms. Arnott.

All surveyor reports accepted as presented.

Board Ratification of Laboratory Initial License:

**Tennessee Valley Pain
Specialists (Drugscan)
2805 W. Governor John Sevier
Hwy.
Knoxville, TN 37920**

Medical Laboratory Director: Steven Robert Mynatt, M.D.
Surgeon

Specialties: Collection Station

Surveyor: Julia Daniels, MT
Consultant II/Surveyor ETRO

Motion: Mr. Johnson.
Second: Ms. Kenwright.

License Approved.

**Innovative Pathology Services,
PLLC
814 E. Woodland Avenue
Room B
Knoxville, TN 37916**

Medical Laboratory Director: James Craig, M.D.
Anatomic/Clinical Pathology

Specialties: Histopathology

Surveyor: Julia Daniels, MT
Consultant II/Surveyor ETRO

Motion: Ms. Kenwright.
Second: Ms. Arnott.

License Approved.

**BioReference Laboratories,
Inc. @ Healthstar OB.Gyn
619 W.17th North Street #F
Morristown, TN 37814**

Medical Laboratory Director: Robert S. Richmond, M.D.
Anatomic Pathology

Specialties: Collection Station

Surveyor: Julia Daniela, MT
Consultant II/Surveyor ETRO

Motion: Mr. Johnson.
Second: Ms. Arnott.

License: Approved.

OTHER BUSINESS:

Board clarification of items relating to operation of
administrative office:

**Item 1
On-line
Apps.**

The on-line application update was presented by Ms. England with the go-live event to be May 15, 2017 if not sooner. Much time and effort has been expended by staff and IT division pertaining to the genesis of the operation.

While I do anticipate some initial issues both with applicants as well as staff at the start of the event this on-line process should expedite all initial applications for licensure especially those individuals seeking licensure as a medical laboratory professionals in Tennessee and also laboratory facilities applying for an initial license in this state.

Facility applications will be brought on-line at the same time; however there must still be surveyor on-site review before the application is presented to the board for ratification.

Training program applications should be on line later this year. All training programs expire on December 31 of each calendar year; we currently have twenty (20) training programs.

No board action taken.

**Item 2
Clinical Procedures/
Esoteric Laboratory**

Questionable Parameter Clarification of Testing Procedures

Ms. England sought board member direction concerning regulation of services/personnel qualifications for those laboratory tests performed in a clinical laboratory environment and have morphed into those laboratories classified as esoteric after board review.

Rules and Regulations Governing Medical Laboratories 1200-06-03-.22.

These tests to include specific gravity, pH, creatinine, etc. and are performed to establish the "validity" of a specimen before performing the "esoteric" test.

Parameters need to be established as to the necessity of a licensed vs non licensed individual performing the "validity" test procedure.

After discussion board members concluded if the results of the "validity" test report is included within the laboratory report to the physician, licensed laboratory personnel are required to perform the test.

**Item 3
Drug Screens/
Collection Stations**

Ms. Karon Hathcoat, West Tennessee consultant/surveyor asked for clarification on the following:

Can a licensed collection station perform drug screens on their children at the request of a parent?

Board members determined these tests do not fall under their current exemption policy because the test does not pertain to drug testing events for employment purposes.

Collection stations per regulation do not perform on-site testing procedures, therefore compliance is not achieved and a citation must be issued to the collection station location.

Statement of Next Meeting

The next Board Meeting will be July 21, 2017 begin at 9 AM CDT in the Iris Conference Room, Ground Floor, MetroCenter Complex, 665 Mainstream Drive, Nashville, TN 37243

Record of Adjournment

With no further business to discuss and with a motion properly presented, the meeting adjourned at 12:40 pm CDT.

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

Meeting Adjourned.