

Marijuana-infused products must be labeled appropriately to ensure patient safety (dosage) as well as comply with possession limits as required by the Department of Public Safety.

Recommendations from the work group identified the development of a State oversight program of marijuana-infused products by two methods: **validating** current dispensary laboratory operations which determine the current labeling, and independent product **testing** by the State. The State laboratory identified for this testing is the Vermont Agricultural and Environmental Laboratory, a component of the Agency of Agriculture, Food & Markets. The State will need several years to fully develop this capacity.

Validating the current dispensary laboratory operations would require the development of a laboratory auditing process to evaluate the systems and procedures of the current laboratories. This auditing would be done by the Vermont Agriculture and Environmental Laboratory and would be reported to the Department of Public Safety as part of the dispensary licensure process. The basis of the State's evaluation would be aligned with currently accepted laboratory practices (ISO, NELAP, GMP). An initial audit of the dispensary laboratories will be performed by Vermont Agriculture and Environmental Laboratory, demonstrating that they are operating under appropriate quality systems, good laboratory practices, and with appropriate testing procedures. Audits would occur annually thereafter, and information derived from the audits would be reported to the Department of Public Safety in its review of licensure.

Laboratory **testing** for cannabinoid potency (THC content) *must be* conducted in-state and by people authorized to possess the products. That is currently limited to employees of the dispensaries and the State. Dispensaries may procure laboratory services from each other. Any third-party laboratory (mobile) would need to become an employee of the dispensary and subjected to the same auditing as the other dispensary laboratories.

The dispensaries must test and document cannabinoid potency at a frequency which ensures the product label. The State will be spot-checking consumer products and in response to complaints. Dispensaries that produce more product lines will be subjected to more frequent checking. Additionally, dispensaries that have severe or systematic failures, either in audits or in consumer product checks, will be subjected to increased testing. The stricter the State laboratory auditing process, the less physical samples will need to be tested. This is a preferred route for the dispensaries.

The State's analytical testing would check for compliance, not only with label guarantees, but other consumer safety parameters (pesticides, microbial and fungal contamination, solvents, and heavy metals). Frequency of these checks would be performed along the same guidelines as potency.

There are challenges expected with verification of potency of infused products. Identifying appropriate analytical (instrument) methods should be relatively straightforward, as methods currently exist and are in use by other states. Challenges, however, will be posed by unique matrices into which the marijuana may be infused. **Standardized extraction** and **reporting methods** will be critical to handle the diversity of these matrices. Dispensary laboratories will use different analytical technologies (instrumentation) to quantify potency; however, they will need to meet State designated standards demonstrating their ability to accurately quantify cannabinoid content. These standards will be performance-based

developed in conjunction with the Vermont Agriculture and Environmental Laboratory and the dispensaries.

Cost recovery is currently anticipated in two ways-

Dispensaries could use Vermont Agriculture and Environmental Laboratory as reference (QA/QC) laboratory for their own internal checks or if analytical issues arise. Fees would be a service level.

Department of Public Safety would reimburse for costs of testing. Fees would be at-cost.

There will likely need to be an initial start-up cost to defray the State laboratory's set up and development costs

Responsibilities

Dispensaries: Must provide correct THC-labeled product to ensure appropriate dosage for patient and compliance with possession limits.

State: Must verify the dispensaries are accurately quantifying THC in products and provide consumer safety testing (pesticides, solvents, heavy metals, etc)

Current status

Dispensaries: Have or have access to laboratory capacity. Only employees of the dispensary can possess the products/standards; any third-party needs to become an employee of the dispensary. Dispensary laboratories are developing analytical capacity and are working towards the same accreditation standards as other types of laboratories (ISO, NELAP, GMP).

State: Agency of Agriculture and Environmental Laboratory has been identified as the State laboratory for oversight. It is accredited through NELAP for several programs, but has not yet begun to develop methodology for testing THC. It has just been allowed to possess the standards. All findings, including outages, non-compliance and concerns will be reported to the Department of Public Safety as part of medical dispensary licensure program. Full testing capacity is expected to take several years, as the new laboratory is built in Randolph.

Agency of Agriculture and Environmental Laboratory Oversight Program Phased-in Approach

