TRI-CITY HEALTHCARE DISTRICT
AGENDA FOR A REGULAR MEETING
February 27, 2025 – 3:30 o'clock p.m.
Assembly Rooms 2 & 3 – Eugene L. Geil Pavilion
4002 Vista Way, Oceanside, CA 92056

The Board may take action on any of the items listed below, unless the item is specifically labeled "Informational Only"

	Agenda Item	Time Allotted	Requestor
1	Call to Order	3 min.	Standard
2	Report from Chairperson on any action taken in Closed Session (Authority: Government Code, Section 54957.1)	2 min.	Board Counsel
3	Roll Call / Pledge of Allegiance	3 min.	Standard
	Approval of Agenda	2 min	Standard
4	Public Comments – Announcement Members of the public may address the Board regarding any item listed on the Board Agenda at the time the item is being considered by the Board of Directors. Per Board Policy 19-018, members of the public may have three minutes, individually, to address the Board of Directors. NOTE: Members of the public `may speak on any item not listed on the Board Agenda, which falls within the jurisdiction of the Board of Directors, immediately prior to Board Communications.	2 min.	Standard
5	January 2025 Financial Statement Results	10 min.	CFO
6	New Business – a) Consideration to approve the 2024-2025 Risk Management Plan b) Consideration to approve the agreement with Hologic for two (2) Fluent Pro Systems & SureCare Service Agreement for a term of 36 months, beginning February 1, 2025 and ending January 31, 2028, for a total annual combined cost of $137,200 and a total combined cost for the term of $411,600.	5 min. 5 min.	General Counsel CNE
7	Old Business – None		
8	Chief of Staff - a) Consideration of February 2025 Credentialing Actions and Reappointments Involving the Medical Staff as recommended by the Medical Executive Committee on February 24, 2025	5 min.	COS

Note: This certifies that a copy of this agenda was posted in the entrance to the Tri-City Medical Center at 4002 Vista Way, Oceanside, CA 92056 at least 72 hours in advance of the meeting. Any writings or documents provided to the Board members of Tri-City Healthcare District regarding any item on this Agenda is available for public inspection in the Administration Department located at the Tri-City Medical Center during normal business hours.

Note: If you have a disability, please notify us at 760-940-3348 at least 48 hours prior to the meeting so that we may provide reasonable accommodations.

	Agenda Item	Time Allotted	Requestor
9.	Consent Calendar (1) Board Committee **(a) Finance, Operations & Planning Committee** **Director Younger, Committee Chair** 1) Approval of an expenditure, not to exceed $307,500 to facilitate the addition of Abhinav Sharma, M.D., a cardiovascular medicine physician to practice medicine in the communities served by the District through an independent physician recruitment agreement. 2) Approval of the renewal of the Medical Directorship agreement with Jamil Alkhaddo, M.D. for the Diabetes Program for a term of 12 months, beginning February 1, 2025 through January 31, 2026, for a total cost not to exceed $28,800. 3) Approval of the renewal agreement between Tri-City Healthcare District and Pulmonary Specialists of North County, Inc. for a term of one year, beginning February 6, 2025 and ending February 5, 2026 for a total cost for the term not to exceed $510,000. 4) Approval of a physician agreement with CompHealth for locum tenens psychiatric on-call coverage for the Emergency Department and inpatient units for a term cost of 16 months, beginning March 1, 2025 and ending June 30, 2026, for an annual cost of $67,503 and a total term cost of $90,004. 5) Approval of the renewal of an agreement with Stericycle, Inc. for regulated medical waste disposal, hazardous waste disposal and sharps waste disposal management for a term of 60 months, beginning March 1, 2025 and ending February 28, 2030, for an annual cost of $194,000 and a total cost for the term of $970,000. 6) Approval of a Physician Recruitment Agreement for Jeffrey Raunig, M.D. for a term of 24 months beginning March 1, 2025 and ending February 28,2027, to facilitate this Family Medicine physician practicing medicine in the communities served by the District to include a sign-on advance for a total cost not to exceed $35,000. (2) **Policies and Procedures** **a) Patient Care Services** 1. Tdap (Tetanus, Diptheria & Pertussis) Vaccine Administration for Antepartum & Postpartum Obstetric Patient Standardized Procedure – RETIRE **b) Infection Control** 1. Infection Prevention Program Plan **c) Laboratory** 1. Blood and Tissue Service Agreement Policy 2. Cytology Specimens Excluded from Routine Submission to the Cytology Section Policy 3. Cytotechnologist Workload Policy 4. Laboratory Quality Management Plan Overview 5. QSE.02 Laboratory Personnel Quality System Essentials 6. QSE.03 Laboratory Equipment Quality System Essentials 7. QSE.04 Laboratory Facilities and Safety Quality System	10 min.	Chair

	Agenda Item	Time Allotted	Requestor
	Essentials 8. QSE.05 Laboratory Purchasing and Inventory Quality System Essentials **c) Mammography Women's Center** 1. Report Inclusions Policy **d) Outpatient Specialty Clinic** 1.Decontamination and Sterilization of Instruments – RETIRE **e) Pulmonary Rehab** 1. Maintenance and Repair of Exercise Equipment **f) Surgical Services** 1. Post Anesthesia Standards of Practice and Documentation Policy (3) Minutes a) Special Meeting – January 30, 2025 b) Regular Meeting – January 30, 2025 c) Special Meeting – February 19, 2025 (4) Reports – (Discussion by exception only) a) Building Lease Report – (January, 2025) b) Reimbursement Disclosure Report – (January, 2025)		
10	Discussion of Items Pulled from Consent Agenda	10 min.	Standard
11	Comments by Members of the Public NOTE: Per Board Policy 19-018, members of the public may have three (3) minutes, individually and 15 minutes per subject, to address the Board on any item not on the agenda.	5-10 minutes	Standard
12	Comments by Chief Executive Officer	5 min.	Standard
13	Board Communications	18 min.	Standard
14	Total Time Budgeted for Open Session	1.5 hours	
15	Adjournment		

Tri-City Medical Center

Risk Management Plan 2024/2025

A. PURPOSE

The Purpose of the Risk Management program is to protect patients, staff and visitors from inadvertent harm. The Risk Management Program is an overarching conceptual framework that is designed to protect the organization's financial assets and intangibles, such as reputation, in the community we serve.

The Risk Management Plan will be the primary tool for implementing the Tri-City Medical Center's (TCMC) overall Risk Management Program. The plan is designed to provide guidance and structure for the organization's clinical and business services that drive the quality patient care while fostering a safe environment.

The focus of the Risk Management Plan is to provide an ongoing, comprehensive and systematic approach to reducing risk exposures or errors. Risk Management activities include identifying, investigating, analyzing, and evaluating risks/errors followed by selecting and implementing the most appropriate methods for correcting, reducing, managing, transferring and/or eliminating the risk/errors.

B. Authority and Role of the Risk Manager

The Risk Manager is empowered by the governing body to implement the functions and activities of the Risk Management Program with the assistance of the patient care and administrative staffs. The governing body has overall responsibility for the effectiveness of the program and providing the necessary resources. The governing body's responsibilities are supported through regular written and verbal communications regarding Risk Management activities that may affect TCMC's finances.

The role of the Risk Manager is to maintain a proactive Risk Management Program in compliance with the provisions of federal, state, and local statutes, applicable scope of practice and regulations. TCMC may participate with voluntary accrediting organizations. The Risk Manager is responsible for creating, implementing, and evaluating the outcome of the Risk Management Plan. These activities should be coordinated with Quality/Performance Improvement, Infection Prevention, Patient Safety and Environment of Care Management. The specific description of the Risk Manager's role can be found in Purpose & Responsibility of Risk Management (8610-293).

The Risk Management Program is formally addressed through designated committees, such as the Patient Safety and Quality Assurance Performance Improvement (QAPI) committees.

C. Scope

Under the direction of the Risk Manager, the Risk Management Program provides for collaboration among all departments, services, and patient care professionals. The Risk Management Program, in collaboration with General Counsel, provides policies, procedures and protocols to address incidents which may create business-related liability, professional liability and general liability. The identification, investigation and management of incidents, harm and other potentially compensable events are a primary responsibility under the Risk Management Plan. This process is directed by the Risk Manager and others who are delegated to participate in the various components of managing adverse events occurring with patients, staff, visitors and organizational assets.

Risk Management will provide consultation, guidance and education to leaders within the following departments, but not limited to, in order to achieve quality care in a safe environment and protect the organization's resources:

a. Administration
b. Billing/Finances
c. Business Development & Marketing
d. Clinical Services
e. General Counsel
f. Health Information Management
g. Human Resources
h. Infection Control
i. Information Technology
j. Materials Management
k. Medical Equipment Management
l. Pharmaceuticals and Therapeutics
m. Regulatory Compliance
n. Safety Management/ Environment of Care
o. Security Management

D. Objectives of the Risk Management Program

The objectives of the Risk Management Program include, but are not limited to identification, mitigation, and prevention of risk.

Identification

a. Utilizing risk management strategies to identify and minimize the frequency and severity of near misses.
b. Evaluating systems that can contribute to patient harm or incident.

Mitigation

a. Practice risk avoidance with assessment, pro-active risk analysis, and strategic planning.

b. Reduce the likelihood of risk once identified.
c. Managing adverse events, errors or incidents to minimize financial loss.

Prevention

a. Promoting quality patient care, in collaboration with QAPI.
b. Minimizing the frequency and severity of adverse events, errors and/or incidents.
c. Supporting a non-punitive culture that promotes awareness and empowers staff to identify risk-related issues.
d. Enhancing environmental safety for patients, visitors and staff through participation in environment of care-related activities.
e. Educating stakeholders on emerging and known risk exposures and risk reduction initiatives.

E. GUIDING PRINCIPLES

1. The Risk Management Plan is an overarching conceptual framework that guides the development of a program for risk management.

2. The plan supports TCMC's philosophy that patient safety and risk management are everyone's responsibilities. Teamwork and participation among management, providers and staff are essential for an efficient and effective risk management program.

3. TCMC supports the establishment of a just culture that emphasizes evidence-based, best practices, learning from error analysis, and providing constructive feedback, rather than blame and punishment. In a just culture, unsafe conditions and hazards are readily and proactively identified and reported.
    a. Medical and/or patient care errors are reported and analyzed, mistakes are openly discussed, and suggestions for systemic improvements are welcomed.
    b. Individuals are still held accountable for compliance with patient safety and risk management practices. As such, if evaluation and investigation of an error or event reveal reckless behavior or willful violation of policies, disciplinary actions will be recommended.

4. The Risk Management Plan stimulates the development, review, and revision of the TCMC's practices and protocols in light of identified risks and chosen loss prevention and reduction strategies. These principles provide the foundation for developing and updating key policies and procedures for day-to-day risk management activities, including the following:
    a. Complaint resolution
    b. Event investigation, root-cause analysis, and follow-up
    c. Adverse event disclosure to patients
    d. Trend analysis of events, near misses, and claims

e. Staff education as it pertains to risk matters

F. **Specific Components**

The Risk Management Program will include the following components:

1. Incident Reporting
   Incident reporting (through our RL Datix software) is intended to provide a systematic, organization-wide program of reporting errors/harm/risk exposures to identify potential future liability and then forward to managers of the incident report and thereafter the manager reports to Quality Department. The Risk Management Program includes an incident reporting system that is used to identify, report, track, and trend patterns of events with the potential for causing adverse patient outcomes or other harm to people, property or other assets of TCMC. It is designed to reduce or eliminate preventable harm and property damage, and minimize the financial severity of claims.

   The Risk Manager tracks and trends incident data in order to report those findings to Quality Improvement and/or the appropriate department(s) for follow-up action.

   The responsibility of determining the reportability of incidents to governmental agencies will be the responsibility of the Regulatory Compliance Manager.

2. Reporting Risk Management activities as part of QAPI
   Recognizing that the effectiveness of risk management activities is contingent upon collaboration and integration with QAPI activities, the Risk Manager will work with Quality/Performance Improvement staff to coordinate activities between the two disciplines. This will enhance the identification and resolution of risk and quality issues.

3. Educational Activities
   The Risk Department will educate as necessary on monitored risk events.

4. Management of patient/patient representative complaints & grievances
   TCMC will have a formal written process for managing patient and family complaints/grievances. This process details response to and resolution of patient/patient representative complaints (Patient Complaints & Grievance Policy (8610-318).

5. Patient Satisfaction
   TCMC will measure patient satisfaction and respond to issues identified in patient satisfaction surveys. The Risk Manager will monitor complaints and

report findings related to quality/performance improvement. Of equal importance is Risk Management's direct participation in resolution of complaints, as appropriate.

G. **Protection of Risk Management Information Included in QAPI**

Risk Management data and information collected should be maintained as a component of TCMC's quality/performance improvement program and reported to QAPI and/or designated subcommittees. This structure may result in findings being considered privileged and confidential and may not be distributed outside the quality/performance improvement process and may only be distributed at the direction and with the written consent of legal counsel.

H. **Claims Management**

The Risk Manager will assist and/or collaborate with General Counsel and Legal Department by, but not limited to:

a. reporting potentially compensable events (PCE), unexpected outcomes or patient complaints to the involved department manager, the insurance carrier as appropriate
b. performing initial and ongoing investigation and interviews
c. documenting activities and correspondence related to the investigation of the incident
d. protecting and preserving patient health information record and/or other documents and evidence for potential future litigation and work directly with the Compliance Department.
e. maintaining confidentiality of protected documents
f. reviewing, vetting and accepting legal service as appropriate

I. **Governing Body Leadership**

The Governing Board is committed to promoting the safety of all patients, staff and visitors. In doing so, the Governing Board authorizes the formal program and adoption of this plan through the Board meeting minutes.

The Governing Body empowers TCMC's Leadership and Management teams with the responsibility for implementing risk management strategies through their leadership, commitment and support.

J. **Review of the Risk Management Plan**

The Risk Management Plan will be reviewed, updated, and approved annually, or as needed. Dated signatures and titles from appropriate parties should be obtained at the time of the approval.

K. **Annual Evaluation of the Risk Management Program**

The Risk Management Program will be evaluated by the governing body annually. Recommendations for enhancements are incorporated into the program prior to final approval.

L. **Confidentiality**

Any and all documents and records that are part of the Risk Management Process shall be privileged and confidential to the extent provided by state and federal law. Confidentiality protections may include attorney-client privilege, attorney work product, Quality Improvement, and Peer-Review protections.

TCMC, to the extent possible, shall avail itself of the protections afforded by the Patient Safety and Quality Improvement Act of 2005 as well as California Evidence Code section 1157. These protections apply to investigation and documentation of patient safety events, data, and reports—referred to in the law as "patient safety work product"—by creating a patient safety evaluation system, through which the organization produces patient safety work product with the intent of analyzing the data for the purpose of improving patient safety and overall care.

The signatures below represent an acceptance of the Risk Management.

_____ Date Approved: _____

Dr. Gene Ma, Chief Executive Officer
Tri-City Health Care District

_____ Date Approved: _____

Tracy M. Younger, Board Chairperson
Tri-City Healthcare District

Tri-City Medical Center

TCHD BOARD OF DIRECTORS
DATE OF MEETING: February 27, 2025
Hologic Fluent Pro System & SureCare Service Agreement PROPOSAL

Type of Agreement		Medical Director		Panel		Other:
Status of Agreement	X	New Agreement		Renewal – New Rates		Renewal – Same Rates

$43,33

Vendor's Name: Hologic

Area of Service: Surgical Services

Term of Agreement: 36 months, Beginning, March 1, 2025 – Ending, February 29, 2028

Maximum Totals:

Total Increase Compared to Current Agreement Equals $21,600		
SureCare Service Agreement Monthly Cost	**Annual Cost**	**Total Term Cost**
$600	**$7,200**	**$21,600**

Fluent Pro System Monthly Cost	**Annual Cost**	**Total Term Cost**
$3,611	**$130,000**	**$390,000**

Total Monthly Cost (Combined)	**Total Annual Cost (Combined)**	**Total Term Cost (Combined)**
$4,211	**$137,200**	**$411,600**

Description of Services/Supplies:

- *Hologic will place 2 Fluent Pro Systems at TCHD for use in the OR for a term of 3 years.*
- *Annual Commitment Spend of $130,000 (minimum already being met annually, no additional cost to TCHD).*
- *SureCare Service Agreement for 2 machines: total spend $21,600 for the 3-year agreement.*

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:		Yes	N/A	No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Melissa Terah / Donald Dawkins

Motion: I move that the TCHD Board of Directors authorize the agreement with Hologic for 2 Fluent Pro Systems & SureCare Service Agreement for a term of 36 months/ 3 years, beginning March 1, 2025 and ending February 29, 2028, for an annual cost of $137,200 and a total cost for the term of $411,600.

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT
February 12, 2025

Attachment A

Initial Appointments

Any items of concern will be "red" flagged in this report. Verification of education, training, experience, current competence, health status, current licensure, liability coverage, claims history and the National Practitioner Data Bank, the following practitioners are recommended for a 2-year appointment with delineated clinical privileges, to the Provisional Staff or Allied Health Professional Staff with customary monitoring.

Medical Staff:

Practitioner Name	Specialty	Staff Status	Initial Appointment Term	Comments
BAKHTAR, Omid MD	Pathology	Provisional	2/27/2025 – 2/27/2027	
EISINGER, Philip MD	Teleradiology	Provisional	2/27/2025 – 2/27/2027	Two open cases – Reviewed by chairman, no concerns found
KUNDA, Anand MD	Pathology	Provisional	2/27/2025 – 2/27/2027	
SCUDERI, Richard MD	Pathology	Provisional	2/27/2025 – 2/27/2027	
SUMMERS, Raymond MD	Pathology	Provisional	2/27/2025 – 2/27/2027	

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – 1 of 1
February 12, 2025

Attachment B

Reappointments:

Any items of concern will be "red" flagged in this report. The following practitioners were presented to members of the Credentials Committee for consideration for reappointment to the Medical Staff or Allied Health Professional Staff, based upon practitioner specific and comparative data profiles and reports demonstrating ongoing monitoring and evaluation, activities reflecting level of professionalism, delivery of compassionate patient care, medical knowledge based upon outcomes, interpersonal and communications skills, use of system resources, participation in activities to improve care, blood utilization, medical records review, department specific monitoring activities, health status and relevant results of clinical performance. Reappointment is for 2-years unless otherwise noted below.

Medical Staff

Department of Emergency Medicine:

Practitioner Name	Specialty	Staff Status:	Reappointment Term	Comments
MELLS, Cary R, MD	Emergency Medicine	Active	2/27/2025-2/27/2027	
SANTA MARIA, Amanda M, MD	Emergency Medicine	Active	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active.**

Department of Medicine:

Practitioner Name	Specialty	Staff Status:	Reappointment Term	Comments
BARCO, Eric P, MMD	Internal Medicine	Active	2/27/2025-2/27/2027	
HELTON, Derek A, MD	Oncology	Refer and Follow	2/27/2025-2/27/2027	**Change in staff status from Active to Refer and Follow.**
LIZOTTE, Paul, DO	Internal Medicine	Refer and Follow	2/27/2025-2/27/2027	
SAHAGIAN, Gregory A, MD	Neurology	Active	2/27/2025-2/27/2027	
SMITH, Richard C, MD	Infectious Disease	Active	2/27/2025-2/27/2027	

Department of Radiology:

Practitioner Name	Specialty	Staff Status:	Reappointment Term	Comments
FRANKE, Mark, MD	Teleradiology	Active Affiliate	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active Affiliate.**
JACOBS, David S, MD	Teleradiology	Active Affiliate	2/27/2025-2/27/2027	**Change in staff status from**

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – 1 of 1
February 12, 2025

Attachment B

				Provisional to Active Affiliate.
KLEIN, Michael V, MD	Teleradiology	Active Affiliate	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active Affiliate.**
REICH, Phillip, MD	Teleradiology	Active Affiliate	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active Affiliate.**

Department of Anesthesiology:

Practitioner Name	Specialty	Staff Status:	Reappointment Term	Comments
VU, Quin, H, MD	Anesthesiology	Active	2/27/2025-2/27/2027	

Department of Surgery:

Practitioner Name	Specialty	Staff Status:	Reappointment Term	Comments
ANDRY, James P, MMD	Orthopedic Surgery	Active	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active.**
FLORES, Bruno C, MD	Neurological Surgery	Active	2/27/2025-2/27/2027	**Change in staff status from Provisional to Active.**
GREIDER, Bradley W, MD	Ophthalmology	Active	2/27/2025-2/27/2027	
MACEWAN, Jennifer H, MD	Otolaryngology	Active Affiliate	2/27/2025-2/27/2025	
SHAFQAT, Jon P, DDS	Oral & Maxillofacial Surgery	Refer and Follow	2/27/2025-2/27/2025	

Resignations *Medical Staff:*

Practitioner Name	Department/Specialty	Reason for Resignation
ASSELIN, Lynette M, DO	Pediatrics	Voluntarily Resignation effective 2/27/2025. Fail to return reappointment application.
BOURLAND, Bryan DO	Surgery/Orthopedic	Fellowship ended 7/31/2024.
CARR, Kenneth MD	Medicine/Cardiology	Voluntary Resignation: E-mail received by MD.
COLETTE, Grant L, MD	Pediatrics	Voluntarily Resignation effective 2/27/2025. Fail to return reappointment application.
EVANS, Jamie, MD	Telepsychiatry	Voluntarily Resignation effective 2/27/2025.

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – 1 of 1
February 12, 2025

Attachment B

IKELHEIMER, Douglas, MD	Telepsychiatry	Voluntarily Resignation effective 2/27/2025.
MADHAV, Kinjal S.	Family Medicine	Voluntarily Resignation effective 11/20/2024.
NEWMAN, Jeffrey L, MD	Family Medicine	Voluntarily Resignation effective 2/27/2025. Fail to return reappointment application.

MBOC (Medical Board of California): No new information at this time

NPDB (National Practitioner Data Bank): No new information at this time

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
MEDICAL STAFF CREDENTIALS REPORT – Part 2 of 3
February 12, 2025

Addition/Deletion of Privilege(s)

The following practitioners have requested addition/deletion of privilege(s) as noted below. Effective **February 27, 2025.**

Practitioner Name	Department/Specialty	Change in Privilege/s
YI, Jung, MD	Anesthesiology	Auto Relinquishment of Cardiac Anesthesia, Transesophageal Echocardiography and Coronary sinus catheter placement due to not meeting proctoring requirements.

Tri-City Medical Center
MEDICAL STAFF

TRI-CITY MEDICAL CENTER
CREDENTIALS COMMITTEE REPORT – Part 3 of 3
February 12, 2025

Proctoring Recommendations

The following providers have successfully completed their initial FPPE (Focused Professional Practice Evaluation) and are being recommended for release of their proctoring requirements for the privilege(s) as noted below.

Practitioner Name	Department/Specialty	Privilege(s)
James Andry, MD	Surgery/Orthopedic	Basic Orthopedic Privileges, Arthroscopy Surgery for Knee, Shoulder, Elbow, Hand, Ankle, Wrist & Hip Joints, Extremity-Fractures Bundle, Extremity-Dislocation.
David J. Cohen, MD	Radiology	Teleradiology Bundle
Jane Hur, MD	Radiology	Teleradiology Bundle
James Layson DO	Surgery/Orthopedic	Knee Arthroplasty/MAKO

Tri-City Medical Center
Finance, Operations and Planning Committee Minutes
February 19, 2025

Members Present	Director Tracy Younger, Director Nina Chaya, Director Adela Sanchez, Dr. Mohammad Jamshidi-Nezhad, Dr. Henry Showah
Non-Voting Members Present:	Dr. Gene Ma, CEO; Janice Gurley, CFO; Jeremy Raimo, COO; Donald Dawkins, CNE; Roger Cortez, CCO; Mark Albright, CIO; Susan Bond, General Counsel
Others Present:	Director George Coulter, Jennifer Paroly, Julie Abraham, Jane Dunmeyer, Miava Sullivan
Members Absent:	None

Topic	Discussions, Conclusions Recommendations	Action Recommendations/ Conclusions	Person(s) Responsible
1. Call to order	Director Younger called the meeting to order at 3:03 pm.		Chair
2. Approval of Agenda		**MOTION** **It was moved by Director Chaya, Director Sanchez seconded, and it was unanimously approved to accept the agenda of February 19, 2025.**	Chair
3. Comments by members of the public on any item of interest to the public before committee's consideration of the item.	Director Younger read the paragraph regarding comments from members of the public.	No comments	Chair
4. Ratification of minutes of January 22, 2024	Minutes were ratified.	Minutes were ratified. **MOTION** **It was moved by Director Sanchez, Dr. Showah seconded, that the minutes of January 22, 2025, are to be approved without any requested modifications.**	Chair
5. Old Business	None		

Topic	Discussions, Conclusions Recommendations	Action Recommendations/ Conclusions	Person(s) Responsible
6. New Business	None		
7. Consideration of Consent Calendar:		**MOTION** **It was moved by Director Sanchez to approve the Consent Calendar and seconded by Director Chaya.** **Members:** **AYES: Younger, Chaya, Sanchez, Jamshidi-Nezhad, Showah** **NOES: None** **ABSTAIN: None** **ABSENT: None**	Chair
a) Physician Recruitment Agreement • Dr. Abhinav Sharma – Cardiovascular Medicine		**Approved via Consent Calendar**	Jeremy Raimo
b) Medical Directorship Agreement Renewal – Diabetic Services Program • Dr. Jamil Alkhaddo		**Approved via Consent Calendar**	Jeremy Raimo
c) Renewal One to Professional Services Agreement – 1206(B) Pulmonary Clinic • Pulmonary Specialist of North County, Inc.		**Approved via Consent Calendar**	Jeremy Raimo
d) Physician Agreement with Locum Tenens – Emergency Room & Inpatient Psychiatric On-Call Coverage • CompHealth		**Approved via Consent Calendar**	Donald Dawkins

Topic	Discussions, Conclusions Recommendations	Action Recommendations/ Conclusions	Person(s) Responsible
e) Regulated Medical Waste Master Agreement Renewal Proposal • Stericycle, Inc.		**Approved via Consent Calendar**	Jeremy Raimo
f) Physician Recruitment Agreement • Dr. Jeffrey Raunig – Family Practice		**Approved via Consent Calendar**	Jeremy Raimo
8. Financials	Janice Gurley presented the financials ending January 31, 2025 (dollars in thousands) **TCHD – Financial Summary** **Fiscal Year to Date** Operating Revenue $ 192,691 Operating Expense $ 199,777 EBITDA $ 10,599 EROE $ 19 **TCMC – Key Indicators** **Fiscal Year to Date** Avg. Daily Census 126 Adjusted Patient Days 48,142 Surgery Cases 3,196 ED Visits 27,982 **TCHD – Financial Summary** **Current Month** Operating Revenue $ 29,939 Operating Expense $ 30,596 EBITDA $ 2,222 EROE $ 734 **TCMC – Key Indicators** **Current Month** Avg. Daily Census 142 Adjusted Patient Days 7,375 Surgery Cases 473 ED Visits 4,256		Janice Gurley

Topic	Discussions, Conclusions Recommendations	Action Recommendations/ Conclusions	Person(s) Responsible
	Graphs: • TCHD-EBITDA and EROE • TCHD Financial Summary • TCMC-Average Daily Census, Total Hospital - Excluding Newborns • TCMC-Emergency Department Visits • TCMC-Acute Average Length of Stay • TCMC-Adjusted Patient Days • TCMC-Paid Full Time Equivalents-13 Month Trend		
a. Dashboard	No discussion	Information Only	Janice Gurley
9. Comments by Committee Members	None	None	Chair
10. Date of next meeting	March 19, 2025		Chair
11. Adjournment	Meeting adjourned 3:26 pm		Chair

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
PHYSICIAN RECRUITMENT AGREEMENT

Type of Agreement		Medical Directors		Panel	X	Other: Physician Recruitment
Status of Agreement	X	New Agreement		Renewal: New Rates		Renewal: Same Rates

Physician Name: Abhinav Sharma, M.D.

Areas of Service: Cardiovascular Medicine

Key Terms of Agreement:

Effective Date: July 1, 2025, or the date Dr. Sharma becomes a credentialed member in good standing of the Tri-City Healthcare District Medical Staff.

Community Need: TCHD Physician Needs Assessment shows significant community need for Cardiology.

Service Area: Area defined by the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients

Terms of the Engagement:	Proposal Costs:
Monthly Income Guarantee, Not to Exceed	$25,000 per month ($300,0000 a year, with a 2-year forgiveness period)
Relocation Allowance	$7,500 (not part of the loan)
Total Amount of Request:	**$307,500**

Unique Features: Dr. Sharma will practice with Dr. Pashmforoush and Dr. Yung at Tri-City Cardiology & Arrhythmia

Requirements:

Business Pro Forma: Must submit a 12-month business pro forma for TCHD approval relating to the addition of this physician to the medical practice, including proposed incremental expenses and income. TCHD may suspend or terminate income guarantee payments if operations deviate more than 20% from the approved pro forma and are not addressed as per agreement.

Expenses: The agreement specifies categories of allowable professional expenses (expenses associated with the operation of physician's practice and approved at the sole discretion of TCHD) such as billing, rent, medical and office supplies, etc. If the incremental monthly expenses exceed the maximum, the excess amount will not be included.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operating Officer

Motion:

I move that the Finance, Operations & Planning Committee approve expenditure, not to exceed $307,500, to facilitate the addition of Abhinav Sharma, M.D., a cardiovascular medicine physician to practice medicine in the communities served by the District. This will be accomplished through an independent physician recruitment agreement (not to exceed a one-year income guarantee with a two-year forgiveness period) between Tri-City Healthcare District, and Abhinav Sharma, M.D.

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
MEDICAL DIRECTORSHIP AGREEMENT – DIABETIC SERVICES PROGRAM

Type of Agreement	X	Medical Directors		Panel		Other:
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Physician's Name: Jamil Alkhaddo, M.D.

Area of Service: Diabetic Services Program

Term of Agreement: Beginning, February 1, 2025 through January 31, 2026

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: Yes

Rate/Hour	Hours Per Month	Hours Per Year	Monthly Cost	Annual Cost
$150	16	192	$2,400	**$28,800**

Description of Services/Supplies:

- Medical Direction of Diabetes Program
- Develops, implements and monitors Diabetic planning to ensure patient care quality and regulatory compliance.
- As a requirement for Joint Commission for accreditation, the program must have physician oversight through a Medical Director

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:	X	Yes		No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operations Officer

Motion:
I move that the Finance, Operations & Planning Committee recommend that the TCHD Board of Directors authorize a renewal of the medical directorship agreement with Jamil Alkhaddo, M.D. for the Diabetes Program for a term of 12 months, beginning, February 1, 2025 through January 31, 2026 for a total term cost not to exceed $28,800.

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
RENEWAL ONE TO PROFESSIONAL SERVICES AGREEMENT - 1206(B) PULMONARY CLINIC RENEWAL

Type of Agreement		Medical Director		Panel		Other:
Status of Agreement		New Agreement		Renewal – New Rates	X	Renewal – Same Rates

Vendor's Name: Pulmonary Specialists of North County, Inc.

Area of Service: Ambulatory Pulmonary Clinic

Term of Agreement: 12 months, Beginning, February 6, 2025 – Ending, February 5, 2026

Maximum Totals:

Monthly Cost	Annual Cost	Total Term Cost
Up to $42,500	$510,000	$510,000

Description of Services/Supplies:

- Ambulatory clinic coverage for both outpatient and inpatient hospital pulmonary consultation coverage
- Includes EBUS and ION procedural codes for new program

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operating Officer

Motion:
I move that the Finance, Operations & Planning Committee recommend that the TCHD Board of Directors authorize the renewal agreement between Tri-City Healthcare District and Pulmonary Specialists of North County, Inc for a term of 1 year, beginning February 6, 2025 and ending February 5, 2026 for a total cost for the term not to exceed $510,000.

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
PHYSICIAN AGREEMENT FOR LOCUM TENENS– EMERGENCY ROOM & INPATIENT PSYCHIATRIC ON-CALL COVERAGE

Type of Agreement		Medical Directors		Panel	X	Back Up Psychiatric Coverage
Status of Agreement	X	New Agreement		Renewal – New Rate		Renewal – Same Rate

Vender Name: CompHealth

Area of Service: Emergency Room and Inpatient Units

Term of Agreement: 16 months, Beginning, March 1, 2025 – Ending, June 30, 2026

Maximum Totals: Within Hourly Fair Market Value

	Rate/Hour	Annual Days/Hours (NTE)	Daily Rate (NTE)	Annual Cost	Term Cost
Medical Director Duties	$315 -$321	200 hours	$2,520 - $2,568	$64,200	$85,600
Administrative fee charged only on days we use them for calls	$32	28 days	N/A	$896	$1,195
Holiday Rate	1.5% of rate (additional 0.5%)	15 hours	N/A	$2,407	$3,209
		Total Cost:		**$67,503**	**$90,004**

On-Call Duties:

- Provide psychiatric phone consults for emergency room and inpatient units upon request
- Provide telehealth consultations.
- Provide clinical guidance to physicians and psychiatric liaisons for ED and IP patients

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X			No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:		Yes	X	No

Person responsible for oversight of agreement: Sarah Jayyousi, Operations Manager-Outpatient Behavioral Health Services / Donald Dawkins, Chief Nurse Executive

Motion: I move that the Finance, Operations & Planning Committee recommends that the TCHD Board of Directors authorize the physician agreement with CompHealth for locum tenens psychiatric on-call coverage for the emergency department and inpatient units for a term of 16 months, beginning March 1, 2025 and ending June 30, 2026, for an annual cost of $67,503 and a total term cost of $90,004.

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
REGULATED MEDICAL WASTE MASTER SERVICE AGREEMENT PROPOSAL

Type of Agreement		Medical Director		Panel	X	Other: Vendor Services
Status of Agreement		New Agreement	X	Renewal – Decrease in Rates		Renewal – Same Rates

Vendor's Name: Stericycle, Inc.

Area of Service: Tri-City Medical Center and Clinics

Term of Agreement: 60 months, Beginning, March 1, 2025 – Ending, February 28, 2030

Maximum Totals:

Regulated Medical Waste Disposal, Sharps Rx Pro™ Pharmaceutical/Sharps Waste Disposal, Hazardous Waste Disposal			
	Monthly Cost	**Annual Cost**	**Total Term Cost**
CURRENT COST	$11,000	$132,000	$660,000
NET CHANGE	- $2,600	- $31,200	- $156,000
NEW COST	**$8,400**	**$100,800**	**$504,000**
Additional Pick-Ups by Weight			
	Monthly Cost	**Annual Cost**	**Total Term Cost**
CURRENT COST	$7,766	$93,200	**$466,000**
		Total Term Cost for Entire Agreement:	**$970,000**

Description of Services/Supplies:

- Services to be provided by Stericycle, Inc.: Regulated Medical Waste Disposal, Sharps Rx Pro™ Pharmaceutical/Sharps Waste Disposal, Hazardous Waste Disposal
- Reducing the monthly pickup cost from $11,000 to $8,400 saving Tri-City Medical Center $31,200 per year
- Stericycle, Inc. also provides Tri-City Medical Center and our clinics with any request additional pick-ups which we are charge by weight

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:		Yes	N/A	No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Benito Oporto, Director-Facilities/Engineering Dept. / Jeremy Raimo, Chief Operating Officer

Motion:
I move that Finance Operations & Planning Committee recommend that the TCHD Board of Directors authorize the agreement with Stericycle, Inc. for regulated medical waste disposal, hazardous waste disposal & sharps waste disposal management for a term of 60 months, beginning March 1, 2025 and ending February 28, 2030, for an annual cost of $194,000 and a total cost for the term of $970,000.

Tri-City Medical Center

FINANCE, OPERATIONS & PLANNING COMMITTEE
DATE OF MEETING: February 19, 2025
PHYSICIAN RECRUITMENT AGREEMENT - Jeffrey Raunig, MD

Type of Agreement		Medical Directors		Panel	X	Other: Recruitment Agreement
Status of Agreement	X	New Agreement		Renewal – New Rates		Renewal – Same Rates

Physician's Name: Jeffrey Raunig M.D.

Area of Service: Family Practice

Term of Agreement: 24 months, March 1, 2025 – Ending, February 28, 2027

Maximum Totals: Within Hourly and/or Annualized Fair Market Value: YES

Terms of the Agreement: (not to exceed)	**Proposal Costs:**
Sign-on Advance	$35,000
Total Loan Amount Request	**$35,000**

Position Responsibilities:

- Physician will practice in Carlsbad, CA, and will receive assistance under a physician recruitment agreement in the form of a loan to be forgiven over a two-year (24 month) period for sign-on advance as long as physician remains practicing in the TCHD service area full time.

Document Submitted to Legal for Review:	X	Yes		No
Approved by Chief Compliance Officer:	X	Yes		No
Is Agreement a Regulatory Requirement:		Yes	X	No
Budgeted Item:	X	Yes		No

Person responsible for oversight of agreement: Jeremy Raimo, Chief Operating Officer

Motion:

I move that the Finance, Operations & Planning Committee recommend that the Board of Directors approve the sign-on advance, not to exceed $35,000 in order to facilitate this Family Medicine physician practicing medicine in the communities served by the District. This will be accomplished through a Physician Recruitment Agreement with Jeffrey Raunig, M.D. beginning March 1, 2025 and ending February 28, 2027, for a total not to exceed $35,000, in the form of a forgivable loan over a 24-month period.

Tri-City Medical Center

ADMINISTRATION CONSENT AGENDA
February 18th, 2025

CONTACT: Donald Dawkins, CNE

Policies and Procedures	Reason	Recommendations
Patient Care Services		
1. Tdap (Tetanus, Diptheria & Pertussis) Vaccine Administration for Antepartum & Postpartum Obstetric Patients Standardized Procedure	RETIRE	Forward to BOD for Approval
Infection Control		
1. Infection Prevention Program Plan	1 year review	Forward to BOD for Approval
Laboratory		
1. Blood and Tissue Service Agreement Policy	2 year review	Forward to BOD for Approval
2. Cytology Specimens Excluded from Routine Submission to the Cytology Section Policy	2 year review, practice change	Forward to BOD for Approval
3. Cytotechnologist Workload Policy	2 year review	Forward to BOD for Approval
4. Laboratory Quality Management Plan Overview	2 year review	Forward to BOD for Approval
5. QSE.02 Laboratory Personnel Quality System Essentials	2 year review	Forward to BOD for Approval
6. QSE.03 Laboratory Equipment Quality System Essentials	2 year review, practice change	Forward to BOD for Approval
7. QSE.04 Laboratory Facilities and Safety Quality System Essentials	2 year review, practice change	Forward to BOD for Approval
8. QSE.05 Laboratory Purchasing and Inventory Quality System Essentials	2 year review, practice change	Forward to BOD for Approval
Mammography Women's Center		
1. Report Inclusions Policy	Practice change	Forward to BOD for Approval
Outpatient Specialty Clinic		
1. Decontamination and Sterilization of Instruments	RETIRE	Forward to BOD for Approval
Pulmonary Rehab		
1. Maintenance and Repair of Exercise Equipment	3 year review, practice change	Forward to BOD for Approval
Surgical Services		
1. Post Anesthesia Standards of Practice and Documentation Policy	3 year review, practice change	Forward to BOD for Approval

Tri-City Medical Center
Oceanside, California

RETIRE – Women and Newborn Services Suspended

PATIENT CARE SERVICES

STANDARDIZED PROCEDURE: TETANUS, DIPHTHERIA & PERTUSSIS (Tdap~~DAP~~) VACCINE ADMINISTRATION FOR ~~ANTEPARTUM~~ OBSTETRIC PATIENTS ~~AND EMPLOYEES~~

~~I. POLICY:~~

~~A. Function: To provide guidelines for administration of the Tdap vaccine to obstetric patients~~antepartum women.

~~1. Tdap vaccine will be offered to all inpatient obstetric~~antepartum patients with every pregnancy (unless already received in the current pregnancy) and if they do not have a contraindication to the vaccination before discharge from the hospital.

~~2. The Registered Nurse (RN) shall:~~

~~a. Identify and provide Tdap vaccine to all inpatient obstetrical~~antepartum women meeting screening criteria.

~~i. Tdap vaccine is contraindicated:~~

~~1) In those with history of serious allergic reaction (anaphylaxis) to any component of the vaccine~~

~~2) In those with history of encephalopathy (coma or prolonged seizure) within 7 days of receiving a vaccine with Pertussis.~~

~~ii. Physician notification with a new order is required to proceed with immunization for the following risk factors:~~

~~1) Moderate or severe acute illness with or without fever until the acute illness resolves.~~

~~2) Guillain-Barré syndrome less than (<) 6 weeks after previous dose with tetanus toxoid-containing vaccine~~

~~3) Unstable neurologic condition (consult MD if patient has any neurologic condition for further advice)~~

~~History of an Arthus reaction (i.e. a severe injection site reaction with hemorrhage or local necrosis typically developing 4 – 12 hours after vaccination) following a previous dose of a tetanus toxoid-containing and/or diphtheria toxoid-containing vaccine~~

~~**Severe allergic reaction to latex**~~

~~**4) The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.**~~

~~Simultaneous vaccination of Tdap with Measles Mumps and Rubella, Rh immune globulin, and Influenza vaccine is safe.~~

~~iii. **Administer each vaccine using a separate syringe and, if possible, at a different anatomic site.**~~

~~**Tdap vaccination can be given at any time during pregnancy.**~~

~~**Optimal timing of administration is between 27 weeks and 36 weeks of gestation.** Tdap may be given in the 2nd or 3rd trimester of pregnancy and should be given once with every pregnancy.~~

~~iv. **If not administered during pregnancy, the Tdap vaccine should be given postpartum if the woman has never received a prior dose of Tdap as an adolescent, adult, or during a previous pregnancy.**~~

~~B. Circumstances:~~

Department Review	Clinical Policies & Procedures	Nursing Leadership	Department of OB/GYN	Pharmacy & Therapeutics	Interdisciplinary Committee	Medical Executive Committee	Administration	Professional Affairs Committee	Board of Directors
06/10, 05/12, 01/15, 08/16, **07/23**	05/12, 02/15, 09/16, 05/20, **07/23, 05/24**	05/12, 02/15, 09/16, 06/20, **08/23,09/24**	06/15, 12/16, n/a	05/12, 09/15, 02/17, 05/21, **09/24**	11/12, 01/16, 04/17, 07/21, **01/25**	11/12, 01/16, 04/17, 10/21, **01/25**	11/21	02/16, 05/17, n/a	12/12, 02/16, 05/17, 12/21

1. Setting: Tri-City Medical Center – Inpatient **Obstetrical**Antepartum care unit.
2. Supervision: None required
3. Considerations for administration:
   a. Requires careful screening of patient's prenatal care or lack of prenatal care, availability of immunization record, assessment of risk factors associated with exposure, and potential for development of Pertussis (if it was developed with previous vaccination).
   b. Reduces the risk of Pertussis exposure from the mother to the newborn**To maximize the maternal antibody response and passive antibody transfer and levels in the newborn.**
   c. Compliance with recommendations from the California Department of Health, Centers for Infectious Disease to prevent infant deaths under 12 months due to Pertussis

II. **PROCEDURE**:
A. The RN shall:
1. Identify and document vaccination history regarding previous Tdap vaccination while screening patient for eligibility for Tdap immunization during**immunization during** the admission process for all inpatient **obstetrical**antepartum patients
   a. The patient is not eligible for vaccination if any of the risk factors below are identified:
      i. Previous severe allergic reactions (i.e. anaphylaxis) to any component of the vaccine.
      ii. History of coma or prolonged seizures occurring less than 7 days after administration of a pertussis vaccine (DTP, DTaP, Tdap) that was not attributable to any identifiable cause.
         1) Note: Family history of seizures is not a contraindication
      iii. Patient received and can verify administration of the Tdap vaccine during this pregnancy.
   b. Physician notification with a new order is required to proceed with immunization for the following risk factors:
      i. Moderate or severe acute illness with or without fever until the acute illness resolves
      ii. Guillain-Barre syndrome less than 6**than (<) 6** weeks after previous dose with tetanus toxoid containing vaccine
      iii. Unstable neurologic condition
      History of an Arthus reaction (i.e. a severe injection site reaction with hemorrhage or local necrosis typically developing 4 – 12 hours after vaccination) following a previous dose of a tetanus toxoid – containing and/or diphtheria toxoid – containing vaccine
      Severe allergic reaction to latex
      iv. **The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions.**
   Shake the prefilled syringe vigorously to obtain a homogeneous, turbid, white suspension before administration. Administer Tdap as per pharmacy dosing, preferable in the bicep muscle.
   Do not use if resuspension does not occur with vigorous shaking.
2. **Attach a sterile needle (22-25 gauge needle with a length that is appropriate to the person's age and body mass) and administer 0.5mL intramuscularly (preferred injection site: deltoid muscle of the arm).**

III. **REQUIREMENTS FOR CLINICIANS INITIATING STANDARDIZED PROCEDURE**:
A. Current unencumbered California RN license.
B. Initial Evaluation: Orientation

~~C. Ongoing Evaluation: Annually~~

~~IV. **DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE:**~~

~~A. Method: This Standardized Procedure was developed through collaboration with Nursing, Medicine, and Administration.~~

~~B. Review: Every two (2) years.~~

~~V. **CLINICIANS AUTHORIZED TO PERFORM THIS STANDARDIZED PROCEDURE:**~~

~~A. All Registered Nurses who have successfully completed requirements as outlined above are authorized to direct and perform Tdap Vaccine Administration for Antepartum Obstetric Patients Standardized Procedure.~~

~~VI. **REFERENCES:**~~

~~**BOOSTRIX (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed) injectable suspension, for intramuscular use, package insert. GlaxoSmithKline Biologicals, October 2022.**~~

~~**Centers for Disease Control and Prevention (CDC), Vaccine Information Statement Tdap (Tetanus, Diphtheria, Pertussis) Vaccine. August 6, 2021.**~~

~~**Update on immunization and pregnancy: tetanus, diphtheria, and pertussis vaccination. Committee Opinion No. 718. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130: e153-7.**~~

~~A. The American College of Obstetricians and Gynecologists Committee. Update on Immunization and Pregnancy: Tetanus, Diptheria, and Pertussis Vaccination. Opinion Number 718, September 2017 (Reaffirmed 2019)~~

~~B. Center for Disease Control and Prevention, Morbidity and Mortality Weekly Report April 27, 2018 Recommendations and Reports, Vol. 67, No. 2~~

~~C. Center for Disease Control, Vaccinating Pregnant Patients, June 29, 2017~~

~~D. Healthcare Personnel Vaccination Recommendations. March, 2018. Immunization Action Coalition. www.immunize.org/catg.d/p2017.pdf~~

~~E. Morbidity and Mortality Weekly Report. Use of Tetanus Toxoid, Reduced Diptheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices-United States. January 24, 2020, Vol. 69, No.3~~

~~F. Standing Orders for Administering Tdap to Pregnant Women. June, 2018. Immunization Action Coalition. www.immunize.org/catg.d/p3078b.pdf~~

~~G. Talking to Pregnant Women About Vaccines. December, 2019. Cdc.gov/vaccines/pregnancy~~

Tri-City Health Care District
Oceanside, California

INFECTION CONTROL

ISSUE DATE: 07/02 **SUBJECT: Infection Prevention Program Plan**

REVISION DATE: 04/09, 05/12, 09/15, 09/18, 05/22
09/18, 01/24, 02/23

Infection Control Department Approval:	~~01/24~~10/24
Infection Control Committee Approval:	~~01/24~~10/24
Pharmacy & Therapeutics Committee Approval:	n/a
Medical Executive Committee Approval:	~~02/24~~01/25
Administration Approval:	03/24
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	03/24

A. **PURPOSE**:
1. The purpose of the Infection Prevention (IP) Program Plan is to outline the annual infection prevention priorities of Infection Prevention and Tri-City Medical Center (TCMC). In order to achieve, an organized systematic plan is developed based upon the annual infection control risk assessment that provides the foundation for an effective infection prevention program.

B. **GOALS**:
1. Overall
   a. Reduce risk of healthcare-associated infections for all patients, employees, and visitors.
2. Targeted
   a. Healthcare-associated infection reduction – at least 30% reduction overall across the infection types that are reported to CMS (MRSA bacteremia, *C.difficile,* CLABSI; SSI Hysterectomy and Colon surgery; CAUTI). (Note: infection counts are based on CMS required reporting regulations, not necessarily all hospital-wide infections)
   b. Hand hygiene compliance program
      i. Incorporate patients and families
         1) Develop a bundle of tools for patients and family involvement
      ii. Consistently sustain ≥96 percent compliance across locations and job classes
         1) At least 96 percent of all locations and job classes must sustain 96 percent compliance or higher (for all locations/job classes submitting at least 40 observations/month)
      iii. Promote engagement
         1) Develop tools for promoting involvement across all job categories
         2) develop new incentives and rewards.

C. **RISK ASSESSMENT**:
1. See Annual Facility Infection Risk Assessment
2. Patient Populations at Increased Risk of Infection
   a. All intensive care unit patients
   b. Immunosuppressed patients (e.g., absolute neutrophil count (ANC) <1000
3. Procedures/Devices that Increase Infection Risk
   a. Central venous catheters
   b. Indwelling urinary catheters
   c. Tubes, drains, other devices inserted percutaneously
   d. Intubation and prolonged ventilator support

e. Surgical procedures
f. ECMO/VAD

4. Epidemiologically Important Pathogens
   a. Legionella
   b. Aspergillus
   c. MRSA
   d. VRE
   e. *C. difficile*
   f. MDR Gram negative bacteria
   g. Carbapenem-resistant *Enterobacteriacae*
   h. *Candida auris*
5. Highly Communicable Diseases
   a. Novel Influenza virus
   b. SARS-CoV
   c. MERS
   d. Viral hemorrhagic fevers (e.g., Lassa fever, Ebola viral disease)
   e. Vaccine preventable disease (e.g., Measles, Pertussis)

D. **GENERAL STRATEGIES TO REDUCE INFECTION RISK:**

1. Identify risk for acquiring and transmitting infections based geographic location, community and population served
   a. Receive public health alerts on community illnesses and trends from the California Department of Public Health (CDPH).
   b. Act as liaison between the medical center and the public health department.
   c. Attend monthly Association for Professional in Infection Control and Epidemiology (APIC) local chapter meetings with other facilities in our area.
2. Identify and control outbreaks
   a. Review of microbiology, immunology, molecular microbiology reports
   b. Institution of prevention and control measures as indicated (e.g., isolation, co-horting of patients and staff, improved hand hygiene, active surveillance cultures, assessment of environmental cleaning, enhanced environmental cleaning)
   c. Exposure follow-up (in conjunction with Employee Health)
3. Perform surveillance for healthcare-associated infections
   a. Follow CDC National Healthcare Safety Network (NHSN) definitions
   b. Comprehensive: inpatient-related and outpatient-detected
   c. Calculation/distribution of monthly infection rates and line listing of infected patients for each inpatient unit/service line
   d. Monthly and as needed analysis of potential for cross-transmission
   e. Targeted surveillance for home health/hospice infections
   f. Monitor incidence of healthcare-associated device-related or procedure-related infections
      i. Catheter-Associated Urinary Tract Infections (CAUTI)
      ii. Central Line-Associated Bloodstream Infections (CLABSI)
      iii. Ventilator-Associated Events (VAE)
      iv. Surgical Site Infections (SSI)
4. Conduct routine monitoring
   a. Biological indicators for sterilizers
   b. Endoscopes
5. Improve Hand Hygiene Compliance
   a. Support compliance monitoring and provide feedback to staff.
   b. Routinely evaluate the availability and acceptability of hand hygiene products.
   c. Provide just-in-time peer coaching.
   d. Provide frequent and tailored education on when and how to perform hand hygiene along with frequent visible reminders.

e. Enlist organizational leaders to serve as role models.
f. Ensure commitment of leadership to achieve and sustain compliance of ≥ 96%.

6. Develop and Support Infection Control Liaison Program
   a. Unit-based staff, outpatient care services clinical staff, and ancillary care staff (i.e., EVS, FNS, Patient Transport) with focused infection control training provided by Infection Prevention.
   b. Responsible for assessing their unit's compliance with infection control policies/procedures and conducting performance improvement activities related to infection prevention (e.g., reducing device-associated infections, monitoring and improving hand hygiene compliance)
   c. Serves as the contact person to disseminate infection control information, updates, and answer staffquestions
7. Ensure compliance with TJC National Patient Safety Goals
   a. Comply with WHO/CDC hand hygiene guidelines
   b. Prevent HAIs due to multi-drug resistant organisms (MDROs)
      i. Annual risk assessment for MDROs
      ii. Implement and assess prevention strategies outlined in this plan and under NPSG 07.03.01
   c. Assess compliance with evidence-based practices for prevention of central line-associated bloodstream infections
      i. Compliance with Central Line Insertions, Access, and Maintenance Bundle
      ii. Standardized insertion training and checklist for providers.
      iii. Chlorhexidine bathing in intensive care units, and for all patients hospital-wide with a central line.
      iv. Daily assessment for central line need
      v. Provide Central Line-Associated Bloodstream Infection rate data and prevention process measures to key stakeholders, including leaders, licensed independent practitioners, nursing staff, and other clinicians
   d. Assess compliance with evidence-based practices for prevention of surgical site infections
      i. Ensure patient education provided in Pre-op visit. Use LMS for staff education.
      ii. Promote standardized, evidence-based practices for patient skin preparation prior to surgery.
      iii. Ensure Peri-Operative Services and Anesthesia infection control policies support prevention strategies.
      iv. Trend surgical procedure specific infection rates and unit rates and provide feedback to key stakeholders
   e. Implement evidence-based strategies for prevention of catheter-associated urinary tract infections
      i. Staff education regarding aseptic insertion of catheter
      ii. Insertion order must include indication for catheter
      iii. Daily assessment for urinary catheter need
      iv. Appropriate maintenance of indwelling urinary catheters
      v. Perform periodic audits on Indwelling Urinary Catheter Maintenance compliance and removal protocol and disseminate process measures on compliance to unit leadership quarterly.
8. Manage HAIs as Sentinel Events When Indicated
   a. Review all HAIs for indications of an unanticipated death or permanent loss of function
   b. Notify Risk Management of suspected sentinel event
   c. Participate in root cause analysis and follow up as needed
9. Construction Rounds and Construction Risk Assessment Meetings

a. Walking rounds with Facilities Engineering monthly to active construction and renovation sites in the medical center and on an as needed basis.
b. Attend construction meetings held by Facilities and Contract services.
c. Review blueprints and risk assessments for all new construction and renovations in clinical areas.

10. Infection Control Rounds
    a. Evaluate compliance with infection control policies/practices.
    b. Written recommendations to manager with their follow-up documented.
11. Policy Review and Revision
12. Committee Participation: Refer to Infection Prevention Program Policy for committee information.
13. Periodic Comprehensive TB Risk Assessment
14. Consultation, Education/Training
    a. In-services, presentations, educational material to staff, visitors/families, medical staff, contract employees, students, and volunteers
    b. Computer-based training modules
    c. Educational videos
    d. Newsletter articles
    e. Educational materials (e.g., brochures, booklets)
    f. On-call availability 24/7 for Infection Prevention consultation
15. Additional Strategies to Reduce Infections for the Immunosuppressed Patient (e.g. absolute neutrophil count [ANC<1000], agranulocytosis)
    a. Ideally a private positive pressure room
    b. No live plants or fresh flowers
    c. Patient must wear tight-fitting surgical mask when outside room
    d. Child visitor restrictions during influenza and RSV season
16. Additional Strategies for Home Health and Hospice
    a. Trend analysis of wound infections, device-related infections (urinary catheter-associated UTIs and central line-associated bloodstream infections)
    b. Promote immunizations to prevent respiratory infections: influenza and pneumococcal pneumonia vaccines (as recommended by ACIP)
17. Additional Strategies for Outpatient Care Services
    a. Since most patient encounters with the healthcare system now take place in outpatient settings, TCMC will maintain infection prevention programs in Outpatient Care Services, and this will include
    b. Training and monitoring of practices on:
        i. the basic principles of disease transmission and the methods to prevent transmission
        ii. Safe injection practices and proper use of single use and single patient devices/ medications
        iii. principles of asepsis and hand hygiene
        iv. OSHA Bloodborne Pathogen Standard
        v. the principles of disinfection and sterilization
        vi. TB and respiratory protection per OSHA

E. SPECIFIC STRATEGIES TO ADDRESS INFECTION RISKS:

1. Based on the Facility Risk Assessment, the following strategies will be employed in FY24 for elements with scores of >6:
    a. Environmental Cleanliness-Terminal Cleaning failure
        i. Staff education and competency check off
        ii. Weekly documented IP oversight
        iii. Implementation of unit specific terminal cleaning checklist
    b. Personal Protective Equipment (PPE) Compliance

i. Compliance monitoring
ii. Staff education and competency check-off

F. **EVALUATION OF PLAN EFFECTIVENESS:**

1. Statistical analysis of infections
2. Trend analysis of infection rates
3. Healthcare-acquired infection rates to include home health.
4. Monthly infection reports to nurse managers, clinical directors, infection control liaisons
5. Quarterly infection reports to Infection Control Committee
6. Infection Control rounds report and annual compliance assessment
7. Support Employee Health Services to monitor compliance with required and recommended immunizations
8. Annual assessment of communicable disease exposures with trend analysis
9. Annual risk assessment for MDROs with trend analysis
10. Periodic assessment of process measures with staff feedback
    a. Evidence based processes to prevent surgical site infections
    b. Evidence based processes to prevent catheter associated bloodstream infections
    c. Evidence based processes to prevent catheter associated urinary tract infections
    d. Evidence based processes to prevent *C.difficile* infections
    e. Evidence based processes to prevent ventilator associated events
    f. Hand hygiene compliance
    g. Isolation precautions compliance

G. **RELATED DOCUMENT(S):**

1. Infection Control Policy: Infection Prevention Risk Assessment
2. Infection Prevention Risk Assessment Table
3. **Infection Prevention Program Evaluation**

H. **REFERENCE(S):**

1. APIC Text of Infection Control and Epidemiology, 2021.
2. Joint Commission, Hospital Accreditation Standards, Chapter: Infection Prevention and Control, www.jointcommission.org
3. CMS Conditions of Participation: IC (reviewed 01/24)
4. Title 22, Calif. Code of Regulations (reviewed 01/24)

Infection Prevention Program Evaluation

Risk	Priority	Data Source	Goal	2023	Goal met?	Prevention Strategies
MRSA HO BSI	Mod	LabID/NHSN	SIR: ≤0.5 (SIR) <1	2 cases (CY2023 SIR 0.74)	Not Met	Standard/Transmission based Precautions/HH/ASP Education on prevention Nasal decolonization for MRSA+ nares, screening on admit Continue to monitor and trend data
MRSA HO infections	Mod	LabID/NHSN	Less than IHI published rate of 3.95/1000 pt days. As of 2020: # of positives/total patient days (MRSA) x 1000 pt	0.11	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention Nasal decolonization for MRSA+ nares, screening on admit Continue to monitor and trend data
VRE HO BSI	Mod	LabID/NHSN	0-1 case (no published benchmark)	1 case	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention Antibiotic Stewardship Continue to monitor and trend data
VRE HO infections	Mod	LabID/NHSN	Trend lower or same (no published benchmark)	3 cases	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention Antibiotic Stewardship Continue to monitor and trend data
ESBL HO infections	Mod	Cerner	Trend lower or same (no published benchmark)	4	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene, Cleaning & Disinfection Patient Care Equipment Education on prevention Antibiotic Stewardship
CRE HA	Mod	Cerner	Trend lower or same (no published benchmark)	4	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene, Cleaning & Disinfection Patient Care Equipment Education on prevention Antibiotic Stewardship
C diff HO Standard Infection Ratio (SIR)	High	LabID/NHSN	SIR ≤0.7 (SIR <1)	1.3 (30% higher rates than the national	Not Met	Adhere to Standard/Transmission based Precautions HH with soap/water Education on prevention/testing per stool guidelines Antibiotic Stewardship

Infection Prevention Program Evaluation

Risk	Priority	Data Source	Goal	2023	Goal met?	Prevention Strategies
				average)		Use bleach for terminal cleaning of Cdiff rooms & for any non-single patient use equipment. Bristal stool chart in Cerner RN documentation Continue to monitor and trend data
Poss/Prob Ventilator Associated Pneumonia (PVAP based on VAE definition)	High	DA2	Number of PVAP cases trend lower	3 cases/ SIR: 0.70	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention VAP bundle Real time review by RT of all ventilator associated event cases Continue to monitor and trend data
VAE Standard Utilization Ratio (SUR)	Mod	NHSN	SUR<1	0.78	Met	IP nurse monitors daily PEEP/FiO2 report and microbial report.RT to continue daily assessement for weaning off vent Daily assessment for Spontaneous Awakening Trials, Daily Utilization review
CLABSI	High	DA2/NHSN	SIR 0.5 (SIR <1)	0.41	Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention CLIP bundle compliance CLABSI bundle Real time review of each case by unit educator Continue to monitor and trend data
CAUTI	High	DA2/NHSN	SIR 0.75 (SIR <1)	0.83	Not Met	Adhere to Standard/Transmission based Precautions and Hand Hygiene Education on prevention Advocate Catheter removal/use external products CAUTI bundle Real time review of each case by unit educator Continue to monitor and trend data
Hand Hygiene compliance	Mod	Verge	>96%	95%	Not met	Adhere to WHO and CDC guidelines for hand hygiene Education (New employee orientation, netlearning) Education to MDs at meetings and Chief of Staff, Continue to monitor and trend data. Audit 40 moments/month by each unit Monthly feedback on HH rates to unit leadership/staff

Infection Prevention Program Evaluation

Risk	Priority	Data Source	Goal	2023	Goal met?	Prevention Strategies
SSI (All 40 types) Total (Superficial, Deep, Organ/Spac e)	High	NHSN	SIR<1	0.96	Met	Share findings with ICC, QAPI, MQPR, GVS and OR Committee ID Pharmacist review for antibiotic compliance IC to perform quarterly rounds (at minimum), or more often as needed with OR management in OR & SPD. Perioperative Surgical Home program implemented for elective colorectal surgeries Perform audits on SSI's with high SIR rates
Environment of Care rounds	Low	Verge	Infection control issues addressed in all EOC rounding (100% of the time)	80%	Not Met	Continue to have Infection Control rounds incorporated with EOC rounding Findings from EOC rounds reported to Manger of each unit to address Findings from EOC rounds are reported to appropriate committees
Infection Prevention Department Resources	High	TCMC P&P	2.0 FTE	2 FTE	Met	CIC Epidemiologist hired FT Sept 2023
Reportable Diseases	Mod	Cerner/DA2	100% compliant with reporting requirements	100%	Met	Cerner Worklist identifies most reportable conditions, Cerner communication is continuously getting more streamline for accurate IP reporting.
Employee TB PPD screening	Mod	Employee Health	>95% compliance	100%	Met	EHS continue to provide PPD upon hire and every other year, and fit testing PAPRs housed and maintained by SPD Continue to monitor compliance rates thru ICC
Annual Employee Respirator Fit testing	High	Employee Health	>95% compliance	100%	Met	EHS continue to provide fit testing for identified staff PAPRs housed and maintained by SPD Continue to monitor compliance rates thru ICC
Bloodborne Pathogen Exposures	High	Employee Health	10% less from previous year	13	Met	Education upon hire and annually. Continue to have PPE available for staff EHS to report to ICC
Employee TB conversions	High	Employee Health	trend lower or same	2	Not Met	Continue TB screening of patients on admission and isolate as appropriate. Work with Employee Health to identify potentially exposed employees. Follow up with exposed employees and report this data through ICC meetings.
Constructio n ICRAs	Mod	IP Dept	All Class 3 or 4 Jobs have ICRA	100%	Met	ICRA compliance is added to EOC rounds to observe compliance.

Infection Prevention Program Evaluation

Risk	Priority	Data Source	Goal	2023	Goal met?	Prevention Strategies
						Infection Prevention maintains documentation of all class 3, 4 ICRAs
AIIR pressure monitoring	Mod	Facilities report	Facilities Enginerring monitors when in use	Compliant	Met	Continue to have Facilities and Engineering monitor and maintain logs per policy
Employee TB conversions	High	Employee Health	trend lower or same	2	Not Met	Continue TB screening of patients on admission and isolate as appropriate. Work with Employee Health to identify potentially exposed employees. Follow up with exposed employees and report this data through ICC meetings.
Constructio n ICRAs	Mod	IP Dept	All Class 3 or 4 Jobs have ICRA	100%	Met	ICRA compliance is added to EOC rounds to observe compliance. Infection Prevention maintains documentation of all class 3, 4 ICRAs
AIIR pressure monitoring	Mod	Facilities report	Facilities Enginerring monitors when in use	Compliant	Met	Continue to have Facilities and Engineering monitor and maintain logs per policy
ICC meetings	Mod	IP Dept	Quarterly meetings at minimum	5	Met	Continue to pre-schedule ICC meetings quarterly at minnimum. Meetings changed to every 2 months.
Emergency Preparedne ss	Mod	IP Dept	Participate in Disaster Management committee and any County drills related to IC	Yes	Met	Continue to be member of Disaster Management committee. Infection Prevention & Control is available for any IC issue. COVID-19 pandemic continued through April 2023. Infection Prevention & Control staff will continue to support and participate in all ways to prevent COVID transmission to staff, patients and other stakeholders of Tri City Medical Center.

Tri-City Medical Center
Oceanside, California

LABORATORY TRANSFUSION MEDICINE
TRANSFUSION MEDICINE QUALITY ASSURANCE

ISSUE DATE: 12/21 **SUBJECT:** Blood and Tissue Service Agreement Policy

REVISION DATE(S):

Department Approval:	**10/24**
Laboratory Medical Director Approval:	**11/24**
Blood Utilization Committee Approval:	**01/25**
Medical Executive Committee Approval:	**n/a**
Administrative Approval:	
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	

A. **DEFINITION(S):**

1. Blood and Tissue Service Agreement – There is a written policy or agreement between the transfusion service and the clinical areas for which it provides transfusion and transplantation support (eg, surgery, emergency room, patient care units) to ensure timely provision of blood, blood components and tissue. (TRM.30866)

B. **POLICY:**

1. Provision of blood components:
   a. The Transfusion Service agrees to supply blood and blood components (blood products) in a timely fashion to the clinical services. The Transfusion Service obtains blood products from the San Diego Blood Bank (SDBB). Transportation of blood products is provided by the supplier on a scheduled basis twice per day. Urgent requests for blood products are obtained from SDBB on a STAT basis and turn-around-time depends on several variables, including the availability of the blood product and special attributes, as well as travel time from the centrally located SDBB facility and to TCMC. STAT delivery times fluctuate according to the time of day (traffic) and whether or not it is a holiday.
   b. The Transfusion Service will maintain approved inventory levels of leukocytes reduced (leukoreduced) packed red blood cells (RBC), leukoreduced-apheresis platelets, frozen plasma and frozen cryoprecipitate. Inventory levels are re-evaluated on a biannual basis. (Refer to the Blood Product Inventory and Ordering procedure.) The Transfusion Service staff will order any specially tested or prepared blood components in compliance with the stated or otherwise determined priority of the order for the products. Provision of special components will depend on their availability from our supplier.
   c. Note:
      i. All cellular blood products provided by TCMC for transfusion will be pre-storage leukoreduced.
   d. Red blood cells, for potential transfusion in emergency areas Emergency Department, Labor and Delivery, Interventional Radiology, and Surgery will be dispensed in validated hand-carried coolers with a minimum of 2-units per cooler (maintained by the Transfusion Service).
2. Turnaround Time Goals for the Transfusion Service:
   a. Adult and Pediatric patients: Emergency Released O negative Units; 2-units available immediately at all times. Minimal labeling involved, immediately prior to release (no testing performed, but will be completed as soon as possible).

b. Neonates: 120 milliliters (mL) of O negative leukocyte reduced, cytomegalovirus (CMV) negative, and Irradiated RBC (less than or equal to 14 days old; hematocrit (HCT) <80%)) available immediately at all times. Minimal labeling involved, immediately prior to release (no testing performed, but will be completed as soon as possible).
c. STAT Type and Screen or Crossmatch testing goal is 60 minutes or less. Routine Type and Screen or Crossmatch goal is four (4) hours or less.
d. Routine non-STAT draws, including "Expedite" ordered in Cerner-PowerChart, between the hours of 0600 and 2200 will be drawn during the next lab phlebotomy round time. To make sure orders make rounds each even hour, they should be ordered by twenty-minutes to the even hour. Routine orders entered after 2200 will be drawn as a routine morning draw at 0600 the following morning.
    i. Refer to the Laboratory Turnaround Times and Delayed Testing Procedure, Laboratory Orders by Priority and Turnaround Time Goals for the Laboratory and Rounding Time Examples.

3. Notification of delay:
    a. Delays may be anticipated in patients with antibody problems and at times when availability of blood products from our supplier is low. In the event of delays the Transfusion Service staff will notify the patient's caregivers (physicians and/or RNs) on the floor or other service areas of the facility of the delay, the reason for the delay, and if possible an estimated time at which appropriate product may be available. The Transfusion Service pathologist will be notified when highly complex reference cases or cases with urgent needs are being delayed so that transfusion alternatives may be identified.
4. Special transfusion needs:
    a. Reconstituted RBC for Neonatal Exchange Transfusion:
        i. Call Transfusion Service to specifically order for each potential recipient. Volume required (mL) and final hematocrit are two ordering requirements. All RBC will contain anti-coagulant- CPDA1, -CPD or -CP2D; be leukocyte reduced, irradiated, hemoglobin S negative, and CMV seronegative.
    b. RBC products for Neonates:
        i. All will contain anti-coagulant- CPDA1, -CPD or -CP2D; be leukocyte reduced, irradiated, and CMV seronegative. Syringe preparation is done by Transfusion Service.
    c. CMV Negative:
        i. Leukoreduced cellular blood products are considered CMV safe. Orders for CMV negative products for pediatric and adult patients will be filled from leukoreduced products. CMV seronegative products will be made available for patients on transplant or other clinical protocols, if ordered as such.
    d. Hemoglobin S negative:
        i. All potential recipients with Sickle Cell disease and Thalassemia will be transfused with HbS negative units, if the diagnosis is listed as primary or secondary on the orders. RBC will be transfused that are Rh system and Kell system compatible, whenever possible.
    e. Irradiated blood products:
        i. Available with transfusion service pathologist approval in consultation with physician for appropriate recipients. May be removed with updated diagnosis or prognosis.
    f. Uncrossmatched blood:
        i. Adults and Pediatrics:
            1) Emergency Released O Negative Units; two units available immediately at all times. Minimal labeling involved, immediately prior to release (no testing performed, but will be completed as soon as possible).
        ii. Neonates:

1) 120 mL (transfer pack, not syringe) of O negative, leukoreduced, irradiated, CMV- RBC (less than or equal to 14 days old; HCT <80%) available immediately at all times. Minimal labeling involved, immediately prior to release (no testing performed, but will be completed as soon as possible).

C. **PROCEDURE**: N/A

D. **FORM(S)**: N/A

E. **RELATED DOCUMENT(S)**:
1. Blood Product Inventory and Ordering
2. Laboratory Turnaround Times and Delayed Testing Procedure
3. Turnaround Time Goals for the Laboratory and Rounding Time Examples
4. Laboratory Orders by Priority

F. **EXTERNAL LINK(S)**: N/A

G. **REFERENCES**:
1. College of American Pathologists. (2023). *Transfusion Medicine Checklist*. Northfield, IL.

Tri-City Medical Center
Oceanside, California

LABORATORY PATHOLOGY
CYTOLOGY QUALITY ASSURANCE

ISSUE DATE: 08/12 **SUBJECT:** **Cytology Specimens Excluded from Routine Submission to the Cytology Section Policy**

REVISION DATE(S): 08/16

Department Approval: 11/24
Laboratory Medical Director Approval:
Medical Executive Committee Approval:
Administrative Approval:
Professional Affairs Committee Approval:
Board of Directors Approval:

A. **POLICY:**
1. Cytopathology Exclusion: The institution defines specimens that may be excluded from routine submission to the cytology department for examination. (CYP.01650)
2. The excluded specimens are designated in conjunction with hospital administration and appropriate medical staff departments.
3. The Laboratory Director establishes this policy and consults the medical staff in deciding this exclusion.

B. **PROCEDURE:**
~~1. Exclude the following specimens from submission to the Cytology Section:~~
~~2.~~**1.** **Do not submit** ~~No~~ gynecological (GYN) Cytology (Pap Smears) ~~are submitted~~ to the cytology section for processing or interpretation
~~3.~~**2.** **Do not submit c**~~C~~erebrospinal fluid (CSF) specimens from patients with suspected and/or confirmed transmissible spongiform encephalopathies (TSE) including Creutzfeldt-jakob disease ~~are excluded from~~**for** routine cytology processing.

C. **REFERENCES:**
1. College of American Pathologists. (2023). *Cytopathology Checklist*. Northfield, IL.

Tri-City Medical Center
Oceanside, California

LABORATORY PATHOLOGY
CYTOLOGY QUALITY ASSURANCE

ISSUE DATE: 06/97 **SUBJECT:** Cytotechnologist Workload Policy

REVISION DATE(S): 05/16, 05/19

Department Approval:	10 /24
Laboratory Medical Director Approval:	05/19
Medical Executive Committee Approval:	n/a
Administrative Approval:	
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **DEFINITION(S)**: N/A

B. **POLICY**:

1. This workload policy pertains to qualified Cytotechnologists and/or primary screening Pathologist using a non-automated screening technique to examine Non-GYN specimens prepared by conventional methods. This policy follows the Clinical Laboratory Improvement Acts of 1988 (CLIA 88) and California law.
   a. In accordance with California State law, there is a maximum manual screening limit of 80 slides per 24 hour period for each individual cytotechnologist. The maximum workload can be completed in no less than an 8-hour workday. This number pertains to the non-automated microscopic screening techniques of conventional smears and cyto-spins.
      i. For primary screening of Non-GYN slides, each cytospin is counted as one-half slide.
   b. Slides from non-gynecologic cases count as whole slides except for concentration and liquid- based techniques that confine the material to less than one-half of the slide surface, which may be counted as one-half.
   c. Rescreening of cases are included in the workload accounting.
2. Manual Screening - Laboratories Subject to US Regulations: Workload data are recorded for cytotechnologists and pathologists who manually screen previously unscreened gynecologic and non-gynecologic (including FNA) slides. (CYP.08500)
   a. Individual Cytotechnologists record their workload daily on the Cytotechnologist Daily Workload Log.
   b. Individual Pathologists who perform primary cytologic screening record their workload daily on the Pathologist's Daily Workload Log. The workload is also summarized on a Pathologist Monthly Workload Log.
   c. Each Cytotechnologist's workload is reviewed semi-annually by the medical director or designee. This review is documented on the Workload Summary Review Log.
3. Individual Maximum Workload - Laboratories Subject to US Regulations: Individual maximum workloads are established for cytology slide screening, including processes for reassessment at least every six months and adjustment when necessary. (CYP.08575)
   a. The maximum screening number may be adjusted downward based on ability, 3 or more major discrepancies per 6-month review, and non-CAP related duties such as preparation and staining of slides.

C. **PROCEDURE**:

1. Screen 10 slides (maximum) for each hour of screening time.

a. This maximum is calculated to support the workload policy and provide optimal time for screening quality.

2. Review Screening Limitations:
   a. A hospital setting necessitates the execution of varying assignments, all of which can distract from the cytologist's primary task of screening. These duties include but are not restricted to the following:
      i. Assisting with fine needles aspirates (FNAs) at outpatient offices and during computed tomography (CT) scans
      ii. Specimen preparation
      iii. Computer data entry
      iv. Coordination and assembly of cytology cases with histologic specimens/special stains
      v. Problem solving
      vi. In-house continuing education
3. Report Results:
   a. Individual cytotechnologist's daily workload is recorded and kept in the Cytology Workload Recording logbook and in individual Daily Screening logbooks.
   b. Pathologists' workload is recorded and kept in the Pathologist Screening logbook.
   c. Major discrepancies are documented on the Cytology Section Non-GYN Major Discrepancy Log and reviewed on a monthly basis.

D. **FORM(S)**:
1. Cytotechnologist Daily Workload Log
2. Pathologist's Daily Workload Log[PRH1]
3. Pathologist Monthly Workload Log
4. Cytotechnologist Workload Summary Review Log
5. Cytology Section Non-GYN Major Discrepancy Log

E. **RELATED DOCUMENT(S)**: N/A

F. **EXTERNAL LINK(S)**: N/A

G. **REFERENCES**:
1. Clinical Laboratory Improvement Amendments of 1988; Federal Register, Section 493.1257.
2. College of American Pathologists. (2023). *Cytopathology Checklist*. Northfield, IL.

Tri-City Medical Center
Oceanside, California

LABORATORY
GENERAL/QUALITY MANAGEMENT

ISSUE DATE: 11/99

SUBJECT: Laboratory Quality Management Plan Overview

REVISION DATE(S): 05/07, 11/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 07/16, 06/18, 06/19, 03/21, 05/24

Department Approval:	~~08/24~~11/24
Laboratory Medical Director Approval:	~~08/24~~11/24
Medical Executive Committee Approval:	~~n/a~~01/25
Administrative Approval:	03/22
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	

A. **DEFINITION(S):**

1. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. The CLIA Program sets standards and issues certificates for clinical laboratory testing.
2. CLIA 88: 1988 amendments to the Public Health Service Act that established quality standards for all laboratory testing the ensure the accuracy, reliability, and timeliness of patient test results. CLIA '88 regulations apply to all clinical laboratories in the United States, including those in hospitals, clinics, and physician offices. They are enforced by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC).
3. Clinical and Laboratory Standards Institute (CLSI) is a volunteer-driven, membership-supported, not-for-profit, standards development organization. CLSI documents are developed by committees consisting of experts in medical testing or related aspects. Each CLSI committee produces consensus documents related to a specific discipline.
4. Quality Assurance (QA): Focuses on the entire laboratory testing process rather than just the equipment. QA encompasses a set of systematic activities and processes aimed at providing confidence that the laboratory consistently produces accurate and reliable results. QA components can include establishing standard operating procedures (SOPs), conducting proficiency testing, training and certifying laboratory personnel and ensuring compliance with regulatory requirements.
5. Quality Control (QC): The set of procedures and policies designed to monitor and maintain the precision and accuracy of laboratory equipment and testing processes. It involves daily checks, calibration, and verification to confirm that instruments are operating correctly and producing reliable results. QC components can include calibrating instruments, conducting internal quality control checks, monitoring environmental conditions and identifying and promptly addressing errors.
6. Quality Management: Oversees the entire laboratory operation, monitoring QC and QA programs as well as administrative considerations that influence the quality and efficiency of the laboratory operation.
7. Quality Management System (QMS): A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.
8. Quality System Essentials (QSE): QSEs represent the fundamental components necessary to ensure the accuracy, reliability, and integrity of laboratory testing processes within the QMS. These essentials encompass aspects such as leadership commitment to quality, adherence to

regulatory standards, continuous improvement initiatives, and employee training and competency assessments.

9. Test Complexity: A test scoring system used by the FDA to categorize laboratory tests. Test complexity is scored as waived, moderate, or high. Test complexity determines the level of quality oversight for the performing laboratory.
   a. Nonwaived: Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity.
   b. Waived: A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result."
   c. Test complexity can be determined by accessing the CLIA database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
10. Test System: The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

B. **POLICY:**

1. The Laboratory Quality Management Plan is designed to objectively and systematically monitor the quality and appropriateness of laboratory services in supporting the hospital-wide strategic plan and to evaluate and pursue opportunities to resolve problems and improve patient care.
   a. All laboratory sections actively participate in the Quality Management Plan. The laboratory sections are:
      i. Hematology, Coagulation, and Urinalysis:
         1) Analyzes blood samples to evaluate the cellular components, including red blood cells, white blood cells, and platelets, to diagnose and monitor condition such as anemia, infections and blood disorders.
         2) Evaluates the clotting ability of blood and identifies disorders such as thrombosis or bleeding disorders, helping manage conditions like deep vein thrombosis and hemophilia.
         3) Examines urine samples to assess kidney function, screen for urinary tract infections, and detect metabolic disorders like diabetes, providing insights into overall health and disease.
      ii. Chemistry: Analyzes bodily fluids like blood and urine to measure levels of various substances, helping diagnose and monitor conditions such as diabetes, kidney disease, and liver disorders.
      iii. Blood Bank/Transfusion Services: Collects, processes, and stores blood products; ensures compatibility for and transfusion and provides blood components for patients in emergency and routine situations.
      iv. Microbiology: Identifies and characterizes microorganisms present in clinical specimens such as blood, urine, and swabs, aiding in the diagnosis and treatment of infectious diseases.
      v. Phlebotomy: Collects blood samples from patients using various techniques, ensuring specimen integrity and patient safety for diagnostic testing.
      vi. Histology (Anatomic Pathology): Examines tissue samples (biopsies, surgical specimens) under a macroscope to diagnose diseases such as cancer, infections, and inflammatory conditions.
      vii. Cytology: Analyzes cellular samples obtained from body fluids or tissues to detect abnormal or cancerous cells, aiding in the diagnosis of conditions like respiratory diseases.
      viii. Point of Care Testing (POCT): Performs rapid diagnostic tests at or near the patient's location, providing immediate results for conditions like glucose levels, cardiac markers, and infectious diseases, enabling timely clinical decisions and interventions.

ix. For a more detailed description of services provided, as well as hours of operation, refer to the Laboratory Scope of Service document.

b. All lab personnel are responsible for the quality system. Section-specific policies and procedures further define personnel responsibilities.

c. Laboratory policies are maintained in a document control system and approved by Laboratory Leadership and the Medical Director. The laboratory sections have documented procedures that further describe how the specific policy objectives and goals are implemented within the section.

d. Technical work instructions are maintained in each section's manuals. The technical procedures specify the equipment and the required resources needed to produce quality patient test results. Section policies and procedures are maintained in the document control system and approved by each section leadership, section director, and the medical director.

2. The laboratory has a mission and vision that aligns with the overall organization.
   a. Mission: The Laboratory Services Department, in partnership with allied health professionals and clinicians at Tri-City Medical Center, will provide accurate, reliable laboratory results in a timely and cost-effective manner contributing to the quality care of our patients.
   b. Vision: The Laboratory's Vision is to be the guide to the future of innovative laboratory technology and to be the reference laboratory of choice for the community.
3. The laboratory quality management plan utilizes the 12 CLSI-recommended QSEs:
   a. Organization: Describes the structure of the laboratory, including assignment of roles and responsibilities as well as communication within in the lab.
   b. Personnel: Describes the human resources of the laboratory, including qualification requirements for hiring new lab employees, competency assessment, and knowledge retention.
   c. Equipment: Describes selection, purchase and installation of equipment, including validation/verification, maintenance, calibration, decontamination and decommissioning protocols.
   d. Facilities and Safety: Describes the lab's physical space and the programs in place to maintain it.
   e. Purchasing and Inventory: Describes lab's purchasing and procurement processes, such as selection of vendors, contracts, receiving of supplies, and inventory management.
   f. Information Management: Describes the lab's information management controls around confidentiality, privacy, security, and accessibility of information stored on both paper and electronic record keeping systems, including storage and retrieval of information.
   g. Documents and Records: Describes policies, process and procedures for document control and records management
   h. Non-Conformance Management: Describes policy around detecting, investigating, reporting, tracking, monitoring and prevention of events that do not conform to existing laboratory policies, procedures and processes. This includes root causes analyses and corrective actions.
   i. Assessments: Describes assessment protocols, for both internal and external monitoring, to verify that they meet regulatory requirements and determine how well those processes are functioning as part of the overall QMS. Includes audits, proficiency tests and quality assurance reviews.
   j. Process Improvements: Describes processes for identifying areas for improvement, assessment, and monitoring to optimize the effectiveness of the QMS and to increase and sustain quality.
   k. Customer Service: Describes processes and procedures that identify customers and their expectations, collect customer feedback and take appropriate follow-up actions.
   l. Process Management: Describes how lab develops, disseminates, controls and changes pre-analytic, analytic, and post-analytic workflow processes and the management processes that support them.

C. **PROCEDURE:**

1. Review the performance of laboratory quality indicators and the effectiveness of any actions taken.
   a. Retain or retire laboratory quality indicators based on their performance, effectiveness of any corrective and preventive measures taken, and how critical they are to patient care.
   b. Select new indicators based on current or potential quality concerns.
2. Review issues and non-conformances throughout the year and include corrective and preventative actions when needed.
3. Review quality and safety reports and document actions taken.
4. Complete the annual review of the quality management plan.

D. **FORM(S):**

1. Annual Review of the Laboratory Quality Management Plan

E. **RELATED DOCUMENT(S):**

1. Laboratory Scope of Service
2. Laboratory Organization Quality System Essentials
3. Laboratory Personnel Quality System Essentials
4. Laboratory Equipment Quality System Essentials
5. Laboratory Facilities and Safety System Essentials
6. Laboratory Purchasing and Inventory Quality System Essentials
7. Laboratory Information Management Quality System Essentials
8. Laboratory Documents and Records Quality System Essentials
9. Laboratory Non-Conformance Management Quality System Essentials
10. Laboratory Assessments Quality System Essentials
11. Laboratory Process Improvement Quality System Essentials
12. Laboratory Customer Service Quality System Essentials
13. Laboratory Process Management Quality System Essentials

F. **EXTERNAL LINK(S):** N/A

G. **REFERENCES:**

1. College of American Pathologists. (2023). Laboratory general checklist. CAP Accreditation Program.
2. Clinical and Laboratory Standards Institute (CLSI). A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management in Clinical Laboratories. Chicago, IL: CAP Press, 2005.
4. Jhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017
5. California Association of Hospital and Health Systems. Guide to Record Retention. 2005.
6. American Association of Blood Banks. Technical Manual, (current edition; updated annually).
7. Department of Health and Human Services, Centers for Medicare and Medicaid Services.
8. Clinical Laboratory Improvement Amendments Of 1988; final rule. Fed Register. 1992(Feb 28):7164 [42CFR493.1213] (10/1/2011)
9. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124208.htm
10. California's Business and Professions Code (BPC) section 1200 et. Seq., www.leginfo.ca.gov/calaw.
11. Title 17 California Code of Regulations (CCR), section 1029 et. Seq. www.calregs.com

Tri-City Medical Center
Oceanside, California

LABORATORY
GENERAL/QUALITY MANAGEMENT

ISSUE DATE: 11/99

SUBJECT: Laboratory Personnel Quality System Essentials

REVISION DATE(S): 05/07, 11/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 07/16, 06/18, 06/19, 03/21, 05/24, 08/24

Department Approval:	08/24
Laboratory Medical Director Approval:	08/24
Medical Executive Committee Approval:	n/a
Administrative Approval:	03/22
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **DEFINITION(S):**

1. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. The CLIA Program sets standards and issues certificates for clinical laboratory testing.
2. CLIA 88: 1988 amendments to the Public Health Service Act that established quality standards for all laboratory testing the ensure the accuracy, reliability, and timeliness of patient test results. CLIA '88 regulations apply to all clinical laboratories in the United States, including those in hospitals, clinics, and physician offices. They are enforced by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC).
3. College of American Pathologists (CAP): TCMC Lab accrediting body. The CAP serves patients, pathologists, and the public by fostering and advocating best practices in pathology and laboratory medicine.
4. Laboratory Information System (LIS): A specialized software platform that manages, tracks, and streamlines laboratory operations, including sample processing, test ordering, result reporting, data storage and workflow automation, ensuring accurate and efficient laboratory management and integration with other hospital information systems.
5. Test Complexity: A test scoring system used by the FDA to categorize laboratory tests. Test complexity is scored as waived, moderate, or high. Test complexity determines the level of quality oversight for the performing laboratory.
   a. Nonwaived: Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity.
   b. Waived: A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result."
   c. Test complexity can be determined by accessing the CLIA database.
6. Test System: The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

B. **POLICY:**

1. Hiring Qualified Individuals:
   a. When hiring new employees, the laboratory follows the requirements in the Human Resources policy, Authorization to Hire New Employees and Engage Consultants. The lab

also follows the CAP personnel requirements defined in the CAP accreditation checklists and in the CAP Personnel Requirements by Testing Complexity. All laboratory personnel associated with laboratory activities must meet or exceed CLIA and/or CDPH personnel requirements.

i. In addition, due to the strict guidelines that govern qualifications to perform testing, the laboratory also maintains the Laboratory Personnel Selection document, which provides the CLIA Regulatory Equivalent of job titles in the lab.

ii. Pathologists are additionally assessed by the Lab Director prior to hire following the criteria outlined in the Pathology Staff Professional Competency Policy.

1) Similar hiring considerations apply to the Pathologists' Assistant (PA) within the PA's scope.

b. All testing personnel in the laboratory (Clinical Laboratory Scientists and Cytotechnologists) are evaluated for current licensure required by the State of California Business and Professions Code. All phlebotomists in the laboratory are evaluated for current certification by the State of California. Licensure monitoring is performed on an annual basis.

i. Refer to the Monitoring Licenses, Professional Registrations, and Certificates policy.

c. Laboratory personnel job descriptions define qualifications and duties for all positions. These descriptions are maintained by the department and are used to generate position postings, and to develop appropriate training materials and competency assessments.

2. Personnel files are maintained on each lab employee. They contain records of educational qualifications (e.g. copies of diplomas, transcripts, primary source verification reports), laboratory personnel licenses (where required), training and continuing education. This file is retained for the duration of employment and includes:

a. Competency
b. Attendance
c. Disciplinary Actions
d. Performance Evaluations and Confidentiality Agreement Forms
e. Employment Information
f. Additional Information, which may include:

i. Summary of training and experience
ii. Job description
iii. Self-competency assessments
iv. Records of continuing education
v. Laboratory New Hire Checklist
vi. Initial Training Checklist and Competency Assessment
vii. Section competency checklists
viii. Work related incidents and/or accident records

g. Note: Health records along with visual color discrimination tests are maintained in the Employee Health Office.

3. Training:

a. Refer to the Laboratory Training and Competency Procedure for more detailed information.

i. The annual employee competency file is distinct from the lab employee personnel file (see above). The employee competency file is used to capture a year of training and competency. This includes annual CAP requirements, competency summaries, Net Learning modules, the lab safety walk, etc.

b. During the first week of new hire training, the section-specific Initial Training and Competency Checklist(s) are started as well as the LIS checklist. These checklists cover the responsibilities for each position. Items on the checklist are not marked as complete unless competency has been demonstrated.

i. If a lab employee moves to another position or receives a promotion, a new Initial Training and Competency Checklist, reflecting the new position, is completed.

ii. For a complete list of the initial training and competency checklist requirements for each position, refer to the Laboratory Job Titles with Competency Assessment Forms Needed table.

4. Competency Assessment:
   a. Refer to the Laboratory Training and Competency Procedure for more detailed information.
5. Laboratory Positions and Responsibilities:
   a. Refer to job descriptions located in Symplr Performance Management System.

C. **PROCEDURE:**
1. Perform initial training and competency assessment using the appropriate checklists.
2. Perform the 6-month competency assessment approximately 6 months after the initial.
3. Perform the 1-year competency assessment approximately 6 months after the 6-month assessment.
4. Perform the annual competency assessment(s) around the end of each calendar year.
5. Retain original documents for the initial, 6-month, and 1-year competency assessments in the permanent personnel file and place a copy in the competency assessment folder.
6. For every year thereafter, file originals in the competency assessment folder.

D. **FORM(S):**
1. Laboratory New Hire Checklist

E. **RELATED DOCUMENT(S):**
1. Authorization to Hire New Employees and Engage Consultants
2. Monitoring Licenses, Professional Registrations, and Certificates
3. Pathology Staff Professional Competency Policy
4. Laboratory Training and Competency Assessment
5. Laboratory Job Titles with Competency Assessment Forms Needed
6. Laboratory Job Titles with Competency Assessment Frequency
7. Competency Reassessment

F. **EXTERNAL LINKS:**
1. FDA Test System Complexity: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm

G. **REFERENCES:**
1. College of American Pathologists. (2023). *Laboratory General Checklist*. CAP Accreditation Program, 09.22.2021, 62–74.
2. Clinical and Laboratory Standards Institute (CLSI). A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management In Clinical Laboratories. Chicago, IL: CAP Press, 2005.
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5. California Association of Hospital and Health Systems. Guide to Record Retention. 2005.
6. American Association of Blood Banks. Technical Manual, (current edition; updated annually).
7. College of American Pathologists. Inspection and Accreditation Checklist, Section 1 General Laboratory.
8. NCCLS. How to define and determine reference intervals in the clinical laboratory; approved guideline C28 A2. Wayne, PA: NCCLS, 2000
9. California Business and Professions Code Section 1260-1275.
10. California Code of Regulation 1050.
11. College of America Pathologists. Reference Range Service (RRS2-A) Kit Instructions. 2010
12. Van der Meulen EA, et al. Use of small-sample-based reference limits on a group basis. Clin Chem. 1994;40:1698-1702
13. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

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15. California's Business and Professions Code (BPC) section 1200 et. Seq., www.leginfo.ca.gov/calaw.
16. Title 17 California Code of Regulations (CCR), section 1029 et. Seq. www.calregs.com

Tri-City Medical Center
Oceanside, California

LABORATORY
GENERAL/QUALITY MANAGEMENT

ISSUE DATE: 11/99 **SUBJECT:** Laboratory ~~Quality~~ Equipment Quality Service

EssentialsManagement Plan Introduction a

REVISION DATE(S): 05/07, 11/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 07/16, 06/18, 06/19, 03/21, 05/24, 9/24

Department Approval:	11/24
Laboratory Medical Director Approval:	11/24
Medical Executive Committee Approval:	n/a
Administrative Approval:	03/22
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **DEFINITION(S):**

1. **Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. The CLIA Program sets standards and issues certificates for clinical laboratory testing.**
2. **CLIA 88: ~~(definition)~~1988 amendments to the Public Health Service Act that established quality standards for all laboratory testing the ensure the accuracy, reliability, and timeliness of patient test results. CLIA '88 regulations apply to all clinical laboratories in the United States, including those in hospitals, clinics, and physician offices. They are enforced by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC).**
3. **Clinical and Laboratory Standards Institute (CLSI) is a volunteer-driven, membership-supported, not-for-profit, standards development organization. CLSI documents are developed by committees consisting of experts in medical testing or related aspects. Each CLSI committee produces consensus documents related to a specific discipline.**
4. **Quality Assurance (QA): Focuses on the entire laboratory testing process rather than just the equipment. QA encompasses a set of systematic activities and processes aimed at providing confidence that the laboratory consistently produces accurate and reliable results. QA components can include establishing standard operating procedures (SOPs), conducting proficiency testing, training and certifying laboratory personnel and ensuring compliance with regulatory requirements.**
5. **Quality Control (QC): The set of procedures and policies designed to monitor and maintain the precision and accuracy of laboratory equipment and testing processes. It involves daily checks, calibration, and verification to confirm that instruments are operating correctly and producing reliable results. QC components can include calibrating instruments, conducting internal quality control checks, monitoring environmental conditions and identifying and promptly addressing errors.**
6. **Quality Management: Oversees the entire laboratory operation, monitoring QC and QA programs as well as administrative considerations that influence the quality and efficiency of the laboratory operation.**
7. **Quality Management System (QMS): A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.**

~~7.~~ **Quality System Essentials (QSE): QSEs represent the fundamental components necessary to ensure the accuracy, reliability, and integrity of laboratory testing processes within the QMS. These essentials encompass aspects such as leadership commitment to quality, adherence to regulatory standards, continuous improvement initiatives, and employee training and competency assessments.** ~~Scope of Service: The scope of service is the description of the tests/services that the laboratory provides to its customers/clients (e.g. tests offered, hours of operation, turnaround times).~~

~~a. Refer to Laboratory Scope of Service.~~

8.

9. Test Complexity: A test scoring system used by the FDA to categorize laboratory tests. Test complexity is scored as waived, moderate, or high. Test complexity determines the level of quality oversight for the performing laboratory.
   a. Nonwaived: —Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity.
   b. Waived: —A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result."
   c. **Test complexity can be determined by accessing the CLIA database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm**

10. Test System: The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

B. **POLICY:**

~~1. Introduction:~~

~~a. **Provide a brief overview/history of the laboratory. Include physical location, certifications, licenses, relation to parent organization, hours of service, short summary of each laboratory unit/discipline.**~~

~~i. **Items to consider including:**~~

~~1) **Goals and objectives of laboratory**~~
~~2) **Mission/vision statement**~~
~~3) **Scope of the quality manual–areas to which this QM applies; include a statement that quality is everyone's responsibility**~~
~~4) **Description of how the manual will be maintained, reviewed and updated**~~
~~5) **Quality policy**~~
~~6) **State the purpose for the quality manual, i.e., it is a set of documents that describe the structure and contents of the laboratory's QMS.**~~

~~2.~~**1.** Laboratory Equipment:
   a. The laboratory ~~will be furnished with~~utilizes ~~items of~~**equipment for** sampling, measurement, and testing ~~equipment required for the correct performance~~**to correctly perform** ~~of~~ each **offered test**.

~~3.~~**2. Equipment Selection:**
   a. The selection of laboratory instruments, equipment and supplies are under the control of the Laboratory Director.
      i. Where the director has delegated the selection process to specific Laboratory management team members, the technical, clinical and operational criteria of the Director must be met.
      ii. The positions designated for instrument, equipment and supply selection are listed on the ~~Delegation of Responsibility section above~~**Director Delegation Table**.

~~4.~~**3.** Validation and Verification:
   a. **Laboratory equipment** is **validated for delivery of reliable results and verified as meeting the manufacturer's specifications for performance prior to use in patient testing.**

~~b. Equipment that affect the quality of the test system will not be used until they have been verified to comply with standard specifications defined for each test, as appropriate.~~

~~c.~~**b.** Equipment is verified:

i. Prior to use in patient testing

~~i.~~**ii. After major maintenance or service**

~~ii.~~**iii. After relocation**

~~d.~~**c. Equipment may only be operated by personnel with documented training and competency in its use.**

~~e.~~**d. Refer to the Instrument and Method Validation and Verification procedure for more information.**

~~5.~~**4. Equipment** Use, **Maintenance, Calibration, Decontamination and** Decommissioning:

a. Laboratory equipment preventative maintenance and function checks must be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer.

b. **Every section of the lab maintains procedures to address the maintenance and calibration of their equipment, as well as decontamination and/or decommission as appropriate. These procedures include**

5. Quality **Assurance and Quality** Control:

a. Refer to ~~respective~~ quality ~~control~~ procedures ~~in~~ **for** each laboratory section **in the Related Documents list below**~~s~~.

~~a. Checks must be within the manufacturer's established limits before patient testing is conducted.~~

~~6. Organization: **This QSE describes the organizational structure of your laboratory, including how the lab is structured, assignment of roles and responsibilities, hiring and management of personnel and communication within the laboratory. Include a statement that the quality manager has delegated authority and direct responsibility to oversee compliance with the laboratory's QMS.**~~

~~i. eight~~

~~a) may specific under CLIA 88 Refer to the Lab Director Delegation document.~~

~~ii. Operations Managers~~

~~1) Reviews all RL Solutions Quality Tracking. Reviews and disseminates reports to appropriate lab staff for their investigation.~~

~~2) Coordinates QA activities of Lab with respect to Patient Care Services.~~

~~3) Participates in the Laboratory Operations Team Meeting and presides in the absence of the Laboratory Administrative Director.~~

~~4) Coordinates meetings with Nursing Unit Manager or directors and other ancillary departments. Coordinates lab CQI and assists in facilitating between lab sections. Represents the laboratory at one or more governance council.~~

~~iii. Operations Managers and Technical Specialists:~~

~~1) Responsible for daily and monthly QA activities.~~

~~2) Reports to Laboratory Operations Team Meetings problems and corrective action plans.~~

~~3) Responsible for maintaining documentation of QA monitors.~~

~~4) Responsible for performing competency assessment and for monitoring the effectiveness of the assessment.~~

~~5) Responsible for forming section Quality Teams when indicated.~~

~~6) Facilitates CQI activities in their section.~~

~~7) Responsible for documenting CQI activities and reporting at Lab Operations Team meetings.~~

~~a) Tis considered open, in that all lab personnel are welcome to attend and contribute.~~

7. Personnel: **The QSE describes the human resources of your laboratory: hiring qualified individuals, training processes, assessing competency to perform and manage laboratory activities, and retaining knowledge in positions when employees leave ("tribal knowledge").**
   a. Laboratory Continuous Quality Improvement (CQI):
      i. Laboratory CQI is conducted throughout each section of the laboratory. CQI is under the direction of the Laboratory Director and the coordination is delegated to the Operations Managers. Each section may organize a Quality Management Team to identify process improvement opportunities and form workgroups who may meet with other section QM teams or with representatives from other units or hospital departments. Using the Laboratory CQI form the teams work through the process improvement using the hospitals established FOCUS/PDCA model. The teams report back to their section's Technical Specialist or Operations Manager and report at the Laboratory Operations Team Meeting.
         1) Refer to the Laboratory Continuous Quality Improvement Form to review the lab-specific FOCUS/PDCA.
      ii. All employees of the Clinical Laboratory have an opportunity to participate in quality improvement in their laboratory section using the Laboratory CQI by completing the Laboratory Quality Improvement form. This document uses the FOCUS / PDCA model for process improvement.
         1) The quality improvement initiative may derive from another employee, patient care unit, outside doctor's office or any other individual or group for which the laboratory services.
      iii. To initiate the proposal the individual obtains a form from their supervisor, completes it and returns it to any supervisor. The proposal is submitted as follows:
         1) Laboratory proposals are submitted to the Laboratory Operations Manager and a workgroup may be assigned depending on the extent of the process. A facilitator is chosen. The work group meets and reports back to the Operations Manager. Alternately, an individual can proceed less formally by working through the CQI form and completing the prompts. Responsibilities of the workgroup or individual are:
            a) Gather all data necessary to develop possible solutions.
            b) Decide which solution is most effective.
            c) Develop and implement the plan.
            d) Decide who will be responsible for monitoring.
            e) Provide status reports on the progress of the workgroup to the Laboratory QA Coordinator or Laboratory Operations Manager.
         2) Once completed, the project will be filed in the Lab CQI Manual.
   b. Compliance with applicable State and Local Laws and Regulations:
      i. Laboratory policies and procedures have been developed to meet the requirements of applicable state and local laws and regulations. These include:
         1) Reportable diseases:
            a) Reference Lab Manual
            b) Mandatory Reporting of Positive HIV and Viral Hepatitis
         2) Transport of specimens:
            a) Courier Manual
            b) ARUP Training Records
            c) Lab QM Plan Remote Site Specimen Tracking And Specimen Quality page 36
         3) Personnel qualifications:
            a) Lab Administrative Manual
            b) Personnel Selection
         4) Retention of records:
            Lab QM Plan
            a) Laboratory Record and Specimen Retention

5) Waste disposal:
Lab Safety Manual
a) Laboratory Waste Management Plan
6) Release of specimens to Medical Examiner or Coroner:
Lab Administrative Manual
a) Release of Lab Specimens Form
b) Forensic Specimens or Foreign Objects Removed from Patients Injured by Deadly Weapon or Criminal Act
c) Evidence Chain of Custody Form
7) Acceptance of orders only from authorized healthcare personnel:
Lab Administrative Manual
a) Authorization for Laboratory Testing
8) Confidentiality of test results:
a) TCMC AP&P # 513 Disclosure of PHI
#515 Use and Disclosure of PHI
b) #522 FAXing of PHILab Administrative Manual
Release of Information by the Laboratory
c) TCMC Confidentiality Acknowledgement & Agreement Form
9) Limited duties of Lab Assistants:
a) Lab QM Plan: Laboratory Assistants, page 32
10) Licensure and certification monitoring:
Lab Administrative Manual
a) Licensure/Certification Monitoring

c. Compliance with CAP Terms of Accreditation:
i. The CAP terms of accreditation are listed in the laboratory's official notification of accreditation which is on file in the Operations Manager's Office. The policy of the Laboratory is immediate notification of CAP regarding the following:
1) Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance.
a)
Notification must occur no later than 2 working days after the laboratory learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency, i.e. CMS, State Department of Health, The Joint Commission, FDA or OSHA).
2) Change in laboratory test menu (notification must occur prior to starting new patient testing).
3) Change in location, ownership or directorship of the laboratory. Notification must occur prior to the change(s) or, in the case of unexpected changes, no later than 2 working days afterwards.

d. Quality Management Responsibilities:
e. Quality Management Activities:
i. Competency Assessment:
1) Refer to the Initial Training and Competency Assessment procedure.
ii. Quality Control List Report/QC Inquiry:
1) The QC Results List Report includes control results from the previous day, method and test combination, which have failed one or more of the Westgard rules defined for the test/method.
2) The report is printed manually from Cerner and is reviewed daily by the Technical Specialist or Lead Technologist. This review consists of entering QA Inquiry for the method, test and control combination listed on the QC report and reviewing corrective action that was taken for the out of control result.

3) All subsequent control runs will be reviewed to ensure the appropriate corrective action was taken for the control to be within acceptable limits.

iii. Quality Review Report (QRR) from RL Solutions:
1) TCMC uses the RL Solutions QRR system for tracking quality problems and near misses throughout the facility.
2) The Laboratory Operation Managers receive risk alert notifications via email when there is a problem or incident involving the Laboratory that needs investigation.
3) The outcome of the investigation determines what action is taken in the lab to correct the problem and is documented in RL Solutions.
4) The QRR reviews are summarized on the QRR Summary spreadsheet for tracking and trending.
5) The incidents are reviewed at the Lab Leadership Meeting and other staff meetings as needed for educational opportunities.
6) No copies of the original RL submission are maintained in the lab.

iv. Supervisor's Investigation Report (SIR)
1) The SIR is documentation generated by a Technical Specialist or Lead in response to a Laboratory-identified problem.
2) The problem is reviewed with all concerned staff and corrective action is documented.
3) SIR's are reviewed at the Lab Operations meeting.

v. Performance Improvement Workgroups:
1) A group of lab staff members who have been trained in PI/CQI serve as teams for the purpose of addressing opportunities for improvement.
2) The membership of the team is voluntary from lab staff that uses it to achieve their performance appraisal goals.
3) The Lab Dashboard serves as the main source of improvement opportunities.
4) The model for PI used in the laboratory is FOCUS/PDCA.

vi. Turnaround Time Reports (TAT)
1) The TAT is used to assess actual turn-around times against stated goals and benchmark standards.
2) Selected critical tests for critical care area are reviewed each month and added to the Laboratory Dashboard.
3) Target TATs are identified and results are monitored for outliers.
4) Outliers may become an opportunity for improvement for the FINE FOCUS teams (see above).
5) Further analysis may be performed on selected critical tests to critical care areas using graphic representation of the three components of TAT
   a) Test order to specimen collection
   b) Collection to receipt
   c) Receipt to result reporting and total TAT (order to result).
6) The reports are reviewed at the staff meeting and reviewed at the Lab Operations Meeting.
7) Selected TAT may be reviewed at other hospital wide quality meetings.
   a) Refer to the Laboratory Turnaround Times and Delayed Testing procedure.

vii. Daily QA Review (Daily Reports)
1) The Daily Reports are generated each day through Cerner and are reviewed by the Technical Specialists or Lead Clinical Laboratory Scientist.
2) The report lists all patient results that have failed predefined limits for acceptability.
3) These limits are:
   a) Correction Report
   b) Critical Results

c) Failed Delta Checks (the difference between the current and previous results)
d) Converted Result Types
e) Review Limits
f) Linear Limits
g) Feasible Limits
h) Blank Reference Ranges
i) Diluted Results

viii. Hand-off Communication
1) Refer to the Laboratory Hand-off Communication procedure.

ix. Additional Laboratory department-specific reports:
1) Strain Typing
2) Transfer Lists
3) Pending Inquiry Logs
4) Microbiology Final Activity Report
5) Antimicrobial Susceptibility Data (Antibiogram)
6) Infection Control Candidate Reports
7) Surveillance and Outbreak Assessments
8) Blood Usage Reports
9) Cord Blood Report
10) Blood Bank Stock Status Summary
11) Blood Bank Correction Reports
12) Blood Bank Exception Reports
13) Blood Bank Inventory Search print
14) Blood Bank Expired Unit Report
15) Antigen Typing Reaction Results forms
16) Antibody investigation documentation
17) Component Preparation logs
18) Blood Bank Patient Results Activity and Patient Typing and Comments Reports
19) Blood Bank Routine QC and equipment preventive maintenance records

x. Laboratory Key Indicators

xi. Proficiency Testing Program
1) See the Proficiency Testing procedure.

xii. Laboratory Quality Meeting "Lab Huddles":
1) The Laboratory assembles the lab management team i.e. Laboratory Director, Administrative Director, Operations Managers, Technical Specialists
2) Review of the various sources of quality assurance monitoring and to identify problems or opportunities to improve the quality and appropriateness of patient care and when necessary implement changes to improve the quality of care.
3) The meeting also serves as an opportunity to disseminate information and gives the staff a chance to address questions to the lab leadership team. The meeting is presided over by the Laboratory Administrative Director or an Operations Manager or designee.
4) The typical agenda of the meeting may include the following topics, discussions, actions to be taken and the individual or group assigned for follow up.
a) QRR review; summary review; physician complaints.
b) Fine Focus/CQI; mandatory; problem corrections.
c) Document Control.
d) Safety / Security; occupational injuries report.
e) Patient Satisfaction.
f) Cerner.

g) Productivity / Delta.
h) Regulatory, Accreditation, CAP, JC.
i) Service Standards; Employee Partnership; Support Card.
j) Revenue and Expense review.
k) Lab Operations.
l) Staff concerns for patient safety
m) Other issues (Student Intern, error reduction, Specimen Labeling FMEA).

xiii. Monitoring Critical Value Communication
1) To check to ensure critical values have been timely reported and correctly documented.

b. Department Specific Quality Assurance Plans
i. Refer to individual laboratory section Quality Assurance Plans.

8. Personnel: **The QSE describes the human resources of your laboratory: hiring qualified individuals, training processes, assessing competency to perform and manage laboratory activities, and retaining knowledge in positions when employees leave ("tribal knowledge").**

a. All testing personnel in the laboratory (Clinical Laboratory Scientists and Cytotechnologists) have been evaluated for current licensure required by the State of California Business and Professions Code. All phlebotomists in the laboratory have been evaluated for current certification by the State of California. Licensure monitoring is performed on an annual basis.
i. Refer to the Monitoring Licenses, Professional Registrations, and Certificates policy.

b. The laboratory must have personnel job descriptions that define qualifications and duties for all positions. Personnel files must contain records of educational qualifications (e.g. copies of diplomas, transcripts, primary source verification reports), laboratory personnel licenses (where required), training and continuing education for each employee. If the files are retained outside of the laboratory, they must be readily available to the inspector on the day of inspection. The inspector reviews the personnel files using the Laboratory Personnel Evaluation Roster.
i. Personnel Records:
1) Personnel records are maintained for all lab staff and may include:
a) Summary of Training and Experience
b) Job Description
c) Annual Performance Appraisals
d) Self-Competency Assessments
e) Records of continuing education
f) Initial orientation checklist
g) Annual competency assessments
h) Department Competency Checklists
i) Work related incidents and/or accident records.
2) Health records along with visual color discrimination tests are maintained in the Employee Health Office (phone 760-940-7270).

c. Laboratory abides by the CAP personnel requirements defined in the CAP accreditation checklists and in the CAP Personnel Requirements by Testing Complexity. All laboratory personnel associated with laboratory activities must meet or exceed CLIA and/or CDPH personnel requirements.

d. Competency:
i. There are records that all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job.
ii. The competency of personnel performing waived testing is assessed for each test system at the required frequency. The competency of personnel performing

nonwaived testing is assessed using all six elements (as applicable) on each test system.

iii. If testing personnel fail to demonstrate satisfactory performance on the competency assessment, the laboratory follows a plan of corrective action to retrain and reassess competency.

1) Refer to Laboratory Training and Competency Assessment Procedure.

e. Laboratory Positions and Responsibilities:

i. Laboratory Assistants:

1) Specimen collection, including patient preparation, labeling, handling, preservation or fixation, processing or preparation and transportation and storage of specimens, provided that venipuncture or skin puncture is performed by a State of California Certified Phlebotomist.

2) Assisting a licensed physician or surgeon or personnel licensed under the State of California Business and Professions Code (other than trainees), in a licensed clinical laboratory.

3) Assist in preventive maintenance and troubleshooting.

4) Preparation of reagents and culture media.

5) Assist in the performance of quality control procedures.

ii. Unlicensed laboratory personnel shall not do any of the following:

1) Record test results, but he or she may transcribe results that have been previously recorded, either manually by a physician or surgeon or CLS, or automatically by a testing instrument.

2) Perform any test or part thereof that involves the quantitative measurement of the specimen or test reagent or any mathematical calculation relative to determining the results or the validity of a test procedure.

3) Perform any phase of clinical laboratory tests or examinations in the specialty of immunohematology beyond initial collection and centrifugation.

4) When any of the following manual methods are employed the activities of the unlicensed laboratory personnel are limited as follows:

a) In the case of qualitative and semi-quantitative "spot, tablet or stick" tests, unlicensed personnel may add reagent to the specimen or vice versa, but the results must be read by a CLS, physician or surgeon.

b) In the case of microbiological tests, the lab assistant may make primary inoculations of test material onto appropriate culture media, stain slide preparations or microscopic examination and subculture from liquid media.

5) When any of the following mechanical or electronic instruments are employed, unlicensed personnel may not perform any of the following activities:

a) Standardize or calibrate the instrument or assess its performance by monitoring results of appropriate standards or controls.

b) Read or record test results except that the personnel may transcribe results that have been previously recorded automatically by a testing instrument.

c) Quantitatively measure any specimens or reagents unless done automatically by the instrument in the course of its normal operation or by the use of previously calibrated and approved automatic syringes or other dispensers.

iii. MLT?

iv. CLS?

9. Equipment: **This QSE describes selection, purchase and installation of equipment: validation/verification, maintenance, calibration, decontamination and decommissioning protocols.**
   b. The laboratory will be furnished with all items of sampling, measurement, and test equipment required for the correct performance of each test. Equipment that affect the quality of the test system will not be used until they have been verified as complying with standard specifications defined for each test, as appropriate.
   c. Laboratory equipment preventative maintenance and function checks must be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer. Checks must be within the manufacturer's established limits before patient testing is conducted. Equipment must be used by personnel with training and competency documented in its use.
      i. Refer to Instrument and Method Validation and Verification.
   d. The selection of laboratory instruments, equipment and supplies are under the control of the Laboratory Director.
      i. While the director has delegated the selection process to specific Laboratory management team members, the technical, clinical and operational criteria of the Director must be met.
      ii. The positions designated for instrument, equipment and supply selection are listed in the Delegation of Responsibility section above.
10. Facilities and Safety: **This QSE describes your laboratory's physical space and the maintenance programs necessary to maintain it. Include floorplans, building maintenance schedules and responsibilities, building safety features, etc.**
   a. The laboratory must be designed and maintained to ensure that the workspace, ventilation, and utilities are appropriate for all phases of testing: pre-analytic, analytic, and post-analytic.
   b. The laboratory will ensure that environmental conditions, such as room temperature and ventilation, do not adversely affect the quality of testing. Whenever the environmental conditions are outside the manufacturer's suggested range for a test system, impact to testing will be evaluated and measures taken to restore optimum environmental conditions.
      i.
   c. Safety precautions must be established and observed to ensure protection from biohazardous materials and from physical, chemical, biochemical, and electrical hazards.
      i.
         1)
         2)
         3)
   d. The laboratory must establish and implement an infection control/bloodborne pathogen plan and a chemical hygiene plan.
      i.
11. Purchasing and Inventory: **This QSE describes your laboratory's purchasing and procurement processes, such as selection of vendors, contracts, receiving of supplies, inventory management, etc.**
   a. Reagents will be properly stored per manufacturer's instructions, labelled appropriately, pass performance qualifications when necessary.
      i. Refer to Reagent Storage, Handling, Labeling, and Lot Confirmation Procedure.
   b. Vendor Credentialing:
      i. Tri-City Medical Center requires vendor and supplier credentialing as a condition for vendor representatives to visit. Credentials are required for each visit and the hospital reserves the right to refuse admission. Credentialing is overseen by the Supply Chain Management Department (SCMD) x3782. The following rules apply and are subject to change as per the SCMD:
         1) All vendors visiting any department within the medical center will be by appointment only.

2) Appointments are arranged between 8 AM and 2 PM Monday – Thursday.
3) No appointments are to be made on Fridays without prior approval.
4) Upon arrival vendors must register with security located in the lobby prior to their appointment.
5) The vendor will be issued a temporary Visitor badge to the credentialed vendor representative upon registration.
6) Vendor representatives are to visit only the department of their appointment.

ii. The following rules apply to vendor service technicians and are subject to change as per the SCMD:
1) Service technicians must possess evidence of TB test and employer product / service competency available at each visit. The evidence may be in the form a card supplied by the vendor and carried by the service technician.
2) Service technicians are required to check in with security in the main lobby who will issue a temporary badge following review of the credentials.
3) After hours check in is through security in the main lobby.

iii. Alternately:
1) Technicians who regularly call on the lab may be issued a badge following successful completion of training and competency assessment.
2) The badge will allow access without checking in at SCMD (Supply Chain Management Department).
3) The badge is good for one year and is subject to change as per the SCMD.
4) Refer the Non-TCHD Worker's Orientation and Identification Badge Process, Non-Employees 451 procedure.

12. Information Management: **This QSE describes your laboratory's information management controls around confidentiality, privacy, security and accessibility of information stored on both paper and electronic record keeping systems, including storage and retrieval of information.**
a. Refer to the Laboratory Record and Specimen Retention procedure.
b.

13. Documents and Records: **This QSE describes your laboratory's policies, process and procedures for document control and records management, from creation through destruction, including retention requirements, document destruction policies.**
a. The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation.
i. Refer to Laboratory Policy and Procedure Document Control
b. Laboratory records and materials are retained for an appropriate time.
i. Refer to the Laboratory Record and Specimen Retention procedure.
c. Review of Content and Format of Patient Reports:
i. The Laboratory Director annually reviews and approves the content and format of laboratory patients reports, printed or computer screen images, to ensure that they effectively communicate patient test results and that they meet the needs of the medical staff. Review guidelines are as follows:
1) Review and approval of tests at the time of implementation of a new report.
2) Review at the time of a major information system change.
3) Annual review of a sampling of test
ii. The following reporting formats will be reviewed using both printed format and end user screen images:
1) Gen Lab
2) Microbiology
3) Blood Bank
4) Anatomic Pathology
iii. Select patients that preferably have an extended length of stay to increase the amount of results reported. Print a report for each report format as follows:

1) Pathnet:
   a) Manual Expedite – printer LabPR07.
   b) Order Result Viewer in Flowsheet mode – screen image
   c) FAX report – printed
2) Powerchart:
   a) Order tab lab results – screen image
   b) Lab Result tab – screen image of result and any comments.

iv. The printed reports and screen image captures will be review by the Laboratory Director and the review documented on the "Content Review of Patient Reports" form.

v. Any changes to the report format must be made through the Information Technology Department using the Change Control form.

14. Non-Conformance Management: **This QSE describes your laboratory's policy around detecting, investigating, reporting, tracking, monitoring and prevention of events that do not conform to existing laboratory policies, procedures and processes. Include root cause analysis and corrective actions taken.**

a. Laboratory Error Monitoring and Quality Management:

i. Principle:
   1) The TCMC Clinical Laboratory strives to provide rapid, accurate laboratory data by continually implementing more accurate and precise methods and by improving our quality assurance techniques. In spite of these efforts, occasional errors will occur due to the human element involved and due to the inherent limitations of current methods.
   2) It is the policy of this laboratory to discover, investigate, and analyze laboratory errors in a manner that facilitates their immediate correction and future prevention. Key indicators are monitored and compared to a benchmark such as practice guidelines, CAP Q-Probe data, or the laboratories own statistical experience.

ii. Procedure:
   1) Refer to the Analytic Error Detection, Specimen Rejection, and Correction of Errors Procedure.
   2) Clinical Laboratory Scientists are responsible for correcting, documenting, and will promptly report to a supervisor any encountered laboratory error. Supervisors must also actively search for possible errors through the established departmental error detection or quality management processes.
   3) Correct errors as soon as possible and document communication of the error.
   4) If the error is Major Insignificant notify the provider.
   5) If the error is Major Significant notify the provider and the Laboratory Director. Complete a QRR form. Higher level reporting may be required as per legal risk management department.

iii. Review and Action:
   1) All major errors (Major Insignificant and Major Significant -) will be investigated and analyzed by rate, section and type. Data will be submitted to the Laboratory Quality Management Meetings and corrective action will be reviewed for each major significant error or group of errors. The effect of the assigned corrective action on eliminating or reducing the incidence of such errors will be subsequently evaluated and documented over a reasonable period of time.

iv. Benchmarks:
   1) Although the ultimate goal is to achieve 0.0% rate of major errors, a threshold of 0.1% is established based on our lab's stable past performance and published data. At this threshold, substantial process

control change must take place to ensure reduction of error rates. Other thresholds may be assigned as appropriate.

v. QA Error report:
   1) Results - The error rate will be determined as a percent of total errors / total tests and compared to the threshold rate of 0.1%. The significance, phase, source and root causes will be tallied and reported.
   2) Conclusions as to acceptable error rate or unacceptable error rate will be determined.
   3) Action- A summary statement about corrective actions taken by whom will be reported.
   4) Evaluation of the Actions – A statement will be made as to whether the actions where appropriate (lead to error reduction) or inappropriate (worse or no change in error rate). If the action is determined to be inappropriate, new error reduction activities or processes are needed.

vi. Recognition / discovery
   1) Passive: Unknown to lab until discovered by clinicians or lab staff. "Accidental" discoveries.
   2) Active: Discovered by primary review (at the bench) or through routine supervisory review.

vii. Investigation and Documentation
   1) Significance / Patient Impact. Determine what impact the error has on the patient and classify as one of the following:
      a) Minor: Discovered and corrected before release to the clinical provider.
      b) Major Insignificant: Discovered by the staff after release to clinical provider but corrected before clinical action could take place (within a few minutes from release).
      c) Major Significant: Discovered by clinician or supervisor after release to clinical provider who could have based clinical management decision on the erroneous result (discovered and corrected too late).

viii. Analytic Phase. Determine at what step in the patient testing and reporting process the error occurred:
   1) Pre-analytic:
      a) Patient and specimen id,
      b) Specimen quality, holding, transport, storing.
      c) Test order communication
   2) Analytical:
      a) New test validation / reference ranges
      b) Quality control. Calibration.
      c) Wrong patient tested.
      d) Inadequate or wrong sample type.
   3) Post-analytical:
      a) Lab report (verbal vs written)
      b) Information system interface.
      c) Secondary communication of result.

ix. Source (physical origin). Determine at what point in the patient testing process the error occurred:
   1) Pre lab: Bedside (non-lab) portion of the pre-analytical phase.
   2) In Lab: Pre-analytical, analytical, and post-analytical processes within the lab environment.
   3) Post Lab: Information system fidelity, communication of lab results by non-lab staff (events outside of the lab).

x. Root Cause / Main culprit. Determine in what category the root cause resides.
   1) Personnel:

a) Clerical (typos, erroneous entries, transcription errors)
b) Technical / process design (skills / competence, not following SOP, etc.)

2) Equipment
3) Reagents
4) Testing environment:
a) Inappropriate temperature, humidity, space, etc.

xi. Analysis and Preventive Actions:
1) Analysis – An error rate will be determined from the Statistical Grid for the period of study and compared against the target. The analysis will consist of:
a) Results: Is the error rate below the target? What are the major contributors to the error rate? Are there major significant errors?
b) Conclusions: Is the error rate acceptable?
2) Preventive Actions: Review any actions taken.
a) Evaluation of preventive actions: Were the actions appropriate? What changes can be made to prevent future errors?

15. Assessments: **This QSE describes your laboratory's assessment protocols, for both internal and external monitoring, to verify that they meet regulatory requirements and determine how well these processes are functioning as part of the overall QMS. This includes audits, proficiency tests and quality assurance reviews. Include a general statement or policy describing what assessments (internal and external) are conducted in the laboratory and how the laboratory monitors these processes.**
a.

16. Process Improvements: **This QSE describes your laboratory's processes for identifying areas for improvement, assessment and monitoring to optimize the effectiveness of the QMS and to increase and sustain quality.**
a. Multidisciplinary Quality Improvement: The professional governance model used for patient care quality improvement involves utilizing multidisciplinary teams formed into working committees which have specific purposes and goals and objectives. Refer to the Quality and Operations Committee Structure for a diagram how the councils and committees interact within the organization. The laboratory is represented in the following councils:
i. Clinical Policies and Procedures Committee:
1) To provide an interdisciplinary mechanism and forum for production and maintenance of the process standards for clinical practice including the interdisciplinary documentation system.
2) To monitor compliance to process standards through open record review.
ii. Patient Safety Committee:
1) To provide an assembly of interdisciplinary membership to oversee the initiation and application of the National Patient Safety Goals.
iii. Environment of Care (Safety) Committee:
1) The purpose of the committee is to create and maintain a safe working environment for all patients, visitors and employees of all job classifications, as required by law, to reduce downtime and to eliminate the potential for employee injuries.
2) Areas of concern for the committee include but are not limited to exposure to infectious agents, chemical hygiene, ergonomics, medication errors, patient falls, and latex safety.
3) The Lab Safety Officer represents the Laboratory.
iv. Other Committees and Councils in which the Laboratory participates:
1) Stroke Code Committee
2) Clinical Value Analysis (Product Review)
3) Clinical Policies and Procedures Committee
4) Scientific Research Committee

5) Clinical Quality Committee
6) Evidence-Based Practice Committee

b. Employee Concerns Regarding Test Quality and Laboratory Safety
   i. It is the general policy of this institution to encourage employees to communicate any concerns or complaints with respect to the quality of patient testing or safety. Complaints or concerns may be addressed to any laboratory Lead staff, Coordinator, Technical Specialist, Operations Manager, Pathologist, and Director or to the anonymous Values Line.
   ii. In addition, the College of American Pathologists has provided an official poster regarding the reporting of quality concerns. This poster has been posted on the Laboratory operations bulletin board under the Quality Section. Laboratory staff may communicate directly with CAP if they have a concern not addressed by laboratory management. CAP holds such communication in strict confidence. It is the policy of TCMC to prohibit harassment or punitive actions against an employee in response to a complaint or concern made to CAP or other regulatory organization regarding laboratory quality or safety according to AP&P 505 Confidential Reporting Line and the Net Learning Module "Codes of Conduct".
   iii. The dedicated confidential CAP telephone line for quality or safety concerns is 866-236-7212.
   iv. Actions: Any complaints, concerns or suggestions will be analyzed for appropriate intervention, corrective action or other preventive actions. Any actions taken will be documented in an appropriate manner such as section QC records, Supervisors Investigation Report, CQI (Fine Focus) Form or Quality Review Reports.

c. Employee Quality Communication
   i. The laboratory encourages employees to communicate any concerns or complaints with respect to the quality of patient testing and safety. The sources for input of the concerns or complaints may be from; lab staff meetings, lab leadership meetings, patient complaints, patient surveys, physician complaints, satisfaction scores, and Values Line. In addition, any multidisciplinary committee or employee work group may serve as a source of input.
   ii. Investigation of concerns and complaints will be conducted by the lab leadership team and corrective action or preventative measures discussed and implemented as appropriate. Documentation will be included in the records of the Lab Leadership Quality Management Meetings and communicated to the staff as appropriate.

d. Annual Review of the Effectiveness of the Quality Management Plan:
   i. The Quality Assurance Plan will be reviewed annually by the Lab Operations Team to assure the program is providing the necessary impact on quality patient care. The TEAM will review the plan for compliance with all accrediting agency requirements. The review is used to ensure that recurrent problems have been addressed and that new or re-designed activities have been evaluated. The review is presented to the appropriate patient care committee and the Medical Executive Council, if requested. In addition, the review is presented in the Annual Review of the Effectiveness of the Laboratory Quality Management Plan Manual.
   ii. As a result of the review process key indicators will be selected to track various dimension of performance such as quality, cost, and delivery of service, satisfaction or safety. The indicators will be listed on the Laboratory Dashboard that serves as the tool to document the processes used to carry out an effective Quality Management Plan.
      1)
   iii. The following is a summary of the steps that may be used in the annual review process:
      1) Education on aspects of quality management including existing indicators.
      2) Defining a balanced set of key indicators to include on the Dashboard.
      3) Creating control charts for selected defined indicators.

4) Reviewing and analyzing the control charts on a regular basis.
5) Prioritization of the indicators most in need of improvement.
6) Identifying and implementing quick and easy improvements.
7) Reviewing the effect of the improvements on performance.

iv. Laboratory Operations Plan: Key indicators of performance as determined by the review process as well as goals selected to align with the Hospital wide Operations Plan are used to develop the Laboratory Operations Plan.

17. Customer Service: **This QSE describes processes and procedures that identify your laboratory's customers, identify customer expectations, collect customer feedback and take appropriate follow-up actions. This should include general expectations of your laboratory's external and internal customers, methods for determining customer satisfaction, methods to gather customer feedback, and the process for complaint identification and resolution.**

a. Laboratory Patient Satisfaction Plan:

i. The Laboratory is committed to providing excellent service to our patients using a combination of practices that includes how we present ourselves to the patient through appropriate scripting; how we respect their privacy and ability to have a peaceful recovery through Operation Shhh...; how we continue the care of our patients after they leave us through Post-Discharge Follow Up Survey; how we care about their encounter with our staff phlebotomists and the quality of the interaction and post venipuncture wound care.

1)

ii. Scripting

1) Phlebotomy Service Standards adopted
   a) Printed on cards and carried by phlebotomists
2) Quiet Time... (Noise Abatement)
3) Keep voices down and stop non-essential conversations near patient rooms and hallways.
4) Wherever possible, close patient's door.
5) Slow down and be mindful of the noise created.
6) Repair or replace noisy phlebotomy carts.

b. Direct to Consumer (DTC) Testing:

i. California Business and Professions Code (BPC) allows persons to request laboratory testing for certain specified tests without an order form an authorized healthcare provider and any licensed clinical laboratory to perform these tests if the test is waived under CLIA. The result may be provided directly to the person requesting the test if the test is on or for his or her own body.

ii. The tests that are authorized by California BPC to be performed at the consumer's request without a prescription are:

1) Pregnancy test
2) Glucose level
3) Cholesterol
4) Occult Blood
5) HIV
6) Other tests for which an over-the-counter test kit is available. Check with a Supervisor.

iii. A test approved only as an over-the-counter collection device may not be conducted under this exception.

1) The following also apply to DTC testing:
2) The laboratory will verify continued authorization to conduct DTC testing every two years starting with 2009.
3) The laboratory will send the test result to a licensed health care practitioner designated by the patient if requested to do so by the patient. The patient may indicate on the requisition the practitioner's name and contact information.

4) The test report will include test results, reference range, interpretation as applicable, and limitations of the test, as applicable, in language readily understood by a layperson.
5) The test report will contain the name, phone number and e-mail address of a licensed health care practitioner and/or the phone number of the Tri-City Medical Center Physician Referral Office.
6) Critical values for any DTC test are handled according to the Critical Value and Critical Results Reporting Procedure.

14. Process Management: **This QSE describes how your laboratory develops, disseminates, controls and changes pre-analytic (pre-examination), analytic (examination) and post-analytic (post-examination) workflow processes and the management processes that support them.**
   a. The Quality Management System includes monitoring of key indicators of quality in the pre-analytic, analytic, and post-analytic phases by regularly comparing performance against targets defined by the laboratory.
   b. Evaluation and Selection of Referral Laboratories:
      i. The selection of the referral laboratory is made by the Laboratory Director after review of the above and consultation with the institutional medical staff (where appropriate).
      ii. Selection of referral laboratories used by the clinical laboratory is based upon licensure, accreditation and quality of performance of the lab.
      iii. All referral laboratories used by TCMC must be licensed by the state in which they operate, be accredited by either the Joint Commission on Accreditation of Hospital Organizations or the College of American Pathologists and must submit copies of their accreditation and licensure documentation.
      iv. This documentation includes copies of the CLIA Certification of Accreditation, College of American Pathologists Certificate of Accreditation and letter of sub-specialty services included in the accreditation and State licensure.
      v. The referral laboratories must maintain an acceptable level of performance as determined by specimen handling, result reporting, timeliness of reporting, and quality assurance practices as determined by the Laboratory Director.
   c. Test Ordering
      i. Refer to the STAT Test Menu, the Laboratory Turnaround Times and Delayed Testing Procedure, and the Code Specimen Collection and Processing Procedure.
      ii. Lab Rounds:
         1) The laboratory will perform rounds every 2 hours around the clock on the even hour.
         7) STAT and ER samples will be collected 24 hours / day. Every effort will be made to respond within 10 minutes.
         8) At 14 minutes prior to the scheduled round, a collection list for the next round will be printed.
         9) Requests entered in Cerner up to 15 minutes prior to the next scheduled round will appear on the collection list and be collected on the next scheduled round.
         10) Requests entered in Cerner less than 15 minutes before the next scheduled round will not appear on the collection list and will not be included in that round but will appear on the collection list for the following round. (See example below).
         11) If an order for a STAT test is received and test is on the STAT TEST MENU, every effort will be made to respond by drawing the specimen within 10 minutes.
         12) STAT requests for tests other than those on the approved STAT TEST MENU will be reclassified as routine and automatically be placed on the next scheduled round if ordered between 6 AM and 6 PM. After 6 PM these tests will be drawn on the next morning run (6 AM).

13) Orders entered by the nursing units as "ASAP" or "NOW" will be handled as routine draws.
2) Problems should be referred to a Phlebotomy Coordinator or Supervisor.

iii. Critical Values and Critical Tests
1) Refer to Critical Tests and Critical Results Reporting

iv. Turnaround Times and Notification of Delays:
1) Refer to the Laboratory Turnaround Times and Delayed Testing Procedure.

d. Patient Safety Plan: Laboratory:

i. Tri-City Medical Center Clinical Laboratory has developed a set of policies and procedures that address the CAP core patient safety goals for pre-and post-analytic laboratory processes.

ii. Laboratory processes related to the Patient Safety Plan are evaluated on an annual basis.

iii. To achieve improvements in patient and sample identification the following policies and procedures have been developed and are in use:

1) At the time of specimen collection:
a) Procedure for Assuring Correct Patient and Specimen Identification
b)
c) Procedure for Assuring Correct Specimen Labeling
Transfusion Service Criteria for Proper ID and Collection of Blood Bank Specimens by Phlebotomy
d) Green I.D. Bands (Emergency Id)
e) Patient Identification and Specimen Collection for Outpatient Transfusion Recipients.
f) Specimen Handling, Transportation, Special Collection, Processing, Aliquoting And Criteria For Rejection
g)
h) Protocol for Handling Problem Samples and Requisitions.
i)
j)
k) Microbiology Specimen Collection Manual
l) Microbiology Specimen Receipt and Accessioning
m) Collection and Transport of Specimens for Anaerobic Culture
n) Guidelines for Stool Specimen Collection for Culture and Parasitology Studies
o) Ivy Bleeding Time

2) At the time of analysis:
a) DXC Operating and Maintenance Procedure
b) DXI Operating Procedure
c) Verification of Therapeutic Drug Monitoring Results
d) Testing and Resulting Diluted Samples
e) Specimen and Aliquot Labeling
f) Emergency Dispense of Uncrossmatched Blood
g) Issuing Through Cerner
h) Patient Historical Information Directed Unit Lookup and Ordering
i) ABORh Blood Grouping
j) Microbiology Specimen Processing
k) Quality Control Guidelines for the Clinical Microbiology Laboratory
l) Microbiology Specimen Acceptability: Evaluation of Lower Respiratory Tract Specimen Quality by Gram Stain
m) Hematology Criteria for Rejection and Handling of Specimens
n) STA Compact Sample Processing

3) At the time of results delivery:
a) Verification of Specimen Identification and Review of Results
b) Critical Value List

c) Procedure for Verification and Communication of Critical Values
d) Procedure for Documenting Phoned or Verbal Communication
e) DXC Operating Procedure
f) DXI (or AXS) Operating Procedure
g) Quality Assessment Monitors
h) Microbiology Laboratory Records
i) Quality in the Microbiology Laboratory: Performance of Personnel
j) Detecting and Correcting Erroneous Microbiology Laboratory Reports
k) Quality Control Guidelines for the Clinical Microbiology Laboratory
l) Abnormal (Prolonged) PTT and PTT Results Guidelines

iv. To improve the verification and communication of life threatening or life altering information regarding:
1) Malignancies:
a) Communication of Unexpected Malignant Diagnoses in Surgical / Cytology Specimens.
b) Cytology Report TAT (III.5 in Quality Assurance Program Cytology Section.
c) HIV and other infections:
2) HIV I / II Ab Test Using Oraquick
a) Lookback Policy –Transfusion Service
b) Microbiology Reporting Results
3) Critical values:
a) Critical Value List
b) Procedure for Confirmation and Communication of Critical Values
c) Procedure for Documenting Phoned or Verbal Communication
d) Type and Screen Antibody Screen
4) Microbiology Reporting Results

v. To improve the identification, communication and correction of errors:
1) Detecting and Correcting Erroneous Lab Results.
2) Correcting Reports and Logs – Transfusion Service
3) Detecting and Correcting Erroneous Microbiology Laboratory reports

vi. Improve coordination of the laboratory patient safety role within healthcare organizations nursing, administration, POCT personnel and providers:
1) Point of Care Quality Care Management Plan.
2) Microbiology Quality Assessment Monitors

vii. To improve hand off communication of pertinent patient test information and the status of ordered tests:
1) Pending Logs / Hand off Communication

viii. Minimizing Venipuncture and Large Volumes of Blood Draws:
1) The laboratory has reviewed its specimen collection policies and phlebotomy practices to minimize unnecessarily large volumes of blood in the following ways:
a) The pediatric and neonatal population has specially reviewed guidelines for specimen collection contained in the NICU SPECIMEN REQUIREMENTS located in the Laboratory Pre-Analytical and Specimen Collection Manual.
b) The general tubes in use are the smaller volumes sizes such as 4.5 mL red and green top, 2.5 mL lavender top and the 6 mL red that replaced the 10 mL red top.
c) The lab collects routine draws using a "rounds" system. By using a system that sweeps the hospital every two hours on the even hours, multiple orders for the same patient can be netted into one collection rather than several repeated draws. This is especially beneficial for patients who are seen by more than one physician

each of whom may write order for blood tests. The two-hour rounds system will allow the requests to accumulate and increase the chance that only one venipuncture will be required.

d) Phlebotomist and Nursing practice is to contact the laboratory when additional orders are requested to check if a current sample is suitable for the additional "add-on" test thereby eliminating an unnecessary repeat venipuncture.

e. Specimen Collection:

i. Refer to the Laboratory Pre-Analytical and Specimen Collection Manual

ii. Specific instructions for the proper collection and handling of specimens are made available to laboratory personnel and anyone collecting patient test material sent to the laboratory.

iii. Specimen collection procedure and specimen handling, if any, are addressed in individual test protocols and/or in the Laboratory Pre-Analytical and Specimen Collection Manual.

f. Remote Site Specimen Tracking and Specimen Quality

i. Laboratory specimens are received from the following remotes sites and clients; North Coast Surgicenter (AP), Center for Endoscopy (AP), North County Oncology.

ii. Specimen Tracking:

1) A tracking system is used to ensure all specimens dispatched from the sites have been received in the laboratory

2) Specimens collected at the off-site locations are tracked via the Specimen Transport to Tri-City Medical Center form and departmental pending logs. The packing logs are prepared by the client or courier and checked against the specimens received in the laboratory. Specimens that are not received in a timely manner are noted and the client location is notified. Specimens that are unable to be located are referred to the Operations Manager or tech in charge for further investigation. Performance improvement may be initiated if frequent problems are identified.

iii. Monitoring Quality and Correcting Problems Identified Specimen Quality Control from Remote Sites:

1) Specimens collected at remote client locations are stored in an appropriate storage temperature (monitored refrigerator, room temperature, monitored 37°C heat block) until transported to the main lab. Once received in the main lab, specimens are monitored for acceptable condition.

2) Specimens received for Histology and Cytology are reviewed for acceptable conditions such as correct labeling, name match between requisition and specimen, completed requisition, pertinent clinical information, specimen source, improper collection or storage, significant container leakage. If a determination is made to reject a specimen, the specimen and requisition are returned to the remote site along with a completed "Rejection Notification Letter". All rejected Histology or Cytology specimens are recorded in the Specimen Rejection Log Book. Performance improvement may be initiated if frequent problems are identified.

a)

g. Reporting Outside Results

i. The policy of the laboratory is to not integrate outside lab results (i.e. those outside laboratory results brought to a physician and requested by the physician to be integrated into the laboratories' reporting data base) into the PathNet record. These reports are sent to medical records where they are scanned and posted to a folder labeled "Outside Results".

h. Laboratory Reference Intervals:

- i. The laboratory reference range must be established or verified for each analyte and specimen source (e.g., blood, urine, cerebrospinal fluid), when appropriate. For many analytes (e.g., therapeutic drugs and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.
- ii. The laboratory evaluates the appropriateness of the reference intervals and takes corrective action if necessary.
- iii. The criteria for evaluation of reference intervals include:
  - 1) Introduction of a new analyte to the test repertoire
  - 2) Change of analytic methodology
  - 3) Change in patient population
- iv. If it is determined that the range is no longer appropriate for the patient population take corrective action.
- v. Evaluation of the reference range may be done using the CLSI (NCCLS) How To Define And Determine Reference Intervals In The Clinical Laboratory; Approved Guideline C28 A2 by validation of the transfer of the manufacturer's reference range.
- vi. The Reference Range Validation Worksheet may be used in the process of collecting data for the reference range study.
  - 1)

i. Test Complexity Determination:

- i. Waived
  - 1) Waived: Test systems are simple laboratory examinations and procedures which:
    - a) Are cleared by FDA for home use,
    - b) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
    - c) Pose no reasonable risk of harm to the patient if the test is performed inaccurately.
- ii. Moderate or High Complexity
  - 1) Each specific test system, assay and examination is categorized by complexity. Using seven criteria and grading scores of 1, 2, or 3 in each criterion, any test system, assay or examination having a score of less than 12 is categorized as moderate complexity, while those with scores above 12 will be categorized as high complexity.
  - 2) The criteria are:
    - a) Knowledge- minimal, on the job, or specialized scientific and technical knowledge
    - b) Training and experience- minimal, limited experience, or substantial experience
    - c) Reagents- stable and reliable, prepackaged and require no special handling, or labile and may require special handling to assure reliability
    - d) Characteristics of operational steps- automatic or easily controlled (temperature, timing steps, etc.) or may require close monitoring, pipetting, calculations, etc.
    - e) Calibration, quality control, proficiency testing materials- stable and readily available or if available may be labile
    - f) Test system troubleshooting and equipment maintenance- test system troubleshooting is automatic or self-correcting or clearly describes or requires minimal judgment and equipment maintenance is provided by the manufacturer, is seldom needed, or can be easily performed. OR troubleshooting is not automatic, requires special knowledge, skills, and abilities, or requires decision making or direct intervention to solve problems.

~~g) Interpretation and judgment- minimal required to perform pre-analytic, analytic and post-analytic processes or extensive independent~~
~~h) Interpretations are required.~~
~~3)~~

C. **PROCEDURE:** ~~N/A~~
~~18.~~**1.** Perform validation and/or verification studies on new instrumentation and assay methods when appropriate.
a. **Refer to the Instrument and Method Validation and Verification procedure.**

~~C.~~**D. FORM(S):**
1. New Method / Test Checklist
2. New Method Validation Summary Form
3. New Method Verification Summary Form
4. Reference Range Validation Worksheet
5. Summary Statement of Acceptable Performance of Instrument or Method Verification

~~D.~~**E. RELATED DOCUMENT(S):**
1. **Director Delegation Table** ~~**Management Plan: Process Management**~~
2. **Instrument and Method Validation and Verification**
3. **Chemistry Quality Assurance Plan**
4. **Chemistry Quality Control Outline**
5. **Hematology, Coagulation and Urinalysis Department Quality Assurance Plan**
6. **Hematology and Urinalysis Quality Control Outline**
7. **Quality Control for Urinalysis**
8. **Quality Control Guidelines for the Clinical Microbiology Laboratory**
9. **Point of Care Quality Assurance Policy**
10. **Point of Care Quality Assurance Procedure**
11. **Phlebotomy Quality Assurance Plan**
12. **Tissue Bank Quality Assurance Program**
13. **Tissue Bank Quality Control and Maintenance**
14. **Transfusion Service Quality Control Program**
15. **Transfusion Service Quality Assurance Plan**
16. **Cytology Specimen and Equipment Quality Assurance**
~~3.~~**17. Pathology Quality Assurance**
~~1. Laboratory Organizational Chart~~
~~2. Laboratory Training and Competency Assessment~~
~~3. Laboratory Policy and Procedure Document Control~~
~~4. Laboratory Record and Specimen Retention~~
~~5. Reagent Storage, Handling, Labeling, and Lot Confirmation~~
~~6. Laboratory Turnaround Times and Delayed Testing~~
~~7. Laboratory Hand-Off Communication~~
~~8. Proficiency Testing~~
~~9. Laboratory Record and Specimen Retention~~
~~10. Monitoring Licenses, Professional Registrations, and Certificates~~
~~11. Criteria for Rejection of Cytology Specimens~~
~~12. The Handling of Sub-Optimally Received Specimens~~

~~E.~~**F. EXTERNAL LINK(S):** N/A

~~F.~~**G. REFERENCES:**
1. College of American Pathologists. (~~2021~~**2023**). *Laboratory General Checklist*. Northwood, IL~~, 09.22.2021, 62–74~~.

2. Clinical and Laboratory Standards Institute (CLSI). A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management ~~in~~**in** Clinical Laboratories. Chicago, IL: CAP Press, 2005.
4. Jhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017
5. California Association of Hospital and Health Systems. Guide to Record Retention. 2005.
6. American Association of Blood Banks. Technical Manual, (current edition; updated annually).
~~7. College of American Pathologists. Inspection and Accreditation Checklist, Section 1 General Laboratory.~~
~~8. NCCLS. How to define and determine reference intervals in the clinical laboratory; approved guideline C28-A2. Wayne, PA: NCCLS, 2000~~
~~9. California Business and Professions Code Section 1260-1275.~~
~~10. California Code of Regulation 1050.~~
~~11. College of America Pathologists. Reference Range Service (RRS2-A) Kit Instructions. 2010~~
~~12. Van der Meulen EA, et al. Use of small-sample-based reference limits on a group basis. Clin Chem. 1994;40:1698-1702~~
~~13.~~**7.** Department of Health and Human Services, Centers for Medicare and Medicaid Services.
~~14.~~**8.** Clinical Laboratory Improvement Amendments Of 1988; final rule. Fed Register. 1992(Feb 28):7164 [42CFR493.1213] (10/1/2011)
~~15.~~**9.** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124208.htm
~~16.~~**10.** California's Business and Professions Code (BPC) section 1200 et. Seq., www.leginfo.ca.gov/calaw.
~~17.~~**11.** Title 17 California Code of Regulations (CCR), section 1029 et. Seq. www.calregs.com

Tri-City Medical Center
Oceanside, California

LABORATORY
GENERAL/QUALITY MANAGEMENT

ISSUE DATE: 11/99

~~Management Plan~~

SUBJECT: Laboratory Facilities and Safety Quality System Essentials ~~Laboratory Quality~~

REVISION DATE(S): 05/07, 11/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 07/16, 06/18, 06/19, 03/21, 06/24

Department Approval:	~~10/22~~11/24
Laboratory Medical Director Approval:	~~10/21~~11/24
Medical Executive Committee Approval:	n/a
Administrative Approval:	03/22
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **DEFINITION(S):**

1. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. The CLIA Program sets standards and issues certificates for clinical laboratory testing.
2. CLIA 88: ~~(definition)~~1988 amendments to the Public Health Service Act that established quality standards for all laboratory testing the ensure the accuracy, reliability, and timeliness of patient test results. CLIA '88 regulations apply to all clinical laboratories in the United States, including those in hospitals, clinics, and physician offices. They are enforced by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC).
3. Quality Assurance (QA): Focuses on the entire laboratory testing process rather than just the equipment. QA encompasses a set of systematic activities and processes aimed at providing confidence that the laboratory consistently produces accurate and reliable results. QA components can include establishing standard operating procedures (SOPs), conducting proficiency testing, training and certifying laboratory personnel and ensuring compliance with regulatory requirements.
4. Quality Control (QC): The set of procedures and policies designed to monitor and maintain the precision and accuracy of laboratory equipment and testing processes. It involves daily checks, calibration, and verification to confirm that instruments are operating correctly and producing reliable results. QC components can include calibrating instruments, conducting internal quality control checks, monitoring environmental conditions and identifying and promptly addressing errors.
5. Quality Management: Oversees the entire laboratory operation, monitoring QC and QA programs as well as administrative considerations that influence the quality and efficiency of the laboratory operation.
6. Quality Management System (QMS): A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.
7. ~~—~~Quality System Essentials (QSE): QSEs represent the fundamental components necessary to ensure the accuracy, reliability, and integrity of laboratory testing processes within the QMS. These essentials encompass aspects such as leadership commitment to quality, adherence to regulatory standards, continuous improvement initiatives, and employee training and competency assessments.

~~8.~~**7.**

~~9.~~**8.** Test Complexity: A test scoring system used by the FDA to categorize laboratory tests. Test complexity is scored as waived, moderate, or high. Test complexity determines the level of quality oversight for the performing laboratory.

a. Nonwaived: —Tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity.

b. Waived: —A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result."

c. **Test complexity can be determined by accessing the CLIA database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm**

~~10.~~**9.** Test System: The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

B. **POLICY:**

1. **Facilities and Safety Overview:**

a. The laboratory is designed and maintained to ensure that the workspace, ventilation, and utilities are appropriate for all phases of testing: pre-analytic, analytic, and post-analytic.

b. The laboratory ensures that environmental conditions, such as room temperature and ventilation, do not adversely affect the quality of testing. Whenever the environmental conditions are outside the manufacturer's suggested range for a test system, impact to testing will be evaluated and measures taken to restore optimum environmental conditions.

i. Refer to the Temperature and Environmental Monitoring procedure.

c. Safety precautions are established and observed to ensure protection from biohazardous materials and from physical, chemical, biochemical, and electrical hazards.

i. **The Formaldehyde and Xylene Safety Program helps protect employees from the hazards associated with formaldehyde and xylene It provides information on how to maintain formaldehyde exposures below the regulatory limits and how to recognize symptoms of over-exposure.**

ii. **The Laboratory Fire Safety procedure outlines lab fire safety rules, code red procedures, and evacuation**.

iii. **The Laboratory Electrical Safety procedure outlines general electrical safety in the laboratory.**

iv. **The Laboratory Spills procedure explains how to remediate biohazardous and chemical spills, as well as the conditions under which lab personnel are not qualified to clean up a spill.**

1) **A Laboratory Spills Badge Buddy is given to each employee for quick reference. Laboratory Spills instructions are posted throughout the lab.**

v. **Regulated medical waste and hazardous waste is disposed of following all federal, state, local, and hospital requirements. Refer to the Laboratory Waste Management procedure.**

vi. **Other lab safety policies and procedures that address lab hazards include:**

1) Laboratory Dry Ice Safety

~~1)~~2) Laboratory Liquid Nitrogen Safety

vii. **A laboratory safety audit is carried out at least annually. Refer to the Laboratory Safety Audit procedure for more information.**

d. The laboratory has established and implemented an infection control/bloodborne pathogen plan and a chemical hygiene plan.

i. **The Laboratory Infection Prevention and Control policy builds on the hospital infection control** guidelines **with information specific to laboratory personnel** and **hospital personnel who handle lab specimens.**

1) The Blood Borne Pathogen Exposure Determination is regularly reviewed. This form evaluates the potential for exposure to blood borne pathogens for each position in the lab.

~~ii.~~ ~~The Refer to the following procedures:~~

~~iii.~~**ii. Chemical Hygiene Plan provides hospital employees with a safe working environment through comprehensive education on chemical health hazards in the laboratory, and describes actionable processes that support a culture of lab safety.**

1) A Task Assessment for each lab section is reviewed each year. These documents **assess the responsibilities performed in each lab section for potential chemical exposure risks. The risks are ranked and engineering and personal protective equipment (PPE) recommendations are made for each task.**

e. **Additional laboratory safety policies and procedures include:**

i. Laboratory Emergency Eye Wash and Drench Shower
ii. Laboratory Ergonomics
~~ii.~~**iii. Laboratory Latex Allergy**
~~iii.~~**iv.** Laboratory Monitoring of Excessive Noise
v. Laboratory Non-Injury Accidents
~~iv.~~**vi. Laboratory Occupational Injury and Illness Reporting and Evaluation**
~~v.~~**vii. Laboratory Ultraviolet Light Exposure**

2. Floorplans:
a. A blueprint of the laboratory floor plan is available on the lab shared drive.
b. The lab floor plan is integrated into annual lab safety training, which includes walking the lab and pointing out all safety resources.
~~a.~~**c. The lab floor plan is integrated into all emergency evacuation route signage posted in the lab.**

3. Building Maintenance Schedules and Responsibilities:
a. **The annual laboratory safety audit includes review of the lab space, such as checking pipes and drains, electrical outlets, and other building assets.**
b. **Building maintenance is managed by the Facilities Department and issues with the building can be reported to facilities or engineering at any time.**
i. **Refer to the Engineering Scope of Service for the assets maintained.**
ii. **Note that laboratory instruments are maintained by laboratory personnel and serviced by contracted specialists.**

4. Building Safety Features:
a. **The laboratory has a comprehensive Laboratory Emergency and Disaster Procedure in place. This document instructs laboratory personnel what their role is during an emergency or disaster (Code Orange).**
i. **A Laboratory Disaster Contingency Plan has also been developed to address potential problems with mission critical systems in the event of an emergency or disaster.**
b. **Lab safety features include an emergency exit, an overhead sprinkler system, numerous methods of egress, readily available fire extinguishers, and more.**
ii. **Safety resources are reviewed on an annual basis as part of the Lab Safety Walk. Refer to the Laboratory Safety Training procedure for additional information.**

5. **Security:**
a. **The lab follows all hospital security policies. Refer to the Security Management Plan.**
b. **The lab is secured by locked doors at all points of entry and is accessible by either numeric code or badge swipe. The emergency exit from the lab to the exterior of the hospital prevents outside access.**
c. **Patients at the lab for phlebotomy or other specimen collection processes are not permitted beyond the phlebotomy section.**

6. **Signage Requirements:**
   a. In addition to all signage required by law and by hospital policy, the lab has numerous customized safety signs posted throughout the department.
   b. **These signs include, but are not limited to:**
      i. **Formaldehyde (Formalin) Spill Procedure**
      ii. **Laboratory Pneumatic Tube System Spill Cleanup**
      iii. Laboratory Spill Chart
      iv. **Laboratory Where to Throw It Sign**
      v. **Emergency Evacuation**
      vi. **Emergency First Aid**
      vii. **Fire Safety**
      viii. **Hand Hygiene**

C. **PROCEDURE:** N/A

D. **FORM(S):**
1. **Laboratory Safety Audit Form**

E. **RELATED DOCUMENT(S):**
1. **Temperature and Environmental Monitoring**
2. **Formaldehyde and Xylene Safety Program**
3. **Laboratory Fire Safety**
4. **Laboratory Electrical Safety**
5. **Laboratory Spills**
6. **Laboratory Waste Management**
7. **Laboratory Dry Ice Safety**
~~7.~~**8.** **Laboratory Liquid Nitrogen Safety**
~~8.~~**9.** **Laboratory Safety Audit**
~~9.~~**10.** **Laboratory Infection Prevention and Control**
~~10.~~**11.** Chemical Hygiene Plan~~Laboratory Training and Competency Assessment~~
12. **Laboratory Emergency Eye Wash and Drench Shower**
13. **Laboratory Ergonomics**
14. **Laboratory Latex Allergy**
15. **Laboratory Monitoring of Excessive Noise**
16. **Laboratory Non-Injury Accidents**
17. **Laboratory Occupational Injury and Illness Reporting and Evaluation**
~~11.~~**18.** **Laboratory Ultraviolet Light Exposure**
~~12.~~**19.** Laboratory Emergency and Disaster Procedure
~~13.~~**20.** **Laboratory Safety Training**
~~14.~~**21.** **Security Management Plan**

F. **EXTERNAL LINK(S):** N/A

G. **REFERENCES:**
1. College of American Pathologists. (2023). *Laboratory General Checklist.* Northwood, IL.
2. Clinical and Laboratory Standards Institute (CLSI). A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management In Clinical Laboratories. Chicago, IL: CAP Press, 2005.
4. Jhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017
5. California Association of Hospital and Health Systems. Guide to Record Retention. 2005.
6. American Association of Blood Banks. Technical Manual, (current edition; updated annually).
7. College of American Pathologists. Inspection and Accreditation Checklist, Section 1 General Laboratory.

8. NCCLS. How to define and determine reference intervals in the clinical laboratory; approved guideline C28 A2. Wayne, PA: NCCLS, 2000
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10. California Code of Regulation 1050.
11. College of America Pathologists. Reference Range Service (RRS2-A) Kit Instructions. 2010
12. Van der Meulen EA, et al. Use of small-sample-based reference limits on a group basis. Clin Chem. 1994;40:1698-1702
13. Department of Health and Human Services, Centers for Medicare and Medicaid Services.
14. Clinical Laboratory Improvement Amendments Of 1988; final rule. Fed Register. 1992(Feb 28):7164 [42CFR493.1213] (10/1/2011)
15. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124208.htm
16. California's Business and Professions Code (BPC) section 1200 et. Seq., www.leginfo.ca.gov/calaw.
17. Title 17 California Code of Regulations (CCR), section 1029 et. Seq. www.calregs.com

Tri-City Medical Center
Oceanside, California

LABORATORY
GENERAL/QUALITY MANAGEMENT

ISSUE DATE: 11/99

SUBJECT: Laboratory Purchasing and Inventory Quality System Essentials

REVISION DATE(S): 05/07, 11/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 07/16, 06/18, 06/19, 03/21, 05/24

Department Approval:	**11/24**
Laboratory Medical Director Approval:	**10/21**
Medical Executive Committee Approval:	**n/a**
Administrative Approval:	**03/22**
Professional Affairs Committee Approval:	
Board of Directors Approval:	

A. **DEFINITION(S):**

1. **Quality Management: Oversees the entire laboratory operation, monitoring QC and QA programs as well as administrative considerations that influence the quality and efficiency of the laboratory operation.**
2. **Quality Management System (QMS): A QMS is a set of policies, processes, procedures, and resources designed to ensure high quality in an organization's services.**
3. **Quality System Essentials (QSE): QSEs represent the fundamental components necessary to ensure the accuracy, reliability, and integrity of laboratory testing processes within the QMS. These essentials encompass aspects such as leadership commitment to quality, adherence to regulatory standards, continuous improvement initiatives, and employee training and competency assessments.**
4. Test System: The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

B. **POLICY:**

1. Lab Contracts: Laboratory contracts exist for contracted labor, equipment rental, equipment service and maintenance, consumables and supplies, software interfaces with corresponding professional services for installation and maintenance, educational affiliations, and referral laboratories for testing not performed on-site.
   a. The Laboratory Director is responsible to ensure sufficient numbers of personnel with appropriate educational qualifications, documented training and experience, and adequate competency to meet the needs of the laboratory. (DRA.11300)
   b. The Laboratory Director or designee is directly involved in the selection of all laboratory equipment, supplies, and services with respect to quality. (DRA.11475)
   c. The Laboratory Director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for selecting referral laboratories. Selection of referral laboratories must be based primarily upon the quality of performance of such laboratories. It is the responsibility of the Laboratory Director or designee to monitor the turnaround time and quality of test results received from referral laboratories. (GEN.41350)

d. Laboratory contracts are entered into the NTracts contract management software for review and approval. See Contract Review Policy 278 and File Maintenance for Contract and Leases Policy 279.
e. Laboratory contracts that have a supply component are reviewed by Supply Chain Department. See the Supply Chain Approval and Authorization Matrix and Signature Authority Policy 232.
f. Laboratory contracts that have an IT component are reviewed by the IT Department.

2. Vendor Selection and Credentialing:
   a. Tri-City Medical Center requires vendor and supplier credentialing as a condition for vendor representatives to visit. Credentials are required for each visit and the hospital reserves the right to refuse admission. Credentialing is overseen by the Supply Chain Management Department (SCMD) x3782. The following rules apply and are subject to change as per the SCMD:
      i. All vendors visiting any department within the medical center will be by appointment only.
         1) Appointments are arranged between 8 AM and 2 PM Monday – Thursday.
         2) No appointments are to be made on Fridays without prior approval.
         3) Upon arrival vendors must register with security located in the lobby prior to their appointment.
         4) The vendor will be issued a temporary Visitor badge to the credentialed vendor representative upon registration.
         5) Vendor representatives are to visit only the department of their appointment.
      ii. The following rules apply to vendor service technicians and are subject to change as per the SCMD:
         1) Service technicians must possess evidence of TB test and employer product / service competency available at each visit. The evidence may be in the form a card supplied by the vendor and carried by the service technician.
         2) Service technicians are required to check in with security in the main lobby who will issue a temporary badge following review of the credentials.
         3) After hours check in is through security in the main lobby.
      iii. Alternately:
         1) Technicians who regularly call on the lab may be issued a badge following successful completion of training and competency assessment.
         2) The badge will allow access without checking in at SCMD (Supply Chain Management Department).
         3) The badge is good for one year and is subject to change as per the SCMD.
         4) Refer the Non-TCHD Worker's Orientation and Identification Badge Process, Non-Employees 451 procedure.
3. Approved laboratory vendors and suppliers are made available in the Premier purchasing system, which is maintained by the Supply Chain Department.
4. New Equipment, once approved by all involved departments, is reviewed an inventoried upon arrival before installation. Refer to the Medical Equipment Management Plan.
   a. After installation, the laboratory performs the appropriate instrument performance verification studies. Refer to the Instrument and Method Validation and Verification Procedure.
5. Inventory Management is maintained by individual laboratory sections.
6. Reagents and Supplies:
   a. Laboratory section leaders work with the Lab Director to select equipment and associated consumables as well as any standalone test kits that are performed by the laboratory.
   b. Reagents are properly stored per manufacturer's instructions, labelled appropriately, **and** pass performance qualifications when necessary.
      i. Refer to the Reagent Storage, Handling, Labeling and Lot Confirmation Procedure.

c. Certificates of Analysis are used in the Histology section to track the quality and pH of formalin used throughout the hospital.
   i. Refer to the Formalin and Xylene Safety Program.

d. Most lab storage conditions are continuously tracked through a temperature and environmental monitoring system. A backup system of manual monitoring is in place for redundancy and in case of monitoring system downtime.
   i. Refer to the Laboratory Temperature and Environmental Monitoring procedure.

B. **RELATED DOCUMENT(S):**

1. Reagent Storage, Handling, Labeling and Lot Confirmation Procedure
2. Formalin and Xylene Safety Program
3. Instrument and Method Validation and Verification
4. Laboratory Temperature and Environmental Monitoring
5. Medical Equipment Management Plan

C. **REFERENCES:**

1. College of American Pathologists. (~~2021~~**2023**). Laboratory general checklist and director assessment checklist. CAP Accreditation Program~~, 09.22.2021, 62–74~~.
2. Clinical and Laboratory Standards Institute (CLSI). A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management ~~in~~**in** Clinical Laboratories. Chicago, IL: CAP Press, 2005.
4. Jhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017
5. California Association of Hospital and Health Systems. Guide to Record Retention. 2005.
6. American Association of Blood Banks. Technical Manual, (current edition; updated annually).
7. Department of Health and Human Services, Centers for Medicare and Medicaid Services.
8. Clinical Laboratory Improvement Amendments Of 1988; final rule. Fed Register. 1992(Feb 28):7164 [42CFR493.1213] (10/1/2011)
9. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124208.htm
10. California's Business and Professions Code (BPC) section 1200 et. Seq., www.leginfo.ca.gov/calaw.
11. Title 17 California Code of Regulations (CCR), section 1029 et. Seq. www.calregs.com

Tri-City Medical Center
Oceanside, California

MAMMOGRAPHY WOMEN'S CENTER

ISSUE DATE: 11/99 **SUBJECT:** Report Inclusions

REVISION DATE: 08/11, 08/18, 09/19

Mammography Department Approval:	**~~05/22~~11/24**
Department of Radiology Approval:	**~~12/22~~02/25**
Pharmacy & Therapeutics Committee Approval:	**n/a**
Medical Executive Committee Approval:	**n/a**
Administration Approval:	**01/23**
Professional Affairs Committee Approval:	**n/a**
Board of Directors Approval:	**01/23**

A. **AUTHORIZED TO PERFORM:**
1. Physicians and Radiology Transcriptionists.

B. **PURPOSE:**
1. To ensure all required information is included in dictated patient's reports.

C. **POLICY:**
1. Mammography reports shall include all essential elements per Mammography Quality Standard Act (MQSA) standards:
   - **a. Name, address, and phone number of Tri-City Medical Center**
   - **~~a.~~b. Ordering physician receiving the report**
   - **~~b.~~c.** Name and medical record number (MRN) of patient
   - **~~c.~~d.** Date of exam
   - **~~d.~~e.** Name of interpreting physician
   - **~~e.~~f.** Final assessment **of findings, classified** in one of the **~~named~~ following** categories:
     - i. "Negative"
     - ii. "Benign"
     - iii. "Probably benign"
     - iv. "Suspicious"
     - v. "Highly suggestive of malignancy
     - vi. "Known-**Biopsy Proven** malignancy"

   ~~NOTE:~~
2. If no final category is assigned due to "incomplete" work-up:
   - **a.** "Incomplete: Need **~~further work-up" shall be assigned~~ additional imaging evaluation"**
   - **b. "Incomplete: Need prior mammogram for comparison"**
3. **An overall assessment of breast density, classified in one of the following categories:**
   "The breasts are almost entirely fatty":
   "There are scattered areas of fibroglandular density."
   "The breasts are heterogeneously dense, which may obscure small masses."
   "The breasts are extremely dense, which lowers the sensitivity of mammography."

D. **EXTERNAL LINK(S):**

1. Mammography Quality Standards Act (MQSA) of 1998
https://www.fda.gov/downloads/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/UCM110849.pdf

E. **REFERENCE(S):**

1. Mammography Quality Standards Reauthorization Act, Pub. L., Title XLII § 263b. (1998).
2. **http://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program.**

Tri-City Medical Center
Oceanside, California

OUTPATIENT SPECIALITY SERVICES POLICY

RETIRE - Follow Patient Care Services Point-of-Use Pre-Cleaning of Reusable Instruments

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ISSUE DATE: 05/11

SUBJECT: Decontamination and Sterilization of Instruments

REVISION DATE:

Department Approval:	~~03/20~~04/24
Infection Control Committee Approval:	~~08/20~~05/24
Pharmacy and Therapeutics Approval:	n/a
Medical Executive Committee Approval:	~~11/20~~01/25
Administration Approval;	12/20
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	12/20

~~A. **PURPOSE:**~~

~~1. In compliance with infection principles, this document outlines the safe and effective method of cleaning, decontamination, and sterilization of surgical instruments used in clinic procedures.~~

~~B. **POLICY:**~~

~~1. The clinic will follow infection control principles when handling contaminated instruments.~~

~~2. Competent and qualified clinic staff will observe the principles of cleaning, decontamination and sterilization.~~

~~C. **PROCEDURE:**~~

~~1. Instruments used in the clinic's procedures will be placed in the covered tray immediately after each use and germicidal solution will be added.~~

~~2. Hinged instruments will be placed in an open position for effective soaking.~~

~~3. Disposable instruments will be discarded according to hospital policy.~~

~~4. A qualified person wearing protective equipment will prepare the instruments to be transported to SPD. Instruments will be initially wiped clean of gross contamination at time of use. Tools will be placed in puncture proof container and sprayed with hospital approved gel cleanser to keep them moist. The puncture proof container will be kept in the soiled equipment cabinet until delivered to SPD.~~

~~5. Containers holding soiled instruments will be collected at the end of each dayand delivered back to SPD by clinic staff. .~~

~~6. Sterile Processing will be responsible for sterilization of the clinic's instruments and performing biological indicator testing and other testing to ensure proper functioning of sterilizers.~~
~~The Clinic will follow the event-related procedures for sterile products/equipment per Infection Control Manual.~~

Tri-City Medical Center
Oceanside, California

PULMONARY REHABILITATION SERVICES

SUBJECT: Maintenance and Repair of Equipment

ISSUE DATE: 06/08
REVISION DATE: 12/12

Department Approval:	**~~05/18~~01/25**
Division of Pulmonary Approval:	**n/a**
Pharmacy and Therapeutics Approval):	**n/a**
Medical Executive Committee Approval): if	**n/a**
Administration Approval:	**08/21**
Professional Affairs Committee Approval):	**n/a**
Board of Directors Approval:	**08/21**

A. **PURPOSE:**

1. To establish guidelines for the repair and maintenance of exercise equipment that has developed a malfunction or is otherwise not suitable for use in it's current condition in the Pulmonary Rehabilitation Program.

B. **POLICY:**

1. In the event of a malfunction of a piece of exercise equipment, the machine shall be unplugged, if electrically powered and shall be prominently tagged with a "Sorry Out of Order" sign.
2. Utilize the Tamis work order system, and submit a work order to BioMed department. Following their assessment of the problem, BioMed shall determine if the repair can be completed in-house or if it needs to be outsourced to a vendor.
3. Yearly preventive maintenance of the equipment is currently under the oversight of Tri-City Medical Center BioMed (Aramark) Department.

C. **GENERAL GUIDELINES:**

1. Tag all malfunctioning equipment with large, plain view signs not to use.
2. Record the equipment information and possible problem in TCMC intranet work orders. Print out requested work order; place in a plastic protector and post in office until work order is completed.
3. Contact Biomed or specific vendor for warranty repairs.
4. Follow up on issue to make sure repair is done and equipment is put back into service.

Tri-City Medical Center
Oceanside, California

SURGICAL SERVICES
PERI-ANESTHESIA NURSING SERVICES

ISSUE DATE: 08/03 **SUBJECT:** Post Anesthesia Standards of Practice and Documentation

REVISION DATE(~~S~~): 10/09, 01/13

Surgical Services Department Approval:	~~03/18~~10/23
Department of Anesthesiology Approval:	~~09/18~~09/24
Operating Room Committee Approval:	~~04/19~~12/24
Pharmacy & Therapeutics Committee Approval:	n/a
Medical Executive Committee Approval:	~~05/19~~01/25
Administration Approval:	06/19
Professional Affairs Committee Approval:	n/a
Board of Directors Approval:	06/19

A. **PURPOSE:**

1. To outline standards of practice and documentation for patients in the Post Anesthesia Care Unit (PACU). Assessment and data collection provide the clinical basis for an individualized plan of care during the post-operative period. A comprehensive plan of care shall be developed and implemented for each patient to achieve optimal outcomes.

B. **POLICY:**

1. Ongoing patient assessment and management in PACU shall include phase-specific components and assessment frequency.
2. Documentation shall appropriately reflect assessment and care provided. Documentation shall include interventions based on the plan of care, response to interventions, consultation and collaboration with the patient/family and other healthcare providers.
3. Patients who have met discharge criteria and are being held in PACU due to bed capacity restraints shall have assessment, vital signs and documentation per the admitting unit's Standards of Care and surgeon's orders.
   a) The PACU RN shall initiate time sensitive orders (such as medications, labs, X-rays) during the holding interval in PACU.

C. **ADMISSION PROCEDURE:**

1. Confirm patient identification upon arrival to PACU. Review medical record and obtain hand-off report from the anesthesiologist and surgical/procedural registered nurse (RN).
2. Place monitors on patient and begin continuous monitoring, including:
   a) Blood pressure cuff (initially set for every 5 minutes)
   b) Pulse Oximeter
   c) EKG
3. Evaluate airway/respiratory status:
   a) Auscultate breath sounds and count respiratory rate
   b) Observe respiratory depth and effort
      i. Hypoventilation, Obstruction or Hypoxia (implement in descending order if previous intervention unsuccessful):
         1) Reposition the patient as tolerated (head of bed elevated, side lying or high fowlers)
         2) Stimulate the patient

3) Institute jaw thrust/support, chin lift
4) Insert oral airway. Notify anesthesia before inserting nasal airway.
5) Manually ventilate patient with bag-valve-mask, notify anesthesiologist and prepare for medication intervention and/or intubation.

ii. Laryngeal Edema/Spasm:
1) Place in high fowlers position
2) Institute jaw thrust
3) Encourage coughing to clear secretions or gently suction to remove secretions or foreign material from cords, avoiding vigorous suctions as it can increase the spasm and result in complete closure of airway.
4) Notify anesthesiologist, manually ventilate patient with bag-valve-mask, and prepare to administer racemic epinephrine mini-nebulizer treatment, steroids, or other interventions to decrease edema.

c) Monitor O_2 saturation via pulse oximetry
i. Pulse oximetry sensor shall be placed on a finger of the hand opposite the blood pressure cuff, when possible.
ii. Administer O_2 to maintain SpO_2 at 94% or greater, or as ordered by anesthesiologist.

4. Measure vital signs and verbally report vital signs to anesthesiologist:
a) Blood pressure
b) Heart rate
c) SpO_2
d) Temperature
e) Respiratory rate

5. Evaluate fluid status:
a) Assess intravenous (IV) line(s)
i. Maintain IV access at all times
ii. Assess IV catheter site(s)
iii. Verify IV fluids, medication dosages and flow rates as indicated
b) Administer fluids per anesthesia orders. Surgeon's IV orders may be initiated before transfer to the floor, as needed.

6. Assess all lines, drains and tubes:
a) Assess type, placement, patency, amount and type of drainage and amount of suction (as applicable)
b) Do not move nasogastric (NG) tubes placed for gastric surgery without a physician order
c) Maintain any continuous irrigations initiated in OR.

7. Assess condition and location of dressings and type and amount of drainage.
a) Reinforce or change dressing per surgeon's order.

8. Neurologic system:
a) Assess level of consciousness
b) Assess movement of extremities
c) Determine dermatome level of block for patients who have received spinal/epidural anesthesia by assessing level of sensation.
i. For patients who have received interscalene, supraclavicular, infraclavicular or cervical plexus blocks:
1) Observe for Horner's Syndrome, as evidenced by facial flushing, constricted pupil, ptosis and congestion on side of block.
ii. Notify anesthesiologist of a block T4 or higher.
iii. Notify anesthesiologist of an ascending block.
d) Assess pupils as indicated by surgical intervention.

9. Cardiovascular system:
a) Obtain baseline cardiac rhythm strip
b) All Phase I patients shall have continuous cardiac monitoring in lead II.

i. For patients receiving local anesthesia, cardiac monitoring is not required unless otherwise ordered.

c) Assess heart sounds, peripheral circulation, capillary refill, and skin temperature and color as indicated by surgical intervention or patient's past medical history.

d) Invasive lines: pulmonary artery catheters/cardiac output, central venous pressure, or arterial catheters, refer to Standards of Patient care.

10. Temperature regulation:
    a) Obtain temperature (temporal artery)
        i. Temp <36°C initiate warming with Bair Paws forced air warming unit
        ii. Temp <35°C initiate warming with Bair Paws forced air warming unit
        iii. Temp <34°C initiate warming withBair Paws forced air warming unit , warmed IV solutions via fluid warmers, heated aerosol for O_2 delivery and place warm blankets around head, neck, and shoulders. Notify anesthesia.
        iv. Temp >37.2°C (99°F) remove extra linens using only one light cover.
    b) Monitor temperature every 15 minutes while active rewarming.
    c) Notify anesthesiologist for shivering not readily controlled with warming interventions and anticipate order for Meperidine.
        i. Continue supplemental O_2 when temperature elevated or decreased and shivering present.
11. Pain management:
    a) See PCS Policy Pain Management
12. Gastrointestinal system:
    a) Assess for bowel sounds in all four quadrants
    b) Assess for nausea/vomiting
        i. Encourage deep breathing, monitor BP and treat hypotension.
        ii. Turn patient to side if vomiting, suction if necessary and provide oral care.
13. Integumentary system:
    a) Complete a head to toe skin assessment
    b) Position for comfort, straighten linens and change if soiled/wet, and activate air mattress pumps (as needed).
    c) Maintain proper body alignment, place effected extremity in proper position
    d) Check for properly fitted appliances, casts, splints, CPM, pneumatic compression stockings as indicated.
14. Complete additional surgery/procedure specific assessments as indicated.

D. **DOCUMENTATION OF ADMISSION ASSESSMENT:**

1. Complete the following sections of Cerner iView, as applicable:
    a) PACU Arrival information
    b) Vital signs (including temperature)
    c) Safety Checks
    d) OR Intake and Output
    e) IV Drips
    f) Pain Assessment and Interventions
        i. Document acceptable pain number, pain tool used, pain level, location, laterality, quality, time pattern and aggravating factors
    g) Peripheral IV
    h) Aldrete I Assessment
    i) Artificial airway
    j) Head-to-Toe Assessment, as relevant to surgery/procedure and patient condition
    k) Dermatome Assessment
    l) Surgical/Procedural Site
    m) All invasive lines, tubes and drains
    n) Post-Operative Hydration (including nausea, vomiting and hydration status)
    o) Antiembolism Devices

p) Warming/cooling measures
q) Nerve blocks
r) PCA/PCEA
s) Intake and Output
t) Additional elements of assessment as indicated by procedure and anesthesia/sedation type

2. Document all medications given on the eMAR

E. **ONGOING ASSESSMENT:**

1. Vital signs:
   a) Take vital signs (blood pressure, heart rate, respiratory rate, and SpO_2) every five minutes X3 then, if stable, every 15 minutes while in Phase I.
   b) Continuously monitor SpO_2 in Phase I.
   c) Take vital signs every 1 hour, while in Phase II and PRN.
   d) Report abnormal vital signs or SpO_2 not corrected by interventions, abnormal diagnostic tests, pain not relieved by prescribed analgesia or failure to attain discharge score ordered for transfer.
   e) For inpatients, once patient meets PACU discharge criteria, follow surgeon's floor orders for vital signs.
2. Pain management:
   a) Assess, treat and reassess pain per PCS Policy: Pain Management
      i. Provide pillow and instruct patient to splint abdomen when coughing if abdominal incision present.
      ii. Implement Patient Controlled Analgesia (PCA) if ordered and teaching has been completed and documented in EHR
3. Monitor intake and output hourly.
4. Neurologic system:
   a) Complete Aldrete assessment every 15 minutes x4 (or until meets baseline), then hourly.
   b) Assess dermatome level of block hourly for patients receiving spinal/epidural anesthesia.
5. Cardiovascular system:
   a) All patients will have continuous cardiac monitoring in lead II with a baseline rhythm strip obtained and posted in Phase I.
   b) Heart sounds, peripheral circulation, capillary refill, and skin temperature and color will be assessed as indicated by surgical intervention or patients past medical history.
6. Respiratory system:
   a) Monitor airway patency and respiratory rate and effort until patient fully reactive and responsive.
   b) Monitor SpO_2.
      i. Titrate oxygen to maintain SpO_2 at 94% unless otherwise ordered.
      ii. Discontinue O_2 when SpO_2 is above ordered level, breathing pattern and vital signs stable and patient is easily arouseable.
      iii. Monitor for at least 15 minutes after O_2 discontinued before transferring patient.
      iv. Position patient in semifowlers position unless contraindicated.
   c) Retain artificial airways (oral, nasal, or endotracheal tube) until gag and/or cough reflex returns or extubation criteria met.
   d) Encourage deep breathing with "stir up" routine (initially every five minutes, then every fifteen minutes with vital signs).
   e) Encourage patient to cough or suction as needed to clear secretions, improve SpO_2 or increase depth of respirations.
   f) Extubation:
      i. Monitor for thirty minutes following extubation before patient transferred unless patient transferred to Critical Care unit.
7. Temperature regulation:

a) Monitor temperature (temporal artery) hourly if temp was 36°C or greater on admission.
b) If patient temperature was less than 36°C on admission, actively warm and recheck temperature every 15 minutes until temp reaches 36°C or greater, then monitor temperature hourly.

8. Gastrointestinal:
   a) Assess for bowel sounds prior to feeding patient
9. Integumentary system:
   a) Maintain proper body alignment, effected extremity in proper position and reposition at least every two hours for patient who is immobile (post-regional anesthesia).
10. Assess surgical site and any additional elements as indicated by procedure and by changes in condition.
    a) A focused assessment should occur every 15 minutes while in Phase I and every 1 hour while in Phase II and PRN

F. **DOCUMENTATION OF ONGOING ASSESSMENT AND CARE:**

1. Document ongoing assessment in iView in Cerner
   a) Vital signs (including temperature)
   b) Pain assessment
   c) Aldrete assessment
   d) Dermatome level
   e) Intake and output
   f) Additional elements of assessment as indicated by procedure and anesthesia/sedation type
2. Document medications given, time, dose, route and effects on the MAR

G. **DISCHARGE/TRANSFER PROCEDURE AND DOCUMENTATION:**

1. For transfer to an inpatient unit, see PANS Policy: Discharge of Post Anesthesia & Post Sedation Patients to Inpatient Units.
2. For outpatient discharge, see PCS Policy: Standardized Procedure: Discharge from Outpatient Post-Anesthesia Service

H. **RELATED DOCUMENT(S):**

1. ASPAN Standards Phase I & II Recovery

I. **REFERENCE(S)**:

1. American Society of Perianesthesia Nurses. (2014). *Perianesthesia Nursing Standards, Practice Recommendations and Interpretive Statements 2015- 2017.* Cherry Hill, NJ: American Society of Perianesthesia Nurses.
2. American Society of Perianesthesia Nurses. (2014). *A Competency Based Orientation and Credentialing Program for the Registered Nurse in the Perianesthesia Setting.* Cherry Hill, NJ: American Society of Perianesthesia Nurses.
3. Schick, L., & Windle, P. E. (Eds.). (2016). *PeriAnesthesia Nursing Core Curriculum: Preprocedure, Phase I and Phase II PACU Nursing* (3rd ed.). St. Louis, MO: Elsevier.

TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A SPECIAL MEETING
OF THE BOARD OF DIRECTORS

January 30, 2025 – 1:30 o'clock p.m.

A Special Meeting of the Board of Directors of Tri-City Healthcare District was held at 1:30 p.m. on January 30, 2025.

The following Directors constituting a quorum of the Board of Directors were present:

Director Sheila D. Brown
Director Rocky J. Chavez
Director Nina Chaya
Director George W. Coulter
Director Gigi S. Gleason
Director Adela Sanchez
Director Tracy M. Younger

Also present were:

Dr. Gene Ma, Chief Executive Officer
Jeremy Raimo, Chief Operations Officer
Janice Gurley, Chief Financial Officer
Henry Showah, M.D., Chief of Staff
Jeff Scott, Board Counsel
Teri Donnellan, Executive Assistant

1. The Chairperson, Director Tracy M. Younger. called the meeting to order at 1:30 p.m. with attendance as listed above.

2. Approval of Agenda

   It was moved by Director Gleason and seconded by Director Brown to approve the agenda as presented. The motion passed unanimously (7-0).

3. Oral Announcement of Items to be discussed during Closed Session

   Chairperson Younger made an oral announcement of the items listed on the January 30, 2025 Special Board of Directors Meeting Agenda to be discussed during Closed Session which included Reports Involving Trade Secrets, one matter of Potential Litigation, one matter of Existing Litigation and Public Employee: Salaries and Benefits.

6. Motion to go into Closed Session

   It was moved by Director Chavez and seconded by Director Gleason to go into Closed Session at 1:32 p.m. The motion passed unanimously (7-0).

7. At 3:30 p.m. the Board adjourned to Open Session with attendance as previously noted.

8. Report from Board Counsel on any action taken in Closed Session.

   Board Counsel Scott stated the Board met in Closed Session and heard Reports Involving Trade Secrets and took no action.

Board Counsel Scott also stated the Board will be returning to Closed Session following the Regular Board meeting to complete unfinished business.

9. At 4:25 p.m. the Board returned to Closed Session with attendance as previously noted, with the exception of Director Gleason, Janice Gurley, Chief Financial Officer and Henry Showah, M.D., Chief of Staff.

10. At 5:10 p.m. the Board adjourned to Open Session with attendance as previously noted.

11. Report from Board Counsel on any action taken in Closed Session.

Board Counsel Scott stated the Board in Closed Session discussed a Potential Litigation Matter and directed staff to take appropriate action concerning the potential litigation matter.

The Board also discussed the Medical Acquisitions Bankruptcy matter and took no action.

Lastly, the Board discussed Public Employee Negotiations and directed the CEO to take appropriate action.

12. Adjournment

There being no further business, Chairperson Younger adjourned the meeting at 5:15 p.m.

_____
Tracy M. Younger
Chairperson

ATTEST:

_____
Adela I. Sanchez
Secretary

TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A REGULAR MEETING
OF THE BOARD OF DIRECTORS
January 30, 2025 – 3:30 o'clock p.m.

A Regular Meeting of the Board of Directors of Tri-City Healthcare District was held at 3:30 p.m. on January 30, 2025.

The following Directors constituting a quorum of the Board of Directors were present:

Director Sheila D. Brown
Director Rocky Chavez
Director Nina Chaya, M.D.
Director George W. Coulter
Director Gigi Gleason
Director Adela Sanchez
Director Tracy M. Younger

Also present were:

Dr. Gene Ma, Chief Executive Officer
Donald Dawkins, Chief Nurse Executive
Jeremy Raimo, Chief Operating Officer
Janice Gurley, Chief Financial Officer
Mark Albright, Chief Information Officer
Jeff Scott, Board Counsel
Teri Donnellan, Executive Assistant

1. Chairperson Younger called the meeting to order at 3:30 p.m. with attendance as listed above.

2. Report from Closed Session

   Board Counsel Jeff Scott reported the Board in Closed Session discussed matters regarding Trade Secrets and took no action. Board Counsel Scott also reported the Board would be returning to Closed Session at the conclusion of Open Session to conduct unfinished business.

3. Pledge of Allegiance

   Director Younger led the Pledge of Allegiance.

4. Approval of Agenda

   Board Chairperson Younger stated agenda item 8b) Consideration to approve the 2024-2025 Risk Management Plan will be deferred to next month's meeting.

   It was moved by Director Gleason and seconded by Director Brown to approve the agenda as amended. The motion passed unanimously (7-0).

5. Public Comments – Announcement

Chairperson Younger read the Public Comments section listed on the January 30, 2025 Regular Board of Directors Meeting Agenda.

6. Special Presentation

a) Patient Experience

A touching video entitled *"I Am Tri-City"* was presented that showed clips from grateful patients and dedicated staff.

Chairperson Younger recognized Jeanne Sinclair who spoke regarding her wonderful care.

7. December, 2024 Financial Statements – Janice Gurley, Chief Financial Officer

Janice Gurley, CFO reported on the current and fiscal year to date financials as follows (Dollars in Thousands):

- Net Operating Revenue – $162,752
- Operating Expense – $169,181
- EBITDA – $8,377
- EROE – ($715)

Janice reported on the fiscal year to date Key Indicators as follows:

- Average Daily Census – 123
- Adjusted Patient Days – 40,767
- Surgery Cases – 2,723
- ED Visits – 23,726

Janice reported on the current month financials as follows (Dollars in Thousands):

- Net Operating Revenue – $27,505
- Operating Expense – $28,103
- EBITDA – $1,546
- EROE – ($3)

Janice reported on the current month Key Indicators as follows:

- Average Daily Census – 136
- Adjusted Patient Days – 7,341
- Surgery Cases – 443
- ED Visits – 4,251

Janice also presented graphs including Average Length of Stay, Paid Full Time Equivalents per Adjusted Occupied Bed and Emergency Department Visits, all of which are trending in the right direction.

8 New Business

a) Affiliation Update – Juniper Advisory Services

Dr. Gene Ma, CEO welcomed and introduced the Juniper Advisory team, Chris Benson, Casey Webb, Alex Norton and Nina Leutz who presented the directionality of our next steps for a long-term partnership.

Juniper Advisory specializes in assisting hospitals with exploring partnerships, ensuring alignment with the organization's priorities. Chris Benson provided an update on past and upcoming work, outlining a structured four-part presentation.

Key points included:

- **Process Overview:** Started in December and continues through the end of the year.
- **Review of Timelines & Objectives:** Focus on partnership goals as identified by Board members, leadership, and clinicians.
- **Philosophy & Approach:** Ensuring alignment with potential partners.
- **Next Steps:** Two-phase process—first, understanding potential partners' interests; second, selecting partners based on shared vision.

No action was taken.

b) Consideration to approve the 2024-2025 Risk Management Plan - *Deferred*

c) Consideration to approve the Subscription Agreement with DISC Surgery Center of Carlsbad, LLC

Jeremy presented a proposal for the District to expand a significant partnership with DISC Surgery Center of Carlsbad, which aims to be San Diego's premier surgery center. The District has an opportunity to subscribe to a 6% stake in the Ambulatory Surgery Center for $552,000. Beyond financial investment, the partnership offers extensive collaboration in clinical care delivery, supply chain, and spine care excellence, positioning it as a valuable opportunity for the District.

Hearing no questions or comments,

It was moved by Director Gleason to approve the Subscription Agreement with DISC Surgery Center of Carlsbad, LLC. Director Brown seconded the motion.

The vote on the motion via a roll call vote was as follows:

AYES:	**Directors:**	**Brown, Chavez, Chaya, Coulter, Gleason, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**None**

9. Old Business - None

10. Chief of Staff

a. Consideration to approve the January 2025 Credentialing Actions and Reappointments Involving the Medical Staff as recommended by the Medical Executive Committee on January 27, 2025.

Dr. Henry Showah, Chief of Staff presented the January 2025 Credentialing Action and Reappointments.

It was moved by Director Chaya to approve the January 2025 Credentialing Actions and Reappointments Involving the Medical Staff as recommended by the Medical Executive Committee on January 27, 2025. Director Brown seconded the motion.

The vote on the motion via a roll call vote was as follows:

AYES:	**Directors:**	**Brown, Chavez, Chaya, Coulter, Gleason, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**None**

11. Consideration of Consent Calendar

It was moved by Director Brown to approve the Consent Agenda. Director Gleason seconded the motion.

The vote on the motion via a roll call vote was as follows:

AYES:	**Directors:**	**Brown, Chavez, Chaya, Coulter, Gleason, Sanchez and Younger**
NOES:	**Directors:**	**None**
ABSTAIN:	**Directors:**	**None**
ABSENT:	**Directors:**	**None**

13. Discussion of items pulled from Consent Calendar

There were no items pulled from the Consent Calendar.

14. Comments by Members of the Public

There were no comments by members of the public.

15. Comments by Chief Executive Officer

Dr. Gene Ma, Chief Executive Officer did not have any comments.

16. Board Communications

Director Sanchez shared her enthusiasm after touring the new DISC facility, expressing how impressed she was. She noted Dr. Bray's excitement about serving the community in the new space.

Chairperson Younger thanked speaker Jeanne Sinclair for her kind thoughts and comments related to her care.

17. Adjournment

There being no further business, Chairperson Younger adjourned the meeting to Closed Session at 4.30 p.m.

_____
Tracy M. Younger
Chairperson

ATTEST:

_____
Adela I. Sanchez
Secretary

TRI-CITY HEALTHCARE DISTRICT
MINUTES FOR A SPECIAL MEETING
OF THE BOARD OF DIRECTORS

February 19, 2025 – 4:00 o'clock p.m.

A Special Meeting of the Board of Directors of Tri-City Healthcare District was held at 4:00 p.m. on February 19, 2025.

The following Directors constituting a quorum of the Board of Directors were present:

Director Sheila D. Brown
Director Rocky J. Chavez
Director Nina Chaya
Director George W. Coulter
Director Gigi S. Gleason
Director Adela Sanchez
Director Tracy M. Younger

Also present were:

Dr. Gene Ma, Chief Executive Officer
Donald Dawkins, Chief Nurse Executive
Jeremy Raimo, Chief Operations Officer
Roger Cortez, Chief Compliance Officer
Janice Gurley, Chief Financial Officer
Mark Albright, Chief Information Officer
Henry Showah, M.D., Chief of Staff
Eva England, Senior Director, Ancillary Services
Jennifer Paroly, Foundation President
Nandan Prasad, M.D., Quality Medical Director
Heidi Benson, Clinical Quality Manager
Jeff Scott, Board Counsel
Susan Bond, General Counsel
Teri Donnellan, Executive Assistant

1. The Chairperson, Director Tracy M. Younger. called the meeting to order at 4:00 p.m. with attendance as listed above.

2. Approval of Agenda

   It was moved by Director Chavez and seconded by Director Gleason to approve the agenda as presented. The motion passed unanimously (7-0).

3. Oral Announcement of Items to be discussed during Closed Session

   Chairperson Younger made an oral announcement of the item listed on the February 19, 2025 Special Board of Directors Meeting Agenda to be discussed during Closed Session which included Reports of the Hospital Medical Audit or Quality Assurance Committees.

6. Motion to go into Closed Session

It was moved by Director Chavez and seconded by Director Coulter to go into Closed Session at 4:02 p.m. The motion passed unanimously (7-0).

7. At 5:35 p.m. the Board returned to Open Session with attendance as previously noted.

8. Report from Board Counsel on any action taken in Closed Session.

Board Counsel Scott reported the Board heard reports from the Hospital Medical Audit and Quality Assurance Committees and took no action.

9. Adjournment

There being no further business, Chairperson Younger adjourned the meeting at 5:37 p.m.

_____
Tracy M. Younger
Chairperson

ATTEST:

_____
Adela I. Sanchez
Secretary

Tri-City Medical Center

ADVANCED HEALTH CARE FOR YOU

Building Operating Leases
Month Ending January 31, 2025

Lessor	Sq. Ft.	Base Rate per Sq. Ft.		Total Rent per current month	Lease Term Beginning	Ending	Services & Location	Cost Center
6121 Paseo Del Norte, LLC 6128 Paseo Del Norte, Suite 180 Carlsbad, CA 92011 V#83024	Approx 9,552	$3.59	(a)	55,226.36	07/01/17	06/30/27	**OSNC - Carlsbad** 6121 Paseo Del Norte, Suite 200 Carlsbad, CA 92011	7095
Cardiff Investments LLC 2729 Ocean St Carlsbad, CA 92008 V#83204	Approx 10,218	$2.58	(a)	40,553.77	07/01/17	01/31/25	**OSNC - Oceanside** 3905 Waring Road Oceanside, CA 92056	7095
Creek View Medical Assoc 1926 Via Centre Dr. Suite A Vista, CA 92081 V#81981	Approx 6,200	$2.70	(a)	20,594.69	07/01/20	06/30/25	**PCP Clinic Vista** 1926 Via Centre Drive, Ste A Vista, CA 92081	7090
SoCAL Heart Property LLC 1958 Via Centre Drive Vista, Ca 92081 **V#84195**	Approx 4,995	$2.50	(a)	22,565.63	10/01/22	06/30/27	**OSNC - Vista** 1958 Via Centre Drive Vista, Ca 92081	7095
BELLA TIERRA INVESTMENTS, LLC 841 Prudential Dr, Suite 200 Jacksonville, FL 32207 V#84264	Approx 2,460	$2.21	(a)	8,470.06	04/01/23	03/31/25	**La Costa Urology** 3907 Waring Road, Suite 4 Oceanside, CA 92056	7082
Mission Camino LLC 4350 La Jolla Village Drive San Diego, CA 92122 V#83757	Appox 4,508	$1.75	(a)	16,033.56	05/14/21	10/31/31	**Seaside Medical Group** 115 N EL Camino Real, Suite A Oceanside, CA 92058	7094
Nextmed III Owner LLC 6125 Paseo Del Norte, Suite 210 Carlsbad, CA 92011 V#83774	Approx 4,553	$4.00	(a)	25,824.26	09/01/21	08/31/33	**PCP Clinic Cairsbad** 6185 Paseo Del Norte, Suite 100 Carlsbad, CA 92011	7090
500 W Vista Way, LLC & HFT Melrose P O Box 2522 La Jolla, CA 92038 V#81028	Approx 7,374	$1.67	(a)	14,741.97	07/01/21	06/30/26	**Outpatient Behavioral Health** 510 West Vista Way Vista, Ca 92083	7320
OPS Enterprises, LLC 3617 Vista Way, Bldg. 5 Oceanside, Ca 92056 #V81250	Approx 7,000	$4.12	(a)	34,015.00	10/01/22	09/30/25	**North County Oncology Medical Clinic** 3617 Vista Way, Bldg.5 Oceanside, Ca 92056	7086
SCRIPPSVIEW MEDICAL ASSOCIATES P O Box 234296 Encinitas, CA 234296 V#83589	Approx 3,864	$3.45	(a)	14,880.52	06/01/21	05/31/26	**OSNC Encinitas Medical Center** 351 Santa Fe Drive, Suite 351 Encinitas, CA 92023	7095
BELLA TIERRA INVESTMENTS, LLC 841 Prudential Dr, Suite 200 Jacksonville, FL 32207 V#84264	Approx 3,262	$2.21	(a)	11,165.33	05/01/23	06/30/25	**Pulmonary Specialists of NC** 3907 Waring Road, Suite 2 Oceanside, CA 92056	7088
Total				**264,071.15**				

(a) Total Rent includes Base Rent plus property taxes, association fees, insurance, CAM expenses, etc.

Tri-City Medical Center

ADVANCED HEALTH CARE FOR YOU

Education & Travel Expense
Month Ending Janaury 2025

Cost Centers	Description	Invoice #	Amount	Vendor #	Attendees
6171	EDU	11425 EDU	325.00	84537	PRATSCHNER IRENE
6171	CHEMOTHERAPY	11325 EDU	338.82	84538	SHINN KARA
6171	CHEMOTHERAPY	11325 EDU	325.00	84539	BACONG CHRISTIAN
6171	ONS/ONCC	122324 EDU	552.00	84530	GUINTIBANO KARL
6185	ONS/ONCC	122324 EDU	552.00	84531	NGUYEN CASEY
6185	ONS/ONCC	122424 EDU	234.00	84532	OLESON JESSICA
6185	ONS ONC	121624 EDU	552.00	84540	DONDERO BRITTNEY
6185	CEN RECERT	121624 EDU	234.00	84525	THATCHER GLOVINDA
7010	CEN RECERT	121224 EDU	210.00	40750	MCCANN, BARBARA
7320	CCAPP	10825 EDU GRANT	391.00	84527	HERLIHY JEANNE
7320	CBT ANXIETY	10825 EDU GRANT	300.00	84529	WILLIAMS RASHEEDA
7500	TRIMMING KNIVE	10225 EDU	193.95	84528	GUTIERREZ LATINA
8510	PAYROLL LAW	012025 EDU	124.00	84513	LUNA BRENDA

**This report shows reimbursements to employees and Board members in the Education & Travel expense category in excess of $100.00.
**Detailed backup is available from the Finance department upon request.