Advantages of Laboratory and Inspection Body Accreditation for the Medical Marijuana Market

In the wake of state legislatures legalizing cannabis for compassionate medical use, state regulatory agencies are left to grapple with the need to establish mechanisms for enforcement and oversight of the legislation’s program requirements for participating patients, growers and dispensaries. An integral component of these rules includes laboratory testing and inspection of the product, as well as of the growing and dispensary operations, as a means for protecting consumer health and assuring safety. State governments should rely on existing, recognized Accreditation Bodies and their accredited laboratories and inspection bodies to support their regulations.

Laboratory accreditation is a formal recognition by an authoritative third party of the competence of a laboratory to perform specific tests. Similarly, inspection body accreditation is a formal recognition of competence to perform specific inspections. It is important to note that independent third-party involvement in assessing laboratory and inspection body competence allows the regulatory agency to maintain control over the regulatory process at a high level, by creating the specific regulatory criteria and by using recognition as the mechanism by which it approves the Accreditation Bodies (AB). Thus a regulatory agency should provide oversight by using existing recognition schemes to approve Accreditation Bodies. Accreditation Bodies then accredit the laboratories and inspection bodies that determine (through quality and safety testing and facility inspection) whether the regulated products or services are in conformance with internationally-recognized standards for competence as well as with any additional specific requirements of the regulations themselves.

Why Accreditation Partnerships are successful:

- The programs can be tailored to specific regulatory needs but are based on common international consensus standards (ISO/IEC 17011 for Accreditation Bodies; ISO/IEC 17025 for laboratories; ISO/IEC 17020 for inspection bodies1).
- Partnerships enable varying degrees of oversight by agencies based on their comfort level.
- Partnerships place the costs of accreditation on the laboratories and inspection bodies being assessed/audited, rather than on the regulatory agency itself.
- Partnerships fit seamlessly into the Accreditation Body’s already-established programs while easily catering to specific regulatory needs.

Benefits of Accreditation to the Regulated Entity:

- Accreditation by a third party provides credibility to the testing and inspection community and establishes a level playing field.
- The Accreditation Body’s involvement in the conduct of assessments and the review of assessment outcomes creates and maintains consistency between assessments.
- Accreditation by a third party allows access to experienced, expert assessors who are technically competent in the fields assigned.
- Growers can make use of information sources like the International Laboratory Accreditation Cooperation (ILAC) web site (www.ilac.org) and its links to the on-line directories of ILAC Arrangement signatory Accreditation Bodies to identify qualified laboratories and inspection bodies.
- Use of Accreditation Bodies that are signatories to the ILAC Mutual Recognition Arrangement (MRA) provides a high level of confidence in the Accreditation Body’s competence. This confidence is based on the requirement for the Accreditation Body to undergo routine, rigorous peer evaluations against long-standing international standards for assessing quality as well as on the satisfaction of the laboratories and inspection bodies assessed and of the regulators themselves.
- The regulated entity can rely upon greater responsiveness, as they no longer have to consider the capacity of the regulatory agency to perform timely and effective assessments and the related costs.
- The regulated entity will enjoy lower overhead costs, due to the relatively reduced expense associated with having a third party Accreditation Body perform the assessments.
Benefits of Accreditation to the Regulators:

- Regulatory agencies maintain oversight/ownership of their individual programs. Regulatory agencies that rely on third-party programs do not delegate their regulatory authority. Instead, through the recognition of third-party Accreditation Bodies, they authorize the participating laboratories and inspection bodies to perform certain technical tasks in order to assess material/product conformity.
- Regulatory agencies will realize an increase in resources that previously were dedicated to performing assessments and managing accreditations. Instead regulatory agencies rely on third-party Accreditation Body assessments in their own enforcement of regulatory requirements.
- There is a potential for the regulatory agency to achieve greater efficiency through reducing its direct compliance assessment costs and resource needs. Thus they are able to leverage expertise and resources in the private sector to serve regulatory objectives.
- Several models of government/regulator and third-party Accreditation Body partnerships have been in place at the federal and state levels for well over a decade.

Benefits to the Patient:

- Patients have greater confidence in the safety of the cannabis product because of the accuracy of the quality and safety tests performed on the cannabis they are purchasing, since the results have been generated by a competent facility accredited by an internationally-recognized third-party Accreditation Body.
- Public oversight of third-party assessment activities provides greater transparency and provides the opportunity to observe how the regulatory agency achieves its regulatory objectives.

Advantages of Using the American Association for Laboratory Accreditation (A2LA):

- A2LA has over thirty five years of experience in providing accreditation services.
- A2LA assessors in this particular field have over twenty years of relevant technical experience.
- A2LA employs full time staff with laboratory testing and inspection experience.
- A2LA has extensive expertise in collaborating with federal, state and local agencies on accreditation programs, customized to meet their needs.
- A2LA is proficient in establishing, tailoring and maintaining accreditation programs to meet the goals of the stakeholders.

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1 ISO/IEC 17011:2004 specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs). It is also appropriate as a requirements document for the peer evaluation process for mutual recognition arrangements between accreditation bodies. ISO/IEC 17025:2005 specifies the general requirements for the competence of laboratories to carry out tests, including sampling. It covers testing performed using standard methods, non-standard methods, and laboratory-developed methods. It is applicable to all organizations performing tests regardless of the number of personnel or the extent of the scope of testing. ISO/IEC 17020:2012 specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.

2 International Laboratory Accreditation Cooperation (ILAC): The primary purpose of ILAC is to establish multilateral arrangements between member accreditation bodies, based on mutual evaluation and acceptance of each other’s accreditation systems. ILAC is the world’s principal international forum for:
- the development of laboratory and inspection body accreditation practices and procedures;
- the promotion of laboratory and inspection body accreditation as a trade facilitation tool;
- the assistance of developing accreditation systems; and
- the recognition of competent test and inspection facilities around the globe.

Over 80 accreditation bodies have signed the ILAC Arrangement to promote the acceptance of accredited test, calibration and inspection data and results. The ILAC Arrangement, a mutual recognition arrangement between the Full Members of ILAC, provides significant technical underpinning to international trade. The key to the Arrangement is the developing global network of accredited laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been evaluated by their peers (against the requirements of ISO/IEC 17011) and shown to meet ILAC’s criteria for competence.