

**State of Michigan
Civil Service Commission**

Capitol Commons Center, P.O. Box 30002
Lansing, MI 48909

Position Code

1. LABSCIA

POSITION DESCRIPTION

This position description serves as the official classification document of record for this position. Please complete the information as accurately as you can as the position description is used to determine the proper classification of the position.

2. Employee's Name (Last, First, M.I.)	8. Department/Agency LICENSING AND REGULATORY AFF
3. Employee Identification Number	9. Bureau (Institution, Board, or Commission) Cannabis Regulatory Agency
4. Civil Service Position Code Description Laboratory Scientist-A	10. Division
5. Working Title (What the agency calls the position) Laboratory Quality Assurance Lead	11. Section Reference Lab
6. Name and Position Code Description of Direct Supervisor PATTERSON, CLAIRE T; STATE DIVISION ADMINISTRATOR-F	12. Unit
7. Name and Position Code Description of Second Level Supervisor MITCHELL, DESMOND D; STATE BUREAU ADMINISTRATOR	13. Work Location (City and Address)/Hours of Work 2407 North Grand River Avenue, Lansing MI 48906 / Monday - Friday 8:00a.m. - 5:00p.m.

14. General Summary of Function/Purpose of Position

The Laboratory Scientist serves as the recognized resource for laboratory testing, quality assurance, quality control, and laboratory audit activities for the Cannabis Regulatory Agency's Reference Laboratory; and leads efforts in the creation, expansion, and maintenance of quality programs at the Reference Laboratory, ensuring alignment with current regulatory requirements and industry standards. This individual directs and executes additional quality assurance tasks and duties as assigned as a recognized resource and is responsible for scheduling and conducting internal audits, both vertical and horizontal, to ensure the laboratory maintains its accreditation status. Additionally, the recognized resource leads technical audits of external laboratories licensed by the agency, ensuring compliance with industry standards and regulatory requirements. This role involves comprehensive data review, daily oversight of established laboratory quality and safety duties, reviewing proficiency testing results, and regularly maintaining and revising the Quality Assurance Manual. The Laboratory Scientist 12 participates in relevant conference calls and division Management System Reviews to provide expert quality assurance insights and lead laboratory efforts to create and maintain a rigorous Quality Management System, ensuring the integrity and accuracy of the data reported by the laboratory through complex data reviews. This individual collaborates with staff in the CRA Reference Laboratory to achieve and maintain ISO 17025 accreditation and perform necessary tasks to ensure continued accreditation while strictly adhering to applicable rules, regulations, policies, and procedures. Additionally, the laboratory scientist is responsible for designing, supervising, and managing proficiency testing programs for the reference laboratory and other licensed laboratories, ensuring rigorous testing standards are met. This individual also develops and supports the creation of sampling and quality assurance plans, ensuring comprehensive quality management across all laboratory functions.

Additional Requirements:

This position may also involve policy research, assistance with enforcement activities, laboratory audits and inspection programs, administrative rules, and responding to subpoenas and inquiries under the Freedom of Information Act, 1976 PA 442.

15. Please describe the assigned duties, percent of time spent performing each duty, and what is done to complete each duty.

List the duties from most important to least important. The total percentage of all duties performed must equal 100 percent.

Duty 1

General Summary:

Percentage: 30

Quality Management System Oversight: The recognized resource is responsible for developing, implementing, and maintaining the laboratory's Quality Management System (QMS). This includes conducting reviews and updates of laboratory Standard Operating Procedures, coordinating and executing internal audits, and preparing and submitting quality systems documentation to leadership and other regulatory bodies as required.

Individual tasks related to the duty:

- Lead the development, implementation, and continuous improvement of the laboratory's Quality Management System (QMS), ensuring that the laboratory is recognized as a leader in quality and compliance in the cannabis industry in preparation for ISO Accreditation and status maintenance.
- Ensure the QMS is appropriately updated to reflect changes in applicable laws and best practices.
- Act as the primary point of contact for all QMS-related inquiries from internal teams, external auditors, and regulatory agencies, offering expert advice and guidance.
- Create and manage procedures for document control, ensuring proper versioning, access, and compliance with regulations.
- Serve as a trusted advisor to senior management, advising on the strategic direction of quality management and offering recommendations for process improvements.
- Guide continuous improvements to laboratory operations by implementing cutting-edge quality tools and techniques.
- Represent the laboratory in high-level meetings with external regulatory bodies and stakeholders, advocating for the laboratory's interests and demonstrating its commitment to quality.
- Conduct internal audits to assess compliance with the QMS, including document review and interviews with laboratory staff.
- Spearhead the laboratory's response to audit findings and regulatory feedback, demonstrating leadership and a commitment to excellence.
- Provide strategic oversight of audit preparations, ensuring that the laboratory is always audit-ready and exceeds expectations.
- Report audit findings and track the resolution of any non-conformities identified during audits.
- Review and validate corrective and preventive actions (CAPA) to ensure they address root causes of quality issues.
- Ensure the laboratory maintains accreditation by monitoring and preparing for external audits by regulatory bodies.
- Develop and implement non-conformance reporting systems to capture quality failures or process deviations.
- Create quality metrics for laboratory processes and track performance against these metrics.
- Review, approve, and distribute laboratory documents such as SOPs, test methods, and training materials.
- Ensure the lab maintains a robust change control process for SOPs, test methods, and equipment.
- Conduct periodic reviews of QMS performance to ensure continuous improvement and effectiveness.
- Coordinate the annual review and updating of the Quality Manual.
- Oversee the creation and maintenance of quality reports for internal stakeholders and regulatory bodies.
- Lead the development, implementation, and continuous improvement of the industry's laboratory audit and inspection program.
- Lead the development, implementation, and continuous operations and improvement of the industry's laboratory proficiency testing program.
- This position has unsupervised access to controlled substances while transporting these substances from laboratories and manufacturers.

Duty 2

General Summary:

Percentage: 25

Auditing, Training and Staff Development: The recognized resource serves as the primary point of contact for the Cannabis Regulatory Agency on Quality Assurance and Quality Control protocols, providing training and oversight for laboratory staff on quality standards, regulatory compliance, and proficiency testing. Leads proficiency testing programs, evaluates staff performance on quality control measures and procedures, and ensures continuous learning within the laboratory. Additionally, the recognized resource manages audits, communicates with stakeholders, and reviews data to maintain compliance with regulatory requirements.

Individual tasks related to the duty:

- Provide training for laboratory staff on quality assurance processes, standard operating procedures, regulatory compliance, and safety standards.
- Organize and implement changes to the proficiency testing programs for all licensed cannabis testing laboratories in Michigan, as required by law.
- Oversee and conduct proficiency testing for all licensed cannabis testing laboratories in Michigan, as required by law, including the CRA Reference Laboratory.
- Oversee and conduct proficiency testing and evaluate the performance of staff to ensure competency in testing procedures and quality control measures.
- Cultivate and maintain a culture of continuous learning, as well as fostering an environment where knowledge-sharing is prioritized.
- Act as the subject matter expert and resource for training on new regulations, technologies, and techniques, ensuring the laboratory stays ahead of industry trends.
- Lead stakeholder discussions and workshops that elevate the overall expertise of all Michigan's analytical cannabis testing laboratories as a collaborative group.
 - Work with senior management to define the laboratory's talent development strategy, ensuring that staff are competent and agile.
 - Create and maintain training records to ensure compliance and records retention guidelines.
 - Develop and deliver training programs for laboratory staff on quality standards, SOPs, and regulatory compliance requirements.
 - Create, maintain and update training materials to reflect changes in quality standards, regulations, and best practices.
 - Monitor staff competency and provide periodic performance reviews to ensure that quality expectations are met.
 - Track and document laboratory training activities, accreditations, and certifications to ensure compliance with regulatory agencies.
 - Organize and oversee proficiency testing for laboratory analysts to assess competency in performing tests accurately.
 - Develop skills assessments for laboratory staff and identify training gaps or areas for improvement.
 - Manage the onboarding process for new laboratory staff, including quality system training and SOP reviews.
 - Develop and maintain a laboratory safety program, including associated materials, resources, training, processes and records.
 - Develop and implement skills certification and employee training program for testing methods and laboratory operations.
 - Attend laboratory audits at various locations throughout the state pre-scheduled days, driving up to 100-450 miles per day required for audit.
 - Schedule, Conduct, and oversee CRA directed sample and technical audits at licensed laboratories throughout Michigan.
 - Interpret complex analytical data and communicate findings clearly and accurately to non-experts, including stakeholders, laypersons, and in legal contexts. Serve as an expert witness in court when required, explaining technical data in a manner that is understandable and accessible to a wide audience, while maintaining the integrity and accuracy of the scientific information.
 - Communicate directly with external stakeholders, including clients, regulatory bodies, and other relevant parties in a timely and professional manner, ensuring satisfaction while maintaining adherence to laboratory standards and regulatory requirements.
 - Provide thorough and timely data review upon request, ensuring that all data is accurate, complete, and compliant with relevant quality standards and regulations. Offer insights and recommendations based on the analysis to support decision-making processes.

Duty 3

General Summary:

Percentage: 25

Data Review and Reporting: The recognized resource acts as the subject matter expert in data integrity, ensuring all testing data meets the highest standards of accuracy and compliance. They oversee the review of raw analytical data, confirm test results are accurately recorded, and develop data review protocols to prioritize quality and consistency. Additionally, the recognized resource monitors complex data issues, provides expert consultation on discrepancies, and leads initiatives to enhance data transparency and accessibility. They ensure compliance with regulatory standards, prepare quality reports for audits, and collaborate with management to improve data review processes and overall laboratory performance.

Individual tasks related to the duty:

- Act as the subject matter expert in data integrity, ensuring that all testing data meets the highest standards of accuracy and compliance.
- Review raw analytical data and ensure it complies with established protocols, procedures, and regulatory standards.
- Confirm that test results are accurately recorded and that deviations from expected results are appropriately documented.
- Lead the development of data review protocols that prioritize data quality and consistency, ensuring the laboratory's findings are trusted by regulators and industry stakeholders.
- Monitor complex issues related to data integrity and ensure that all test reports are complete and accurate before release.
- Act as the recognized resource for data-related issues, providing expert consultation to resolve discrepancies, out-of-specification results, and other challenges.
- Lead initiatives to enhance data transparency and accessibility, ensuring that critical information is readily available for management review, regulatory inspections and Freedom of Information Act Requests.
- Provide strategic guidance on the development and implementation of data management software, ensuring that the laboratory's data systems are state-of-the-art and compliant with all regulatory standards.
- Evaluate results from proficiency testing and inter-laboratory comparisons to ensure consistent performance.
- Review the laboratory's final reports and ensure that they meet all necessary quality standards before being sent to clients or regulatory bodies.
- Prepare internal and external quality reports, including summaries of audit results, corrective actions, and improvements.
- Assist in the preparation of monthly, quarterly, or annual quality performance reports for leadership.
- Ensure data review processes are standardized, with clearly defined criteria for approving or rejecting results.
- Participate in meetings to discuss quality trends, non-conformance issues, and data integrity challenges.
- Conduct trend analysis of test results over time to identify patterns or issues in testing methods.
- Provide detailed reports for regulatory audits, including data integrity assessments, OOS investigations, and corrective actions.
- Ensure that data review procedures are aligned with industry regulations such as ISO/IEC 17025, GLP, and cannabis-specific standards.
- Serve as the primary spokesperson for quality assurance during external audits and inspections, ensuring that the laboratory's data review practices are recognized as best-in-class.
- Work closely with management to ensure that data review processes align with strategic laboratory goals, offering data-driven recommendations for continuous improvement.
- Develop and review data quality metrics, ensuring continuous monitoring for improvements in data collection and analysis.
- Assist leadership with process improvement projects.
- Performing other duties or roles as assigned.

Duty 4

General Summary:

Percentage: 20

Calibration, Maintenance, and Equipment Validation: The recognized resource directs and monitor analytical procedures used by the reference laboratory, including the sample analysis of cannabis, cannabis products, and cannabis extracts using GC/MS/MS, GC/MS, LC/MS/MS, HPLC, ICP-MS, qPCR, plating, and other methods. They review all analytical results in routine research, and validation/verification testing to ensure compliance with Quality Assurance/Quality Control standards set by the laboratory. Active leadership in running laboratory procedures, testing, and analyses is also required.

Individual tasks related to the duty:

- Oversee the calibration, maintenance, and validation of laboratory equipment to ensure accurate and precise results.
- Ensure all instruments are properly calibrated in accordance with the manufacturer's specifications and regulatory standards.
- Develop and implement a calibration schedule for all laboratory equipment, ensuring compliance with specifications.
- Serve as the authoritative resource on equipment calibration and validation protocols, mentoring staff and other departments on best practices and compliance standards.
- Build strong relationships with equipment manufacturers and third-party vendors to ensure exceptional service and support for the laboratory's equipment.
- Lead troubleshooting efforts for any equipment failures or malfunctions, providing expertise in identifying root causes and implementing effective corrective actions.
- Act as the laboratory's go-to expert on all matters related to equipment performance, maintenance, and validation, providing advice and guidance to both staff and management.
- Maintain records of equipment calibration, including calibration certificates and service histories.
- Monitor equipment performance and track trends in analytical results to detect drift or malfunction prior to results being impacted.
- Perform routine equipment inspections to ensure functionality and readiness for use.
- Coordinate the repair or replacement of equipment found to be out of specification.
- Establish and document equipment qualification protocols to verify that instruments are operating within the required specifications.
- Ensure all new equipment is validated before use in testing and maintain appropriate validation documentation.
- Maintain an equipment inventory and ensure all items are properly labeled and easily traceable.
- Work with vendors to ensure timely maintenance and calibration services for all equipment.
- Develop and update preventive maintenance procedures to reduce downtime and ensure continuous testing capabilities.
- Ensure that laboratory instruments meet applicable regulatory standards (e.g., ISO 17025, GLP).
- Conduct root cause analysis of any equipment-related issues and implements corrective actions.
- Document any deviations from established equipment protocols and ensure timely corrective actions are taken.
- Review and approve service reports and calibration certificates from third-party vendors.
- Provide final review of daily testing and reporting data to ensure alignment with quality control standards.
- Conduct ongoing evaluation of test appropriateness and fit for use.
- Conduct research and testing of cannabis related testing methodologies as directed.

16. Describe the types of decisions made independently in this position and tell who or what is affected by those decisions.

This individual serves as a recognized resource for quality assurance and quality control in the CRA Reference Laboratory. This individual is responsible for numerous complex and simple decisions related to the integrity and quality of laboratory operations. These decisions directly affect the efficiency and accuracy of the entire Cannabis Reference Laboratory Testing program, the health and safety of laboratory personnel and consumers, compliance with state and federal regulations, and general service to and relations with laboratory clients.

17. Describe the types of decisions that require the supervisor's review.

Unexpected budget demands, significant or unusual deviations from laboratory procedures, reasons to believe that standard operating procedures, policies, methods, validations, need to be revised or temporarily suspended, and matters that are politically sensitive or have policy-related impacts on the agency or department.

18. What kind of physical effort is used to perform this job? What environmental conditions in this position physically exposed to on the job? Indicate the amount of time and intensity of each activity and condition. Refer to instructions.

This is a laboratory-based position with travel of 100-450 miles per day, occasionally, using state vehicles. Environmental conditions/hazards: Standard laboratory hazards are encountered daily due to handling of samples that may contain hazardous materials. Proper care and attention to safety must be continuously exercised to minimize risk of exposure. Standing and sitting for long periods of time and use of lab and computer equipment that may require repetitive hand movements.

19. List the names and position code descriptions of each classified employee whom this position immediately supervises or oversees on a full-time, on-going basis.

Additional Subordinates

20. This position's responsibilities for the above-listed employees includes the following (check as many as apply):

- | | |
|---|--|
| <input type="checkbox"/> Complete and sign service ratings. | <input type="checkbox"/> Assign work. |
| <input type="checkbox"/> Provide formal written counseling. | <input type="checkbox"/> Approve work. |
| <input type="checkbox"/> Approve leave requests. | <input type="checkbox"/> Review work. |
| <input type="checkbox"/> Approve time and attendance. | <input type="checkbox"/> Provide guidance on work methods. |
| <input type="checkbox"/> Orally reprimand. | <input type="checkbox"/> Train employees in the work. |

22. Do you agree with the responses for items 1 through 20? If not, which items do you disagree with and why?

Yes

23. What are the essential functions of this position?

The Laboratory Quality Specialist leads and manages quality programs at the CRA Reference Laboratory, ensuring compliance with regulatory standards and industry best practices. Key duties include conducting internal audits, reviewing data and proficiency testing results, delivering ISO 17025 training, and maintaining the Quality Assurance Manual. The role involves ensuring laboratory accreditation, overseeing proficiency testing programs, and supporting the creation of quality management plans. The position also requires travel, policy research, and participation in enforcement activities and laboratory audits.

24. Indicate specifically how the position's duties and responsibilities have changed since the position was last reviewed.

Establishment

25. What is the function of the work area and how does this position fit into that function?

The Laboratory Division performs centralized functions for the agency to support the administration of the MMMA, MMFLA, MTA, and MRTMA inclusive of scientific, testing, and policy research including administrative rules; coordination of cannabis testing for enforcement and investigative purposes; validation, verification, and vetting of cannabis testing methods; conducting audits and inspections; regulatory compliance; inspections and investigations; and responding to subpoenas and inquiries under the Freedom of Information Act, 1976 PA 442.

26. What are the minimum education and experience qualifications needed to perform the essential functions of this position.

EDUCATION:

Possession of a bachelor's degree in chemistry, biochemistry, biology, microbiology, forensic science, or a related pure or applied science.

EXPERIENCE:**Laboratory Scientist 12**

Three years of professional experience carrying out a variety of tests, analyses, or production and research activities involving chemical, biochemical and biological samples, specimens, and products equivalent to a Laboratory Scientist, including one year equivalent to a Laboratory Scientist P11.

KNOWLEDGE, SKILLS, AND ABILITIES:

Knowledge of organization, planning, staffing, training, auditing, and reporting.

Knowledge of the principles of inorganic and organic chemistry, organic chemistry, microbiology, and cannabis physiology.

Knowledge of the fundamentals of analytical instrumentation and biological testing.

Knowledge of statistical techniques and QC programs for laboratory operations.

Ability to carry out laboratory procedures, tests, and analyses.

Ability to interpret results and prepare reports, both oral and written, related to the work.

Knowledge of cannabis testing methods.

Ability to organize projects and daily activities based on priority.

Proficient in leadership and management techniques.

Ability and willingness to delegate assignments, authority, and responsibility, using established management controls for follow-up.

Knowledge of laboratory planning, development and evaluation methods.

Knowledge of Good Laboratory Practices.

Familiarity with ISO 17025 accreditation requirements.

Ability to motivate and lead others in the accomplishment of tasks.

Ability to persuade and motivate others.

Ability to present ideas effectively to management.

Knowledge of laboratory regulations and compliance standards

Knowledge of lab quality control and quality assurance standards

Ability to ensure accuracy and precision of laboratory procedures through sound judgment and wise decision making

Ability to maintain quality assurance program, proficiency testing and the competency of all laboratory personnel for high complexity laboratory testing.

Ability to review of Quality control data, peer data and proficiency testing and implementing remediation and correction with appropriate documentation.

Ability to ensure accuracy and precision of laboratory procedures through sound judgment and wise decision making

Ability to present a professional image and establish a comfortable rapport with licensees and stakeholders

Interest in science and willingness to work in a dynamic and developing laboratory space

Ability to consistently perform high quality work doing routine and repetitive tasks

Ability to follow written procedures closely

Flexibility and willingness to work as part of a team

Knowledge of computer hardware and software

Ability to give significant attention to detail

CERTIFICATES, LICENSES, REGISTRATIONS:

None

NOTE: Civil Service approval does not constitute agreement with or acceptance of the desired qualifications of this position.

I certify that the information presented in this position description provides a complete and accurate depiction of the duties and responsibilities assigned to this position.

Supervisor

Date

TO BE FILLED OUT BY APPOINTING AUTHORITY

Indicate any exceptions or additions to the statements of employee or supervisors.

NA

I certify that the entries on these pages are accurate and complete.

PAIGE EMMONS

8/12/2025

Appointing Authority

Date

I certify that the information presented in this position description provides a complete and accurate depiction of the duties and responsibilities assigned to this position.

Employee

Date