

**MEDICAL LABORATORY BOARD
MINUTES**

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

Members Absent: Dennis Carter, MD

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Jerry Kosten, Rules Manager
Nicole Armstrong, Advisory Attorney
Robbie Bell, Director-Health Related Boards, Ex-Officio Board Member
Deputy General Counsel: Ms. Wilma James

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Staff Absent: 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
Taylor Carpenter, Medical Technologist Consultant/Surveyor
East Tennessee Regional Office

All surveyors were attending a regional CLIA meeting.

CLIA Representative: Ms. Brown attended the CLIA meeting.

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 9:00 am, CDT.

Board members introduced themselves to the audience.

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

Mr. Crowe introduced Ms. Darius Wilson to the Board and to the audience. Ms. Wilson is the program director for the medical laboratory technician training program-Southwest Tennessee Community College, in Memphis.
Ms. Wilson assumes the Education board member vacancy formerly held by Ms. Linda Lahr.

Board Minutes: A motion to approve the January 24, 2007 Personnel & Education Committee Minutes was made by Dr. Neff.
Second: Dr. McDonald.
The minutes were approved.

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A motion to approve the minutes from the January 25, 2007 Board meeting was made by Ms. Duncan.
A second to the motion was made by Dr. Ferguson.
The minutes were approved.

Board Report
Personnel & Education Committee:

Ms. Duncan presented a report of the actions of the Personnel & Education Committee meeting, April 11, 2007.

Motion to accept this report: Dr. Neff.
Second: Dr. McDonald.
The report was approved.

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

Consent Orders: Deputy General Counsel: Wilma James

Cynthia McNutt
Knoxville, TN 37921
License # 19798

Ms. McNutt's license was suspended on this date and will continue in suspension until an evaluation by the Tennessee Professional Assistance Program (TNPAP) can be performed. This evaluation must be performed within thirty (30) days) and Ms. McNutt is to follow all TNPAP recommendations.

Should this advocacy agency (TNPAP) recommend a contract, Ms. McNutt's suspension will continue until the contract is signed.

Ms. McNutt will be placed on probation to run concurrent with this contract and will continue on probation until the time she complies with each and every term, but the term of probation shall be no less than three (3) years in duration. If the contract is extended, the term of probation shall also be extended to the new term of the contract.

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Ms. McNutt was accessed the costs of this action, established by an Affidavit of Costs, prepared by Counsel for the Department.

No civil penalties were assessed in this case.

A motion to accept this consent order was made by Dr. Ferguson.
Second: Dr. Neff.
Approved.

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

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 that had a history of arrest (drug related arrest/illegal drug use).

Motion to accept this report: Dr. McDonald.
Second: Ms. Duncan.
Report Approved.

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

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Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

No rules were promulgated by the Board during this meeting.

B. Board Discussion

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

A teleconference was established between the Board, Dr. Livingston and his colleagues during the meeting.

After this discussion, Board members decided this facility would need to obtain a laboratory facility license.

The Board's decision was based on information presented during this discussion relating to laboratory testing procedures providing information concerning patient testing physicians for the prognosis, diagnosis, treatment or health advice for that physician's patients.

These results (clinical tests) would be performed on individuals exposed to radiation encountered in radiological events (biological events or other mishaps).

This laboratory operation falls under the guidance of the "Tennessee Medical Laboratory Act", Tennessee Code Annotated, T.C.A §68-29-101.

Motion: Dr. McDonald.

Second: Dr. Neff.

Approved.

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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. Neff.
Report: Approved.

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

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*

Unsatisfactory/ Unsuccessful Proficiency Testing:

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

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

last quarter.

Middle Tennessee Regional Office

Unacceptable/Unsuccessful Proficiency Testing:

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

1st Lab-Analyte: TSH 2nd Lab-WBC, RBC, Hgb, Hct & Platelets

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.

West Tennessee Regional Office

Unacceptable/Unsuccessful Proficiency Testing:

There were 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 these reports: Ms. Duncan.

Second: Ms. McDonald-Spakes.

Approved.

* In the absence of the regional surveyors, Ms. England gave the report.

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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 introduced the newly appointed Assistant Commissioner of Health, Christy Allen. Ms. Allen comes to the Department with previous state service in the Department of Commerce & Insurance.

Ms. Bell also reported to the Board that she will be retiring on June 15th. She has thirty years service with the State in varied job titles throughout her career. Ms. Bell expressed her enjoyment of working with all the Boards in the Office of Health Licensure & Regulation.

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. These rules will become effective on May 30, 2007.

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 become effective on March 12, 2007.

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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 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

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: Ms. Duncan
Second: Ms. Cooper
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.

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

Bureau of Investigations (BIV) Report:

Mr. Michael Sobowale gave this report.

New Complaints January-March 2007: One (1)

Closed Complaints: Two (2); closed no action.

Currently Opened Complaints: Three (3)

Complaint Allegations: Unlicensed Practice.

Geographical Area: East Tennessee

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

Motion to Accept Report: Dr. Neff.

Second: Ms. Wilson.

Approved.

Office of Health Licensure & Regulation:

Lisa Tittle

Interim Assistant Commissioner of Health

There was no report given 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

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Motion: Dr. Neff.

Second: Dr. Ferguson.

Approved

2. Safedin H. Beqaj, Ph.D.

Brentwood, TN 37027
Director: Molecular Diagnostics

Motion: Dr. McDonald
Second: Dr. Ferguson
Approved

Board Policy: The Board established no new policies this meeting.

Other Business: There was no other business discussed during the meeting.

Statement of Next Meeting:

The next meeting will be held July 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 a.m., CDT on a motion properly
filed by Dr. McDonald.
Second: Dr. Ferguson.
Approved.

These minutes were approved by the Board on July 12, 2007.

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

1. **St. Mary's Health System, Inc.**
900 E. Oak Hill Avenue
Knoxville, TN 37917-4505

Facility Representative: Jo Ann Orr, MT(ASCP)
Regional Laboratory Coordinator

This facility requested an exemption to permit Registered Nurses, and Licensed Practical Nurses to perform and report troponin levels utilizing the i-STAT system in the Emergency Department.

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

2. **Cumberland Medical Center**
421 South Main Street
Crossville, TN 387555

Facility Representative: Carolyn Smith, MT
Administrative Laboratory Director
Audrea Crye, MT
Data Entry/LIS

This facility requested exemptions for Licensed Nurses (RN's & LPN's) to perform and report Cardiac Testing Procedures to include (CKMB, Myoglobin, Troponin-I, and BNP). These procedures will be performed in the Emergency Department utilizing the Biosite Triage Meter.

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

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

Facility Representative: Theresa Nickel
Laboratory Resource Manager

This facility request was for Registered Radiology Technologists (RRT's) to perform and report creatinine testing procedures in the Out Patient Radiology Department utilizing the i-STAT instrument.

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

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

Facility Representative: June Cantrell
Point of Care Manager

This exemption request is to permit Registered Nurses, (Nursing Supervisors, Intensive Care Relief Coordinators and Intensive Care Clinical Coordinators, the Code Team), to perform and report sodium, potassium, chloride, pH, pCO₂, glucose, BUN, hematocrit and creatinine throughout this facility.
The instrument utilized is the i-STAT.

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

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

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Facility Representative: Nancy Rousseau, MT
Laboratory Manager

This facility request was for Licensed Nurses (RN's & LPN's) to perform and report Cardiac Markers, (CKMB, Troponin-I, Myoglobin and BNP) in the Emergency Department. The Biosite Triage Meter is the instrument utilized in these events.

Anatomic/Clinical Pathology

Specialties: Histopathology, Oral Pathology, Cytopathology

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

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

Dr. Ferguson recused himself from the discussion and vote.

2-Laboratory Corporation of America
100 William North Blvd.
Tullahoma, TN 37388

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

Specialties: Collection Station

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

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

Mr. Crowe and Dr. Neff recused themselves from the discussion and vote.