



- March 2014; intense lobbying by parents of kids with severe epilepsy
- Governor directs MDH to work on proposal
- Bill signed by Governor **May 29, 2014**
- Law required product be available by **July 1, 2015!!!!**

MN Statutes 152.25

Commissioner Duties

(d) The commissioner shall require each medical cannabis manufacturer to contract with an independent laboratory to test medical cannabis produced by the manufacturer. The commissioner shall approve the laboratory chosen by each manufacturer and require that the laboratory report testing results to the manufacturer in a manner determined by the commissioner.



Rulemaking

- **Target date for expedited rule
January 1, 2015**
- **OMC approaches PHL in July, 2014**
- **Proposed lab testing requirements
scheduled to be presented at
Interested Parties Conference,
August 8, 2014.**



- No funding or resources provided for rulemaking or laboratory certification
- No standards for allowable contaminant levels
- Little information on effective types/levels of cannabinoids
- Compressed timeline

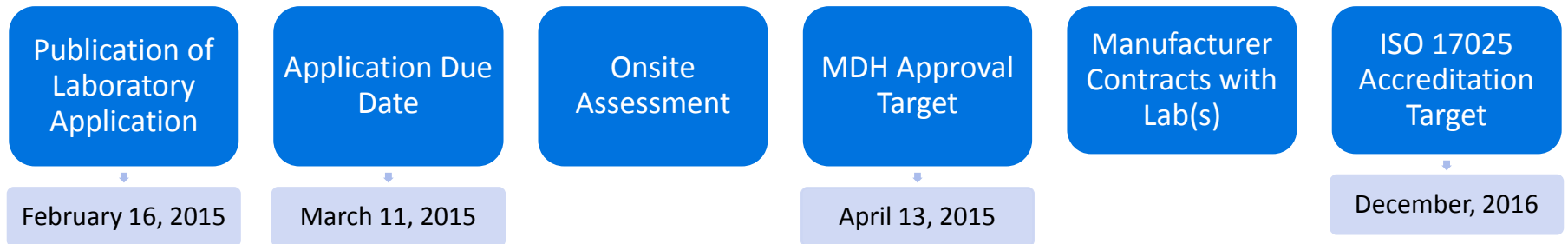


- Utilized MN-ELAP staff and rules as guidelines
- Interim approval pending ISO 17025 accreditation
- “Borrowed” analyte list from other state’s requirements

“Specifications”

- **Analytes**
 - High level list, specific analytes identified by applicant
 - Cannabinoids
 - Metals
 - Residual solvents
 - Pesticides
- **Methods**
 - Specified by applicant
- **Acceptance criteria**
 - Not specified
- **Reporting**
 - Labs keep data “on file”

Laboratory Certification Timeline





Medical Cannabis

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Medical Cannabis Laboratory Application Process and Forms

Application Process

- ▶ [Medical Cannabis Laboratory Approval Application Process Summary \(PDF: 132KB/1 page\)](#)
- ▶ [Medical Cannabis Laboratory Application Process and Required Documentation \(PDF: 193KB/1 page\)](#)
Full details on the application process.
- ▶ [Medical Cannabis Laboratory Approval Program - Initial Application \(PDF form\)](#)

FAQ

- ▶ [Laboratory Application - FAQ](#)
Answers to questions that have come up during the RFP process.
Updated 3/2/2015

Overview

The laboratory application process consists of a three-step process to ensure a thorough and fair assessment of laboratories.

1. The laboratory must submit the application and all required documentation
2. Laboratories who meet the requirements will be contacted for a site visit
3. Minnesota Department of Health Approval

Once a laboratory has received MDH approval, the Minnesota medical cannabis manufacturers are free to establish contract relationships.

*It is required that all approved laboratories achieve ISO 17025 certification by December of 2016.

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Spotlight

[Medical Cannabis Educational Symposium](#)[UPDATE - Intractable Pain](#)[Medical Cannabis Registry](#)[Statistics](#)

Contact Us

Questions? Call us M-F 8 a.m.-4:30 p.m. at 651-201-5598 (metro), toll-free at 844-879-3381 (non-metro) or email health.cannabis@state.mn.us.

Email Updates

Sign up for medical cannabis updates.

Email Address

Required Documentation

- **Completed application form**
- **Signed and Notarized attestation form stating operational and financial independence from all Minnesota medical cannabis manufacturers**
- **Quality Assurance Manual**
- **Standard Operating Procedures**
- **Sample handling, receipt and acceptance procedures and policies**
- **Demonstration of capability and acceptable performance (e.g. PTs, certificates)**
- **Method validation procedures for testing methods**
- **The name and educational qualifications of technical manager**

On-Site Assessment

- **Purpose: to determine the ability of the laboratory to conduct testing for the scope of accreditation requested**
- **Documentation requested includes:**
 - **Detection limits**
 - **Training records**
 - **Proficiency testing results**

Logistical Issues

- **Lab needed to be within MN**
- **Mobile laboratories ok, but how to assess**
- **What to do with labs with facility in other state but not in MN?**
 - **Wanted us to do onsite in other state and then approve for MN**
- **What if no laboratories applied?**



Outcome

- 4 labs applied
- 1 rejected due to failure to provide required documentation
- Onsite assessment of 3 labs
- 2 labs approved
- 1 lab has received ISO 17025 accreditation from A2LA

March 14, 2016

A2LA Accredits First Cannabis Laboratory to ISO/IEC 17025

By Aaron G. Biros

🗨️ No Comments



The laboratory in Minnesota is able to test for pesticides, residual solvents, heavy metals, potency and microbial contamination.

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Frederick, MD- The American Association for Laboratory Accreditation (A2LA) completed its first cannabis testing accreditation for Legend Technical Services, Inc., based in St. Paul, Minnesota. A2LA assessed the laboratory to ISO/IEC 17025 which include the general requirements for the competence of testing and calibration laboratories. The laboratory is now able to test medical cannabis in compliance with Minnesota's Medical Cannabis Registry Program.

Their scope of accreditation (certificate 2950.01) will include testing for cannabinoid potency and profile, terpenes, pesticides, residual solvents, Mycotoxins, heavy metals and analyzing aerobic bacteria, yeast and mold, E. coli, Salmonella and gram-negative bacteria in medical cannabis products.



*The American Association for
Laboratory Accreditation
(A2LA)*



*Roger Brauning, biosafety
program manager at A2LA*

According to Roger Brauning, biosafety program manager at A2LA, this bodes well for cannabis laboratory standards in the future. "We are pleased to provide accreditation to cannabis testing laboratories and recognize the potential international standards have to help ensure safety of all legal products entering the marketplace," says Brauning. "Legend Technical Services, Inc.'s accreditation with A2LA recognizes their commitment to providing the highest quality laboratory services and confidence in the safety of cannabis products that they test."

A2LA's cannabis accreditation program aims to establish a set of standards for quality in testing for cannabis edibles, concentrates and flower. Many states where cannabis is legal require ISO/IEC 17025 for cannabis laboratories as a baseline standard.



Ongoing

- **Need process to handle complaints**
- **Manufacturer not getting the “right answer”**
- **Product quality complaints from consumers**
- **OMC added compliance function**
- **PHL provides technical assistance**

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