

**MEDICAL LABORATORY BOARD
MINUTES**

Date: January 26, 2007

Time: 9:00 a.m., CST

Location: Bureau of Health Licensure and Regulation
TN Department of Health
Heritage Place
Iris Room
227 French Landing, Ground Floor
Nashville, TN 37243

Members Present: Norman Crowe, Chairman
Independent Lab Manager/Representative
Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
John C. Neff, MD
Trudy Papuchis, MD
Thomasa Cooper, Medical Technologist
Yvonne Davis, Medical Technologist
Martha Duncan, Medical Technologist
Linda Lahr, MT
Alison McDonald-Spakes, Cytotechnologist
Delores Voigt, MT Hospital Administrator
Gloria Jenkins, Citizen Representative

Members Absent: Edward McDonald, MD

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Jerry Kosten, Rules Manager
Nicole Armstrong, Advisory Attorney
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office
Robbie Bell, Director-Health Related Boards, Ex-Officio Board Member

Minutes

Medical Laboratory Board
January 26, 2007

Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor
East Tennessee Regional Office

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

CLIA Representative: Irmgard Brown, CLIA Manager

Quorum: A sufficient number of board members were present to constitute a quorum.

Presiding Officer: The meeting was called to order by the Board Chairman, Norman Crowe at 9:05 am, CST.

Board members introduced themselves to the audience.

Mr. Crowe introduced Ms. Carpenter to the audience and members of the Board. Ms. Carpenter is the Medical Technologist Consultant/Surveyor for the East Tennessee Regional Office and will be working with Ms. Daniels.

Welcome: Mr. Crowe welcomed guests and visitors to the meeting.

Board Minutes: A motion to approve the October 11, 2006 Personnel & Education Committee Minutes was made by Dr. Neff.

Second: Ms. Lahr.

The minutes were approved.

A motion to approve the Board minutes from the October 12, 2006 meeting was made by Dr. Neff.

Second: Ms. Voigt

The minutes were approved.

Board Report

Personnel & Education Committee:

Ms. Duncan presented a report of the actions of the Personnel & Education Committee meeting, January 25, 2007.

Minutes
Medical Laboratory Board

January 26, 2007

Motion to accept this report: Dr. Ferguson.

Second: Ms. Lahr.

The report was approved.

Contested Cases: There were no contested cases presented during this meeting.

Consent Orders: There was no consent orders reviewed during this meeting.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN

TNPAP State Director

Mr. Harkreader gave the following report to the board:

Monitoring Status as of December 31, 2006: TNPAP is currently monitoring six (6) individuals.

Statistics for the period July 1, 2006 to December 31, 2006 stated four (4) referrals with six (6) individuals in monitoring status and zero (0) individuals in evaluation status.

There were a total of two (2) individuals discharged from this program with one (1) individual noncompliant with monitoring and reported to TDOH and one (1) individual TNPAP considered monitoring unnecessary.

The referral sources indicated three (3) individuals were referred to TNPAP from the Board's administrative office, and one (1) individual referred from their employer.

The history of referrals TNPAP indicates four (4) individuals who had a history of arrest (drug related arrest/illegal drug use).

Motion to accept this report: Dr. Neff.

Second: Ms. Duncan.

Report Approved.

A copy of Mr. Harkreader's report is on file in the Board's administrative office.

Minutes
Medical Laboratory Board
January 26, 2007

The Board voted to amend the 2007-2008 contract with TNPAP to reflect an increase in fees paid to this advocacy group.

Motion: Dr. Ferguson
Second: Ms. Voigt
Approved.

Board Report-Rules:

Jerry Kosten-Rules Manager

A .Rules Amendments:

- 1-Rule 1200-6-1-.01(32) & 1200-6-1-.22(1) (e), (2) (d).
Rule 1200-6-1-.03 Necessity of Licensure.
Rule 1200-6-3-.02 Licensing Procedures CT Special Analyst.
- 2-Rule 1200-6-1-.22(a) (5) Upgrade MLT to MT.
- 3-Rule 1200-6-1-.12 Continuing Education Definition.
- 4-Rule 1200-6-1-.18 Unethical Conduct.

There were no comments presented to Mr. Kosten concerning this rulemaking hearing December 19, 2006.

A motion to adopt these amendments was made by: Dr. Neff.
Second: Dr. Ferguson.
Motion: Approved.

2-Bill Jolley
Vice President
Allied Health Commission
Rural Health Issues
Nashville, TN

Dr. Kathleen McEnerney
Dean, College of Health Sciences
Tennessee State University
Nashville, TN

Dr. McEnerney addressed the Board concerning the (Board) entering into grants, agreements, scholarships with the purpose of evaluating and guiding the development of education, distribution and availability of the allied health workforce to provide an improvement in the quality of health care,
T.C.A. §63-1-1.

These individuals are interested in developing an Allied Health Commission that would focus specifically on allied health issues.

Board members requested copies of a study on this subject performed by MTSU concerning the lack of health care professionals in the workforce.

Mr. Jolly agreed to provide this information for Board review.

No Board action was taken on this matter.

3-Gordon K. Livingston, Ph.D.
Technical Director
Cytogenetic Biodosimetry Laboratory (CBL)
Oak Ridge, TN 37831

Documentation was presented to board members for determination of necessity of licensure for this facility. Board members expressed concern associated with the manner in which the test results would be utilized, and the implications of how this facility would react and treat victims of biological terrorism.

Board members requested further information from Dr Livingston before making a decision on the licensure status for this laboratory. This decision was tabled until the April 2007 meeting along with a request for Dr. Livingston to appear before the Board for further discussion

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

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information. The Director's report is on file in the administrative office. Motion: Dr. Ferguson.

Second: Ms. Duncan.

Report Approved:

Minutes
Medical Laboratory Board
January 26, 2007

Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab Facilities:

Jack T. Bechtel, M.D.
Highlands Pathology Laboratory Consultants, PC
1 Medical Park Blvd.
Bristol, TN 37620

Dr. Bechtel currently directs:

1. Spectrum Tennessee Network at Bristol Regional Medical Center.
2. Wellmont Bristol Regional Medical Center Point of Care.
(Located in #1 facility)
3. Wellmont Health System Medical Park Blood Center-Bristol, TN.

Motion: Dr. Neff.
Second: Dr. Papuchis.
Approved.

Dr. Ferguson recused himself from this discussion and vote.

Reinstatement of License: There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

Reports:

Regional Consultant/Surveyor – Proficiency Testing (PT) &
Complaint Investigations/Licensed Laboratory Facilities

East Tennessee Regional Office

Julia Daniels, Consultant II/Surveyor;

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported three (3)
facilities demonstrating unsuccessful participation in
PT events.

Minutes
Medical Laboratory Board
January 26, 2007

The events were:

- 1-Bacterial ID-clerical error (remedial training).
- 2-Gram Stain Morphology-sample problem (technical training & education by pathologist).
- 3-D-Dimer-manufacturer technical assistance required (voltage problem)-instrument recalibrated and patient specimens repeated with acceptable results.

Complaint Investigations: The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter.

Middle Tennessee Regional Office

Sandra S. Bogard, Consultant II/Surveyor
Onezean Otey, Jr., Consultant I/Surveyor

Mr. Otey gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two of three events): two (2).

1-Analyte: fibrinogen

2-Analyte: magnesium

Laboratories with a second occurrence of unsuccessful PT: zero (0).

Complaint Investigation:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigation(s) during this quarter.

Minutes
Medical Laboratory Board
January 26, 2007

West Tennessee Regional Office

Karen Hathcoat, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

One (1) facility had a first occurrence of unsuccessful proficiency testing (two out of three in a row). The facility provided the surveyor with an acceptable Plan of Correction.

Facilities with a second occurrence of unsuccessful proficiency testing is zero (0).

Complaint Investigations:

There were zero (0) complaint investigations conducted by this regional office the past quarter.

Motion to accept these reports: Ms. Duncan.
Second: Ms. McDonald-Spakes.
Approved.

Discussion/Clarification for Staff and Surveyors:

No questions were presented during this meeting.

Department Reports/Discussion:

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell asked for the Board's endorsement of a Health Related Boards Policy and Procedure concerning Patient Safety: Culture of Learning, Justice and Accountability.

This policy resolves that Health Related Boards will strive for a culture that balances the need for a non-punitive learning environment with the equally important need to hold persons accountable for their actions. This policy strives to foster a learning environment based on behavior, not the outcome of events.

Minutes

Medical Laboratory Board

January 26, 2007

This process will be considered in the reviewing of complaints filed with the Boards, their consultants, and staff.

Motion to Adopt Policy: Dr. Neff

Second: Ms. Voigt
Approved.

Office of General Counsel Report:

Nicole Armstrong,
Advisory Attorney

Ms. Armstrong reported on the following:

Rules:

1-Temporary licensure, advertising, use of titles, screening panels (05-1327) (Tenn. Comp. R. & Regs. 1200-6-1-.03, .13, .19; 1200-6-3-05, .20) These rule amendments went to rulemaking hearing on September 29, 2005; they were adopted by the Board on October 13, 2005 and sent to the Attorney General for review on October 28, 2005 where they remain.

2-Laboratory licensure, P.O.L., chemical terrorism (06-1010) (Tenn. Comp. R. & Regs 1200-6-3-.02, .03,.16) These rule amendments went to rulemaking hearing on March 17, 2006; they were adopted by the Board on April 13, 2006 and sent to the Attorney General for review on April 20, 2006. They will become effective on March 12, 2007.

3-Examination fee, CE revisions, licensure requirements, lab renewal, cytology preparatory exemption (06-1153) (Tenn. Comp. R. & Regs. 1200-6-1-.06, .12 .22; 1200-6-3-.02, .19, .21) These rule amendments went to rulemaking hearing on June 16, 2006; they were adopted by the Board on July 13, 2006, and sent to the Attorney General for review on July 18, 2006, where they remain today.

4-Continuing education, unethical conduct, licensure requirements, chemical terrorism exemption (06-1421) (Tenn. Comp. R. & Regs. 1200-6-1-.03,.12,.18,.22; 1200-6-3-.02) These rule amendments went to rulemaking hearing on December 19, 2006. They will be presented to the Board for adoption on January 26, 2007.

Minutes
Medical Laboratory Board
January 26, 2007

Litigation:

The Office of General Counsel, Tennessee Department of Health, has one (1) open case pertaining to the Tennessee Medical Laboratory Board.

Topics for Discussion:

Conflict of Interest Policy

Board members were reminded by Ms. Armstrong to consider recusing themselves from any discussion of vote pertaining to meeting business if the subject material might have any relation to member business or any decision that might appear to be a conflict of interest.

Motion to Accept Report: Dr. Neff
Second: Ms. Lahr
Approved.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of the financial report for the fiscal year 2006-2007 was mailed to each Board member earlier in the month.

A copy of this report is included in each member's board book and also on file in the administrative office.

The Board reviewed the report for projected 2006-2007 year.

A motion to approve this report: Ms. Voigt.
Second: Ms. Duncan.
Approved.

Bureau of Investigations (BIV) Report:

There was no report as to the number of cases in BIV.

There is one (1) individual that continues to be monitored and continues to pay case costs.

Motion to Accept Report: Dr. Neff.
Second: Dr. Carter.
Approved.

Minutes
Medical Laboratory Board
January 26, 2007

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

No report was given by Ms. Eads during this meeting.

Waived Testing Procedures: There were no additions or deletions to the Waived Test List.

Review Eligibility of Medical Laboratory Director:

1. Charlotte Q. Brown, Ph.D.
Chapel Hill, NC 27517
Director: Molecular Diagnostics

Motion: Dr. Neff.
Second: Dr. Ferguson.
Approved.

Board Policy:

Tennessee Medical Laboratory Board Position Statement

Tennessee Chronic Kidney Disease Screening Act of 2005

The Tennessee Chronic Kidney Disease Screening Act of 2005 (Tenn. Code Annotated §68-5-803(b)) encourages health care providers to counsel patients at risk of kidney disease, and urges those health care providers to test at-risk patients for chronic kidney disease. Laboratories are ordered to report the glomerular filtration rate on any serum creatinine test ordered by a health care provider.

The Tennessee Medical Laboratory Board does not enforce the Tennessee Chronic Kidney Disease Screening Act of 2005. The Tennessee Medical Laboratory Board does not have any authority to promulgate rules to implement the law, nor may it advise the public on compliance with the law.

Motion to Adopt Policy: Dr. Neff.
Second: Ms. Lahr.
Approved.

Minutes
Medical Laboratory Board
January 26, 2007

Other Business:

There was no other business discussed during the meeting.

Statement of Next Meeting:

The next meeting will be held April 12, 2007 beginning at 9:00 am
CDT in the Iris Room, Heritage Place 227 MetroCenter, Nashville, TN 37243.

Record of Adjournment:

The meeting adjourned at 11:30 pm, CST on a motion properly
filed by Dr. Ferguson,
Second: Ms. McDonald-Spakes
Approved.

Norman Crowe
Chairman, Tennessee Medical Laboratory Board

Date

Page 1
Attachment 1
Medical Lab Board
Point of Care Exemption Requests
January 12, 2007

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. **Fort Sanders Regional Medical Center
1901 Clinch Avenue**

Knoxville, TN 37916

Facility Representative: Debra Ogle, MT
Laboratory POC Tech Specialist

This facility requested an exemption to permit Registered Nurses, Licensed Practical Nurses, and Perfusionists perform and report activated clotting times, (ACT's) before, during, and after procedures that require hospitalization of the patient. These tests are to be performed hospital wide. The instrument utilized in these procedures is the Hemochron, Jr.

Motion: Dr. Neff
Second: Ms. Duncan
Approved.

2. **Parkwest Medical Center**
9352 Parkwest Blvd.
Knoxville, TN 37923

Facility Representative: Debra Ogle
Laboratory POC Tech Specialist

This facility requested exemptions for Licensed Nurses (RN's & LPN's) and Perfusionists to perform and report activated clotting times (ACT's) before, after, and during procedures that require hospitalization of the patient. These tests are to be performed hospital-wide. The instrument that will be utilized is the Hemochron, Jr.

Motion: Dr. Neff.
Second: Dr. Ferguson.
Approved

Page 2
Attachment 1
Medical Laboratory Board
Point of Care Exemption Request
January 26, 2007

3. **Bristol Regional Medical Center**
1 Medical Park Blvd.
Bristol, TN 37620

Facility Representative: Carol Stevenson

This facility request was for Licensed Nurses (RN's & LPN's) to perform and report activated clotting times, (ACT's), on 3 West, Progressive Coronary Care Unit, utilizing the Hemochron Signature Plus instrument.

Motion: Dr. Neff
Second: Ms. Duncan
Approved.

Dr. Ferguson recused himself from the discussion and vote.

4. **Holston Valley Medical Center**
130 West Ravine Road
Kingsport, TN 37660

Facility Representative: Richard Doyle

This exemption request is to permit Licensed Nurses (RN's & LPN's), Respiratory Therapists to perform and report Troponin, Myoglobin, CK-MB, and BNP in the Progressive Admission Unit utilizing the Biosite Triage Meter.

Motion: Dr. Neff.
Second: Ms. Lahr.
Approved.

Dr. Ferguson recused himself from the discussion and vote.

5. **Jackson-Madison County General Hospital**
706 West Forest Avenue
Jackson, TN 38301

Facility Representative: Jerry Barker
Assistant Laboratory Director

Page 2
Attachment 1
Medical Laboratory Board
Point of Care Exemption Request
January 26, 2007

This facility request was for Licensed Nurses (RN's & LPN's) to perform and report BUN, and creatinine analyses in the Department of Radiology utilizing the Ortho Vitros DT 6011 Analyzer with the DTSCHE component.

After discussion, the Board voted to deny this request. The facility instrument of choice is a table-top instrument with a resulting multi-step process for patient testing of samples.

The Board has approved hand held instruments for point of care testing procedures. Recommendations were made by Board members to perform this analysis utilizing previously approved instruments.

Motion to Deny: Dr. Neff.
Second: Ms. Davis.
Exemption Denied.

6. **Southern Tennessee Medical Center Laboratory**
185 Hospital Road
Winchester, TN 37398

This exemption request was postponed to the April 2007 meeting by laboratory request.

7. **St. Thomas Hospital**
Dept. of Pathology
4220 Harding Road
Nashville, TN 37202

Facility Representative: Wilma Hausler, MT
Q/A Point of Care Specialist

This facility request is for a modification to permit Paramedics, Emergency Medical Technicians and Licensed Practical Nurses to perform and report Cardiac Markers in the Emergency Department. The Biosite Cardiac Triage Meter will continue to be the instrument of choice for these testing procedures. The original exemption was granted in October 2001.

Motion: Dr. Neff
Second: Dr. Ferguson.
Approved.

Ms. McDonald-Spakes recused herself from this discussion and vote.

Page 3
Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
January 26, 2007

8. **Williamson Medical Center**
2021 Carothers
Franklin, TN 37067

Facility Representative: Patti J. Walton, MT (ASCP)
Point of Care Coordinator

This request was to permit Licensed Nurses (RN's & LPN's) to perform and report Cardiac Markers (CK-MB, Troponin, and Myoglobin) in the Emergency Department and Chest Pain Center. The instrument utilized in the performance of these tests is the BioSite Triage Meter.

Motion: Dr. Neff.
Second: Ms. Lahr.
Approved.

9. **Diagnostic Laboratories-VUMC
22nd & Pierce 4605 TVC
Nashville, TN 37232-5310**

Facility Representative: Terri Tubb
Point of Care Testing

This request is for the addition of Licensed Practical Nurses (LPN's) to the original exemption request of January 2003. This request is for the performance of serum creatinine levels in the Department of Radiology.

Motion: Dr. Neff.
Second: Ms. Duncan.
Approved.

Page 1
Attachment 2
Initial Facility Licenses
Medical Laboratory Board
January 26, 2007

**INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION/
BOARD RATIFICATION:**

**1-Pathgroup Chattanooga
4071 South Access Road
Chattanooga, TN 37406**

Medical Laboratory Director: Richard B. Hessler, M.D.

Anatomic/Clinical Pathology

Specialties: Histopathology, Oral Pathology, Cytopathology

Surveyor: Julia Daniels, Consultant II/Supervisor
East TN Regional Office

Motion: Dr. Ferguson
Second: Ms. Lahr
Approved.

Dr. Papuchis recused herself from the discussion and vote.

2-Allermetrix, Inc.
400 Sugartree Lane, Suite 500
Franklin, TN 37064

Medical Laboratory Director: Gary A. Kitos, Ph.D.
Director: Chemistry
Director: Microbiology

Specialties: General Immunology

Surveyor: Sandra S. Bogard, Consultant II/Surveyor MTRO
West TN Regional Office

Motion: Dr. Neff.
Second: Ms. McDonald-Spakes.
Approved.

Page 2
Attachment 2
Initial Laboratory Facilities
Medical Laboratory Board
January 26, 2007

3-Spectrum Tennessee Network at Lebanon
1424 West Baddour Parkway Suite B
Lebanon, TN 37087

Medical Laboratory Director: Robert M. Gray M.D.
Anatomic/Clinical Pathology

Specialties: Collection Station

Surveyor: Onezean Otey, Jr., Consultant I/Surveyor
Middle TN Regional Office

Motion: Ms. Duncan.
Second: Ms. Voigt
Approved.

Dr. Ferguson recused himself from the discussion and vote.

**4-Laboratory Corporation of America
1301 McCallie Avenue
Chattanooga, TN 37404**

Medical Laboratory Director: Pennell C. Painter, Ph.D.
Director-General LLS

Specialties: Collection Station

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Motion: Dr. Papuchis
Second: Ms. Duncan.
Approved.

Mr. Crowe recused himself from the discussion and vote.

Page 3
Attachment 2
Initial Laboratory Facilities
January 26, 2007

**5-Laboratory Corporation of America
9625 Kroger Park Drive, Suite 50
Knoxville, TN 37922**

Medical Laboratory Director: Lisa Duncan, M.D.
Anatomic/Clinical Pathology

Specialties: Collection Station

Surveyor: Julia Daniels, Consultant II/Surveyor ETRO

Motion: Ms. Lahr.
Second: Ms. Duncan.
Approved.

Mr. Crowe recused himself from the discussion and vote.

**6. Spectrum TN Laboratory Network at Cookeville-PSC
315 N. Washington Avenue Suite 180
Cookeville, TN 38501**

Medical Laboratory Director: Robert M. Gay, M.D.
Anatomic/Clinical Pathology

Specialties: Collection Station

Surveyor: Onezean Otey, Jr., Consultant I/Surveyor MTRO

Motion: Ms. Duncan.
Second: Ms. Voigt.
Approved.

Dr. Ferguson recused himself from the discussion and vote.

Page 4
Attachment 2
Initial Laboratory Facilities
January 26, 2007

**7. Watauga Pathology Associates
400 N. State of Franklin Road
Johnson City, TN 37604**

Medical Laboratory Director: Patrick N. Costello, M.D.
Anatomic/Clinical Pathology

Specialty: Histopathology, Oral Pathology, Cytopathology

Surveyor: Julia Daniela, Consultant II/Surveyor

East TN Regional Office

Motion: Dr. Neff
Second: Dr. Papuchis
Approved