

**MEDICAL LABORATORY BOARD
MINUTES**

Date: July 12, 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/Representative
Dennis Carter, MD
Jere Ferguson, MD, Vice-Chairman
Edward McDonald, MD
John C. Neff, MD
Trudy Papuchis, MD
Thomasa Cooper, Medical Technologist
Yvonne Davis, Medical Technologist
Gloria Jenkins, Citizen Representative
Alison McDonald-Spakes, Cytotechnologist
Delores Voigt, MT Hospital Administrator
Darius Y. Wilson, MAT, Educator

Members Absent: Martha Duncan, Medical Technologist

Staff Present: Lynda S. England, Medical Technologist, Director
Jerry Kosten, Rules Manager
Nicole Armstrong, Advisory Attorney

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Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
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

Staff Absent: Cheryl H. Thacker, Medical Technologist, Consultant
Taylor Carpenter, Medical Technologist Consultant/Surveyor
East Tennessee Regional Office

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 a.m., 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 April 11, 2007 Personnel & Education Committee minutes were made by Dr. Ferguson.
Second: Dr. Neff.
The minutes were approved.

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

Second: Dr. Papuchis.

The minutes were approved.

Board Report

Personnel & Education Committee:

Mr. Crowe presented a report of the actions of the Personnel & Education Committee meeting, July 11, 2007.

Motion to accept this report: Dr. McDonald.

Second: Ms. Voigt.

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

Mr. Harkreader gave the following report to the board:

Statistics for the period July 1, 2006 to May 31, 2007 stated eight (8) referrals with eight (8) individuals in monitoring status and one (1) individual in evaluation status. Six (6) individuals signed monitoring agreements with this agency.

There were a total of three (3) individuals discharged from this program with one (1) individual noncompliant with monitoring and reported to TDOH, and one (1) individual TNPAP considered monitoring unnecessary, with one (1) individual that refused services.

The referral sources indicated seven (7) individuals were referred to TNPAP from the Board's administrative office, and one (1) individual was referred by their employer.

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

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Mr. Harkreader asked the Board to consider authorizing funds for financial aid for applicants who could not afford to contract with this program (hardship purposes).

Motion to accept this report: Dr. Neff.

Second: Dr. Ferguson.

Report Approved.

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

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

No rules were promulgated by the Board during this 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

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: Dr. Carter.

Report: Approved.

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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.

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. McDonald

Second: Dr. Carter.

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): one (1).

Hematology, Chemistry, Endocrinology & Toxicology

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

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Complaint Investigation:

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

Motion to Accept Report: Dr. Carter.

Second: Ms. McDonald-Spakes.

Approved.

West Tennessee Regional Office: Ms. Hathcoat

Unsatisfactory /Unsuccessful Proficiency Testing:

There was one (1) facility 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: Dr. Carter

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:

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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.**

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. Ferguson.
Second: Ms. Voigt.
Approved.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is currently in your books.

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Bureau of Investigations (BIV) Report:

Ms. Juanita gave this report.

New Complaints April-June 2007: Zero (0)

Closed Complaints: Zero (0)

Currently Opened Complaints: Zero (0)

Care of Services: Two (2)

Motion to Accept Report: Dr. Neff.

Second: Dr. Ferguson.

Approved.

Waived Testing Procedures:

Regina B. Perry, MSN, APRN-BC appeared before the Board requesting serum lead levels be added to the waived test list. This test procedure would be performed in conjunction with the LeBonheur Community Outreach Mobile Health Unit. This unit visits the outer areas and conducts health assessments for those individuals that are unable to access local Health Department locations. This screening process would become part of a “wellness” checkup for children exposed to lead toxicity. After discussion it was determined that CLIA classified this mobile health unit as a “POL”. Board members agreed with this CLIA categorization. No action was taken.

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

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Review Eligibility of Medical Laboratory Director:

1. Li Cai, Ph.D.

Cary, N.C.
Director: Molecular Diagnostics

This license is approved with receipt of an acceptable criminal background check.

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

2. Gordon K. Livingston, Ph.D.
Knoxville, TN
Director: Cytogenetics Biodosimetry

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

3. Xiao Xiang Zhang
Brentwood, TN 37027
Director: Clinical Cytogenetics

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

Board Policy:

The Board established no new policies this meeting.

Other Business:

The Board voted to activate an education advisory committee for the review and update of Rules 1200-6-2 (Training Programs for Medical Laboratory Personnel) per TCA 68-29-109(1).

Motion: Dr. McDonald.
Second: Dr. Papuchis.
Approved.

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Statement of Next Meeting:

The next meeting will be held October 11, 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 3:10 p.m. on a motion properly
filed by Ms. Cooper.
Second: Ms. Wilson.
Approved.

These minutes were ratified by the board during the October 11, 2007 meeting.

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Attachment 1
Medical Lab Board/Point of Care Exemption Requests
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REQUEST FOR EXEMPTION-POINT OF CARE (POC) TESTING PROCEDURES

1. **SkyRidge Medical Center**
2305 Chambliss Avenue

Cleveland, TN 37312

Facility Representative: Stacy Allison
Administrative Laboratory Director
Bernadette DePrez
Assistant CEO

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

1-Permits Licensed Nursing Personnel (RN's & LPN's) to perform and report oxygen saturation parameters utilizing the Oxicom 3000 instrument in the Catheterization Laboratory.

Motion for Approval: Dr. McDonald.
Second: Dr. Ferguson.
Approved.

2-Permits Licensed Nursing Personnel (RN's & LPN's), and Licensed Respiratory Therapists (RT's) to perform and report troponin, sodium, potassium, chloride, TCO₂, glucose, BUN, creatinine, ionized calcium, hematocrit, hemoglobin and blood gases on the i-STAT instrument.

These clinical analyses are to be performed in the Emergency Room, Critical Decision Unit (CDU), Nursery and ICU.

Motion: Dr. Ferguson.
Second: Dr. Carter.
Approved.

2. **SkyRidge Medical Center-West Campus
2800 Westside Drive
Cleveland, TN 37312**

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Facility Representative: Stacy Allison
Administrative Laboratory Director
Bernadette DePrez
Assistant CEO

This facility requested exemptions for Licensed Nurses (RN's & LPN's), and Licensed Respiratory Therapists (RT's) to perform and report troponin, sodium, potassium, chloride, TCO₂, glucose, BUN, creatinine, ionized calcium, hematocrit, hemoglobin and blood gases utilizing the i-STAT instrument. These clinical procedures will be performed in the Urgent Care Center and the Outpatient Services Center.

Motion: Dr. McDonald.

Second: Dr. Neff.

Approved

**3. Memorial Hospital
2525 deSales Avenue
Chattanooga, TN 37404**

Facility Representative: Beverly Griffith
Point of Care Coordinator

This facility request was for two (2) Point of Care Exemptions:

1-Permits Licensed Nurses (RN's & LPN's) and Radiology Technicians to perform and report pO₂ and O₂ saturation parameters in the Cardiac Cath Lab utilizing the i-STAT analyzer.

Motion: Dr. McDonald.

Second: Dr. Carter.

Approved

2-Permits Cardiac Nurses (RN's) to perform and report sodium, potassium, glucose, hematocrit, and blood gases in the Endovascular Surgical Suites utilizing the i-STAT instrument.

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Motion: Dr. McDonald.

Second: Dr. Carter.

Approved.

**4. Baroness Erlanger Hospital Laboratory
975 East Third Street**

Chattanooga, TN 37043-2112

Facility Representative: Mary Hooper, MT
Laboratory Support Services Manager

This exemption request is to permit Licensed Respiratory Therapists, and Registered Nurses, to perform and report sodium, potassium, chloride, CO2, glucose, ionized calcium, PT, blood gases, troponin, lactate, BUN, hematocrit and creatinine throughout this facility. The instrument utilized is the i-STAT.

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

5. **Parkridge Medical Center
2333 McCallie Avenue
Chattanooga, TN 37404**

Facility Representative: Helen Richardson
Laboratory Manager

This facility request was to permit Respiratory Therapists and Radiology Technologists to perform and report activated clotting times (ACT's) in the Cardiac Services Departments utilizing the Hemochron Signature Elite. This is an addition of licensed health care professionals to a previously granted exemption on January 15, 1998.

Motion: Dr. McDonald.
Second: Dr. Neff.
Approved.

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

This item tabled until the October meeting.

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

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

This facility made the following requests to the Board:

1-Permits Licensed Nurses (RN's & LPN's), Registered Respiratory Therapists (RRT's), Registered Radiological Technologists and Registered Cardiovascular Invasive Specialists (CIS) to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin, hematocrit, ACT, and PT/INR in the CCU-Non-Invasive Cardiology Unit utilizing the i-STAT analyzer.

Motion: Dr. McDonald.
Second: Dr. Ferguson.
Approval.

2-Permits Licensed Nurses (RN's & LPN's), Registered Respiratory Therapists (RRT's), Registered Radiological Technologists (RT-R), and Registered Cardiovascular Invasive Specialists (RCIS), to perform and report PT/INR in the CVICU, Cath Laboratory, and Campus Operating Rooms utilizing the i-STAT analyzer.

Motion: Dr McDonald.
Second: Dr. Neff.
Approval.

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3-Permits the Core Staff (RN's, Nurse Practitioners and Nurse Midwives) in the Women's OB-ER to perform and report AmniSure® Rupture of Membranes Test.

Motion: Dr. McDonald.
Second: Dr. Neff.
Approval.

8. **St. Thomas Hospital**

**Dept. of Pathology
4220 Harding Road
Nashville, TN 37202**

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

This request was for a modification to earlier exemptions granted in April, 1994 and modified in July 2003. This exemption modification permits Licensed Nurses (RN's & LPN's), Registered Respiratory Therapists (RRT's), Radiological Technicians (RT's), and Registered Cardiovascular Interventional Specialists (RCIS) to perform and report activated clotting times (ACT's) in all Intervention Units within the facility.

Motion: Dr. Neff.
Second: Dr. Ferguson.
Approval.

Dr. McDonald and Ms. McDonald-Spakes recused themselves from the discussion and vote.

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

Facility Representative: Terri Tubb
POCT Coordinator

This exemption request was to permit Emergency Medical Technicians (EMT's) to perform and report blood gases, electrolytes, hematocrit, glucose, and ionized Calcium during neonatal stabilization prior to transportation from community hospitals to VUMC.

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Motion: Dr. Neff.
Second: Dr. Ferguson.
Approval

**10. Nashville General Hospital at Meharry
1818 Albion Street
Nashville, TN 37208**

Facility Representative: Thomas Smalling, MT,ASCP (MP)
Director of Laboratory Services

This facility requested the following exemptions:

1-Permits Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) in the Center of Lifestyle and Health Management to perform and report glycosylated hemoglobin (HgA1c) using the Bayer DCA 2000+ analyzer.

Motion: Dr. McDonald.
Second: Dr. Ferguson.
Approval.

2-Permits Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report urinalysis dipstick analyses utilizing the Bayer Clinitek 50 in the Emergency Room and the Internal Medicine Clinic.

Motion: Dr. Ferguson.
Second: Dr. Carter.
Approval.

- | | |
|---|--|
| 11. Indian Path Medical Center
2000 Brookside Drive
Kingsport, TN 37660 | Johnson City Medical Center
400 State of Franklin Road
Johnson City, TN 37604 |
| Johnson City Specialty Hospital
203 E. Watauga Avenue
Johnson City, TN 37601 | Sycamore Shoals Hospital
1501 West Elk Avenue
Elizabethton, TN 37643 |

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The request for each of the four (4) hospitals listed above and was for the following exemption:

1-Permits Registered Nurses (RN's) to perform and report Amnisure® (Rupture of Fetal Membranes) in the Labor & Delivery Area.

Motion: Dr. McDonald
Second: Dr. Carter
Approval.

Johnson City Medical Center (ONLY)

2-Permits Registered Nurses (RN's) and the Rapid Response Team to perform and report lactate, sodium, potassium, chloride, BUN, glucose, creatinine, ionized Calcium, TCO2, hematocrit, calculated hemoglobin, and Anion Gap utilizing the i-STAT analyzer. These tests are to be performed in the Intensive Care Unit.

Motion: Dr. McDonald

Second: Dr. Neff

Approved

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Attachment 2

Medical Laboratory Board/ Initial Facility Licenses

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

**1-Spectrum Laboratory Network at Chattanooga
1829 Gunbarrel Road, Suite A-2
Chattanooga, TN 37412-7184**

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

Specialties: Collection Station

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

Motion: Dr. Neff.
Second: Dr. McDonald.
Approved.

2-Advanced BioServices, LLC
1728 North Eastman Road, Suite 1-B
Kingsport, TN 37664

Medical Laboratory Director: Neil F. Mooney, M.D.
Physician, General Practice

Specialties: Blood Donor/Plasma Center

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

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

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3-Cytogenetic Biodosimetry Laboratory-REACT/TS
PO Box 117 MS 16
Oak Ridge, TN 37831

Medical Laboratory Director: Gordon Livingston, Ph.D.
Director: Cytogenetics Biodosimetry

Specialties: Cytogenetics Biodosimetry

Surveyor: Julia Daniels, Consultant II/ETRO

Motion: Dr. Ferguson.

Second: Dr. Neff.
Approved.