

**MEDICAL LABORATORY BOARD
MINUTES**

Date: October 11, 2007

Time: 9:00 a.m., CDT

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
John C. Neff, MD
Trudy Papuchis, MD
Thomasa Cooper, Medical Technologist
Martha Duncan, Medical Technologist
Yvonne Davis, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist

Members Absent: Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Edward McDonald, MD
Gloria Jenkins, Citizen Representative
Delores Voigt, MT Hospital Administrator
Darius Y. Wilson, MAT, Educator

Staff Present: Cheryl H. Thacker, Medical Technologist Consultant
Denise Burton, Administrative Assistant
Jerry Kosten, Rules Manager
Nicole Armstrong, Advisory Attorney

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Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office
Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Taylor Carpenter, Medical Technologist Consultant/Surveyor
East Tennessee Regional Office

Staff Absent:

Lynda S. England, Medical Technologist Director

CLIA Representative:

Sandra S. Bogard, 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 CDT.

Board members introduced themselves to the audience.

Welcome:

Mr. Crowe welcomed guests and visitors to the meeting.

Board Minutes:

A motion to approve the July 11, 2007 Personnel & Education Committee minutes was made by Ms. Duncan.

Second: Dr. Neff.

The minutes were approved.

A motion to approve the minutes from the July 12, 2007 meeting of the Board was made by Dr. Neff.

Second: Ms. Duncan.

The minutes were approved.

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Board Report

Personnel & Education Committee:

Ms. Duncan presented a report of the actions of the Personnel & Education Committee meeting, October 10, 2007.

Motion to accept this report: Ms. McDonald-Spakes

Second: Dr. Neff.

The report was approved.

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

Consent Orders: There were no consent orders presented during this meeting.

Board Report-Tennessee Professional Peer Assistance Program (TNPAP):

Mike Harkreader, MA, RN

TNPAP State Director

The report was given by Ms. Armstrong in the absence of Mr. Harkreader:

Statistics for the period July 1, 2006 to June 30, 2007 stated six (6) individuals signed monitoring agreements, with eight (8) referrals and ten (10) individuals in monitoring status.

Two (2) individuals were discharged from this program with one (1) individual noncompliant with monitoring and one (1) individual refusing services.

The referral sources indicated seven (7) individuals were referred to TNPAP from the board's administrative office, and one (1) individual referred by "other" sources.

The history of referrals TNPAP indicates eight (8) individuals had a history of arrest (drug related arrest/illegal drug use/DUI).

Motion to accept this report: Ms. Duncan.

Second: Ms. Davis.

Report Approved.

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

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Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

A proposed rules rewrite was tabled until the January 10, 2008 meeting.

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

In Ms. England's absence board members reviewed her director's report. This report included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information.

Motion: Ms. McDonald-Spakes.

Second: Ms. Duncan.

Report: Approved.

The director's report is on file in the administrative office.

Direct More Than Three (3) Labs

Rule 1200-6-3-.13(5) Medical Lab Facilities: No requests; no action taken on this matter.

Reinstatement of License:

There were no requests for facility licenses to be reinstated during this meeting.

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Reports/Discussion:

Reports:

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

East Tennessee Regional Office: Ms. Daniels

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported zero (0) facilities demonstrating unsuccessful participation in proficiency testing events.

Complaint Investigations:

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

Motion to Accept Report: Dr. Neff

Second: Ms. Duncan.

Approved.

Middle Tennessee Regional Office: Onezean Otey, Jr.

Unsatisfactory/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two of three events): three (3)

Complaint Investigation:

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

Motion to Accept Report: Dr. Neff.

Second: Ms. Duncan.

Approved.

West Tennessee Regional Office: Ms. Hathcoat

Unsatisfactory /Unsuccessful Proficiency Testing:

There was zero (0) facilities having a first occurrence of unsuccessful proficiency testing (two out of three in a row). 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 this Report: Ms. Duncan.

Second: Dr. Neff.

Approved.

Discussion/Clarification for Staff and Surveyors:

No questions were presented during this meeting.

Office of General Counsel Report:

Nicole Armstrong.
Advisory Attorney

Ms. Armstrong reported on the following:

Rules:

1-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. **They became effective July 1, 2007.**

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2-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 were adopted by the Board on January 26, 2007 and sent to the Attorney General for review on February 8, 2007, where they remain today.

Litigation:

The Office of General Counsel, Tennessee Department of Health, has No (0) cases 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. Duncan.

Approved.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is currently in your books.
Accepted as written; no vote.

Bureau of Investigations (BIV) Report:

Ms. Armstrong gave the report:

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New Complaints July-September, 2007: One (1)
Closed Complaints: Seven (7)
Currently Opened Complaints: Zero (0)
Care of Services: Three (3)
Unlicensed Practice One (1)

Motion to Accept Report: Ms. Duncan.

Second: Ms. McDonald-Spakes.

Approved.

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Waived Testing Procedures:

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

Review Eligibility of Medical Laboratory Director:

Board Policy:

The Board established a policy on compliance with Criminal Background Checks for all new applicants:

The Tennessee Medical Laboratory Board adopts the following policy regarding name/social security number based criminal background checks:

The Board shall require the applicant to submit to an FBI/TBI fingerprint scan through the State of Tennessee's approved vendor or its equivalent as determined by the Board. In order to confirm the identity of the applicant and verify any criminal convictions disclosed on the application for licensure, only a criminal background check based on an applicant's fingerprints will be accepted.

Adopted by the Tennessee Medical Laboratory Board on the 11th of October, 2007.

Motion to adopt policy: Dr. Neff

Second: Dr. Papuchis

Adopted.

Other Business:

Staff presented questions for discussion:

1-Can Ph.D. applicants working under a temporary license while waiting to challenge a national boarding examination assume director duties while working on that temporary license? (Rule 1200-6-1-.13) Also is it necessary that the medical laboratory director "of record" continue to make monthly visits to the laboratory or can those duties be performed by the Ph.D. working on the temporary license? (Rule 1200-6-3-.14(6)).

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After discussion, board members determined that the Ph.D. holding the temporary license does not have the authority to assume the responsibilities of a medical laboratory director unless he/she possesses a current license

issued by this board. Monthly visits are a requirement of all licensed medical laboratory directors.

2-Baptist Memorial Health Care Corporation
Corporate Legal Services
H. Waid Ray

Mr. Ray requested assistance from the Board concerning the testing of blood and/or urine specimens for employment purposes and whether or not a physician's order is required for these services to be performed.

After discussion, members determined more information concerning this inquiry is necessary and recommended Mr. Ray make an appearance

during

the January 10, 2008 meeting.

Statement of Next Meeting:

The next meeting will be held January 10, 2008 beginning at 9:00 am CST in the Iris Room, Heritage Place 227 Metro Center, Nashville, TN 37243.

Record of Adjournment:

The meeting adjourned at 11:30 am on a motion properly filed by Ms. Cooper.
Second: Ms. Wilson.
Approved.

The minutes were approved by the Board during the January 10, 2008 meeting.

REQUEST FOR EXEMPTION-POINT OF CARE (POC) TESTING PROCEDURES

1. **Wellmont Holston Valley Medical Center-Point of Care**
130 W. Ravine Road
Kingsport, TN 37660

Facility Representative: Richard Doyle

This facility requested the following exemption(s) from the Board:

The performance of measured blood gases, pH, sodium, potassium, glucose, chloride, ionized calcium, lactate, hematocrit and hemoglobin with associated parameters on the GEM Premier 3000. These tests are to be performed by Registered Nurses and Respiratory Therapists in the Cardiac Intensive Care Unit on patients who may be housed in the ICU, ICS, CCU or CCS Units of this facility.

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

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

Facility Representative: Carol Stevenson

This facility requested exemptions to permit Licensed Paramedics to perform and report Troponin, Myoglobin, CK-MB and BNP in the Emergency Department.
The instrument utilized in these testing procedures is the Biosite Triage Meter.

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

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3. **Parkridge Medical Center**

**2333 McCallie Avenue
Chattanooga, TN 37404**

Facility Representative: Helen Richardson
Laboratory Manager

This facility request was for an exemption to permit Perfusionists, Licensed Practical Nurses (LPN's), Licensed Registered Nurses (RN's), Respiratory Therapists, and Radiology Technologists to perform and report activated clotting times (ACT's) in the Cardiac Services Department.

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

4. **Methodist LeBonheur Healthcare
University Hospital
1265 Union Avenue
Memphis, TN 38104**

Facility Representative: Harriet Bateman,
Point of Care Coordinator

This exemption request is to permit Registered Radiology Technologists and Registered Nurses, to perform and report BUN, and creatinine testing procedures utilizing the i-STAT instrument (the Chem 8 cartridge) in the Department of Radiology and Diagnostic Centers.

The specific locations are:

Methodist Breast Center Germantown
7945 Wolf River Blvd.
Germantown, TN 38138

Methodist LeBonheur Germantown Hospital
7691 Poplar Avenue
Germantown, TN 38138

Methodist Diagnostic Center Germantown
1377 S. Germantown Road
Germantown, TN 37138

Methodist Diagnostic Center Midtown
1801 Union Avenue
Memphis, TN 38104

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Methodist University Hospital
1265 Union Avenue

Methodist Diagnostic Center North
3950 New Covington Pike

Memphis, TN 38104

Memphis, TN 38128

Methodist North Hospital
3960 New Covington Pike
Memphis, TN 38128

Methodist Diagnostic Center South
1300 Wesley Drive
Memphis, TN 38116

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

Ms. Davis and Ms. Cooper recused themselves from the discussion and vote.

5. **Centennial Medical Center**
2300 Patterson Street
Nashville, TN 37203

Facility Representative: Mollie Wynn, MT(AMT)
POC Coordinator

This facility request was for an exemption to permit Registered Nurses and Registered Radiology Technicians to perform and report creatinine levels in the Medical Imaging Department utilizing the i-STAT instrument and methodology.

The correlation studies were not performed and part of this request package. Dr Neff motioned to deny this request. A second to this motion was made by Dr. Papuchis. Request denied.

Ms. Duncan excused herself from this discussion and vote.

6. **Maury Regional Hospital Laboratory**
1224 Trotwood Avenue
Columbia, TN 38401

Facility Representative: Amy Bridges
Point of Care Coordinator

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This request was for Registered Nurses (RN's) to perform and report hemoglobin and hematocrit in the Outpatient IV Therapy Department utilizing the i-STAT instrument and methodology. This is a new location for an exemption granted earlier. Correlation studies

accompanied the original request.

Motion: Dr. Neff.

Second: Ms. Duncan.

Approval.

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Attachment 2

Medical Laboratory Board/ Initial Facility Licenses

July 12, 2007

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

1-Accupath Diagnostic Laboratories d/b/a US Labs

**201 Summit View Drive
Brentwood, TN 370274**

Medical Laboratory Director: Ronald Thomason, M.D.
Anatomic/Clinical Pathology
Hematology

Specialties: Hematology/Flow Cytometry, Molecular Diagnostics,
Clinical Cytogenetics, Histopathology

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

Motion: Ms. Cooper.
Second: Ms. Davis.
Approved.

Mr. Crowe recused himself from the discussion and vote.

**2-ABG Laboratory-St. Mary's Medical Center North
7565 Dannaher Way
Powell, TN 37849**

Medical Laboratory Director: Bruce Henschen, M.D.
Pulmonology

Specialties: pH and blood gases

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

Motion: Ms. Duncan.
Second: Ms. Davis.
Approved.

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**3-Tri-Cities Skin & Cancer Dermatopathology Laboratory
1009 North State of Franklin Access Road, Suite A
Johnson City, TN 37604**

Medical Laboratory Director: Timothy Gardner, M.D.

Dermatopathology, Dermatology

Specialties: KOH, Wet Prep, Virology Limited, Histopathology

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

Motion: Ms. Duncan.
Second: Ms. Davis.
Approved.

**4-American Red Cross, Murfreesboro Fixed Site
836 Commercial Ct.
Murfreesboro, TN 37129**

Medical Laboratory Director: Claire Meena-Leist, M.D.
Anatomic/Clinical Pathology

Specialties: Blood Donor Center, Hematocrit

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

Motion: Ms. Duncan.
Second: Ms. Davis.
Approved.

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5-CCL Patient Service Center
1 Sheridan Square, Suite 102
Kingsport, TN 37660

Medical Laboratory Director: C. Timothy Via, M.D.
Anatomic/Clinical Pathology

Specialties: Collection Station

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

Motion: Ms. Duncan.
Second: Ms. McDonald-Spakes
Approved.