

October 24, 2019

## **Marijuana Control Board - Comments to Proposed Changes**

The Marijuana Control Board proposes to adopt regulation changes in 3 AAC 306 of the Alaska Administrative Code, dealing with marijuana testing oversight, including the following:

- 3 AAC 306.100 is proposed to increase the license fee for marijuana testing facilities.
- 3 AAC 306.620 is proposed to require the board's contractor to examine a marijuana testing facility prior to being issued a license.
- 3 AAC 306.635 is proposed to require compliance with the Marijuana Testing Facility Compliance Document.
- 3 AAC 306.640 is proposed to require changes to standard operating procedures be submitted and approved by the board's contract.

Americans for Safe Access (ASA) is an independent nonprofit organization that does not have a financial stake in any laboratory in Alaska. ASA is aware of the risks of unregulated and untested products in the marketplace and supports mandatory third-party testing of cannabis and cannabis-containing products prior to sale. We respectfully submit the following comments with regards to the proposed changes.

### **3 AAC 306.100 - Proposed increase in the license fee for marijuana testing facilities.**

The current initial laboratory testing fee is \$1000 and the renewal fee is \$2000, which is consistent with the structure of other initial and renewal fees given that the renewal fees listed in 3 AAC 306.100(d) are 40-100 percent higher than the initial fees. The proposed change is a renewal fee of \$5000, which is not consistent with other fee schedules, none of which have a renewal fee five times that of the initial fee.

Cannabis testing laboratories must acquire specialized laboratory equipment that can cost over a million dollars. They also employ technicians who require specialized training and education in specific areas of testing, which leads to higher overall operating costs. Also, it can take months to validate instruments and testing methodologies, all of which must be done prior to testing any samples. Thus, a lab may be forced to pay a license renewal fee prior to receiving samples, and a high fee could force small operations to close before they have a chance to provide their services to the industry and gain a loyal client base.

Americans for Safe Access would propose that the renewal fee be left unchanged.



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**3 AAC 306.620 - Proposed to require the board’s contractor to examine a marijuana testing facility prior to being issued a license.**

Americans for Safe Access supports the proposed changes to 3 AAC 306.620. In 2014, ASA and the American Herbal Products Association partnered to create standards for the cannabis industry and ASA launched the Patient Focused Certification program to provide the industry with an independent, third-party compliance mechanism.

An initial site inspection is only one step in ensuring continued compliance with industry standards and local laws and regulations. Facilities should be inspected annually or biannually, and independent auditing contractors that carry out such inspections while also verifying standard operating procedures and protocols, record keeping, and legal and regulatory compliance are an efficient and cost-effective way to ensure that the highest standards are met without placing undue burden on MCB’s resources. We would request that the Marijuana Control Board solicit a Request for Qualifications to identify a pool of contractors that could meet the board’s requirements.

**3 AAC 306.635 - Proposed to require compliance with the Marijuana Testing Facility Compliance Document.**

The Marijuana Testing Facility Compliance Document outlines standards to which laboratories must adhere. These standards include provisions for record keeping, staff training, and sample homogenization. In order to ensure that laboratories meet the standards of the Compliance Document, Americans for Safe Access would propose that laboratories be permitted to seek an independent certification or accreditation that has been verified by the MCB and awarded by an approved contractor. The cost for certifications and assessments would be borne by the laboratory, meaning that comprehensive oversight of laboratory operations could be provided without straining the Marijuana Control Board’s employees or financial resources..

Americans for Safe Access would also propose to add provisions to the Compliance Document and the rules and regulations to require that authorized representatives of independent testing laboratories collect representative samples of the plant material or product(s) to be tested. When businesses are allowed to submit their own samples to laboratories for testing, there is no guarantee that they are submitting the correct volume of sample (based on representative sampling guidelines) or that they have not adulterated the sample in order to pass testing.

**3 AAC 306.640 - Proposed to require changes to standard operating procedures be submitted and approved by the board’s contract.**



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Advancing Legal Medical Marijuana Therapeutics and Research

Americans for Safe Access is opposed to requiring laboratories to submit changes to standard operating procedures (SOPs) for approval. The Marijuana Testing Facility Compliance Document outlines the standards to which laboratories must adhere, which includes the implementation of a Quality Management System (QMS). The QMS should have procedures for making changes to SOPs and other policies and procedures and should define how the documentation changes are tracked, reviewed, and approved. Most QMS systems require a specific Quality Manager or other authority figure, such as the Laboratory Director, to be responsible for maintaining and implementing changes to SOPs, policies, and procedures.

SOPs may be added or updated for minor reasons, such as spelling errors or an insignificant change in procedure, or for major ones, such as implementing a new test method. Senior laboratory staff (e.g., Quality Managers, Laboratory Directors) are tasked with maintaining significant numbers of these procedures, all of which undergo a review annually, at a minimum. Requiring that any change be submitted for approval prior to implementation could impede a laboratory's workflow, delay the implementation of any necessary changes to procedures, and create a bottleneck at the Marijuana Control Board if the pace at which changes are submitted exceeds the pace at which they can be reviewed.

In our comments above regarding 3 ACC 306.635, we propose that laboratories be required to adhere to industry standards and that they be permitted to seek independent certification or accreditation of their adherence thereto. Were this proposal to be implemented, certifying or accrediting bodies that the Marijuana Control Board approves after a competitive process would review changes to laboratories' standard operating procedures on an annual and/or biannual basis. This would transfer some of the oversight burden from the Marijuana Control Board to an independent, board-approved contractor while ensuring rigorous compliance with laws, regulations, and standards designed to promote product quality and protect patient and consumer safety.



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