Washington Management Service (WMS)

Position Description

For assistance completing this form, contact your WMS Coordinator.

Position Information			
Position Title:	Position Number/Object Abbreviation:		
Medical Test Site Survey and Investigation Manager	70041911		
Incumbent's Name (If filled position):	Agency/Division/Unit:		
Lori Eschenbacher	DOH/HSQA/OHSO		
Address Where Position Is Located:	Work Schedule:	Overtime Eligible:	
Home-Based	Part Time 🗌 Full Time 🖂	Yes 🗌 No 🖂	
Supervisor's Name and Title: Kate Fiola, Executive Director, Acute and Continuing Care	Supervisor's Phone: 360-236-2906		

Organizational Structure

Summarize the functions of the position's division/unit and how this position fits into the agency structure (attach an organizational chart).

This position supports the Department's mission to work with others to protect and improve the health of people in the state of Washington.

The Health Systems Quality Assurance (HSQA) division is responsible for oversight of Washington State's health care delivery system which includes licensing and regulating over 463,000 health professionals in 83 health professions and 9,000 facilities. HSQA also works closely with communities and local health partners to build strong health systems and prevention programs across the state to help ensure communities have access to good health care and emergency medical services.

The role of the Office of Health Systems Oversight (OHSO) is to support the department's mission by contributing to safe care for Washingtonians by providing oversight of state licensed and federally regulated clinical and behavioral health entities, and by ensuring they meet applicable standards. We achieve this through timely, comprehensive, consistent, and fair inspections, investigations, providing reports that identify areas of non-compliance with existing regulations and when required, initiate enforcement action to protect the public. We also serve as the contracted agency for Centers for Medicare and Medicaid Services (CMS) for federal enforcement standards. Our vision is to be an effective partner in ensuring health and safe patient care in the community we oversee.

This position reports to the Executive Director of Acute and Continuing Care Section in OHSO. This position uses independent judgment, experience, and knowledge to protect the health and safety of the public by enforcing and assuring compliance with state and federal laws and regulations by overseeing and directs the inspections and investigations of medical testing laboratories. Additionally, this position is one of the principal contacts for the Federal Clinical Laboratory Improvements Act (CLIA) Exempt program approved and administered by CMS.

Position Objective

Describe the position's main purpose, include what the position is required to accomplish and major outcomes produced. Summarize the scope of impact, responsibilities, and how the position supports/contributes to the mission of the organization.

This position is responsible for overseeing and directing statewide Medical Test Site (MTS) survey program and partners with the Office of Community Health Systems (OCHS) Program Manager to administer the ongoing Federal CLIA program as part of the federal exemption granted to the Department.

This position directs and manages the inspection and investigation processes, and promotes and applies the agency's overall mission, priorities, values, and strategic goals both internally and externally. This position applies and interprets



state and federal laws and regulations related to clinical laboratories, monitoring laboratory proficiency testing, and recommending enforcement actions. This position is responsible for planning, organizing, and leading the MTS survey program including assisting in statewide policy for the MTS and Federal CLIA programs.

Assigned Work Activities (Duties and Tasks)

Describe the duties and tasks, and underline the essential functions. Functions listed in this section are primary duties and are fundamental to why the position exists. For more guidance, see <u>Essential Functions Guide</u>.

The management objective of this position is to support the department's mission to protect public health and safety by ensuring timely inspections of over 6,000 state-licensed and federal certified MTSs. This position assists in assuring timely complaint responses, including investigations of alleged violations of law and rule by licensees and regulated entities are conducted.

Support the program consultant in the development of program rules consistent with CLIA regulations, assisting with bill analyses during legislative session and program fiscal information in partnership with MTS program consultant.

Primarily responsible for the survey program aspect for continuing the CMS Federal CLIA exemption process when the exemption period is up for renewal. This includes responding to questions and submitting corresponding documents to CMS for the exemption renewal process and working with the CMS Seattle and Baltimore Offices.

Leads the survey unit including planning, organizing, and controlling the work performed by the unit; assures appropriate and optimum use of the organization's resources and enhances the effectiveness of employees through timely appraisal and professional development opportunities; support effective communications throughout the unit; maintaining the highest standards of personal/professional and ethical conduct and support the state's goals for a diverse workforce.

Directs the responsibilities and activities of at least five (5) Advisory Laboratorian positions assigned to the unit. Works with the Operations Unit to establish performance management standards, expectations, and measurements for unit staff and works to ensure they are met. Holds staff accountable by identifying performance levels and taking action when necessary. Implements development and training plans.

Communicates with all external stakeholders regarding the inspection and investigation program including the public, inter-agency, intra-agency, and state and local government. Provides linkage to professional organizations for agency types licensed by the state.

Monitors and reviews inspection and investigation unit work product (e.g., drafts of Statements of Deficiency, Plans of Correction, critical correspondence, etc.) prior to issuance to ensure quality in terms of compliance with all office protocols as well as consistent application of standards set in law. Coordinates with the program staff in Office of Community Health Systems, Office of Customer Service, and the Office of Investigative and Legal Services as needed, to ensure alignment in applying licensing standards.

<u>Collect and organize all electronic, digital, and paper file materials for purposes of preparing and approving the investigative file to be closed out for archiving or forwarding for enforcement action.</u>

Establishes timelines and makes assignments for inspections and investigation of regulated entities according to state and federal laws, rules, and policies. Ensures timely and complete inspections and investigation of all assigned facilities.

Develops and revises, as necessary, inspection and investigation guidelines and procedures to ensure timely, accurate, and complete inspections or investigations.

Participate in the process for developing the MTS budget and spending plan to include allotment adjustments, allocations, and spending performance.



Ensures inspections and investigations are completed in accordance with agency policies, procedures, and expectations.

Ensures assigned regulated entities are in compliance with state and federal laws and regulations.

Participates in case management teams, assists in assigning priority levels and resources, and contributes to decisions to recommend initiating legal action.

Provides consultation and technical assistance to both internal and external customers and stakeholders relating to regulations, inspections, and investigations.

Provides policy development support to assigned regulated entities, including program support, rules development, development of policies and procedures, and implementation activities.

Supports the vision, mission, and goals of the agency, division, and office.

Accountability – Scope of Control and Influence

This position is critical to ensure inspections and investigations are timely, fair, and effective in identifying and correcting systemic deficiencies that can pose serious risks to patient safety.

This position provides management and oversight of the state inspection and investigation process of licensed MTSs and of the statewide Medical Test Site survey program and the Federal CLIA exemption process.

Management includes the development, implementation, and constant assessment of the procedures and business practices that are used to perform these inspections and investigations. The purpose of these inspection and investigation programs is to protect the public by ensuring the facilities comply with all the state and federal laws and regulations pertaining to patient safety, delivery of care, and CLIA laboratory practices.

This position reviews and provides input to proposed legislation that regulates over 6,000 MTSs.

The scope of this position also includes the interpretation and application of existing policy, and assisting in the formulation, application, and implementation of new policy, as warranted. This position: assesses workload and policy impacts of legislative and regulatory changes; reviews existing agency rules and regulatory practices for possible modification or repeal; serves as a resource for policy formulation, dissemination, explanation, and enforcement of agency policies in dealing with staff and patients; promotes, fosters, trains, and maintains organizational culture and ethics in staff members, to preserve agency role in state inspection and investigation functions, objectivity in decision-making, and preservation of the public safety and health.

This position applies and implements existing department policy through the participation in case management teams determining whether to pursue corrective action in matters involving MTSs regulated by the department.

As the manager of the survey unit, this position is responsible for management and decision-making for the group within office guidelines, including personnel, resources, procedural, and fiscal issues. This position reports to the Executive Director and is responsible for staff assigned to the survey unit. This position helps develop department policy through work with the health programs in determining actions to take, analysis of the regulatory environment, and development of case theories.

Responsible for case management activities related to procedural decisions made while determining the course of inspection and investigation of MTS facilities that are highly complex, visible, or have the potential for substantial impact on departmental policy.

Supports the development of program rules by the MTS program consultant in compliance with Federal CLIA rule updates.

Directs and supervises at least five (5) direct reports classified as Advisory Laboratory positions.



Describe the scope of accountability.

This position must ensure effective regulatory oversight that comprises the core state and federal standards for ensuring safe delivery of clinical care services by over 6,000 MTS facilities. Specifically, the position is responsible for:

- Performance and compliance with the state and federal CLIA laws and regulations regarding state licensed MTSs.
- Monitoring and tracking trends in inspection and investigation activities/performance, identifies issues before problems develop and implements change.
- Recommending unit staffing and budget enhancements to Executive Director for inclusion in agency budget/decision packages; monitoring spending for activities related to assigned facilities.
- Handles highly complex and highly visible issues and issues of state-wide impact.
- Provides input on proposed legislation bill analyses and unit/program fiscal information as requested.
- Participates in the process for developing the office budget and spending plans to include allotment adjustments, allocations, and performance.
- Manages the work activities within the allotted budget of approximately \$1.6 million and spending plans for the
 office consisting of private local fee revenue for maximum return on investment including staffing, expenditures,
 acquisition, and use of resources conforming to agency and division mission. Ensuring unit activities are within
 budgeted funds.
- Ensuring the survey program meets strict CMS CLIA expectations that are inspected annually and reviewed every 4-6 years to retain approval.

This position impacts and develops departmental policy through work with the regulated facilities in determining actions to take, including determination of appropriate thresholds for enforcement action, development of inspection and investigative strategies, and through case management:

- Supervises a team of Advisory Laboratorians responsible for the inspection and investigation of clinical laboratory services provided in state-licensed and CLIA-certified facilities as well as responding to program and public concerns regarding inspection or investigation activities.
- Provides decision-making regarding personnel issues as they arise.
- Supervises initial and routine inspection as well as investigation activities to promote best practices.
- Assesses needs, identifies objectives, and collects and records relevant information for scheduling and assignment of inspection and investigation activities. Prioritizes actions that must occur, and establish communication with affected parties.
- Sets focus of inspection and invesestigations (implement department directives) and suggests new direction as warranted.
- Serves as a resource for policy formulation, dissemination, explanation, and enforcement of agency policies in dealing with staff and patients, report trends, findings, and practice changes to department and associated boards and commissions.
- Manages and directs the personnel, data, and physical resources of the survey unit.
- Acts as an effective communication link and reliable source of information for others. Keeps interested parties informed of changes or new developments and ensures that they receive clear communications.



- Promotes, fosters, trains, and maintains organizational culture and ethics in staff members, to preserve agency role in regulatory functions, objectivity in decision-making, and the preservation of public safety and health.
- Identifies training activities for survey staff.
- Serves as part of the leadership team in the Office of Health Systems Oversight including coordination of efforts between the clinical laboratory facilities inspection and investigation unit to ensure consistency between management, fiscal, and supervisory practices are maintained.
- Participates in the strategic planning and performance management process through:
 - Reporting unit effectiveness to the Executive Director;
 - Directing the assigned unit's accomplishments of agency, division, and office goals and objectives, and reporting results; and
 - Participating in process improvement activities related to the division and office.
- Participates in emergency preparedness activities as needed in the event of an emergency.
- Actions to be taken to the Executive Director, OHSO Director, or Deputy Director and other senior managers for decisions include policy issues that involve multiple facilities, professions, agencies, political bodies, or those that generate a high media profile.

Describe the potential impact of error or consequence of error (impacts unit, division, agency, state).

Failure to effectively manage the inspection and investigation of assigned facilities to ensure they are safe, would have a direct negative impact on the quality of life of the thousands of Washington citizens who partake in the services on a regular basis. Specific potential impacts include:

- <u>Office</u>: Inefficiency/poor use of resources, morale issues, failure to conduct timely inspections of facilities and investigations of complaints may jeopardize the health and safety of the public.
- <u>Office, Division, Agency, and WA State</u>: Errors may result in charges of constitutional rights violations, and inappropriately restricting access to health care. The decisions influenced or directed by this position may generate expensive litigation.
- <u>Agency</u>: Legal liability for failure to follow due process in enforcement actions, licensing inspection, or administrative procedures where enforcement actions do not match accepted standards.
- <u>WA State</u>: Public health and patient safety may be jeopardized by unsafe health delivery services, mismanagement of financial trust, and loss of trust with public and regulated oversight.
- Failure to meet agency and federal performance measures and legal mandates by not inspecting and investigating medical test sites could result in the reduction or elimination of federal CMS CLIA exemption status and decertification as federal agent for these inspections.
- Endanger and compromise state residents' public health and safety by not ensuring compliance with state and federal laws and regulations.
- Failure to meet agency performance measures and legal mandates by not inspecting and investigating regulated facilities.

Financial Dimensions

Describe the type and annual amount of all monies that the position directly controls. Identify other revenue sources managed by the position and what type of influence/impact it has over those sources.



Operating budget controlled.

• Responsible for managing implementation of spending plans for funds allocated in the biennium budget of approximately \$1.6 million from licensure fees for state licensed MTSs.

Other financial influences/impacts.

Supervisory Responsibilities

Supervisory Position: Yes No I If **yes**, list total full time equivalents (FTE's) managed and highest position title.

Five (5) full-time Advisory Laboratorian FTEs.

Decision Making and Policy Impact

Explain the position's policy impact (applying, developing or determining how the agency will implement).

Responsible for developing a plan to meet state requirements for inspections of approximately 6,000 facilities. Agency representative for assuring the state MTS Survey Program complies with the Federal CLIA exemption requirements. Specifically, establishes and administers the procedures and protocols for performing the inspections and investigations of assigned types of facilities. Also contributes to any rulemaking process whereby licensing standards for facilities are established.

Is the position responsible for making significant recommendations due to expertise or knowledge? If yes, provide examples of the types of recommendations made and to whom.

This position determines whether facilities are complying with federal and state laws and regulations. This position will review and determine if a facility is out of compliance and whether it should be allowed to submit a plan of correction that would bring it into compliance. This position also consults with the Executive Director to determine if immediate corrective action due to the seriousness of a violation will be required.

It is through the position's expertise and experience that these decisions are made. An example would be being able to distinguish whether a practice in a facility was the standard healthcare laboratory practice applied by many facilities even though it might not be a technical violation of the law.

This position makes recommendations based on knowledge related to laboratory practices in the community and clinical health care systems.

As state representative to the Federal CLIA program, recommends policy, guideline, and regulatory language relevant to the continuing implementation of the Federal CLIA Exemption program.

Explain the major decision-making responsibilities this position has full authority to make.

Authority to design and implement work plans for assigned staff and administrative matters. Reviews unit performance and accomplishments compared to agency, division, and office performance goals and standards. Designs and implements change when unit performance fails to meet agency, division, and office goals or standards. Authority to contribute to the content and form of inspection reports and documentation for MTSs. Decides approach and methods for communicating and building relationships with MTSs and the public.

Describe whether decisions are of a tactical or strategic nature and how decisions are made. For example, is there known precedent, is it somewhat unfamiliar, or unknown and unexplored?



Proposes, recommends, and implements tactical and strategic decisions pertaining to inspections and investigation of MTSs based upon knowledge, experience, risk of harm, and regulatory familiarity. Evaluates/analyzes existing and potential legal/regulatory changes to determine fiscal and staffing resource needs and prepares long range needs assessment and recommends alternative solutions for MTS compliance oversight. Employs agency policy and directives to tactically implement staff assignments and budgetary oversight of assigned resources for assigned facility types. Identifies current trends in the delivery of healthcare, new technologies, and demands by the public to develop new practice procedures regarding the inspections and investigations within MTSs. This strategic planning also considers the need for future staffing to accomplish the mission.

What are the risks or consequences of the recommendations or decisions?

- The decisions and recommendations made by this position affect the outcomes in individual cases where access to an unsafe laboratory could result in patient harm.
- The decisions and recommendations also affect future health care facilities by establishing policies and procedures that will govern their licensing and enforcement action.
- Failure to make informed, evidence-based decisions could result in immediate harm to patients due to unsafe facilities, reduced access to care due to untimely licensing activities, and an overall decline in the quality of health care provided to the public.
- Errors in facility licensing or enforcement decisions may result in charges of constitutional rights violations, and inappropriately restricting access to health care. The decisions influenced or directed by this position may generate expensive litigation.
- Failure to meet agency and federal performance measures and legal mandates by not inspecting and investigating medical test sites appropriately could result in the reduction or elimination of federal CMS CLIA exemption status and decertification as a federal agent for these inspections.

Qualifications - Knowledge, Skills, and Abilities

List the education, experience, licenses, certifications, and competencies.

Required Education, Experience, and Competencies.

Experience defined below may have been gained through lived experience, volunteer experience, professional paid experience, or a combination of experience and education.

Option 1: Ten (10) or more years of clinical laboratory experience in high complexity testing in settings such as: hospital laboratory, clinical laboratory, or industrial medical laboratory which includes four (4) years of supervisory, consultative, or surveying experience. (Clinical laboratory experience includes: Immunohematology (Transfusion Services), Chemistry, Hematology, Microbiology, Diagnostic Immunology, and/or Cytogenetics).

AND

National certification as a Medical Technologist (MT), Clinical Laboratory Scientist (CLS) or a Medical Laboratory Scientist (MLS) with American Society of Clinical Pathologists (ASCP), National Certification Agency for Medical Laboratory Personnel (NCA), American Medical Technologists (AMT), or equivalent nationally recognized certification agency.

OR

Option 2: A bachelor's degree in laboratory science, biology, microbiology, chemistry, medical technology, or a closely related field; **AND** six (6) years of clinical laboratory experience, which includes four (4) years of supervisory experience in high complexity laboratory setting. (Clinical laboratory experience includes: Immunohematology (Transfusion Services), Chemistry, Hematology, Microbiology, Diagnostic Immunology, and/or Cytogenetics.)



AND

National certification as a Medical Technologist (MT), Clinical Laboratory Scientist (CLS) or a Medical Laboratory Scientist (MLS) with American Society of Clinical Pathologists (ASCP), National Certification Agency for Medical Laboratory Personnel (NCA), American Medical Technologists (AMT), or equivalent nationally recognized certification agency.

OR

Option 3: A master's degree in laboratory science, biology, microbiology, chemistry, medical technology, or a closely related field; **AND** four (4) years of clinical laboratory experience, which includes four (4) years of supervisory experience in high complexity laboratory setting. (Clinical laboratory experience includes: Immunohematology (Transfusion Services), Chemistry, Hematology, Microbiology, Diagnostic Immunology, and/or Cytogenetics.)

AND

National certification as a Medical Technologist (MT), Clinical Laboratory Scientist (CLS) or a Medical Laboratory Scientist (MLS) with American Society of Clinical Pathologists (ASCP), National Certification Agency for Medical Laboratory Personnel (NCA), American Medical Technologists (AMT), or equivalent nationally recognized certification agency.

All options must include laboratory experience evaluating: principles, practices, techniques and procedures of clinical laboratory work in laboratory specialties such as Immunohematology (Transfusion Services), Chemistry, Hematology, Microbiology, Diagnostic Immunology, and/or Cytogenetics according to state and federal CLIA certification laws, rules, and regulations.

Key Competencies:

Achievement Orientation - Adds value through personal contribution, technical knowledge, and group achievements.

Analysis and Problem Solving - Demonstrates ability to identify problems and address them by designing effective solutions.

Attracts Top Talent – Attracting and selecting the best talent to meet current and future business needs.

Balances interested parties – Anticipating and balancing the needs of multiple internal and external interested parties.

Being Resilient – Rebounding from setbacks and adversity when facing difficult situations.

Builds Effective Teams – Building strong-identity teams that apply their diverse skills and perspectives to achieve common goals.

Collaborates - Building partnerships and working collaboratively with others to meet shared objectives.

Communication - Delivers accessible communications (written, oral, and visual) that convey a clear understanding of the unique needs of different audiences.

Cultural Humility - Models and facilitates the development and integration of diverse perspectives through learning about and honoring the different cultures represented in the agency.

Customer and Public Service Orientation - Consistently demonstrates the commitment and capacity to provide culturally relevant services to customers and the residents of Washington.



Decision Quality – Making good and timely decisions that keep the organization moving forward.

Demonstrates Self-Awareness – Using a combination of feedback and reflection to gain productive insight into personal strengths and weaknesses.

Develops Talent – Developing people to meet both their career goals and the organization's goals.

Directs Work – Providing direction, delegating, and removing obstacles to get work done.

Drives Results - Consistently achieving results, even under tough circumstances.

Ensures Accountability – Holding self and others accountable to meet commitments.

Equity and Inclusion - Removes barriers to accessing shared resources and promotes a culture of equity, social justice, and belonging.

Interpersonal Skills - Adapts to and works effectively with a variety of situations and people.

Leadership - Coaches, inspires, and motivates staff and others to accomplish agency mission.

Manages Conflict – Handling conflict situations effectively, with a minimum of noise.

People Impact Orientation - Applies an outward mindset to their work.

Plans and Aligns – Planning and prioritizing work to meet commitments aligned with organizational goals.

Self-Development – Actively seeking new ways to grow and be challenged using both formal and information development channels.

Stress Tolerance - Ability to work under pressure to meet strict guidelines. Effectively handle and diffuse highly stressful or adverse situations, making good decisions, working calmly and accurately, and helping to calm others.

Technical and Professional Competence - Applies professional and technical knowledge and skills to fulfill job

requirements and models and encourages a commitment to critical thinking.

Preferred/Desired Education, Experience, and Competencies.

- Experience providing consultation or surveying clinical laboratory settings according to state and federal CLIA certification laws, rules, and regulations.
- Knowledge of principles and practice of clinical laboratory enforcement actions including formal and informal administrative actions.
- Knowledge of the federal and state laws regarding operation of clinical laboratory facilities and agencies, clinical laboratory practices, the regulatory standards of six (6) accrediting organizations, the regulatory standards set for all laboratory directors, technical supervisors and all testing personnel working in the clinical laboratory health care settings.
- Experience and competency managing resources and improving performance outcomes in a regulatory, public health, or clinical environment (hospital, nursing, or related profession or facility).
- Ability to assess and evaluate health risks and patient safety/harm and develop management plans.

Special Requirements/Conditions of Employment

List special requirements or conditions of employment beyond the qualifications above.



Due to the sensitive nature of work involving vulnerable individuals through facility oversight activities, this position is subject to passing a criminal history background check prior to employment.

Working Conditions		
Work Setting, including hazards:	Although the position's work requires regular in-person attendance to perform duties at various locations throughout Washington state, the official duty station for this position is home-based. When not traveling for work, the incumbent may work from home, from a DOH facility, or work remotely from an alternate location. This management position would be expected to be available to go on-site- to facilities throughout the state. Exposure to hazards may include but not limited to those found in mobile, home, DOH office, or health care facility environments. Duties require moving objects weighing up to 30 lbs.	
Schedule (i.e., hours and days):	Standard business hours are Monday – Friday from 8 a.m. to 5 p.m., but the incumbent may be expected to adjust the work schedule to meet business needs. May need to work more than 40 hours per week to meet critical deadlines or address workload peaks. May be asked to work Holidays and weekends. A flexible work schedule may be considered at the incumbent's request, subject to supervisory approval.	
Travel Requirements:	Regular travel will be required as needed. When traveling for work, incumbent may travel alone or with another person, may stay overnight, or for several days and nights, in/or out of state to perform the functions of the position including but not limited to on-site investigations of facilities. When driving for state business, the incumbent must be able to legally operate a state or privately-owned vehicle; OR provide alternative transportation while on state business.	
Tools and Equipment:	Duties require the use of standard office furniture and equipment and other communication devices (e.g., desk, filing cabinet, computer, printer, telephone, fax machine, copy machine, etc.) to input data into state and federal databases related to work activities and communicate verbally and in writing with others.	
Customer Relations:	Frequent contact (likely daily) with facilities, patients, or complainants, including some contact with those who may be angry, distraught, or frustrated. Presentations to industry associations, onsite with assigned facilities, and phone interface with facility staff and patients. Contact with other state, federal, CMS, other agency staff, or external customers may be required.	
Other:	The DOH campus is smoke-free, drug-free, alcohol-free, scent-neutral environment.	

Acknowledgement of Position Description

The signatures below indicate that the job duties as defined above are an accurate reflection of the work performed by this position.

Date: 01/09/2025	Supervisor's Signature (required): /s/Katie Fiola, Executive Director	
Date: 1/22/25	Appointing Authority's Name and Title: Jonnita Thompson, Deputy Assistant Secretary, HSQA Signature (required): /s/Jonnita Thompson	
As the incumbent in this position, I have received a copy of this position description.		
Date:	Employee's Signature:	

Position details and related actions taken by Human Resources will be reflected on the Position Evaluation Summary form.

