

**64CSR111 – Medical Cannabis Program – Laboratories**  
**Department of Health and Human Resources**  
**Bureau for Public Health**  
**Office of Laboratory Services**

**Summary of Public Comments**

**Comment:**

2.2. Accreditation body means an organization which:

2.2.c. is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) for Testing; (proposed rule is missing the term Laboratory in the name of the arrangement).

**Response:**

The Department has reviewed this comment and finds clarification is needed. The rule will be amended accordingly.

**Comment:**

2.5. "Certificate of accreditation," we suggest strengthening this definition to – "means a document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization standard ISO/IEC 17025 or and other standards requirements relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing, or dispensing of medical cannabis". By requiring "ISO/IEC 17025 or" this "or" may introduce an uneven playing field and inconsistencies in West Virginia's program.

**Response:**

The Department has reviewed this comment and finds clarification is needed. The rule will be amended accordingly.

**Comment:**

4.2.d. We suggest clarifying this with "A copy of the laboratory applicant's most recent valid certificate of accreditation granted from an ILAC MRA recognized accreditation body.

4.2.g. We recommend clarifying this with "A description of the accredited tests which are capable of being conducted by the laboratory applicant at the location to be approved." (Accredited laboratories may be performing tests that are not part of a laboratory's accredited Scope of Accreditation. This will ensure that the Bureau is getting a list of accredited tests).

**Response:**

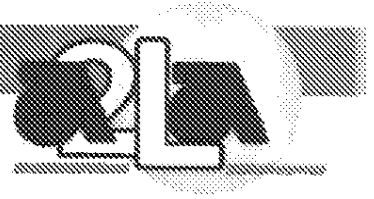
The Department has reviewed this comment and finds clarification is needed. The rule will be amended accordingly.

**Comment:**

11. We are unclear on this clause: "An approved laboratory must follow the methodologies, ranges and parameters acceptable to the bureau which are contained in the scope of the certificate of accreditation issued to the laboratory." We recommend that this requirement be further defined as to what is expected to be listed for ranges on the Scope of Accreditation.

**Response:**

The Department has reviewed the comment and agrees that clarification is required. The range requirement has been removed from the scope of accreditation in the rule. The ranges will be further defined in the cannabis laboratory guidance document under development.



July 8, 2019

Ms. April L. Robertson  
General Counsel  
One Davis Sq, Suite 100, East  
Charleston, WV 25301

**Public Comment 64CSR111 – Medical Cannabis Program - Laboratories**

Dear Ms. Robertson,

I am writing to you on behalf of the American Association for Laboratory Accreditation (A2LA) to voice our support for the proposed rule 64CSR111. We commend the West Virginia Department of Health and Human Resources on relying on accredited testing laboratories to support the Bureau and the industry in helping to assure a safe medical product for the citizens of West Virginia.

In reviewing the ruling, we are providing the following comments for consideration:

2.2. Accreditation body means an organization which:

2.2.c. Is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) for Testing; (proposed rule is missing the term Laboratory in the name of the arrangement).

2.5. "Certificate of accreditation," we suggest strengthening this definition to – "means a document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization standard ISO/IEC 17025 ~~or and~~ other standards requirements relevant to the operation of laboratories conducting tests on medical cannabis and other items used in the growing, processing, or dispensing of medical cannabis". By requiring "ISO/IEC 17025 or" this "or" may introduce an uneven playing field and inconsistencies in West Virginia's program.

4.3.d. We suggest clarifying this with "A copy of the laboratory applicant's most recent valid certificate of accreditation granted from an ILAC MRA recognized accreditation body.

4.2.g. We recommend clarifying this with "A description of the accredited tests which are capable of being conducted by the laboratory applicant at the location to be approved." (Accredited laboratories may be performing tests that are not part of a laboratory's accredited Scope of Accreditation. This will ensure that the Bureau is getting a list of accredited tests).

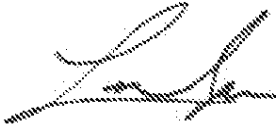
11. We are unclear on this clause: "An approved laboratory must follow the methodologies, ranges and parameters acceptable to the bureau which are contained in the scope of the certificate of accreditation issued to the laboratory." We recommend that this requirement be further defined as to what is expected to be listed for ranges on the Scope of Accreditation.

A2LA supports this proposed rule as a commonsense approach to ensure that a reliable accreditation framework is in place.

As a 501(c)3 science-based membership association, A2LA works to promote and support quality in testing and as a signatory to the ILAC MRA and a provider of accreditation to laboratories that conduct cannabis testing, we look forward to continuing to serve the State of West Virginia and its citizens.

If you have any questions about A2LA or the A2LA medical cannabis accreditation program, please feel free to contact me, Randall Query at [rquery@A2LA.org](mailto:rquery@A2LA.org) or Anna Williams at [awilliams@A2LA.org](mailto:awilliams@A2LA.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Lonnie Spires". The signature is fluid and cursive, with a prominent loop at the end.

Lonnie Spires  
President and CEO  
American Association for Laboratory Accreditation (A2LA)  
[lspires@A2LA.org](mailto:lspires@A2LA.org)