

**MEDICAL LABORATORY BOARD
MINUTES**

Date: October 09, 2008

Time: 9:00 am 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
Jere Ferguson, MD, Pathologist Vice-Chairman

John C. Neff, MD Pathologist, Educator
Trudy Papuchis, MD Pathologist Hospital Administrator
Yvonne Davis, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist
Christopher H. Seay, Medical Technologist
Delores Voigt, MT Hospital Administrator
Annie Washington, Medical Technologist
Darius Y. Wilson, MAT, Ed.D. Educator

Members Absent: Dennis Carter, MD Non-Pathologist Physician
Edward McDonald, MD Pathologist
Gloria Jenkins, Citizen Representative

Staff Present:
Lynda S. England, M.T., Director
Ernest Sykes, Jr., Advisory Attorney
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
Middle 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:
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Hathcoat, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Minutes

**Medical Laboratory Board
October 09, 2008**

CLIA Representative: Sandra S. Bogard, M.T. CLIA Manager

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

Called to Order: The meeting was called to order at 9:02 am CDT by Mr. Crowe.

Election of Board Chair: Ms. Wilson made a motion to nominate Mr. Crowe as board chair for 2009 calendar year.

A second to that motion was made by Dr. Ferguson.

With no additional nominations Mr. Crowe was elected with full vote of the Board.

The gavel was passed to vice-chair for the vote and returned to Mr. Crowe after the vote was completed.

Presiding Officer: The meeting agenda was conducted by Mr. Norman Crowe
Board members introduced themselves to the audience.

Conflict of Interest Policy: 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 relativity to member business or any decision that might appear to be a conflict of interest.

Board Minutes: A motion to approve the July 09, 2008 Personnel & Education Committee minutes was made by Dr. Neff.
Second: Mr. Seay.
The minutes were approved.

A motion to approve the minutes from the July 10, 2008 meeting of the Board was made by Dr. Ferguson.
Second: Ms. Voigt.
The minutes were approved contingent on the the appropriate corrections by Ms. England.

**Minutes
Medical Laboratory Board**

October 09, 2008

Board Report

Personnel & Education Committee:

Ms. Wilson presented a report of the actions of the Board's Personnel & Education Committee meeting, held October 09, 2008.

A motion to accept this report was made by Dr. Ferguson. A second to the motion was made by Ms. Davis. The report was approved as read.

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 statistical report for the period July 1, 2007 to June 03, 2008 stating nine (9) individuals that were monitored during this period. Four (4) of those individuals signed monitoring agreements. Eight (8) individuals were referred from entities other than the Department of Health.

Seven (7) individuals were discharged from this program with two (2) individuals successfully completing the TNPAP program. Three (3) individuals refused monitoring services (reported to TDOH), and one (1) individual TNPAP considered monitoring unnecessary. One (1) individual was noncompliant with monitoring and was reported to TDOH.

The referral sources indicated seven (7) individuals were referred to TNPAP relating to seeking board credentials. One (1) individual was referred by their employer.

The history of referrals TNPAP indicates six (6) individuals had a history of arrest (drug related arrest/illegal drug use/DUI). One (1) individual was referred for impairment in the workplace and one (1) was referred to TNPAP by the employer.

Minutes

**Medical Laboratory Board
October 09, 2008**

Motion to accept this report: Ms. McDonald-Spakes
Second: Mr. Seay.
Report Approved.

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

Note: Review of TNPAP materials via internet will
count as clock hours toward continuing education
credits.
A certificate of completion documenting review
of these materials can be completed at the end of the
internet session. Internet site: www.TNPAP.org

Board members authorized the renewal of the 2009
contract with the TNPAP program.

This agency advocates for those licensed medical laboratory
personnel for those licensed medical laboratory personnel in
need of assistance for problems with substance abuse via
alcohol, medications, or gambling.

As of August 4, 2008 the budget Adjustment reflected
\$17,000.00 that needed to be made for the GR-05-
16359-03 2007-2008 contract necessary because of recent
unexpected increases in operational costs.

A motion was made by Dr. Neff to adopt the contract.
A second to the motion was made by Dr. Ferguson.
Contract Approved.

Board Report-Rules:

Ernest Sykes, Jr., Board Attorney

A public rulemaking hearing was conducted before the Board to consider the
promulgating of amendments to rules pursuant to T.C.A. §4-5-204 and 68-29-105.

These rules were considered for amending during this hearing:

- 1.1200-6-1-.12 Continuing Education Requirements,
- 2.1200-6-1-.22 Qualifications, Responsibilities, Duties of Laboratory Personnel,
- 3.1200-6-2-.08 Relative to Advertising,
- 4.1200-6-2-.20 Relative to Advertising and
5. 1200-6-3-.20 Relative to Advertising.

Minutes
Medical Laboratory Board
October 09, 2008

(See July 2008 Board Minutes for complete description of rule amendments)

Attorney Ernest Sykes, Jr. conducted the rulemaking hearing in conjunction with The Uniform Administrative Procedures Act T.C.A. §4-5-204.

Public comments were voiced by Dr. David L. Smalley, Laboratory Director, and Ms. Sean O'Connell, Training Coordinator, from the Tennessee Division of Laboratory Services for the Tennessee Department of Health.

Both individuals expressed concern in the proposed amendment which would limit the required continuing education hours one would obtain via the Internet, in multi-media and/or electronic formats to no more than one-half of the required twenty-four (24) clock hours in a two (2) calendar year period. The continuing education amendment, in question, would pertain only to those individuals outside the state who have not actively practiced their profession, and whose license is expired, retired or revoked in Tennessee and wished to reinstate their license.

Board members took into consideration the public comments and the rule making hearing was concluded after all parties stated they were satisfied all comments had been heard.

Board members voted to promulgate the rules as stated in the rule making document, without changes.

Motion: Dr. Neff.
Second: Dr. Papuchis

A roll call vote was taken with all members stating aye. (See Members Present)

Mr. Sykes read a *Statement of Economic Impact on Small Businesses* and requested Board consideration of adoption or modification of this document.

Motion: Dr. Ferguson.
Second: Ms. Washington.
Statement Adopted as read.

Mr. Sykes read a document, *Regulatory Flexibility Analysis of Rules Being Considered for Authorization to Conduct a Rulemaking Hearing* that he prepared as a required document to have this hearing.

Board members adopted this document.

Motion: Dr. Ferguson.
Second: Mr. Seay.
Document Adopted.

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 the report which included administrative office activities performed during the past quarter.

Motion: Dr. Ferguson.
Second: Dr. Neff.
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 were presented to the Board for review during this meeting.

Reinstatement of License:

No requests for the reinstatement of a facility license was presented for review during this meeting.

Minutes

**Medical Laboratory Board
October 09, 2028**

Reports/Discussion:

Reports:

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 one (1) unsuccessful performance for bacteriology with a statement of deficiencies requesting corrective actions.

Complaint Investigations:

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

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

Unsatisfactory/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two of three events) were zero (0).

Complaint Investigation:

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

West Tennessee Regional Office: Ms. England

Unsatisfactory /Unsuccessful Proficiency Testing:

One (1) facility had a first occurrence of unsuccessful proficiency testing (two out of three in a row). The facility was unsatisfactory with the analyte PO2, arterial blood gas. The facility submitted an acceptable plan of correction and credible allegation of compliance.

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

**Minutes
Medical Laboratory Board
October 09, 2008**

Complaint Investigations:

There was zero (0) complaint investigation conducted during the past quarter.

Motion to Accept This Report: Ms. Davis.
Second: Mr. Seay.
Report: Approved.

Topics for Discussion:

Pennell C. Painter, Ph.D.
Director of Operations
Lab Corp-Knoxville, TN 37920

Dr. Painter made a presentation to board members concerning the concept of a separate license for point of care testing exemptions. All licensed facilities would continue to be compliant with regulations pertaining to medical laboratories Rules 1200-6-3.

Dr. Painter discussed the plausibility of the main clinical laboratory having to discontinue the testing of a specific analyte because of proficiency testing failure in the point of care arena by non licensed laboratory personnel.

A laboratory submits proficiency competency results for analytic tests performed as part of a blind survey to the laboratory to the Center for Medicare and Medicaid (CMS) for purposes of federal (CLIA) regulation. An analyte might be listed (reported) only once even though the lab might do the test on different instruments and utilizing different methodologies.

CLIA and Tennessee licensure regulations monitor clinical lab testing procedures at the test level, therefore failure of proficiency testing (PT) would result in the testing of that particular clinical analyte **wherever** the testing is performed in the hospital arena including the main laboratory.

After discussion, board members decided to review the legal plausibility of offering separate licenses to laboratory facilities, one license for the main laboratory and a second for Point of Care activities.

Mr. Sykes will report to the members during the January 2009 meeting After conducting legal research on this subject. .

No Board action was taken on this matter.

**Minutes
Medical Laboratory Board
October 09, 2008**

Board Report-Rules:

Ernest Sykes, Jr.
Advisory & Litigating Attorney

Mr. Sykes reported on the following:

Rules:

1-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. The rules were signed by the Attorney General and returned to OGC in late June 2008. They will become effective by the end of 2008.

2-Continuing education, qualifications of testing personnel, use of titles in advertising (Tenn. Com. R. & Regs 1200-6-1-.12, .22 1200-6-2-08, 1200-6-3-.20) These rules amendments were authorized on January 10, 2008 to go to rulemaking hearing. The Justification Memo submitted March 19, 2008 received final approval on June 19, 2008.

The rulemaking hearing has been scheduled for this Board meeting.

Litigation:

The Office of General Counsel, Tennessee Department of Health, has three (3) open cases pertaining to the Tennessee Medical Laboratory Board.

A motion to accept this report was made by: Dr. Neff.

Second: Mr. Seay.

The report was accepted as read.

Financial Report:

Jim Patt

Fiscal Office

A copy of this report was included in the board books and is currently on file in the administrative office.

The report was accepted as written; no board action was taken.

Minutes

Medical Laboratory Board

October 09, 2008

Bureau of Investigations (BIV) Report:

Juanita Stone: Disciplinary Coordinator

Report was given by Mr. Sykes.

The following actions were reported to board members:

Complaints in 2008: Fourteen (14)

Complaints July-August 2008: Eleven (11)

Open Cases: Three (3)

Closed Complaints: Four (4)

Closed No Action: (2)

Closed-Referred to OGC: (2)

Currently Opened Complaints: Eleven (11)

All complaints must go through the Bureau of Investigations for consultant and attorney review before they are closed or referred to the Office of General Counsel for litigation.

Motion to Accept Report: Mr. Seay.

Second: Ms. Washington.

The report was accepted as read.

Waived Testing Procedures:

No additional testing procedures were added to the waived test list.

Review Eligibility of Medical Laboratory Director:

Robyn M. Atkinson, Ph.D.

Knoxville, TN 37923

Medical Laboratory Director: Microbiology

Motion: Dr. Neff.

Second: Dr. Ferguson.

License Approved.

Board Policy:

Blood Volume/Tagged Albumen Analyses*

The board members reviewed a policy statement regarding blood volume detection using tagged albumin as related to laboratory medicine.

Motion: Dr. Neff.

Second: Mr. Seay.

Policy Adopted.

Minutes

Medical Laboratory Board

October 09, 2008

Cytogenetic Screening in the Home*

Board members adopted a policy statement regarding performance microscopic review of clinical cytogenetic specimens as part of the testing process and must be performed in a licensed laboratory facility, licensed by this Board, Rule 1200-6-3-.27.

Motion: Ms. McDonald-Spakes.

Second: Dr. Neff.

Policy Adopted.

(See policy attachments at end of minutes)

Other Business:

2009 Committee & Board Meeting Schedule

Committee	Full Board
January 14, 2009	January 15, 2009
April 15, 2009	April 16, 2009
July 15, 2009	July 16, 2009
October 14, 2009	October 15, 2009

Presentation to Departing Board Members:

Ms. Elizabeth Miller, Director of Health Related Boards, presented Dr. Jere Ferguson, Ms. McDonald-Spakes and Ms. Yvonne Davis with commemorative plaques recognizing their contributions to the Board in the interests of the citizens of Tennessee. Dr. Ferguson, and Ms. McDonald-Spakes have served two (2) terms representing the pathologists, and the Cytotechnologists licensed in this state.

Ms. Davis has served one (1) term representing medical technologists in this profession.

Statement of Next Meeting:

The next meeting will be held January 15, 2009 beginning at 9:00 am CST in the Iris Room, Heritage Place 227 Metro Center, Nashville, TN 37243.

**Minutes
Medical Laboratory Board
October 09, 2008**

Record of Adjournment:

The meeting was adjourned at 1:34 pm CDT, on a motion properly presented by Dr. Ferguson.

Second: Mr. Seay.

Adjourn Request Approved.

Norman Crowe
Chairman, Tennessee Medical Laboratory Board

Date

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

1. **Baptist Memorial Hospital West
10820 Parkside Drive
Knoxville, TN 37934-1956**

Facility Representative: Teresa Wilson
Regional Laboratory Coordinator

The exemption request(s) from this facility laboratory director were:

1) to permit Perfusionists to perform and report pH, blood gases (PCO₂, PO₂), hemoglobin, SO₂, sodium, potassium, ionized calcium, and glucose during open heart procedures in the surgical suites. The instrument and methodology utilized in the performance of these tests will be the AVL-OPTI Analyzer, and

Motion: Dr. Neff.
Second: Dr. Ferguson.
Exemption Granted.

2) to permit Perfusionists to perform and report activated clotting times (ACT) during open heart surgery in the surgical suites utilizing the Hemochron instrument and methodology.

Motion: Dr. Neff.
Second: Dr. Ferguson.
Exemption Granted.

2. **University of Tennessee Medical Center/Lab Corp.
1924 Alcoa Hwy. U108
Knoxville, TN 37920**

Facility Representative: Debbie Headrick, BS MT (ASCP)
Point of Care Coordinator

This facility laboratory director requested the following exemptions to be considered by board members:

1) to permit RTR and Cardiovascular Technicians to perform and report sodium, potassium, chloride, BUN, glucose, creatinine, ionized Calcium, Hgb/Hct, TCO₃, (CHEM 8+ cartridge), ProTime cartridges, CG8+Cartridges (pH, PCO₂, PO₂, Na, K, iCA, Glu, Hct). The instrument utilized in the performance of these tests is i-STAT in the Cardiovascular Laboratory.

**Page 2
Attachment 1
Medical Lab Board/POCT Exemption Requests
October 09, 2008**

The medical laboratory director requested this item be removed from the exemption request packet.

- 2) to permit Registered Nurses to perform and report ProTime utilizing the Chem8+ cartridges: CG8+ Cartridges (pH, PCO₂, PO₂, Na,K,iCa, Glu and Hct), and the Creatinine Cartridges utilizing the i-STAT instrument. These tests are to be performed in the Cardiovascular Recovery Unit.

Motion: Dr. Papuchis.
Second: Ms. Washington.
Request Approved.

- 3) to permit RTR and Cardiovascular Technicians to perform and report activated clotting times (ACT) in the Cardiovascular Lab utilizing the Hemochron 801 and the Hemochron Elite instruments.

The medical laboratory director requested this item be removed from the exemption request packet.

- 4) to permit Registered Nurses and RTR to perform and report activated clotting times (ACT's) in the Endovascular Lab utilizing the Hemochron 801 and the Hemochron Elite instruments.

Motion: Dr. Papuchis.
Second: Ms. Washington.
Request Approved.

- 5) to permit Registered Nurses to perform and report activated clotting times (ACT) in the Cardiovascular Recovery Unit utilizing the Hemochron 801 and the Hemochron Elite Instruments.

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

- 6) to permit RTR and Cardiovascular Technicians to perform and report Cooximetry analyses in the Cardiovascular Laboratory utilizing the Avoximeter instrument and methodology.

The medical laboratory director requested this item be removed from the exemption request packet.

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

Dr. Ferguson chaired this discussion.

**Page 3
Attachment 1
Medical Lab Board/POCT Exemption Requests
October 09, 2008**

**3- St. Mary's Medical Center
900 E. Oak Hill Avenue**

Knoxville, TN 37917-4505

Facility Representative: Teresa Wilson
Regional Laboratory Coordinator

This exemption request was to permit Registered Nurses and Radiology Technicians to perform and report blood urea nitrogen (BUN), and creatinine in the imaging department utilizing the i-STAT instrument and methodology.

Motion: Dr. Neff.
Second: Dr. Ferguson.
Exemption Granted.

**4. Cumberland Medical Center
421 South Main Street
Crossville, TN 38555**

Facility Representative: Carolyn W. Smith
Administrative Director of Laboratory

This request was for Licensed Registered Nurses, and Licensed Practical Nurses to perform and report Cardiac Testing Markers in the Emergency Room.

This is a duplicate exemption request granted in April of 2007 and was not implemented until now. Laboratory management was not requesting this exemption in advance but believed the point of care would begin after the board meeting.

No further action was necessary on behalf of the board.

**5. Laughlin Memorial Hospital
1420 Tusculum Boulevard
Greenville, TN 37745**

Facility Representative: Debbie Epley
Laboratory Services Director

This exemption request was to permit Licensed Nursing Personnel (RN's), Registered Cardiac Invasive Specialists (RCIS), and Registered Respiratory Therapists (RRT's) to perform and report activated clotting times, blood gases, hematocrit & calculated hemoglobin in the Post Anesthesia Care Unit (PACU), and Intensive Care Unit utilizing the i-STAT instrument and methodologies.

**Page 4
Attachment 1
Medical Lab Board/POCT Exemption Requests
October 09, 2008**

Motion: Dr. Neff.

Second: Dr. Ferguson.
Exemption Approved.

6. **LeBonheur Children's Medical Center**
50 North Dunlap
Memphis, TN 38103

Facility Representative: Elizabeth Young, MT (ASCP)
Point of Care Coordinator

This facility exemption request was to permit Registered Nurses (RN's), Licensed Practical Nurses, and Emergency Department Technicians II (EDTII) to perform and report specific gravity testing procedures utilizing a digital refractometer in the Emergency Department.

Motion: Dr. Neff.
Second: Ms. Washington.
Exemption Request Approved.

Ms. Davis recused herself from the discussion and vote.

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

Facility Representative: June Cantrell
Point of Care Coordinator

The representative presented the following point of care exemption requests for board member review:

1-to permit Registered Nurses (RN's), and Licensed Practical Nurses (LPN's) to perform and report Oxyhemoglobin Saturation, Hemoglobin Concentration, and to compute Oxygen Content measurements utilizing the AVOXimeter 1000E instrument and methodology in the Cardiac Catherization Laboratory.

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

Page 5
Attachment 1
Medical Lab Board/POCT Exemptions
October 09, 2008

2-to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), and Paramedics to perform and report pH, pCO₂, pO₂, sodium, potassium, glucose, ionized calcium, and hematocrit utilizing the i-STAT instrument and methodology.

This request included the addition of Paramedics and also added a location (Emergency Department) to exemptions previously granted in April 2007 and January 2008. The Paramedics are employees of the hospital and working in the emergency department. This approval does not include EMT's.

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

3-to permit Paramedics (to include EMT's) servicing the Emergency Department to inoculate reagent cartridges, **in route** to the facility for the performance of cardiac markers (Myoglobin, BNP, CKMB, and Troponin I).

The inoculation/preparation steps were the would be performed in the ambulance with the laboratory/nursing personnel perform the actual test. (The nursing staff has previously been granted an exemption to perform the cardiac marker tests.) The instrument utilized in the performance of these tests is the Biosite Triage System.

Motion to Deny Request: Dr. Neff.
Second: Ms. Washington.
Request Denied.

Board members determined this action was the dosing of an analytical sample before insertion into an instrument and therefore is equivalent to be part of the actual testing process and not considered part of the pre-analytical process. The request was denied because the institution could not demonstrate accurate monitoring of those individuals who would perform this testing procedure (education, quality control, continued competency) of the non-hospital employees. The inoculation would be performed by Paramedics and EMT's that may or may not be employees of the hospital.

The facility was encouraged to make another request with the appropriate information about monitoring this analytical event especially for non hospital employees for board review at a later date.

Page 6
Attachment 1
Medical Laboratory Board/POCT Exemptions
October 09, 2008

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

Facility Representative: Shelly Winn
Point of Care Coordinator

This facility requested the following exemptions:

1-to permit Licensed Radiology Technicians to perform and report creatinine testing in the Imaging Center (on site) utilizing the StatSensor instrument.

Motion: Dr. Ferguson.
Second: Mr. Seay.
Request Approved.

2-to permit the addition of Licensed Paramedics to perform and report Cardiac Markers (CKMB, Myoglobin, and Troponin I) in the Emergency Department utilizing the Biosite Triage Panel.
The Paramedics are employees of the hospital.
(The original request was granted January 10, 2008.)

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

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

9. **Jackson Madison County General Hospital**
708 West Forest Avenue
Jackson, TN 38301

Facility Representative: Shelia Boswell
Point of Care Supervisor

This request was to permit Certified Registered Nurse Anesthetists (CRNA's) to perform and report arterial blood gases, sodium, potassium, ionized calcium, hematocrit, and calculated hemoglobin using the EG7+ cartridge with the i-STAT instrument in the Operating Rooms.

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

Page7
Attachment 1
Medical Laboratory Board-POC Exemptions
October 09, 2008

10. **Vanderbilt University Medical Center**
22nd and Pierce 4605 TVC
Nashville, TN 37232-5310

Facility Representative: Terri Tubb

Point of Care Coordinator

This facility presented the following requests for approval:

1-to permit Radiologic Technologists to perform and report creatinine testing procedures in Imaging Centers (both-off-site) located in Hillsboro Village and Cool Springs utilizing the i-STAT analyzer. These facilities have different CLIA numbers from the clinical laboratory: the full cartridge is waived by CLIA. All other tests on the cartridge will be blocked. There will be a different director other than the designated medical laboratory director for the hospital lab. No Board action was necessary because these actions are outside the Board's authority because regulation will be under their CLIA certificate.

2-to permit Licensed Paramedics employed by VUMC to perform and report activated clotting times (ACT's) in the Cardiac Catheterization Laboratory and the Electrophysiology Laboratory utilizing the Hemochron System. This is a modification of an exemption granted in 1997.

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

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

Facility Representative: Mollie Wynn, M.T. (AMT)
Point of Care Coordinator

This facility appeared before the board to request the following point of care exemptions:

1-to permit Registered Nurses (RN's), Licensd Practical Nurses (LPN's), Respiratory Therapists (RT's), Radiological Technologists, and Registered Cardiovascular Invasive Specialists (RCIS) to perform and report blood bases, electrolytes, glucose, ionized Calcium, hemoglobin, hematocrit, activated clotting times, PT/INR, and creatinine utilizing the i-STAT instrument.

Page 8
Attachment 1
Medical Laboratory Board/POC Exemptions
October 09, 2008

These clinical analyses are performed in all Intensive Care Units and all Post Catheterization areas of this facility.

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

Approved.

2-to permit Registered Nurses (RN's), Licensed Practical Nurses (LPN's), and Licensed Pharmacists to perform and report PT/INR utilizing the i-STAT Instrument in the CMC Coumadin Clinic. (i-STAT is not waived)

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

12. **Southern Hills Medical Center**
391 Wallace Road
Nashville, TN 37211

Facility Representative: Jennie Daniel, M.T.
Point of Care Coordinator

This request was for the following exemptions:

1-to permit Registered Nurses (RN's), Registered Cardiovascular Specialists (RCIS), and Radiology Techs (RT's) to perform and report O2 Saturation, and activated clotting times (ACT's) in the Cardiac Cath Lab utilizing the i-STAT instrument.

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

2-to permit Registered Nurses (RN's), and Licensed Practical Nurses (LPN's) to perform and report activated clotting times (ACT's) in the Critical Care Unit utilizing the i-STAT.

Motion: Dr. Neff.
Second: Ms. Washington.
Request Approved.

Page 1
Attachment 2
Medical Laboratory Board/ Initial Facility Licenses
October 09, 2008

INITIAL FACILITY LICENSES:

REGIONAL SURVEYOR RECOMMENDATION/BOARD RATIFICATION:

1-American Red Cross Tennessee Valley Region
Crossville Fixed Site
11 East 1st Street
Crossville, TN 38555

Medical Laboratory Director: Claire Meena-Leist, M.D.
ABP Blood Banking/Transfusion Medicine

Specialties: Donor Center/Collection Station
(Spun Hematocrit)

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

Motion: Dr. Neff.
Second: Mr. Seay.
License Approved.

TENNESSEE MEDICAL LABORATORY BOARD
POLICY ON CONTINUING EDUCATION VIOLATIONS

The Tennessee Medical Laboratory Board requires each licensee to successfully complete twenty-four (24) hours of approved continuing education pertaining to laboratory technology or laboratory management for the two calendar year (January 1-December 31) period that precedes the licensure renewal year.

In the event a licensee is found to be deficient in the number of required continuing education hours for a particular renewal cycle, that person will have ninety (90) days in which to cure the deficiency by making up the required number of hours. That ninety day cure period will start on the date on which the Department staff mails the licensee a notice of deficiency.

If such licensee fails to demonstrate that he or she has cured the continuing education deficiency within the ninety day cure period, the Department will file a licensure complaint and the licensee will be prosecuted in accordance with the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-301, *et seq.*

Adopted October 09, 2008 by the Tennessee Medical Laboratory Board.

TENNESSEE MEDICAL LABORATORY BOARD

LAPSED LICENSE POLICY

**POLICY FOR ENFORCEMENT BY
BOARD CONSULTANT(S) AND
MEDICAL TECHNOLOGIST CONSULTANT(S)
STAFF AND SURVEYOR(S)**

A policy relating to Chapter 1200-6-1.09 (1) & (2) Rules for Medical Laboratory Personnel was adopted during the January 16, 2003 board meeting, and revised during the October 9, 2008 board meeting.

This policy pertains to the responsibilities of testing personnel regarding the renewal and/or the reactivation of their licenses and shall be referred to as the Lapsed License Policy.

It is a violation of the law and of the board's rules to practice on an expired license.

Any individual working in the capacity of a Medical Laboratory Professional on a lapsed license or beyond the period of a valid temporary permit shall be considered an incident of unprofessional conduct and the licensee will be disciplined.

The disciplinary policy of the Board shall be:

Infraction: Practicing Medical Technology on a lapsed (expired) license (permit) less than three (3) months.

Disciplinary Action: Shall remit applicable renewal and reinstatement fees.

Infraction: Practicing Medical Technology on a lapsed (expired) license (permit) three (3) months or longer.

Disciplinary Action:

A. Shall remit all applicable renewal & reinstatement fees.

B. Shall remit a civil penalty of \$100.00 per month for each month practiced on a lapsed license (permit).

C. License will not be reinstated until civil penalty is paid in full.

Discipline for practicing on a lapsed license will be assessed by the Department by Agreed Citation, which will detail the licensee's rights and obligations under the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-301, *et seq.* The discipline assessed in accordance with this Lapsed License Policy constitutes formal discipline against a practitioner's license, and as such it is reportable to the disciplinary databanks and will be noted on the practitioner's licensure profile.

This information reflects the Board's policy and the consultant(s) and staff are authorized to interpret and act on this policy.

Adopted this the 16th day of January, 2003 by a member majority roll call vote of the Tennessee Medical Laboratory Board. Revised October 9, 2008.

TENNESSEE MEDICAL LABORATORY BOARD

POSITION STATEMENT REGARDING LABS WHICH CONDUCT EMPLOYMENT-RELATED URINE DRUG SCREENS

It is the position of the Tennessee Medical Laboratory Board that a laboratory which either 1) limits its testing exclusively to employment-related urine drug and/or alcohol screens or 2) devotes blocks of time to employment-related urine drug and/or alcohol screens, as such tests are defined below, is not a "medical laboratory" as defined by T.C.A. § 68-29-103(9) during, and only during, the periods of time that such employment-related urine drug and/or alcohol screens

are being conducted and therefore is not required to be licensed by, and is not subject to the disciplinary authority of, the Medical Laboratory Board.

For the purposes of this position statement, “employment-related drug and/or alcohol screens” are urine analyses that are performed at the request of an employer or prospective employer under any one or more of the following three circumstances:

1. Pre-employment drug screens when the purpose of the screening is to detect recent usage of drugs and/or alcohol prior to extending an offer of employment;
2. Drug screens performed when there is some suspicion that the employee is under the influence of drugs and/or alcohol in the workplace; and
3. Drug screens conducted as part of an employer’s random screening policy or as required of the employer by law, rule or regulation.

Such employment-related drug and/or alcohol screens are presumed to be conducted solely for the purpose of making *employment* decisions about the subject person. As such, employment-related drug and/or alcohol screens:

- Are not “performed to obtain information for diagnosis, prophylaxis, or treatment or where any examination, determination, or test is made on any sample used as a basis for health advice, or where any sample is collected for the purpose of transfusion or processing of blood or blood fractions, or for the training of medical laboratory personnel.” (Quoting T.C.A. § 68-29-103(9));

and they therefore

- Are not medical laboratory tests as described by T.C.A. § 68-29-121(a);

and they therefore

- Do not require a physician’s or other health related practitioner’s order.

Adopted this the 10th day of July, 2008 by the Tennessee Medical Laboratory Board.

TENNESSEE MEDICAL LABORATORY BOARD
POSITION STATEMENT REQUIRING MICROSCOPIC TESTING FOR

CYTOLOGY SCREENINGS TO BE PERFORMED IN A LICENSED LABORATORY

It is the position of the Tennessee Medical Laboratory Board that microscopic testing performed as a component of cytogenetic screening is in fact an active part of the cytology screening process.

As such, the microscopic testing portion of the cytogenetic screening process must be performed in a laboratory which is licensed by the Medical Laboratory Board, and it may not be performed off-site.

Adopted October 9, 2008 by the Tennessee Medical Laboratory Board.