

EHL Laboratory Quality Systems Manager

Requisition	41204
PCN(s)	18-7503
Working Title	Quality Manager
Job Class Title	Laboratory Quality Systems Manager
Division	Environmental Health
City/Location	Anchorage

NOTE: This document is **NOT a mechanism to apply, it just has more information than online. All applicants must follow the instructions in the official posting at:**

[https://www.governmentjobs.com/careers/alaska/jobs/4143728/quality-systems-manager-pcn-187503?location\[0\]=anchorage&department\[0\]=Environmental%20Conservation&sort=PositionTitle%7CAscending&pagetype=jobOpportunitiesJobs](https://www.governmentjobs.com/careers/alaska/jobs/4143728/quality-systems-manager-pcn-187503?location[0]=anchorage&department[0]=Environmental%20Conservation&sort=PositionTitle%7CAscending&pagetype=jobOpportunitiesJobs)

Introduction

The Environmental Health Laboratory (EHL) is seeking applicants for Laboratory Quality Systems Manager.

NOTE: This position is advertised as a Range 20; however, it qualifies for a pay differential to Range 21. Additionally, it has been submitted for a salary evaluation which is pending with unknown expectation of completion.

This is a highly technical position with substantial responsibility reporting directly to the Chief of the EHL. The EHL supports or participates in 7 federal regulatory programs implemented in the State of Alaska for such organizations as Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and National Oceanographic and Atmospheric Administration (NOAA), to name a few. This position is assigned with ensuring that the EHL complies with the quality criteria for each federal and state regulatory programs for which testing is performed and is charged with maintaining and adding to EHL's International Organization for Standardization (ISO) 17025 accreditations.

This position supervises 4 professional staff. This includes 2 Laboratory Certification/Approval Officers, who perform audits to certify/approve external laboratories to perform testing compliant to Alaskan Drinking Water, Marijuana, and Dairy regulatory programs. Also included are 2 staff charged with the bookends of customer service from sample receiving, setting up projects and bottle kits, to review and dissemination of analytical data as a project manager.

Incumbent has independent responsibility for managing the laboratory quality systems, including the quality manual, quality procedures, work instructions, proficiency tests, certifications, accreditations, training, internal and external audits, corrective actions, document control, standard operating procedures, method validation/verifications. The incumbent also participates in preparing federal grant reports, and performs performance evaluation of equipment and personnel, calibrations, and quality review. Additionally, this position is responsible for oversight of EHL's Safety, Risk Management, and Emergency Response activities.

This professional position requires exceptional organizational, analytical, and decision-making skills, the ability to perform effectively independently and as part of the management team, excellent written and verbal communication, and strong interpersonal skills. The position is responsible for following the policy and procedures of the State of Alaska, the EHL Quality Management System (including ISO 17025), and federal and state criteria for supported programs to ensure continued compliance and legal defensibility.

Mission & Culture

DEC's mission is to conserve, improve, and protect Alaska's natural resources and environment to enhance the health, safety, economic, and social well-being of Alaskans. Clean water, land, and food are essential to every Alaskan. This position supports DEC's mission by producing legally defensible data to protect our environment and public health, including ensuring safe food and drinking water to Alaskans.

This Quality Manager position is key to client satisfaction and success of testing at the EHL, as well as the Laboratory Certification Program. Ensuring compliance with various federal programs and maintaining ISO accreditation is integral to producing legally defensible regulatory data. Additionally, the health of Alaskans is protected by the oversight of the audits group works to ensure defensible data by drinking water, dairy, and cannabis labs.

Team Benefits

As a valued member of the team, the incumbent will have opportunities for training, a supportive work environment, and to perform work that impacts lives and livelihoods.

Work Environment

The EHL is located in its own building near the U-Med district in Anchorage, Alaska with easy parking, close to public transportation with sidewalks, and access to Far North Bicentennial Park and Campbell Tract trails. The EHL also has bike racks and shower facilities for those that use alternate transportation or lunch time exercise (walk or run).

Desired Competencies

- Attention to Detail: Is thorough when performing work and conscientious about attending to detail.
- Audit Reporting: Knowledge of the principles, practices, and techniques used to report audit findings (criteria, condition, cause, effect, and recommendation).
- Quality Management: Knowledge of the principles, methods, and tools of quality assurance, quality control, and reliability used to ensure that a project, system, or product fulfills requirements and standards.
- Accountability: Holds self and others accountable for measurable high-quality and timely results. Determines objectives and sets priorities for independent daily tasks. Accepts responsibility for own actions and decisions. Complies with established control systems and rules.
- Compliance: Knowledge of procedures for assessing, evaluating, and monitoring programs or projects for compliance with Federal laws, regulations, and guidance.
- Analytical Thinking/Problem Solving: uses a logical, systematic, sequential approach to address problems or opportunities or manage a situation by drawing on one's knowledge and experience base and calling on other references and resources as necessary.
- Self-Management: Sets well-defined and realistic personal goals; displays a high level of initiative, effort, and commitment towards completing assignments in a timely manner; works with minimal supervision; is motivated to achieve; demonstrates responsible behavior.
- Standards: Knowledge of standards that either are compliant with or derived from established standards or guidelines.

- Change Management: Knowledge of change management principles, strategies, and techniques required for effectively planning, implementing, and evaluating change in the organization.

Minimum Qualifications:

A bachelor's degree from an accredited college with a major in chemistry, biology, or microbiology; or a bachelor's degree from an accredited college in a Life Science or Environmental Science that includes at least 16 semester hours of Microbiology or Biology and 16 semester hours of Chemistry;

AND

Four years of professional laboratory experience, two years of which must have been in clinical, microbiological, or environmental analysis in a facility with a Quality Management System.

Special Note:

"A bachelor's degree . . . with a major in" means awarding of the degree and that the completed coursework included 24 semester hours in that major, of which at least 16 semester hours are upper division.

Required Information:

List any documents that applicants must provide as part of their application.

Requirement 1: Cover letter with at least one example for how you possess each of the desired competencies in the posting. This will be used as a writing sample. 1-inch margins, min 12 pt font, max 6 pages.

Requirement 2: To demonstrate the required education, please attach transcripts, unofficial are acceptable.

Additional Required Information:

List any additional documents that applicants must bring at the time of interview.

Requirement 1: Three (3) professional references

Requirement 2: Last two (2) performance evaluations. Supervisor letter of recommendation may be used as a substitute if evaluations are unavailable.

Special Notice:

List specific notices or requirements for the position that an applicant must be aware of before applying. If applicable.

Special Notice 1: Please review Job Class Specifications at:
<https://www.governmentjobs.com/careers/alaska/classspecs/891063?keywords=laboratory%20quality%20systems%20manager&pagetype=classSpecifications>

Special Notice 2: Occasional (1-2 times per year) out of state travel expected.

Special Notice 3: This position may participate in an on-call rotation to respond to notifications and alarms from the building after hours and on weekends and will receive stand-by pay when assigned.

Special Notice 4: Please review the attached Position Description below, starting page 5.

Supplemental Questions:

Q1: Please describe your experience working in a laboratory (beyond coursework) in more detail than what is in your resume. How are you qualified for this position?

Q2: Please describe your experience following regulations, regulatory methods, and quality systems including your experience with ISO 17025, if any.

Q3: Please describe how you manage your time to account for shifting priorities in a fast-paced environment.

Q4: Please describe your experience supervising professional staff.



STATE OF ALASKA

Position Description

Class Title:
Laboratory Quality Systems
Manager

**Position Control
Number (PCN): 187503**

Recruitment Type: Normal

1. Position Control Information			
Class Title: Laboratory Quality Systems Manager	Title Code: PG0746	Grade: 20	
	Salary Schedule:	200	
Bargaining Unit: Supervisory Unit	Bargaining Unit Code:	SS	
Department: Environmental Conservation	Department Number:	18	
Division: Environmental Health			
Region/Section/Unit: Environmental Health Laboratory			
Location: Anchorage	Location Code:	EBA	
Time Class: Full Time/OMB Authorized	Seasonal Code:	FR - Full time regular	Time Class Code: FACL
FLSA Exempt: Yes	Strike Class:	3	
Position requires the incumbent to possess a Commercial Driver's License (CDL), to maintain registration with the federal CDL Drug & Alcohol Testing Clearinghouse, and to provide consent to the Employer to review driver information in accordance with 49 CFR 382:			No
Position requires possession of, or access to, firearms or ammunition:			No
Home Unit: ZEHL			
AKPAY Organizational Routing Code: 18010106			
Labor Distribution Code (LDP): N/A			
Physical Work Address: 5251 Dr. Martin Luther King Jr Ave, Anchorage			
Work Phone: 907-375-7799			
Supervisor Information			
PCN: 187306 Title: Chief, Environmental Health Laboratories			
Physical Work Address: 5251 Dr MLK Jr Ave Anchorage			
Work Phone: 907-375-8206			

Type of Action:	Update
Effective Date:	04/14/2023
Division of Personnel Section:	Classification
Reviewed By:	Carlos Meda Frias, Human Resource Consultant 1, on 04/14/2023
Approved By:	Carlos Meda Frias, Human Resource Consultant 1, on 04/14/2023
Closed out by:	Sandra Tagaban, Human Resource Technician 2, on 04/17/2023

2. Duties

2.1. In one or two sentences, state the main purpose of the position.

The incumbent for this Quality Systems Program Manager position oversees Alaska State Environmental Health Laboratory (ASEHL) compliance to federal certification agencies, currently six, requirements/standards as well as to ISO 17025 standards for quality management and competence of testing and calibration for laboratories. This position supervises the Regulatory Section of the ASEHL which consists of EPA Drinking Water and FDA Dairy, includes testing laboratories within and outside the Alaska, as well as Marijuana testing laboratories within Alaska. This position also manages the Quality Plan for the ASEHL, acts as Risk Manager, Safety Officer, and Emergency Response Manager, and functions as the Acting Laboratory Chief in his/her absence.

2.2. Starting from the most to the least important, list the functional areas assigned to the position. Within each functional area, describe the duty statement associated; estimate the percentage of time spent performing the duties; and define each area as essential (E) or marginal (M).

Functional Area Title: Quality Systems Management		
E/M	% of Time	Duty Statement
E	50 %	<p>Reviews, revises, updates and controls the Quality Procedures or policies of the Quality Plan by leading, managing and performing regular reviews of Quality Control (QC) and Quality Assurance (QA) records and random, regular and focused technical audits of staff training and laboratory processes. Results are reported to the Section Supervisors and Chief, Laboratory Services.</p> <p>The incumbent presents and discusses the laboratory Quality Policy Statement with all incoming personnel. Provides refresher training in Quality Policies to all laboratory staff. This position also prepares and presents Quality Moments (training) at EHL All Staff meetings and coordinates annual ethics training for all staff in the ASEHL building.</p> <p>Approves and maintains the Standard Operating Procedures (SOP) for all testing procedures that provide decision-making data for programs department wide. The incumbent assures each SOP meets specific formatting, validation, and ASEHL intranet posting requirements. The incumbent is also responsible for maintenance of the QA files on the laboratory network drive, which includes all working documents utilized for staff for updating SOPs or operational processes.</p> <p>Coordinates implementation and maintenance of conformance to the Quality Procedures, Technical Procedures, Administrative Procedures, and Work Instructions. Monitors the nonconformance process and assures corrective/preventive actions take place for all errors, accidents, or near misses per the Quality Plan. Reviews and approves, if appropriate, any deviations to existing procedures. Investigates all customer complaints and assures documented corrective actions are taken.</p> <p>In conjunction with the Chief, Laboratory Services and Technical Service Supervisors, coordinates the laboratory's validation and verification processes for new certified procedures, as well as instrument implementation plans. This is done by conformance to standard requirements specified by national accrediting agencies or standards of practice.</p> <p>Solicits and addresses recommendations/inputs from supervisory peers and makes QA/QC decisions based on the improvement or developmental needs of the laboratory.</p> <p>Oversees the document control process for the ASEHL, by advising proper identification, filing, retrieval, and archival processes identified by the Quality Plan or controlling agencies. Distributes and controls all QP documents.</p> <p>Oversees the equipment maintenance process as stated in the Quality Plan by overseeing</p>

and providing technical guidance to staff in creating, maintaining, and auditing manual and electronic monitoring systems for the proper maintenance of laboratory equipment specified by accrediting agencies or equipment manufacturers.

Oversees the proficiency testing program for all analysts within the ASEHL and evaluates results.

In conjunction with the Laboratory Chief, evaluates trends and recommends corrective actions to fulfill the requirements of "process improvement".

Coordinates with the Maintenance Specialist on maintaining laboratory facility equipment in accordance with published standards by certifying agencies.

Functional Area Title: Regulatory Programs

E/M	% of Time	Duty Statement
E	30 %	<p>The incumbent is responsible for the ASEHL Regulatory Operations Section which manages 3 laboratory approval programs. In conjunction with the Chief, ASEHL, this manager oversees the EPA Drinking Water certification program which certifies private laboratories throughout and outside Alaska to test drinking water samples from Public Water Systems for chemical and microorganisms, the FDA Dairy approval program approve screening laboratories for raw milk, and reviews and provides recommendation to the Alcohol Marijuana Control Office (AMCO) for commercial labs testing cannabis samples for chemistry and microbial contaminants.</p> <p>The incumbent takes appropriate supervisory actions to include evaluating and correcting performance deficiencies. Prepares performance evaluations and reviews goals, expectations, and development plans prepared by subordinate staff. Oversees the professional development of subordinate staff. The incumbent has direct supervision of positions that provide additional quality program support by performing in house audits and participation in Quality section initiatives.</p> <p>The Quality Manager also supervisory oversight and provides technical review for the EPA Drinking Water Certification Officers (CO), the FDA Dairy Laboratory Evaluation Officers (LEO), and coordinates laboratory evaluation activities for the cannabis program. This position must act as or maintain as a backup for one or more of these audit programs. Additionally, oversees the Project Management and Shipping and Receiving activities and maintains a competency in these areas as well.</p> <p>In consultation with all other ASEHL technical and administrative supervisors, prepares all laboratory sections for compliance to Federal and/or Associations published standards, to maintain current laboratory certifications required to maintain state "Primacy." Such standards will include those of the United States Department of Agriculture (USDA), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), and ISO (International Organization for Standardization).</p> <p>Will oversee the ASEHL preparation for certification by American Association of Laboratory Accreditation (A2LA) and compliance to International Organization for Standardization (ISO) standards of 17025 (General requirements for the competence of testing and calibration laboratories, and the AOAC Food Testing Guidelines. ISO certification will become the umbrella that assures all other agency requirements will be met.</p> <p>Participate in various collaborations, workgroups, and stakeholder meetings.</p> <p>Manages ASEHL laboratory accreditations and certifications inspections. The incumbent provides chaperone service for inspectors, from National agencies or ASEHL clients, performing inspections. The incumbent assures ready accessibility to all records, record all copies provided to inspectors, monitor all activities during the inspections, escorts inspectors to secured or controlled/contaminated areas, and issues proper personal safety equipment/clothing.</p>

Functional Area Title: Facility Health, Safety, and Risk Management		
E/M	% of Time	Duty Statement
E	10 %	<p>Acts as risk manager for the Chief, Laboratory Services and ASEHL staff. Ensures the laboratory workplace is maintained and operated in a manner compliant with Occupational Safety Health Administration (OSHA) and Animal Plant Health Inspection Service (APHIS) regulations. This requires the preparation and maintenance of a laboratory Health and Safety Plan to address the known hazards existing in the laboratory and the procedures employed to reduce the threats posed by these hazards.</p> <p>Provides technical assistance to regulated industries, the public, and field offices and administrative offices. Acts as a technical expert in legal proceedings.</p> <p>Monitors and assesses laboratory operations to preclude adverse media coverage, court action and fines, as well as suits by private parties.</p> <p>The Health and Safety Plan also addresses the specific hazards found in the laboratory: use of hazardous chemicals, handling blood borne pathogens, handling compressed gases, and safety requirements when working in a confined space.</p> <p>Coordinates with the Maintenance Specialist on maintaining safety equipment in accordance with published standards by certifying agencies.</p> <p>Responsible for initial and ongoing safety training of all laboratory personnel, interns, and extended stay visitors by providing training on requirements found in the laboratory Health and Safety Plan, and operations of safety equipment.</p> <p>Responsible for maintaining appropriate records of safety training, accidents, and injuries. This includes the mandatory postings of safety records and reports per OSHA and APHIS regulations.</p> <p>Leads all laboratory safety efforts: Periodically Review the Health and Safety Plan, approve training material, address concerns raised by staff and conducts monthly facility inspections.</p> <p>Researches and participates in responses to F.O.I.A. or P.R.R. requests made to the laboratory.</p> <p>May also participate in on-call rotation to response to alarms and notifications from building systems including fire, security, temperature control for samples, testing, and supplies, power, and mechanical systems.</p>

Functional Area Title: Emergency Response		
E/M	% of Time	Duty Statement
E	5 %	<p>In conjunction with the Chief, Laboratory Services, the incumbent is responsible for the creation and maintenance of a disaster plan to address the laboratory's support role with Local, State and Federal agencies, in the event of a manmade or natural disaster. Subsequent presentations to the staff will be conducted to maintain an "active alert status". Maintenance of a current call back roster is the responsibility of this Manager. Contingencies for natural disasters like earthquakes, volcano eruptions, flooding, power failures and fires is included in this plan.</p> <p>In consultation with the Chief, Laboratory Services, the incumbent creates and maintains a bioterrorism plan to support Local, State and Federal agencies, in the event of a bioterrorism event. Guidance from Center for Disease Control (CDC), EPA, and the Alaska Public Health Laboratory is followed and incorporated into the plan. Such items as facilities and personnel,</p>

biological or chemical terrorism agents, and a triage plan are included. This plan also includes but is not limited to the Drinking Water Program Bioterrorism Action Plan overseen by EPA Region 10, the Avian Influenza reporting plan of the National Animal Health Laboratory Network (NAHLN) and the emergency food testing action plan by the Food Emergency Response Network (FERN).

In conjunction with the Chief, Laboratory Services communicates with the U.S. Department of Homeland Security, Federal Bureau of Investigation, and Alaska Department of Homeland Security on security and preparedness issues and grants which affect ASEHL. The incumbent communicates the ASEHL`s security needs to the agencies and ensures that ASEHL meets the current and potential needs of the agencies.

With the Chief, part of the Alaska Public Health Laboratory Sentinel Response contacts and the Quarterly interagency meetings related to items of epidemiological concern.

Functional Area Title: Other Duties

E/M	% of Time	Duty Statement
M	5 %	May be assigned other duties.

Percentage Total: 100%

3. Other Work Details

3.1. List the computer software and hardware used to perform the duties described. Estimate how often each is used (e.g. daily, 2-3 times a week, 1-2 times a month, etc.).

Daily: the incumbent will have quality management responsibility for the Laboratory Information Management System (LIMS) software; Microsoft Office, Word, Excel computer programs.

Weekly: FDA reporting software (NFSDX), computer software used within EH Division; computer software for central monitoring of refrigerators and freezers; computer software that is unique for each instrumentation or procedure.

3.2. List the equipment and materials used to perform the duties described, including machinery, tools, instruments, vehicles, etc. Estimate how often each is used (e.g. daily, 2-3 times a week, 1-2 times a month, etc.).

The incumbent will have quality management responsibilities and exposure for personal protective equipment this list or more on a daily basis; microscopes, centrifuges, biological safety cabinets; chemical fume hoods; diagnostic microbiology equipment; molecular biology devices; pH meters; animal colony cages; immuno-fluorescence readers; tissue homogenizers; tissue washers; vortex mixers; laboratory pure water generation systems; autoclaves; scientific glassware washers; refrigeration and freezing equipment, balances, incubators, water baths, sonicators; pipettors; Biological Safety level 2 requirements; fume hoods; exhaust hoods; handling devices for biohazard waste; label printers; compressed gases; air compressors; toxic solvents storage devices; mice maintenance equipment; safety equipment; micro plate readers; micro plate pipettes; PCR equipment; digestion equipment; HPLC chemistry analyzer; gas chromatography analyzer (GC) with a mass spectrometer (GC-MS); liquid chromatography tandem mass spectrometer (LC-MS-MS); inductively coupled plasma mass spectrometer (ICP-MS); spectrophotometers; cryoscope; dairy related tests kits and reagents; shellfish related test kits and reagents; food and water test kits and reagents; glass microscope slides and cover slips; tissue stains; transport swabs and media; and various media associated with bacteriology.

3.3. List the guides and references regularly used to perform the duties described. Examples include federal and state laws and regulations, professional standards, building codes, trade practices, contracts, and policy and procedure manuals. Explain how and why these guides and references are used. Estimate how often each is used (e.g. daily, 2-3 times a week, 1-2 times a month, etc.).

Daily - Environmental Health Laboratory Quality Plan.

Weekly - general requirements for the competence of testing and calibration laboratories, ISO/IEC 17025; Laboratory Safety Plan; 300+ SOPs/WIs Laboratory Procedure documents.

Monthly - EPA Requirements for Quality Management Plans, EPA QA/R-2; National Shellfish Sanitation Program Model Ordinance, US FDA, Center for Food Safety and Applied Nutrition, Office of Seafood; FDA Bacteriological Analytical Manual; USDA Bacteriological Manual; CFR 7, 9, 21; Association of Analytical Communities; Alaska Statutes and Administrative Codes: 18AAC30, 31, 32, 34, 36, 55 and 90; AS3, 17, 18, 44, and 46, 3AAC306, to include the Cannabis Testing Laboratory Compliance Document; National Shellfish Sanitation Program Manual Part I and II; Federal standards for laboratory analysis; Federal Fair Labor Standards Act; State of Alaska personnel rules and employee contracts; State of Alaska administrative manuals; OSHA requirements for Laboratories 54 CFR 2329-2984; DHSS Safety and Blood Borne Pathogens 29 CFR 1910.1030; Instrument Procedure manuals; DOT and IATA regulations for shipment of diagnostic specimens, infectious specimens and dangerous goods; Berge's Manual of Definitive Microbiology; FDA Food Analysis Manual; Animal Welfare Act of 1966 as amended; Manufacturer's instructions; certification procedures for operation of bio-safety hoods; standards of water QC; municipality rules and regulations

regarding the disposal of infectious waste and chemical reagents into the sewer; division policies and procedures.

3.4. Describe the level of authority and independence the incumbent of the position exercises. List the actions the incumbent takes or the decisions the incumbent makes on a regular basis without obtaining prior approval from a higher level employee. For example, explain how the position has the authority to commit the organization, or any parts thereof, to a course of action.

This position has authority to halt immediately any process or testing that fails to comply with regulations/standards of federal or accrediting agencies. Such failures may have significant impact on the laboratory. The Chief of Laboratory Services will be notified and apprised of the violation(s) as soon as possible. Only the Quality Manager and Chief have the authority to resume operations once the Quality Manager has halted operations.

Prepare comments on federal proposals.

All scientific, technical procedure development and final recommendations for the program.

Accept or reject specimens for laboratory testing of real or suspected biological, chemical, or radiological terrorism.

3.5. Describe the nature of the contacts the incumbent has with other people in order to perform the duties described. Include who is contacted, the reason for the contact, and how often the contact is made.

The Quality Systems Manager will have complete oversight over all supervisors and staff regarding compliance to regulations and standards. Daily consultation, education, and training of all laboratory program staff is essential to this position. Any issue that presents a potential risk to other staff, customers, the Division of Environmental Health, the Department of Environmental Conservation, the public, or the State falls into the area of responsibility of this position.

Contact with accreditation officers and audit personnel of governmental and national/international level agencies through phone, email, one-on-one, and group settings is also integral to this position.

Work cooperatively and effectively with other people at all levels of the department, remain calm under stress, perform a broad range of supervisory responsibilities, and instruct others through organized QA, safety, and ethics training.

3.6. Describe the consequence of an error made by a prudent employee in the performance of the essential functions assigned to the position. What is the consequence of that error to individuals, operations, and programs?

Errors or violations of the Quality Plan in which this person has responsibility may have significant impact and consequences, to include decertification of the laboratory. Fatalities, lawsuits, injuries, and major contaminations may occur.

The importance of operating any laboratory in total and "strict compliance" to the standards of practice defined by a myriad of regulations, standards, organizations, and agencies is paramount. The consequences of "out of control" systems is a huge liability for the State and everyone involved. To preclude such damages relating to public health, environmental health, or political or public ridicule, the Environmental Health Laboratory will operate using the most stringent of standards of Quality Systems Management, those identified by the International Organizations of Standardization (ISO).

Errors will be avoided or minimized by setting the "bar" at this level, the ASEHL will become prepared and

compliant for all standards for which it must comply and eligible for ISO certification. This certification will better enable us to serve our clients and is a testament to the ASEHL's commitment to Quality, in testing, customer support, and operational management. The variability of situations, high level of complexity, exposure to biological and chemical hazards, necessity of rapid and accurate results, and the extreme consequences of error create a high stress atmosphere which distinguishes this laboratory from commercial, independent operations.

This sentinel laboratory, with its mission of certifications and surveillance becomes the State's primary and initial defense of most food and waterborne and zoonotic diseases associated with public health. The success of the ASEHL mission is a direct reflection upon the level and volume of response required by public health responders, once a biological or chemical agent reaches the public.

During a public health emergency, this position may be required to work non-standard hours and may also have to be on stand-by status for an indeterminate amount of time, to identify the source of an outbreak and eliminate spread. It may be necessary for the incumbent to become immunized against virulent agents as vaccines become available.

This position is tasked with ensuring that the risk of potential errors is minimized and that should a potential error occur, that it is documented correctly, communicated clearly to the affected stakeholders and accrediting bodies, and that the lab system responds accordingly to determine root cause and minimize future opportunities for it to occur again.

3.7. List critical requirements of the position not previously described (e.g., skills in keyboarding, writing, negotiating, communications, etc.).

It is paramount that the incumbent of this position possesses the highest level of keyboarding, writing and communication skills possible. Consultation with staff without confrontational episodes will be required.

The incumbent must have good communication skills (both verbal and written) and understand the importance of communicating within division, department, interdepartmental and with the public.

This position requires excellent negotiating skills and the ability to council, direct, and lead employees and settles grievances.

The incumbent must be able to interpret procedures, state and federal regulations, and statutes, and shape program policies to fulfill requirements.

It is important for the incumbent to have good working knowledge of common accounting practices and federal, state, and local laws, policies and procedures pertaining to public health and environmental health laboratory practices.

In depth knowledge of laboratory administration and operations, Quality Management principals, and technical disciplines including marine toxins, microbiology, analytical chemistry, molecular biology, and environmental health. Bench experience performing procedures in these disciplines is required for an operational understanding.

The incumbent must have the ability to plan for and use financial resources efficiently to deliver priority services. Ability to demonstrate leadership skills, including mentoring staff as well as set and meet deadlines, with a strategic use of time to accomplish division and program goals.

The incumbent must be able to develop and carry out the strategic plan for the Environmental Health Laboratory and accomplish the goals as approved by the Divisional Director.

Ability to perform root cause analysis to correct nonconformities and preclude future occurrences.

The incumbent must be able and willing to adjust to changing circumstances and identify and undertake programmatic improvements. Substantial independent scientific and technical judgment is also required.

Knowledge of chemistry, biology, statistical methods, good laboratory practices, and scientific methods and measurements. Extensive knowledge of laboratory techniques and methods of application utilized in one or more scientific testing disciplines.

Knowledge of principles of organization and supervisory practices and techniques. Develop staff, define program priorities, and schedule implementation and completion of program objectives. Ability to establish

and maintain effective working relationships with laboratory staff, department program staff, and persons contacted in the course of work.

Interpretation of procedures, regulations, and statutes, and direct appropriate program-wide actions. Initiate regulatory responses (including product detention or destruction) in response to violation of state or federal law, as well as determining appropriate laboratory procedures.

Ability to communicate effectively, both verbally and in writing. Initiate contact with other local, state or federal agencies.

3.8. List licenses, certifications, registrations, physical or other standards required by state or federal law or regulation to perform the duties described. Cite the specific authority (e.g. law or regulation, such as the OSHA Bloodborne Pathogens Act).

This position requires that the incumbent possess a minimum of 5 years of experience as a supervisor, director, manager or certification officer of a certified environmental health, public health, or private analytic testing laboratory that operates with a Quality Management System preferably with ISO 17025 accreditation.

In addition, 5 years of bench experience working in a laboratory performing similar procedures as the EHL is required. The incumbent should have at a minimum, a Bachelor's degree in a Biological, Chemical, or Medical Technological discipline. A Master's or Ph.D. in any of these related disciplines is not a necessity but a plus. Training as a Certified Quality Auditor or Specialist in Quality Management is a plus in this position. Previous experience as a Laboratory Director, Section supervisor, laboratory manager for High Complexity Testing as defined by CFR 42: Chapter IV, Part 493, Subpart M is a plus but not required.

Knowledge and experience in laboratory management and Quality Management Systems is required. A working knowledge and experience in analytical testing disciplines of marine toxicology, molecular biology, organic and inorganic chemistry, microbiology, and food, water and/or dairy lab procedures is a plus.

The ability to effectively communicate both orally and in writing is essential. Strong diplomatic skills and the ability to handle interpersonal relationships are also required. Long-range vision, strategic planning and financial management skills are also required.

Experience and training in laboratory safety and experience in a leadership role is highly desired.

National recognition as a subject matter expert and publications (s) in peer-reviewed journals is a plus. A certification in Quality Management is a plus. Board certifications recognized by American Society of Clinical Pathology, Health and Human Services, National Certifying Agency or any other associated laboratory credentialing agencies is a plus. Certification as a Medical Technologist is a plus.

A Valid Driver's License is required.

4. Work Demands

The following identifies some of the physical and mental demands and potential hazards typically encountered by this position. These are job demands which can be ***reasonably anticipated and are an expectation of the job***.

Keeping in mind the essential functional areas and duty statements described in section 2, select the rating that best matches the requirement of this position according to the following descriptions:

Rating **Description**

Not Required (N): Not required of this position.

Present (P): Requirement **is** present, but **is not** essential to the position. (For example, a receptionist may encounter aggressive or angry people, but this is not an essential assignment.)

Occasional (O): Required 33 percent of the time or less **and** essential to the position. (For example, a lifeguard swims only occasionally, but it is essential that a lifeguard be able to swim; a correctional officer must control aggressive/angry people who are life threatening.)

Frequent (F): Required over 33 percent of the time **and** essential to the position.

Items checked below must be consistent with the duty statements listed in section 2.

4.1 Physical Requirements

Title	Rating			
	N	P	O	F
Sitting				F
Walking				F
Standing				F
Running	N			
Jumping	N			
Bending or twisting			O	
Squatting or kneeling			O	
Crawling	N			
Reaching above shoulder level			O	
Reaching below shoulder level			O	
Ascending or descending using a ladder or other conveyance			O	
Climbing stairs			O	
Driving cars, light duty trucks			O	
Driving heavy duty vehicles	N			
Using floor mounted foot controls to operate equipment (e.g., not driving a car)		P		
Repetitive motion of hands/fingers (e.g., keyboarding, turning pages)				F
Fine manipulation with fingers			O	
Pinching with fingers			O	
Grasping with hand, gripping			O	
Load, unload, aim, and fire handguns, shotguns or other firearms	N			

Lifting/carrying up to 25 pounds			O	
Lifting/carrying 26-50 pounds			O	
Lifting/carrying more than 50 pounds			O	
Pushing/pulling up to 25 pounds			O	
Pushing/pulling 26-50 pounds			O	
Pushing/pulling more than 50 pounds		P		
Balancing on moving surfaces	N			
Balancing on narrow surfaces	N			
Balancing on slippery surfaces	N			
Balancing on uneven surfaces	N			
Restraining/grappling with people in a public protection environment	N			
Seeing objects at a distance		P		
Seeing objects peripherally			O	
Using depth perception			O	
Seeing close work (e.g., typed print)				F
Distinguishing colors			O	
Hearing conversations or sounds			O	
Hearing via radio or telephone			O	
Communicating through speech			O	
Communicating by writing/reading				F
Distinguishing odors by smell			O	
Distinguishing tastes	N			

4.2 Work Environment

Title	Rating			
	N	P	O	F
Work in/exposure to inclement weather			O	
Work in/exposure to cold water	N			
Work/live in remote field sites	N			
Work in confined areas (under desks, in heating vents, etc.)			O	
Exposure to dust, chemicals, or fumes			O	
Exposure to hazardous equipment (e.g., guns, chainsaws, explosives)			O	
Exposure to electrical current (not outlets)			O	
Swimming/scuba diving	N			
Work at heights up to 25 feet (e.g., towers, poles)			O	
Work at heights over 25 feet (e.g., towers, poles)	N			
Work in urban or highway traffic (other than driving)	N			
Work around moving machinery or mobile equipment			O	
Work around moving mechanical parts			O	
Work on and off moving equipment	N			
Work on slippery or uneven surfaces	N			
Work/travel in boat/small aircraft/helicopters	N			

Exposure to high noise levels			O	
Exposure to infection, germs, or contagious diseases (e.g., hospital, lab, clinic, etc.)			O	
Exposure to blood, body fluid, or materials potentially contaminated by blood or body fluids (e.g., hospital, lab, clinic, public protection environment)			O	
Exposure to needles or sharp implements (e.g., hospital, kitchens)			O	
Use of hot equipment (e.g., kitchen ovens, lab equipment)			O	
Exposure to wild/dangerous animals		P		
Exposure to insect bites or stings	N			
Exposure to aggressive/angry people in a public protection environment	N			

4.3 Other Work Demands

Title	Rating			
	N	P	O	F
There are no other work demands.				

4.4. Explain any special physical, mental, or behavioral requirements of the position that have not already been addressed.

Potential exposure to bioterrorist agents, mental stress from being on constant alert and preparedness, frequent exposure to laboratory mice. Ability to reason and deduce.

5. Supervisory Authority

This page must be completed if PCN **187503** is assigned supervisory or lead level authority (this includes Labor, Trades and Crafts foreman positions). In the chart below, list each position PCN **187503** supervises or leads. Record **187503**'s level of authority for each area of responsibility according to the definitions below. Subordinate positions listed must be consistent with those reflected on the staffing chart, and levels of authority must be substantiated in all other applicable portions of the PD (i.e. duties, guides, actions, decisions).

Note: These ratings are not dependent upon whether the position has actually exercised the authority, but rather what level is assigned.

Level Definition of Level of Authority Assigned

- 1 = Has authority to take action; notification to supervisor may or may not be necessary afterward.
- 2 = Effectively recommends and discusses decision with supervisor; then takes action.
- 3 = Presents recommendations to supervisor; supervisor makes decision and directs position to take action.
- 4 = No authority to take or recommend action.

Is PCN **187503** assigned supervisory or lead level authority for one or more of the responsibilities listed in the chart below? **Yes** If no, skip this section.

PCN 187503 's Responsibilities and Assigned Level of Authority

Positions Directly Supervised or Led by PCN 187503	Employ (includes authority to hire, transfer, layoff, OR recall)	Discipline (includes authority to suspend, demote, OR issue written warnings)	Discharge	Adjudicate Grievances (includes authority to respond to a first level grievance under a collective bargaining agreement)	Assign Work	Set Task Priorities	Check Quality of Work	Evaluate Performance	Instruct & Train Staff
187233	2	2	2	2	1	1	1	1	1
187417	2	2	2	2	1	1	1	1	1
187836	2	2	2	2	1	1	1	1	1
TBD-PC2	2	2	2	2	1	1	1	1	1

6. Department Request & Certification

Information at Time of Request

Class Title: Laboratory Quality Systems Manager	Code: K0088 Grade: 20
Bargaining Unit: Supervisory Unit	Bargaining Unit Code: SS
Department: Environmental Conservation	Department Number: 18
Division: Environmental Health	
Region/Section/Unit: Environmental Health Laboratory	
Location: Anchorage	Location Code: EBA
Time Class: Full Time/OMB Authorized	Time Class Code: FACL
FLSA Exempt: Yes	Strike Class: 3
Position requires the incumbent to possess a Commercial Driver's License (CDL), to maintain registration with the federal CDL Drug & Alcohol Testing Clearinghouse, and to provide consent to the Employer to review driver information in accordance with 49 CFR 382:	No
Position requires possession of, or access to, firearms or ammunition:	No
Home Unit: ZEHL	
AKPAY Organizational Routing Code: 18010106	
Physical Work Address: 5251 Hinkle Rd, Anchorage	
Work Phone: 907-375-8200	
Supervisor Information	
PCN: 187306 Title: Chief, Environmental Health Laboratories	
Physical Work Address: 5251 Hinkle Road Anchorage	
Work Phone: 907-375-8206	

Requested Changes

Physical Work Address: 5251 Dr. Martin Luther King Jr Ave, Anchorage
Work Phone: 907-375-7799
Supervisor Information
PCN: 187306 Title: Chief, Environmental Health Laboratories
Physical Work Address: 5251 Dr MLK Jr Ave Anchorage
Work Phone: 907-375-8206

Requested Actions

Reclass Up, Update

Reason for the Request

Updating the PD and requesting change of range to 22. The LQSM has technical responsibilities of every section without the budgetary responsibilities and supervisory authority of the Chief. This position has authority to halt immediately any process or testing that fails to comply with regulations/standards of federal or accrediting agencies. Such failures may have significant impact on the laboratory. The Chief of Laboratory Services will be notified and apprised of the violation(s) as soon as possible. Only the Quality Manager and Chief have the authority to resume operations once the Quality Manager has halted operations.

Does this submission require OMB Approval?

No

If yes, has it been approved by the OMB?

If no, please select the criteria which approves this submission:

Position submitted for update or reclass of two or fewer ranges

American Recovery and Reinvestment Act

Is this permanent position established to work on ARRA (American Recovery and Reinvestment Act) related projects/assignments?

No

Certification

Supervisor

I certify that the information provided in this submission is accurate and complete to the best of my knowledge.

Patryce McKinney, Chief, Environmental Health Laboratories, on 03/08/2023

Division

I certify that the information provided in this submission is accurate and complete to the best of my knowledge.

DeeAnn Fetko, Administrative Operations Manager 1, on 03/13/2023

Department

I certify that the information provided in this submission is accurate and complete to the best of my knowledge and the required budgetary authorization exists to implement the requested action.

Megan Kohler, Division Director - Px, on 03/14/2023

7. Staffing Chart & Attachments

Staffing Chart (187503)

8. Classification Analysis

The Department of Environmental Conservation, Division of Environmental Health submitted a Position Description (PD) update for PCN 187503. The request is to update the duties of the position. The position is currently vacant.

Contact:

Contact was made with Patryce McKinney (Chief, Environmental Health Laboratories) to discuss the duties of the position and Class Studies option. Notified submission is processed as update.

Analysis:

All duties, responsibilities, and authorities listed within this position description were considered for this analysis.

PCN 187503 is assigned to the Environmental Health Laboratory section. The position primarily oversees the Alaska State Environmental Health Laboratory (ASEHL) to ensure compliance with federal certification agencies, requirements and standards, as well as ISO 17025 standards. The work of this position involves planning, directing, and performing the work necessary to implement and maintain the Quality Management System in the Environmental Health Laboratories. This includes evaluating policies and practices for compliance with regulations, accreditation standards, and scientific best practices; auditing laboratory activities; and directing correction of deficiencies.

Positions in the Chemists series evaluate, develop, modify and conduct analytical methods, procedures and instrumentation techniques to detect, identify, quantify, study and present authoritative findings regarding the molecular structure, properties, transformations and effects of transformations of chemical compounds and substances as either part of clinical and forensic investigations or to ensure the compliance of materials, products, testing and related activities with State and federal regulations and other established standards. In contrast, the work of PCN 187503's primary focus is on performing activities to maintain the Quality Management System in the Environmental Health Laboratories. This includes activities such as evaluating policies and practices for compliance with regulations, accreditation standards, and scientific practices; performing laboratory audits; and ensuring corrective action of nonconformance processes. In addition, PCN 187503 does not work within a scope that involves investigating/interpreting of composition, molecular structure and properties of substances, transformations, and the effects of such substances and transformations; therefore, allocation of PCN 187503 to the Chemist series is not appropriate.

Positions in the Forensic Science Laboratory Administrators job class series direct, administer, coordinate, and ensure the application of sound scientific and legal principles involved in the State of Alaska's forensic operations related to the detection, collection, testing, analysis, and reporting of evidence through one or more forensic disciplines providing support and training to all stakeholders in the criminal justice system in Alaska. In contrast, PCN 187503 performs duties to implement and maintain the Quality Management System in an environmental health laboratory. The scope of work involves diverse activities such as quality control, conducting audits, performing research, and ensuring regulatory compliance. Additionally, the work assigned to PCN 187503 does not involve forensic operations related to the detection, collection, testing, analysis, and reporting of evidence and which employs forensic disciplines to provide support/training to stakeholders in the criminal justice system; therefore, allocation of PCN 187503 to the Forensic Science Laboratory Administrators series is not appropriate.

The Laboratory Quality Systems Manager job class plans and directs Quality Management System programs and practices in the State's Environmental Health Laboratories to ensure compliance with federal and State regulations, International Organization for Standardization (ISO) accreditation standards, and scientific best practices. This is a single-position job class responsible for administering the Environmental Health Laboratories' quality system. Incumbents direct and oversee the activities required to implement the quality control system and evaluate quality system data for the entire laboratory and its regulatory programs. Similarly, PCN 187503 functions as the Quality Systems Program Manager and oversees the Alaska State Environmental Health Laboratory (ASEHL) to ensure compliance with six (6) different federal certification agencies, including the International Organization for Standardization (ISO) 17025. The position conducts regular and focused technical audits of staff training and laboratory processes; approves and maintains the department-wide Standard Operating Procedures (SOP) for all testing procedures; ensures that each SOP meets specific formatting, validation, and ASEHL intranet posting requirements; and investigates all

customer complaints to ensure corrective actions are documented. The position also oversees the document control process for the ASEHL by advising proper identification, filing, retrieval, and archival processes identified by the Quality Plan or controlling agencies. Assignments associated with this position require overseeing the equipment maintenance process as stated in the Quality Plan. This responsibility involves providing technical guidance to staff in creating, maintaining, and auditing manual and electronic monitoring systems for the proper maintenance of laboratory equipment specified by accrediting agencies or equipment manufactures. PCN 187503 continues to meet the definition and characteristics of the Laboratory Quality Systems Manager by the laboratory-wide authority and primary responsibility for the Quality Management System in the Environmental Health Laboratories (EHL); therefore, allocation to this job class is appropriate.

Conclusion:

PCN 187503 remains allocated to the Laboratory Quality Systems Manager job class and is appropriately placed in the Supervisory bargaining unit. Supervisory authority is assigned to the position.

FLSA determination:

PCN 187503 is compensated on a salary basis at a rate not less than \$684 per week, exclusive of board, lodging or other facilities and requires a bachelor's degree from an accredited college in chemistry, biology, microbiology, or in a Life or Environmental Science. The position's primary duty involves planning, directing, and performing the work necessary to implement and maintain the Quality Management System in the Environmental Health Laboratories. Performing this work requires advanced knowledge which is intellectual in character and requires consistent exercise of discretion and judgment. The advanced knowledge is in a field of science or learning and is customarily acquired by a prolonged course of specialized intellectual instruction. In addition, the position's primary duty performs office/non-manual work directly related to the management/general business operations of the Division of Environmental Health. Auditing laboratory activities to ensure compliance with federal certification agencies requires exercising discretion and independent judgement with respect to matters of significance; therefore, PCN 187503 meets the administrative and professional criteria for exemption under the Fair Labor Standards Act (FLSA) and is not eligible for overtime.