Additional Consideration:

We will need a legislative change to both MMFLA and MRTMA for CRA Laboratory Division staff to be able to sample, transport, and test marijuana products.

Initial CRA Laboratory Division Configuration

- **One State Division Administrator 17** - The purpose of the separate division admin/division is we want the lab to be completely independent to avoid any accusations of impropriety or scientific bias; we need this lab to be completely objective and science based. This division director will need the authority to make very high-level decisions regarding recalls, summary suspensions, audits, etc. These are decisions that will likely have significant economic impact on all licensees involved.
- **One Lab Scientist Manager 14** - will be responsible for day-to-day operations for the reference lab, guiding general projects, audits, requests for investigations, training, review reporting etc.
- **One Lab Evaluation Specialist 12** - will be there to oversee the actual laboratory/quality assurance and ensure all tests are conducted appropriately, that Lab Techs follow SOPs, coordinate sample collection for investigations, peer review reporting.
- **Two Lab Techs 8-10** - will be responsible for sampling, day to day testing, laboratory upkeep, setup and execution of any experiments, and basic reporting.
- **One Lab Assistant 6-8** - will be responsible for basic sample preparation and accessioning, lab cleanup, answering phone calls.

- If it is necessary to cut two of these positions, CRA recommends first cutting the Lab Assistant 6-8 and the Lab Evaluation Specialist 12.
- If it will be necessary to cut one position only, and we can choose which position that is, then I would recommend cutting the Lab Assistant 6-8. If that is not possible, then we can resort to cutting the Lab Scientist Manager temporarily, but this will not be sustainable in the long term, as the Division Director will be incredibly overloaded.

CRA Enforcement Division Scientific Section:

The scientific section maintains oversight over the licensed safety compliance facilities and ensures they are conducting accurate testing of all marijuana products in accordance with the administrative rules. Laboratory scientists (LSS) conduct inspections of labs outside of the field operations requirements as labs have additional requirements and oversight. This includes specific organizational structure, review of SOPs, accreditation, and method validations.

On a scheduled basis reports are provided to the section by the Operations Support Section (OSS) data specialist. This data must be reviewed and acted upon as directed by section

procedure by the assigned staff. These reports are identified by the section manager as a need the section has to determine areas where focus should be dedicated. These reports may include test failure data, test results based on time frames or based on licensees, or any other reporting that may have the potential to impact public health and safety or considered a violation of the administrative rules.

Based on the information contained in the referral, either LSS staff or analysts will review referrals from other sections for investigations. This information will be reviewed with specific attention to the concern for rule/statute violation, public health or safety concerns, evidence within the provided information and information necessary to make a determination of violations. If it is determined that an investigation should be completed, a CMP will be assigned to the appropriate staff member and an investigation will be completed. If an investigation is not necessary, the information should be documented in the licensee record with a comment that an investigation was not necessary or there was not enough information to conduct an investigation.

Investigations are conducted by LSS's when information specific to science, laboratory practice or testing has been determined to require investigation. The analysts conduct investigations based on information related to data stored in Metrc, suspicious transfers, manifests, package adjustments etc. The investigation procedure is followed, and issues of noncompliance/violations of rule or statute are documented. Investigations are provided to the section manager to review and determine if the evidence and information contained in the investigation report is acceptable for forwarding to legal for disciplinary purposes or if the complaint should be closed as unfounded.

(a) Inspections of Labs

(b) Investigations related to Labs

(c) Review of submissions from labs

    i. Method validations

    ii. SOPs

(d) Review of lab proficiency test data

(e) Organize interlaboratory comparison events and evaluate results

(f) Update and make changes to licensee map

(g) Review lab testing reports to identify anomalies

(h) Review referrals for investigation

(i) Review audit data to identify investigation needs

(j) Oversight of MDARD x MRA Chemical residue investigation program

(k) Metrc investigative assistance

(l) MTI Information requests

(m) Beverage/ research review and approval process.

Proposed CRA Laboratory Division:

The purpose of the CRA Laboratory Division is to create a non-biased, scientifically based, technically competent program to provide oversight over all CRA licensees to ensure that they are providing products to consumers which are relatively free from contaminants. This program will be responsible for the oversight and conduction of a comprehensive proficiency testing program for labs which will include more frequent, blind, proficiency tests. Currently, the CRA oversees a proficiency testing program, but the program is incredibly limited due to our inability to possess and prepare marijuana samples for testing. The reference laboratory will be responsible for assisting the cannabis testing industry on a national level by assisting with the testing, optimization, validation, and verification of standard methods to ensure that cannabis testing laboratories are performing testing according to peer-reviewed, validated methods. This ensures accuracy and precision in testing, which is one of the core areas of complaints received by the current CRA Scientific Section. Another of the primary functions of the reference laboratory is to provide confirmation of test results. This will occur in several ways: (1) in the form of ongoing audits from various licensees in order to confirm test results and identify illicit product. (2) in investigations, the reference laboratory will provide quick, accurate testing, to support CRA Enforcement investigations and (3) in recalls, the reference laboratory will serve to confirm/deny laboratory test results and can be used to better dial in on proposed recall breadth. The reference laboratory will provide this support as a separate division from the enforcement division to ensure integrity of lab results as well as integrity of the CRA. By separating the investigative procedures from the confirmatory results of a reference lab, we eliminate the possibility of internal bias towards a predetermined outcome. The laboratory will also serve as an industry wide-reference for confirmation of methods and will serve as a source of troubleshooting if the licensed laboratories are in dispute about the use or scope of a specific method and will also serve as a national site for validation and development of new methods. Finally, this division will provide oversight of ISO 17025 audit functions for all licensed labs in Michigan. We have, historically, seen vastly different expectations from the 3, primary ISO 17025 third party accreditation bodies in the state. By creating and implementing a more comprehensive oversight program which focuses on auditing the auditors for consistency, we can ensure that more laboratories are properly trained in the essential laboratory management skills which are outlined by the program.

(a) Provide results to support CRA enforcement investigations without placing undue financial burden on CRA-licensed laboratories.

(b) Provide results to support a CRA mandated, industry wide, audit procedure on an on-going basis.

(c) Optimize current standard methods.

(d) Validate and verify newly developed methods, or methods which are in pilot.

(e) Provide ongoing review of audit programs administered by 3rd party ISO-accrediting bodies.

(f) Development of a comprehensive laboratory proficiency testing program which will highlight short-comings in a single-laboratory testing environment to ensure laboratory accuracy, precision, and consistency.

(g) Support CRA during industry recalls by identifying and narrowing the scope of recalls.

(h) Review lab testing reports provided by the CRA enforcement division to improve upon areas of testing deficiency

(i) Provide support for CRA chemical residue investigation program

(j) Confirm label claims on products for product expiration as necessary

(k) Provide oversight and technical assistance as necessary to support CRA research-project functions

ISO/IEC 172025 Compliance requirements: EST $24,990

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories is the main ISO/IEC standard used by testing and calibration laboratories. In most countries, ISO/IEC 17025 is the standard for which most labs must hold accreditation in order to be deemed technically competent. In many cases, suppliers and regulatory authorities will not accept test or calibration results from a lab that is not accredited.

Preliminary steps to receive ISO 17025 Accreditation and compliance:

- ✓ Learn about the Standard - complete
- ✓ Perform a Gap Analysis anticipated cost after initial set up – will require initial assessment
- ✓ Plan your project.
- ✓ Train your organization – ISO/IEC training will be required for supervisory and technical staff
    1. Median Ntl cost for training is **$12,715**
- ✓ Document your Quality Management System – Implementation and maintenance of internal laboratory management system.
- ✓ Implement your QMS and conduct business.
- ✓ Audit your QMS – building an internal audit program / contracting auditors.
- ✓ Accreditation Audit – cost for assessment, accreditation, and recertification each time a test is added, analytes expanded, matrices added, or as needed annually.

Median cost of initial assessment: **$7250**, Median cost of post-initial assessment: **$6000**. Post-initial assessments occur regularly or as a laboratory adds to its scope of accreditation.

Maintenance of laboratory instruments and space: EST $347,785

Preventive maintenance is a requirement under ISO/IEC 17025 aimed at preventing the failure of equipment before it occurs. By replacing worn parts before they fail, it increases the likelihood that equipment or instrumentation are performing reliably. Some preventive maintenance can be performed in-house, but often it requires a service contract with the vendor, especially with proprietary instrumentation; these service contracts can be costly. While laboratories may have been performing preventive maintenance on their equipment prior to accreditation, the frequency with which the laboratory must perform preventive maintenance may have increased due to ISO/IEC 17025 accreditation and is therefore a cost-factor.

Based on average national costs, we can estimate approximately **$83,395** in preventive maintenance contracts for microbiology equipment as well as **$217,462** in contracts for chemistry equipment. Preventive maintenance for chemistry equipment can greatly increase costs.

Typically, service contracts on chemistry equipment is about 10% of the purchase price; a service contract on a $300,000 gas chromatography/mass spectrometry (GC/MS) instrument can cost about $30,000 per year for preventive maintenance and service.

The annual cost of supply and equipment purchases to maintain compliance with ISO/IEC standards for a lab which analyzes pesticides and a wide range of cannabinoids is approximately **$25,300**.

Calibration is the comparison of a measured value obtained by equipment (or instrument) with those of a standard with known accuracy. All laboratories are required to calibrate their instruments and equipment used during testing. The median cost of calibrations **was $10,927**.

Proficiency testing which is compliant with ISO 17025 standards and reflective of our requirements for licensed labs will cost approximately **$9000** annually.

Laboratory Operation Costs: EST $51,667

Initial Costs

These included document control software, laboratory information management systems (LIMS) and temperature monitoring systems.
The median total software and/or system cost is, initially, about $**44,627**. Annual maintenance cost of the LIMS software is approximately **$5,000**.

Recurring Costs

Annual costs for consumables in an environmental laboratory space is approximately **$80,000** in this post-pandemic landscape. With the onset of the pandemic, we saw a sharp increase in the price of laboratory consumables as manufacturers struggled to keep up with growing demand of these products for the maintenance and upkeep of COVID testing laboratories.

Rental Space Costs

Annual costs for rental space is approximately $33,265 annually.

1872 sq ft. x $17.77/ sq. ft. = $33,265

Citations

https://www.aphl.org/aboutAPHL/publications/Documents/FS-2018Feb-ISO-IEC-Accreditation-Costs-Survey-Report.pdf

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