Laboratory Regulation and Standards

Testimony to Joint Committee on Implementing Measure 91

February 9th, 2015

SUMMARY

- Two aspects of laboratory operations must be regulated to ensure public health and safety:
  1. Inspection of laboratory to certify that quality and technical standards are met
  2. Tests and specifications necessary for each of the different product types, e.g. what tests are done and what acceptable results are for the different product types

- A State agency or recognized third party may serve as an inspector. The inspection and accreditation shall be performed using an internationally recognized standard, **ISO 17025.**

- Oregon Office of Public Health Laboratories, Laboratory Compliance Section should be responsible for deployment of cannabis laboratory accreditation program
  - Internationally recognized, expert, third party inspectors should be leveraged to reduce staff and budgetary burdens placed on State agencies

- Current programs such as the Oregon Environmental Laboratory Accreditation Program (ORELAP) should be utilized as a model for a cannabis laboratory accreditation program
  - Representatives from the Oregon Health Authority, Department of Agriculture, Oregon Liquor Control Commission, along with experts from academia, private sectors, and other governmental agencies should develop cannabis laboratory accreditation program
  - Sections of ORELAP Policy and Procedure Manual relating to quality management system standards should be used for cannabis laboratory accreditation program.
  - Technical sections must be developed specifically for scope of cannabis testing

- ORS 438.605 thru ORS 438.620 is not appropriate as direct reference for a cannabis laboratory accreditation program
  - See Appendix I for suggested statutory language

- The Oregon Health Authority should license all firms that meet requirements of cannabis laboratory accreditation program. The Oregon Health Authority should collect licensure fee that sufficiently covers budgetary requirements for deployment of cannabis laboratory accreditation program.

CASCADIA LABS LLC

Presented by Jeremy L Sackett -- Co-founder & Operations Director
20340 Empire Ave Ste E1 -- Bend, Oregon 97701 -- 541.213.2315

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CANNABIS LABORATORY ACCREDIATION PROGRAM

This program should be based on the current ORELAP and administered by same agency. A revision of ORELAP policy and procedure manual would need to be undertaken, along with expansion of technical scope, to effectively include cannabis laboratories to the program. It is scientifically justified and likely more cost effective to use ORELAP as a starting point and mirror it within a cannabis laboratory accreditation program that is administered by the same agency.

It is recommended that the Laboratory Compliance Section within Office of Oregon State Public Health Laboratories administer the cannabis laboratory accreditation program. This Section administers environmental lab accreditation, clinical lab regulation, health screen testing permits, substance of abuse lab registration, and the laboratory response network.

It is recommended that the cannabis laboratory accreditation program include three components for which a series of requirements must be met and demonstrated within an application. If all requirements are met, then the cannabis laboratory is issued a license from the Laboratory Compliance Section to operate within legal Oregon cannabis markets

Cannabis Laboratory License Requirements:

1. Standardized Quality Management Systems
    a. Section 4, ISO 17025
    b. Additional requirements directed by the expert advisory committee

2. Technical Competency
    a. Section 5, ISO 17025
    b. Additional requirements directed by the expert advisory committee

3. Diversion Control Mitigation Measures

    The diversion control component of the license should be similar to that of other legal cannabis businesses licensed to operate within Oregon. This component should include sample inventory control, security, background checks, and a system to report batch testing results (particularly failing results) to appropriate agencies.

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FINANCIAL CONSIDERATIONS

Laboratories in every industry must be able to demonstrate compliance with relevant quality standards for their industry. Best practices dictate that quality management systems be deployed in all quality control laboratories. These quality management systems assure accuracy, reliability, and, overall defensibility of all results in a court of law. The cost of quality management systems is a sunk cost for doing business as a competent and qualified quality control laboratory. Regulation to require a laboratory meet quality standards will not add additional cost to products in the related marketplace.

To reduce overall cost to products in a regulated marketplace where testing is required to assure public health and safety, the testing should be moved as far up the supply chain as possible. The producers and processers that are manufacturing product to bring to market should be responsible for quality control of batches they produce. Larger batches can only be utilized if a statistically relevant sample is taken from the batch. A qualified and trained laboratory representative should be responsible for taking the sample from manufacturer's batch using an established and standardized procedure.

Additionally, the separation of different product types into separate categories, each having specific set of tests based on the critical quality attributes of each product type, will overall reduce the testing burden because testing will be based on product type and not all tests will be necessary for each product type. For instance, microbial contaminant (i.e. mold) testing would not be necessary for plant material that was to undergo extraction processing with organic solvents. By establishing testing requirements specific to each product type, some tests will be eliminated from specific points within the supply chain and therefore reduce financial burden to participate in regulated system for small businesses.

The points considered above are components of an overall concept called Quality by Design. Quality by Design is used in the pharmaceutical and biotechnology industries to lower cost while very effectively mitigating risk to public health and safety. Quality by Design utilizes a scientifically justified and risk-based approach to characterize through quality control testing only those quality attributes that are critical for consumer safety and product efficacy.

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APPENDIX I.

§ 438.AAA

Definitions for ORS 438.BBB, 438.CCC

As used in ORS 438.AAA, 438.BBB, 438.CCC, and 438.DDD:

(1) Accrediting authority means the official accrediting authority for the Oregon cannabis laboratory accreditation program comprised of the Director of the Oregon Health Authority or designee, the Director of the Oregon Liquor Control Commission or designee and the Director of Agriculture or designee.

(2) Authority means the Oregon Health Authority.

(3) Cannabis laboratory means a fixed location that performs chemical, physical, microbiological or biological testing of cannabis samples or the collection of cannabis samples.

(4) Cannabis testing means laboratory analysis of any cannabis product subject to regulation pursuant to rules adopted or enforced by the Oregon Health Authority, the Oregon Liquor Control Commission or the State Department of Agriculture.

§ 438.BBB

Standards for accreditation

(1) The Oregon Health Authority, in concurrence with the accrediting authority, will adopt by rule standards for any laboratory seeking accreditation and performing cannabis quality control testing for a fee or for determining compliance with cannabis statutes, rules or regulations.

(2) In developing standards under subsection (1) of this section, the authority shall cooperate with and may seek advice from any other state agency that may have adopted cannabis rules or regulations.

(3) The standards adopted under this section may address testing and sampling procedures or methods, record keeping, disposal or retention of testing materials or samples, or any other practice related to work performed by cannabis quality control laboratory.

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§ 438.CCC

Cannabis laboratory accreditation program

The Oregon Health Authority, in concurrence with the accrediting authority, shall establish by rule and implement a cannabis quality control laboratory accreditation program. The standards for accreditation may be equivalent to, and may exceed, standards set forth by International Organization of Standardization.

§ 438.DDD

Accreditation and license fees

(1) In conjunction with the cannabis laboratory accreditation program established under ORS 438.CCC (Cannabis laboratory accreditation program), the Oregon Health Authority may establish and collect a fee for laboratory accreditation under the program. A fee imposed under this section shall not exceed the cost of administering the program.

(2) Prior to imposing the fee under subsection (1) of this section, the authority shall obtain the approval of the Oregon Department of Administrative Services and report to the appropriate legislative committee.

(3) All moneys collected by the Oregon Health Authority under this section shall be deposited in a dedicated account of the authority. Such moneys are continuously appropriated to the Oregon Health Authority to pay the costs of the authority, the State Department of Agriculture and the Oregon Liquor Control Commission in administering the cannabis laboratory accreditation program established under ORS 438.CCC

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International Laboratory Accreditation Cooperation

How does using an Accredited Laboratory benefit Government and Regulators?

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Accreditation in support of Regulation

In the early days of accreditation in the 20th Century, it was predominantly seen as a voluntary activity. However, now, in many economies, accreditation has been widely embraced by governments and accreditation has become "mandatory" in many regulated areas as more and more governments and regulators appreciate the benefits that accreditation brings to help governments meet their responsibilities and safeguard the public.

For example, in the Asia-Pacific region, APEC (the Asia Pacific Economic Cooperation) endorses accreditation, with the Asia Pacific Laboratory Accreditation Cooperation (APLAC) recognised as an APEC Specialised Regional Body. Accreditation is now used to underpin the conformity assessment component of the APEC agreements.

Similarly, ASEAN (the Association of Southeast Asian Nations) with its ten member states, has included accreditation in the ASEAN sectoral MRA for electrical and electronic equipment as a means of meeting the mandatory requirements of each member and to facilitate the implementation of the ASEAN Free Trade Area (AFTA).

In Europe, the Council of the European Union and the European Parliament have agreed on a Regulation that provides a legal framework for the provision of accreditation services across Europe. The Regulation, which will apply from January 2010, will cover the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. The Regulation recognises the benefits of accreditation by legislating that accreditation be used as a means to show compliance with mandatory requirements. The Regulation also recognises the European co-operation for Accreditation (EA) as the co-ordinating organisation for the national European accreditation infrastructure.

In the Americas, regulators and government entities throughout the region are increasingly relying on results from accredited laboratories to meet their mandatory requirements in areas as diverse as food safety, environmental protection, toy safety, and the quality of concrete, steel, electrical products and a variety of other products and services. The InterAmerican Accreditation Cooperation (IAAC) is committed to disseminating the concepts and advantages of accreditation and is responsible for ensuring that accreditation bodies in the region operate their programs to stringent international requirements.

The mainstream acceptance of accreditation by pan-regional bodies, and domestic regulators within individual governments, also helps member governments of the World Trade Organisation (WTO) to meet their responsibilities of the Technical Barriers to Trade Agreement (TBT Agreement), and Sanitary and Phyto Sanitary Agreement (SPS Agreement).

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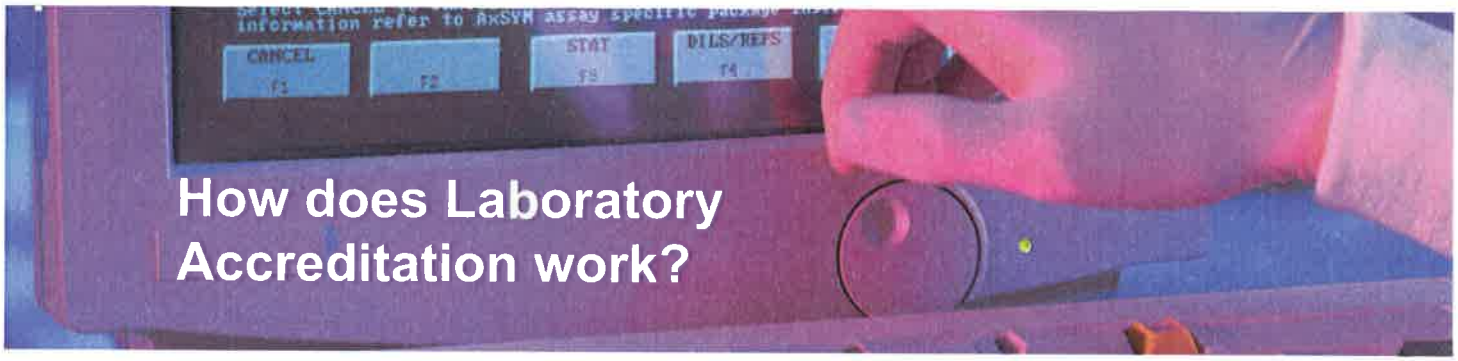

How does Laboratory Accreditation work?

Laboratory accreditation is generally provided by one recognised accreditation body within a country. In some developing economies without established accreditation bodies, laboratories may have to seek accreditation from an established accreditation system in another country.

Specialist technical assessors from the accreditation body conduct a thorough evaluation of the laboratory's practices, staff and equipment that impact on the production of test or calibration data. The laboratories are evaluated against particular international standards that are used throughout the world, either ISO/IEC 17025 *"General requirements for the competence of testing and calibration laboratories"*, or ISO 15189 *"Medical laboratories – Particular requirements for quality and competence"*.

Accredited laboratories are regularly re-examined to ensure that they maintain high standards of technical expertise. Laboratories may also be required to participate in regular proficiency testing programs as an on-going demonstration of their competence.

Government representatives, at their option, are welcome to take part in on-going assessments in order to maintain their confidence in the accreditation system.

How does laboratory accreditation differ from ISO 9001 certification? ISO 9001 certification demonstrates that a laboratory has an established quality management system, but it does not address technical competence. Laboratory accreditation takes the next step, using criteria and procedures specifically developed to determine technical competence.

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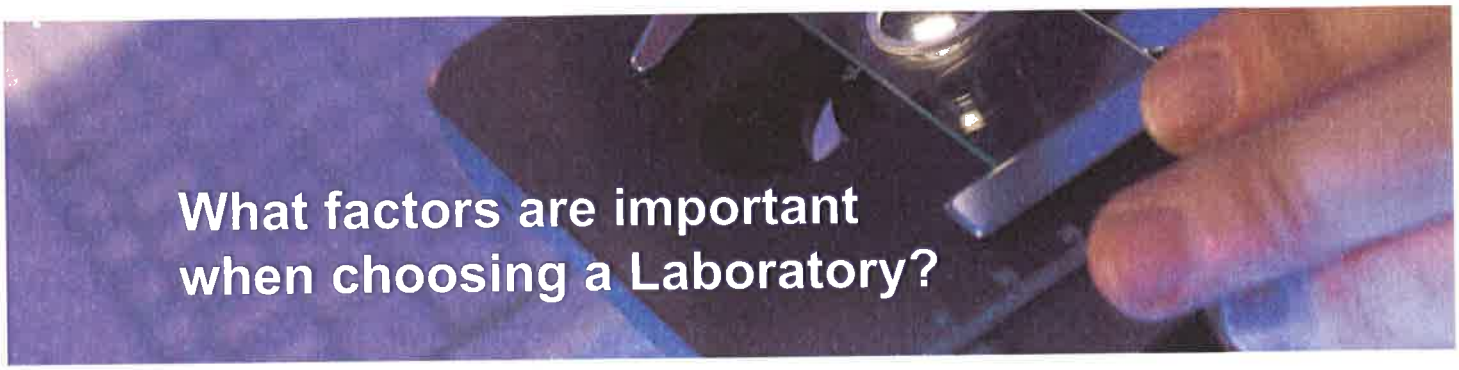

What factors are important when choosing a Laboratory?

When selecting a testing, calibration or measurement laboratory, you need to be sure that it can supply you with accurate and reliable results that meet your requirements.

The list of the test, calibration, or measurement procedures for which the laboratory is accredited is specified in a laboratory's Scope of Accreditation, which can either be provided by the laboratory upon request, or is contained within the directory of accredited laboratories produced by the accreditation body.

You should check that the laboratory is accredited for the specific work that you require to be undertaken.

When an accredited laboratory carries out work covered by accreditation, it usually includes an accreditation symbol or endorsement on their test or calibration reports.

The technical competence of a laboratory depends on a number of factors, including:

- Qualifications, training and experience of the staff
- Correct equipment – properly calibrated and maintained
- Adequate quality assurance procedures
- Proper sampling practices
- Appropriate and valid testing procedures and methods
- Traceability of measurements to national standards
- Accurate recording and reporting procedures
- Suitable testing facilities

By being accredited, the laboratory is demonstrating that these requirements, amongst others, have been and continue to be met.

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