

**MEDICAL LABORATORY BOARD
MINUTES**

Date: January 10, 2008

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

Dennis Carter, MD
Edward McDonald, MD
John C. Neff, MD
Trudy Papuchis, MD
Yvonne Davis, Medical Technologist
Gloria Jenkins, Citizen Representative
Alison McDonald-Spakes, Cytotechnologist
Christopher H. Seay, Medical Technologist
Delores Voigt, MT Hospital Administrator
Darius Y. Wilson, MAT, Ed.D. Educator

Members Absent: Jere Ferguson, MD, Vice-Chairman
Thomasa Cooper, Medical Technologist

Staff Present:

Lynda S. England, MT Board Director
Ernest Sykes, Advisory Attorney
Nicole Armstrong, Advisory Attorney
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

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- Staff Absent:** Cheryl H. Thacker, Medical Technologist Consultant
- CLIA Representative:** Sandra S. Bogard, CLIA Manager
- Quorum:** A sufficient number of board members were present to constitute a quorum.
- Called to Order:** The meeting was called to order beginning at 9:10 am CST.
- Election of Board Chair:** Dr. McDonald made a motion to have Mr. Norman Crowe continue as chairman for the Board for the 2008 calendar year.
- Second: Dr Neff.
No further nominations were made.
Nomination: Approved
- Presiding Officer:** The meeting agenda was continued by Mr. Norman Crowe,

Board members introduced themselves to the audience.
- Welcome:** Mr. Crowe welcomed guests and visitors to the meeting and introduced Christopher H. Seay, who represents the Medical Technologist Supervisor licensure category board position.
- Mr. Crowe also introduced Ernest Sykes, Jr., the newest advisory and litigating attorney for the Board.
- Mr. Crowe recognized Mr. Al Partee the General Counsel for the Department of Health. Mr. Partee gave board members a short explanation of the plans for organizing the Office of General Counsel.
This division provides attorney services for this board.
- Board Minutes:** A motion to approve the October 09, 2007 Personnel & Education Committee minutes were made by Dr. Neff.
Second: Dr. McDonald.
The minutes were approved.

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A motion to approve the minutes from the October 10, 2007 meeting of the Board was made by. Dr. Neff.

Second: Ms. Voigt

The minutes were approved.

Board Report

Personnel & Education Committee:

Ms. Wilson presented a report of the actions of the Personnel & Education Committee meeting, January 09, 2008.

Motion to accept this report: Dr, McDonald

Second: Ms. Davis.

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 Mr. Harkreader:

Statistics for the period July 1, 2006 to December 12, 2007
Stated seven (7) individuals signed monitoring agreements, with five (5) referrals.

Five (5) individuals were discharged from this program
With two (2) individuals successfully completing the program,
two (2) individuals refusing monitoring services (reported to TDOH),
and one (1) individual TNPAP considered monitoring unnecessary.

The referral sources indicated five (5) individuals were referred to TNPAP from the board's administrative office.
The history of referrals TNPAP indicates five (5) individuals had a history of arrest (drug related arrest/illegal drug use/DUI).

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Motion to accept this report: Dr. McDonald.
Second: Dr, Carter,
Report Approved.

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

Board Report-Rules:

Ernest Sykes, Board Attorney

Nicole Armstrong, Former Board Attorney

The following amendments were reviewed by the Board and
set for a Rulemaking hearing during the next meeting on
April 10, 2008.

Chapter 1200-6-1 General Rules Governing Medical Laboratory
Personnel Continuing Education
1200-6-1-.12

(1)(a) Except as set forth at subpart (4) (b) of this rule,
the following organizations, entities, and their affiliates and
chapters are authorized to present, sponsor, or approve continuing
education courses:

(4) Continuing Education Formats

(a) continuing education courses may be presented in the
traditional lecture and classroom formats, or, with successful
completion of a written post experience examination to evaluate
material retention, in multi-media and/or electronic formats.

(b) Notwithstanding the provisions of paragraph (1) (a) of
this rule and subparagraph (4) (a), if a continuing education course
includes a laboratory experience as a component of the course,
the laboratory experience must be provided by a CLIA –approved site
or at an accredited college or university.

(6)(e) Unless the licensee has actively practiced in another state
while the Tennessee license has been retired, revoked or expired,
no more than one-half (1/2) of the required continuing medical
education shall be taken via the Internet or in multi-media and/or
electronic formats as provided in subparagraph (4) (a).

Authority T.C.A. §68-29-105

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Rule 1200-6-1-.22 General Rules Governing Medical Laboratory

Personnel Qualifications, Responsibilities and
Duties of Testing Personnel

(1) (g) 4 Only the laboratory experience which occurs at a CLIA-approved site or provided by an accredited college or university.

(1) (g) 5 Only the laboratory experience which has been properly documented to the Board's satisfaction.

Authority T.C.A. 68-29-103 and 68-29-105.

Rule 1200-6-2-.08 General Rules for Medical Laboratory
Training Programs Advertising

(6) Use of Titles in Advertisements. Any medical laboratory training program licensed by the board which includes in its advertisements the names of its laboratory personnel must use one of the personnel titles authorized by Rule 1200-6-1-.03 (3) this rule in every "advertisement" that term is deemed in Rule 1200-6-2-.08(2) (a) it publishes or the failure to do so will constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory training program to disciplinary action pursuant to T.C.A. §68-29-126 (113), 68-29-127 (9), 68-29-127 (10) and/or 68-29-129 (8).

Authority: T.C.A. §63-1-102, 63-1-146, 68-29-105, 68-29-126, 68-29-127 and 68-29-129

Rule 1200-6-3-.20 General Rules Governing Medical Laboratory Facilities

Use of Titles in Advertisements

(6) Any medical laboratory licensed by the Board which includes in its advertisements to names of its laboratory personnel must use one of the personnel titles authorized by Rule 1200-6-1-.03(3) this rule in every "advertisement" [that term is defined in Rule 1200-6-3-.20 (2) (a)] it publishes or the failure to do so will

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constitute an omission of a material fact which makes the advertisement misleading and deceptive and subjects the medical laboratory to

disciplinary action pursuant to T.C.A. §68-29-126 (9), 68-29-126 (13) and 68-29-129 (8).

Authority: T.C.A. §63-1-102, 63-1-145, 63-1-14, 68-29-105, 68-29-126

Motion to approve amendments: Dr. McDonald.
Second: Ms. Davis.
Approved.

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 gave this report which included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information.

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

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

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

1-Paul J. Sides, M.D.
Department of Pathology
Wellmont Holston Valley Hospital
130 W. Ravine Road
Kingsport, TN 37660

Via audio conference, Dr. Sides confirmed he currently directs the following laboratories:

Wellmont-Hawkins County Memorial Hospital Lab. Rogersville, TN
Wellmont-Hawkins County Memorial Hospital-POC, Rogersville, TN
Wellmont-Hancock County Hospital-Sneedville, TN.

Dr. Sides wants to direct the Wellmont-Hawkins County Memorial Hospital Blood Gas Laboratory located in Rogersville, TN.

The configuration of the Rogersville, TN hospital administrative services, requires Dr. Sides hold three (3) licenses for the same physical location. The location in Sneedville requires Dr. Sides hold the fourth (4) clinical laboratory director license.

Board members discussed this scenario with East Tennessee Regional Surveyor, Julia Daniels. Ms. Daniels performs the biennial surveys on the above listed clinical laboratories.

Ms. Daniels recommended that perhaps the clinical laboratory specialty that would require an fourth (4th) license be added to the Tennessee license #4085 because Dr. Sides currently directs the this hospital facility.

Dr. Sides agreed that this action would be in the best interest of the facility. Ms. Daniels will make recommendation to “add a specialty” to the license #4085 after conducting an on-site survey.

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A motion to approve the “addition of specialty” and not issue a fourth (4) clinical laboratory license was made by Dr McDonald.
Second: Dr. Neff.

Approved to add the specialty to license #4085.

2-R. Samuel Kincaid, M.D.
Cookeville Pathology Laboratory
115 Peachtree Avenue
Cookeville, TN 38501

Via audio conference Dr. Kincaid confirmed he directed the following clinical laboratories:

DeKalb Community Hospital-Smithville, TN
Stones River Hospital-Woodbury, TN
Cookeville Regional Medical Center-Cookeville, TN

Dr. Kincaid has asked to be the director of a fourth (4th) clinical laboratory, the Medical Center of Manchester, located in Manchester, TN.

After board discussion, a motion was made by Dr. McDonald to add the clinical laboratory directorship for the clinical laboratory in Manchester under Dr. Kincaid's direction.

Second: Dr. Neff.

Request Approved.

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: Julia Daniels

Unsatisfactory/ Unsuccessful Proficiency Testing:

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

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No patient results were affected by these PT events.

Complaint Investigations:

The East Tennessee Regional Office conducted zero (0)

investigation(s) during the last quarter.

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): two (2)

Complaint Investigation:

The Middle Tennessee Regional Office has conducted two (2) complaint investigation(s) during this quarter.

West Tennessee Regional Office: Karen Hathcoat

Unsatisfactory /Unsuccessful Proficiency Testing:

Three (3) facilities had 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 Report: Dr. Neff.

Second: Ms. McDonald-Spakes.

Approved.

A complete report is on file in the Department's administrative office for this board.

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Discussion/Clarification for Staff and Surveyors:

No questions were presented during this meeting.

Office of General Counsel Report:

Ernest Sykes
Advisory Attorney

Mr. Sykes 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.

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 one (1) open case pertaining to the Tennessee Medical Laboratory Board.

Topics for Discussion:

Conflict of Interest Policy:

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Board members were reminded by Mr. Sykes 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.

Direct Access Testing:

Document on file in the administrative office.

Drug Screens for Employment Purposes

Response on file in the administrative office.

Motion to Accept Report: Dr. McDonald.

Second: Dr. Carter

Approved.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is currently in your books.

The report was accepted as written; no vote.

Bureau of Investigations (BIV) Report:

Juanita Stone: Disciplinary Coordinator BIV

Ms. Stone gave this report:

New Complaints October-December, 2007: Six (6)

Closed Complaints: Seven (7)

Closed No Action: (6)

Closed-Referred to OGC: (1)

Currently Opened Complaints: Three (3)

Care of Services: Three (3)

Unlicensed Practice One (1)

Motion to Accept Report: Ms. McDonald-Spakes

Second: Ms. Wilson.

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:

No applications were reviewed during the meeting.

Board Policy:

No Board Policies were established during this meeting.

Other Business:

Statement of Next Meeting:

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

Record of Adjournment:

The meeting was adjourned at 1:36 pm CST, on a motion
properly presented by Dr. McDonald.
Second: Dr. Carter
Adjourn Request Approved.

Minutes were approved April 10, 2008 by the Board.

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

1. **Henry County Medical Center**
301 Tyson Avenue
Paris, TN 38242

Facility Representative: Shelley Winn, MT

Point of Care Coordinator

This facility requested an exemption to permit Licensed Registered Nurses (RN's), and Licensed Practical Nurses (LPN's) to perform and report Cardiac Testing Procedures to include CKMB, Myoglobin, and Troponin 1 in the Emergency Department utilizing the Biosite Triage Panel.

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

Note: Dr. Papuchis recused herself from the discussion and vote.

**2. Methodist Healthcare North Hospital
3960 New Covington Pike
Memphis, TN 38128-0504**

Facility Representative: Jane Nichols, BS MT (ASCP)
Laboratory Director & POC Coordinator

This facility exemption request was to permit Registered Respiratory Therapists (RRT's) to perform and report lactate testing procedures using the i-STAT instrument (lactate CG4+ cartridge).

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

Ms. Davis, Ms. Wilson and Mr. Seay recused themselves from this discussion and vote.

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**3. Cookeville Regional Medical Center
142 West Fifth Street
Cookeville, TN 38501**

Facility Representative: June Cantrell, MT (ASCP)
Point of Care Manager

This facility request was for an exemption to permit Respiratory Therapists

to perform and report ionized calcium, pO₂, pH, pCO₂, glucose, hematocrit, and creatinine utilizing the i-STAT instrument and methodologies. These tests will be performed throughout the facility.

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

**4. Baptist Memorial Hospital-Memphis
6019 Walnut Grove Road
Memphis, TN 38120**

Facility Representative: Karen S. Clark, BS MT (ASCP) SH
Point of Care Coordinator

This exemption request permits Registered Nurses, to perform and report creatinine testing procedures utilizing the i-STAT instrument and methodology in the Out-Patient Department.

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

Ms. Wilson recused herself from this discussion and vote.

**5. Diagnostic Laboratories-VUMC
22nd & Pierce 4605 TVC
Nashville, TN**

Facility Representative: Terri Tubb MT (AMT)
POC Coordinator

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Attachment 1
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This facility request was for:

1-the addition of Licensed Registered Nurses (LPN's) to the exemptions previously requested and granted during the Board's quarterly meeting held on October 16, 2003 (on file in the administrative office).

These tests are too numerous to list in these minutes.

These tests are to be performed in both the Vanderbilt University Hospital (VUH) and the Vanderbilt Children's Hospital (VCH).

The instruments that are to be utilized in the performance of these tests are the Gem 3000 Premier, Hemochron, Jr., AVL Omni 6, and the Gem OPL Co-Oximeter. (As listed in the original exemption request.

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

2-a modification to a previous exemption granted in July of 2003 to add Paramedics working with the Life Flight Services to perform and report ABG's, electrolytes, hemoglobin, hematocrit, BUN, creatinine and glucose testing utilizing the i-STAT instrument. Registered Nurses were granted the original exemption.

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

**6. Summit Medical Center Laboratory
5655 Frist Blvd.
Hermitage, TN 37076**

Facility Representative: Lawanda Davis, MT
Administrative Director

This request was to permit Licensed Magnetic Resonance Imaging Technicians, CT Technologists, and X-ray Technologists to perform and report creatinine testing Procedures utilizing the i-STAT instrument and methodology in the Out-Patient Imaging Center located on the hospital campus.

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

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

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

This request was for Registered Nurses and Registered Radiology Technicians to perform and report creatinine testing procedures utilizing the i-STAT.

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

**8. Erlanger Medical Center East Campus
Imaging Center
1755 Gunbarrel Road
Chattanooga, TN 37421-3185**

This exemption request was to permit Licensed Respiratory Therapists, Licensed Radiology Technicians and Registered Nurses to perform and report sodium, potassium, BUN, creatinine, chloride, hematocrit, ionized calcium, CO2, troponin, lactate, and glucose testing procedures utilizing the i-STAT instrument and methodologies.
These tests would be performed in the Imaging Center located on the hospital campus.

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

Mr. Crowe recused himself from this discussion and vote.

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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-Dominion Diagnostics, LLC
215 E. Moody Avenue
Knoxville, TN 37920**

Medical Laboratory Director: David Hancock, M.D.
Medical Doctor
Specialties: Collection Station

Surveyor: Taylor Carpenter, Consultant I/Surveyor
East TN Regional Office

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

2-LabCorp –Chattanooga
979 East 3rd Street Suite A-15
Chattanooga, TN 37403

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

Specialties: Collection Station.

Surveyor: Julia Daniels, Consultant 2/Surveyor
East TN Regional Office

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

Mr. Crowe recused himself from the discussion and vote.