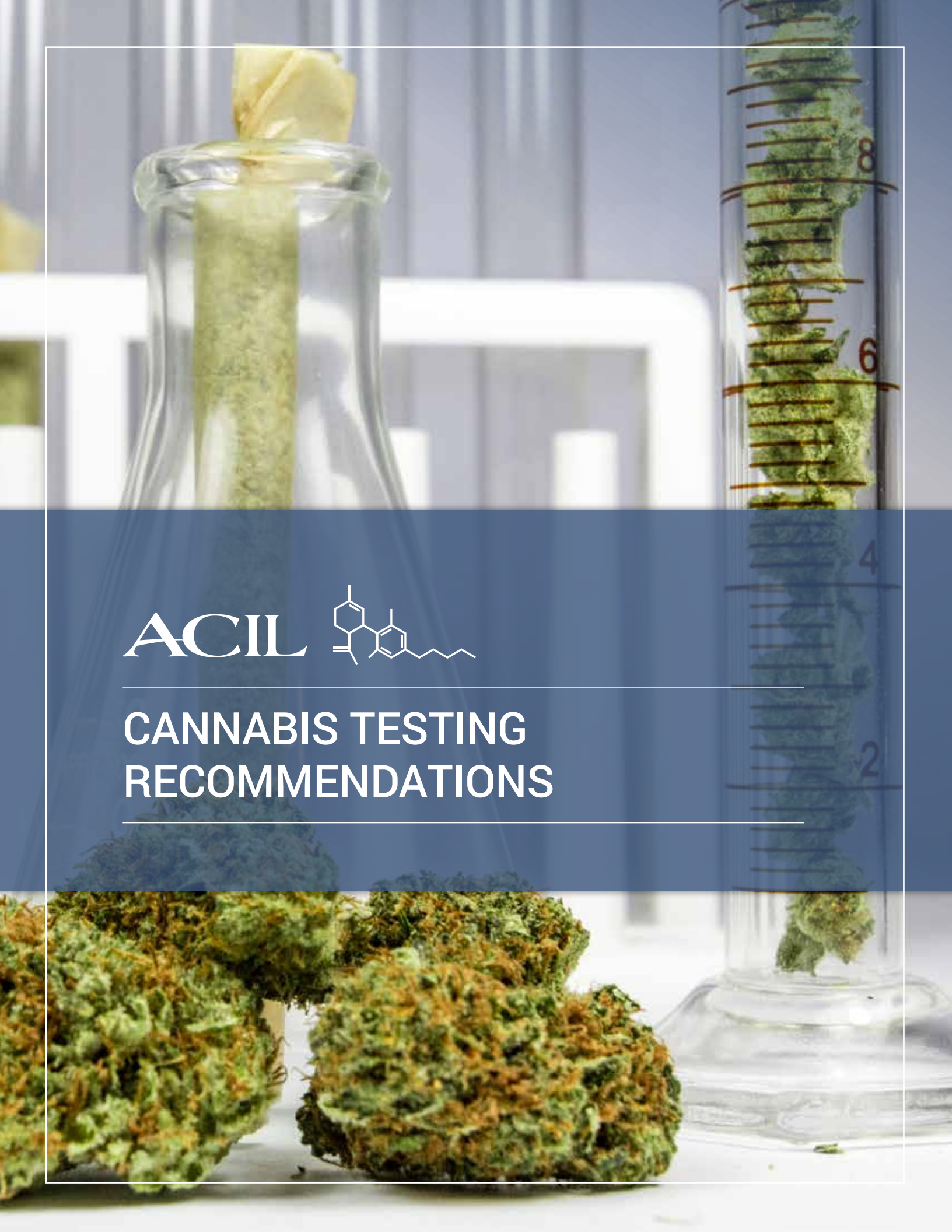


ACIL

CANNABIS TESTING RECOMMENDATIONS

CONTENT

Special thanks to ACIL's member volunteer and professional community for completing this document.

THE VALUE OF INDEPENDENT TESTING

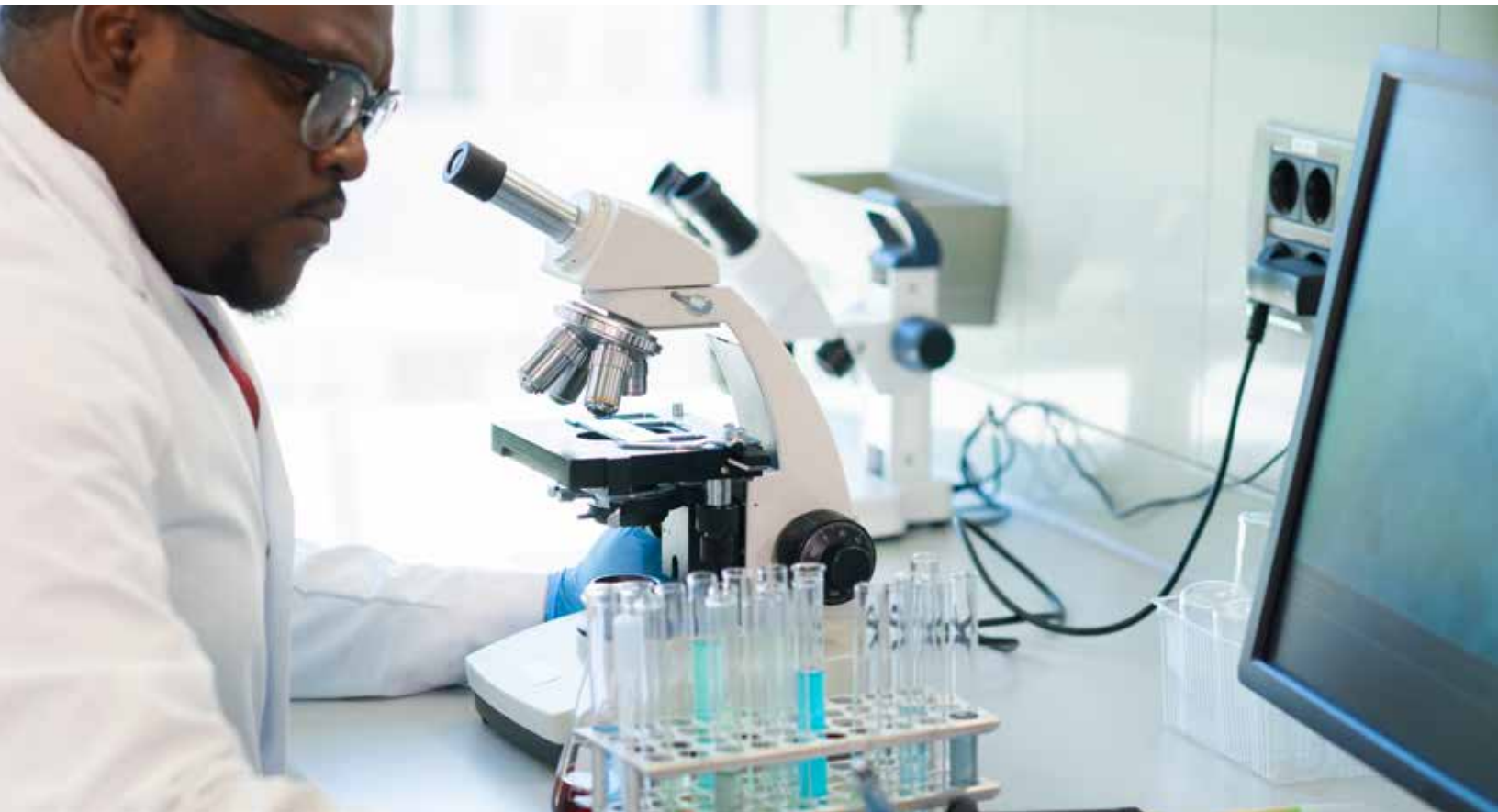
The American Council of Independent Laboratories (ACIL), founded in 1937, is the trade association representing independent, commercial scientific and testing laboratories. Its members are professional services firms engaged in testing, product certification, consulting, and research and development.

As independent commercial laboratories, ACIL members provide the objective, scientific data on which manufacturers and government agencies base conclusions about safety, performance and other criteria for products and services used in our everyday lives.

Independent, third party laboratories exist to validate product claims and uncover dangerous deficiencies, providing an objective benchmark for evaluators to consider when accepting or rejecting goods and services. During national, state or local emergencies, testing laboratories stand ready to provide professional services and augment capacity due to spikes in demand. As a national resource, we offer breaking news during real or perceived public safety and health emergencies, so that the public can easily access topical information from some of the most dedicated scientific and engineering minds in the country.

In general, as a society we place tremendous value on an independent review or verification and the resulting confidence it provides. ACIL supports the use of accredited independent laboratories to provide assurance that products and other objects of testing activities conform to requirements for safety, health, environment, electronics performance, and security. Use of accredited laboratories instills confidence in all stakeholders. Independent conformity assessments and testing are efficient and effective tools to demonstrate regulatory compliance.

Governments should recognize and utilize accredited private sector, independent conformity assessment activities to help them meet their legislative and regulatory mandates.



ACIL CANNABIS TESTING RECOMMENDATIONS

States that legalize use of cannabis products for either medical or recreational use under federal illegality create new responsibilities for themselves in areas previously governed solely by federal law. A key challenge for these "legal states" is the creation of a cannabis testing industry that ensures public health and safety and responsible use of cannabis products.

States have implemented a variety of approaches to address these responsibilities that can generally be viewed as public policy experimentation. From these experiments, best practices and cautionary tales for future regulators have started to emerge in the cannabis testing space.

ACIL thinks best practices can be drawn from existing regulatory approaches and policies designed to ensure safety and efficacy of ingested consumer products. This paper seeks to convey insights and guidance from testing industry experts regarding best practices for testing cannabis and its products.

The following issues represent ACIL views of best practices for cannabis testing at the federal level:

1. Accredit laboratories nationally, based on conformance to internationally recognized consensus standards of laboratory practice, as assessed by non-governmental accrediting bodies conforming to equivalent standards of practice. ACIL and the Independent Laboratory Institute (ILI) along with partners developed the Cannabis Laboratory Accreditation Program (CanNaLAP) to serve as a basis for organizing and administering a national accreditation program.

2. ACIL seeks to work with the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), and U.S. Department of Agriculture (USDA) to develop a regulatory framework to allow small quantities of cannabis and/or tetrahydrocannabinol (THC) containing products to be shipped across state lines for testing purposes. Testing laboratories need reference, calibration, and performance evaluation materials from suppliers in other states. These materials contain THC and they are essential to ensuring accurate test results and use of testing data from multiple states in public health studies.

3. Collaborate with existing federal agencies responsible for product safety, efficacy and consumer product inspection services, such as USDA Food Safety and Inspection Service (FSIS), FDA & DEA, to develop standards and protocols for sampling, handling, inspecting and testing cannabis products for human and veterinary uses.

4. Allow appropriately accredited laboratories to accept cannabis samples from the general public, including home cultivators, patients, and journalists. Allow cannabis testing laboratories to perform other types of testing such as Food Safety, Product Safety, and Pharmaceutical Environmental. This will expand the reach and benefits of cannabis testing to the public by allowing public access to testing resources to support product development, safe/responsible uses, and health outcomes.

5. Ensure that sampling and testing for regulatory purposes is independent, representative, and consistent with scientific best practices established through consensus standards generated by professional scientific organizations such as the Association of Analytical Communities (AOAC), United States Pharmacopeia (USP), and the American Society for Testing and Materials (ASTM). ACIL supports reductions of duplicative testing along the supply chain by supporting the regulatory testing of cannabis products in their final form - those marketed for human consumption.

NATIONAL CANNABIS LABORATORY ACCREDITATION PROGRAM

Cannabis labs need a national accreditation program to underlie efforts to regulate cannabis product testing in states approving medicinal and recreational use. To ensure public health and safety, ACIL, the national trade association for independent scientific organizations (www.acil.org), seeks to establish a national standard for cannabis lab accreditation as a mechanism to ensure the effective performance of all cannabis testing labs operating in the United States. CanNaLAP is a published standard of practice developed for cannabis laboratories through a consensus process involving all stakeholders; labs, states agencies. CanNaLAP is based on ISO/IEC 17025, the international standard for laboratory practice. ACIL values laboratory accreditation schemes based on international and nationally recognized standards of laboratory practice.

ACIL encourages the adoption of the Independent Laboratory Institute's (ILI) Cannabis Laboratory Accreditation Program that details standardized requirements for testing of cannabis and cannabis-derived products. ACIL seeks a harmonized national lab accreditation program for labs who are testing cannabis plant, extract, or products. Our primary goal is for FDA and USDA support and endorsement of the CanNaLAP scheme as a means to establish standards of competency for testing market participants. We urge these agencies to specify the CanNaLAP scheme for the product testing programs they intend to implement. The CanNaLAP scheme is limited to cannabis product testing. It excludes technical components typically required for clinical and/or pharmaceutical testing.

CanNaLAP addresses specific responsibilities and obligations of laboratories implementing cannabis testing protocols. It is a comprehensive consensus standard based on international standards of laboratory practice (ISO 17025). It sets up standards that will allow the U.S. to deliver safe, reliable, and efficacious product testing services for cannabis derived therapeutic agents.

Benefits of a National Cannabis Laboratory Accreditation Program (CanNaLAP):

- Laboratory accreditation services will be provided by experienced laboratory professionals affiliated with internationally recognized Accrediting Bodies (ABs) assessing conformity to specified standards of practice.
- State parties to CanNaLAP reciprocity agreements can license accredited laboratories to practice in their states.
- States retain authorities to allow accredited labs to operate within their jurisdictions.
- Laboratories avoid separate if not redundant accreditation services.
- States remain Accrediting/Licensing Authorities, deciding policies specific for implementing their state laws, while operating under a national framework for laboratory practices that ensures protection of human health and safety across the United States.
- A national cannabis laboratory accreditation program can, and should, set the national standard for cannabis testing activities.
- Allows laboratories to access markets across state lines

ACIL member commercial laboratories strongly support conformity assessments performed by appropriately recognized ISO/IEC 17011 (International Organization for Standards www.iso.org) compliant ABs as a means to both improve their quality management systems and reduce the costs imposed by multiple redundant accreditation schemes. CanNaLAP provides the necessary standard of lab practices.

To work as envisioned, CanNaLAP needs multilateral mutual recognition arrangements of the International Laboratory Accreditation Cooperation (ILAC), www.ilac.org, and the National Cooperation for Laboratory Accreditation (NACLA), www.nacla.net, to allow international and national accreditation of laboratories by nongovernmental ABs.

The ACIL supports use of appropriately recognized non-governmental AB's as primary assessors in a national cannabis laboratory accreditation scheme. These include NACLA, the International Organization for Standardization (ISO) https://www.iso.org/, and International Laboratory Accreditation Cooperation (ILAC) https://ilac.org/. Under the ACIL model presented below, states that recognize non-governmental ABs to perform laboratory accreditation services retain control of their laboratory oversight authority through licensure of appropriately accredited laboratories to practice in their states.

The goal of all laboratory accreditation programs is to ensure conformance to defined program requirements and technical standards. This assurance, when backed by appropriate assessments conducted by qualified staff operating in accordance with defined standards of practice, provides for the detection and correction of substandard practices leading to protection for end users of data and the public at large.

Today, states provide cannabis laboratory accreditation and licensing services to testing laboratories that desire to operate in, or provide services to/for, facilities/sites located in their states. Significant variability exists in accreditation standards, requirements and the state of conformity assessments provided by states to laboratories. ACIL seeks to standardize practices to ensure uniform application of recognized quality assurance for labs providing tests and measurements to the nascent cannabis Industry.

Under the ACIL scheme, labs choosing to become accredited nationally to the CanNaLAP standard can access markets for their services in other states through reciprocity agreements and payment of licensing fees to states where the testing lab desires to provide services.

If laboratory accreditation is to be provided by states, history implies a two-tier system will emerge with national accreditation representing the top tier. National accreditation appears essential for its ability to facilitate standardized practices and efficient access to out of state markets for testing services. State “regulation based" accreditation programs tend to interfere with the development of a superior system based on transparent standards of practice accepted by participants and regulators as “best practices”.

Facility/site specific state accreditation is required by commercial laboratories desiring to serve customers in the public interest in all states where cannabis is legal. CanNaLAP obligates these labs to obtain accreditation services from recognized ISO 17011 compliant non-governmental ABs, at their expense, to demonstrate conformity to program requirements.

ACIL MODEL FOR NON-GOVERNMENTAL NATIONAL ACCREDITATION

The “big idea” is for states, FDA, USDA and DEA to recognize ISO/IEC 17011 ILAC and/or NACLA-recognized non-governmental ABs to perform primary cannabis laboratory conformity assessments under the CanNaLAP standard of practices.

Commercial testing laboratories observe that conforming non-governmental Accrediting Bodies are timely, professional, impartial, thorough, and cost effective. These non-governmental assessors represent excellence overall and laboratories report a high value from their accreditation experience.

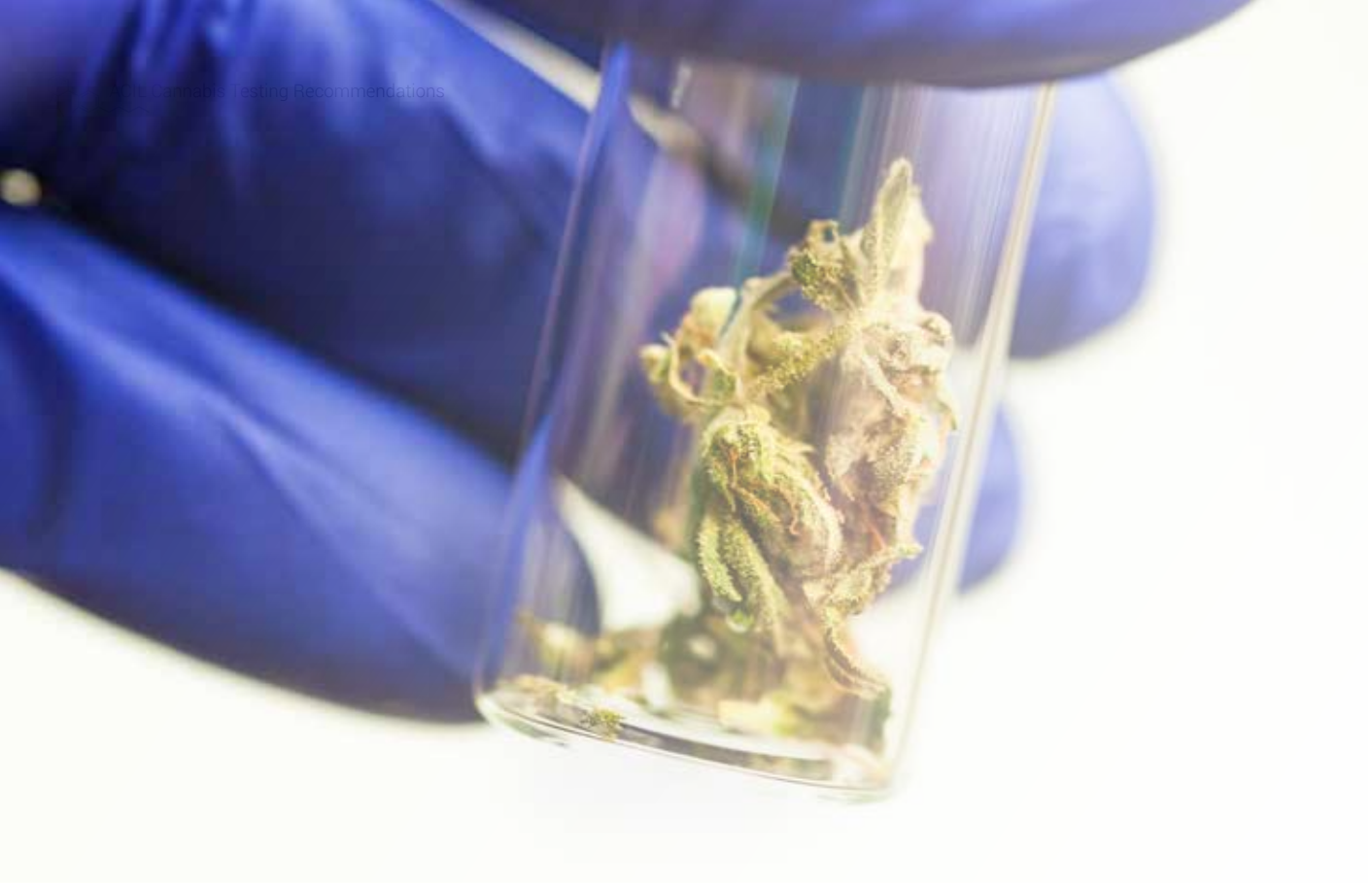
Through the third-party AB scheme, any laboratory seeking CanNaLAP accreditation would choose a provider of accreditation services from a pool of non-governmental ABs accepted by the state agency Accrediting Authority (AA) implementing a cannabis regulatory and testing laboratory accreditation and licensing program. Through this mechanism, the national standard, CanNaLAP, becomes a consistent set of practices implemented by labs in different states to the same end - consistently accurate testing results of known quality.

Under this scheme, laboratories will choose an AB recognized by the state's markets in which they want to participate based on which AB provides the best value accreditation services to the laboratory. After completing the assessment process, the laboratory would be free to purchase a license to provide laboratory services in the state(s) and/or from any state that has entered into a CanNaLAP reciprocity agreement.

ACIL encourages laboratories and state agencies involved in this effort to ensure the mechanism created to allow non-governmental AB entry to the specific state program does not add redundancies, effort, or costs over those currently experienced by laboratories. A CanNaLAP program that delivers non-governmental ABs along with “all in” costs above those currently experienced for laboratories in the individual state programs is unacceptable to the laboratory community.

A separation of licensure and accreditation services and establishing laboratory licensing fees commensurate with the level of effort and costs required to support a licensing, rather than an accreditation program appears key to managing operational costs of state laboratory accrediting authorities. While they retain the authority to accredit laboratories, states, as AAs, are generally poor providers of laboratory accreditation or AB services. Commercial laboratories universally recognize non-governmental ABs conforming to international standards as “best in class” agents to fulfill lab conformity assessment needs. Non-governmental ABs are more competent and more capable than most, if not all, state accreditation bodies today. There appears no reason to perpetuate the failed configuration of basing laboratory accreditation programs in governmental AB's for a new industry like cannabis testing.

ACIL BELIEVES ALL STATES SHOULD BE INVOLVED IN CanNaLAP ACCREDITATION THROUGH LICENSING AND ENFORCEMENT ACTIVITIES.



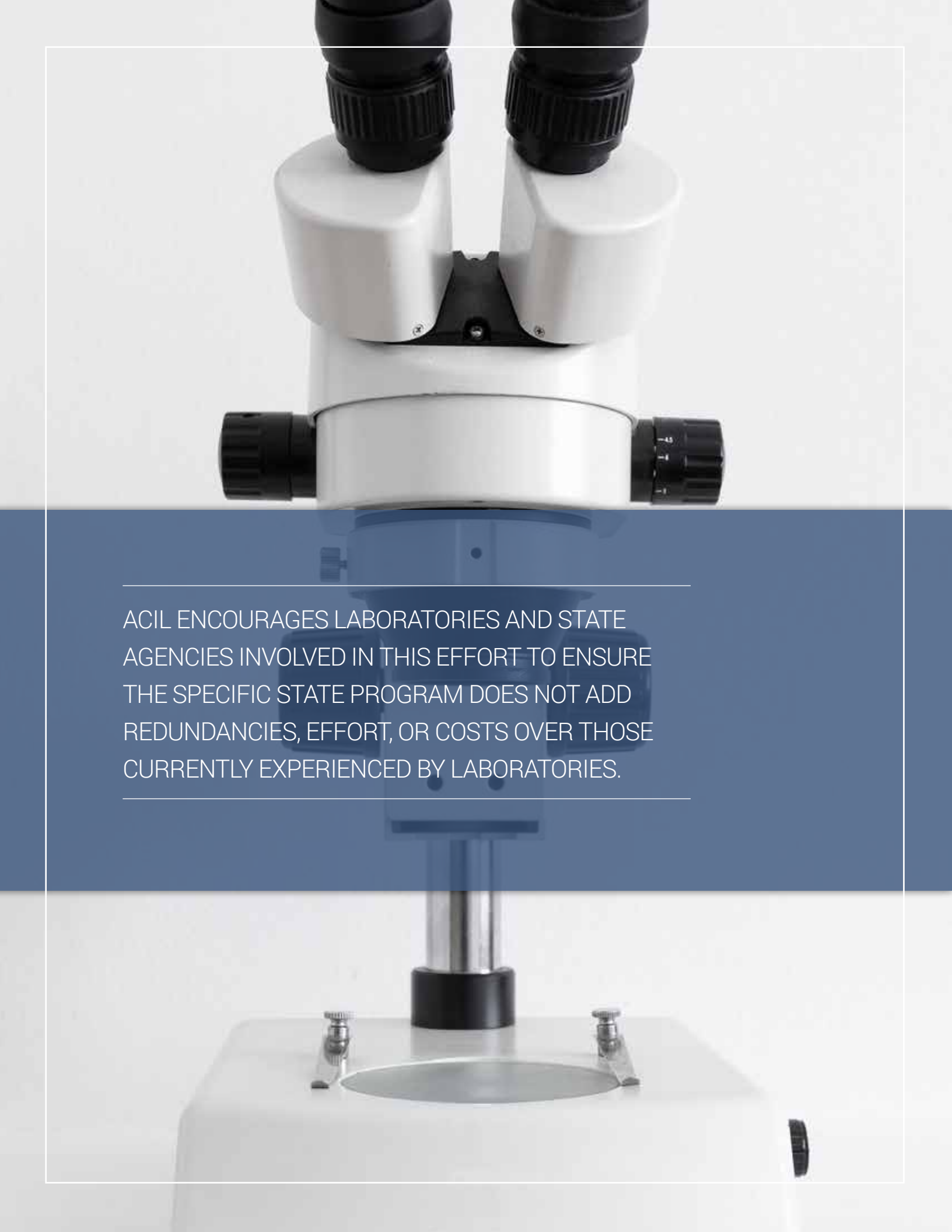
ACIL believes all states should be involved in CanNaLAP accreditation through licensing and enforcement activities. To the extent states wish to continue providing AB services for cannabis testing labs, they should be allowed a reasonable amount of time to bring their AB programs into compliance with ISO/IEC 17011 and become recognized by ILAC and/or NACLA.

States that do not provide AB services will retain technical expertise and oversight capabilities sufficient to provide the regulatory and programmatic support required by municipal/government agencies and laboratories with technical and regulatory questions. State agency laboratory technical support should not be bundled with the provision of accreditation services. An outsourced AB program will simultaneously reduce costs and enable states to focus resources on technical assistance needed to support their Public Health Departments and other essential governmental activities.

A third-party non-governmental accreditation solution does not eliminate states responsibilities to accredit laboratories. Under the CanNaLAP model, states would be responsible for licensing accredited laboratories based on the scope of accreditation they received from the non-governmental AB. States will retain programmatic control and enforcement authority through rule of law in their jurisdictions. ACIL sees no relationship between the provision of accreditation services and the enforcement of state regulations. Under ACIL's scheme, states remain responsible for reviewing the implementation of non-governmental AB accreditation of labs through their business licensing responsibilities.

There is no federal oversight responsibility for cannabis testing. Accordingly, a national accreditation scheme lacks a reason to exist. This paper is written anticipating a future where cannabis is used in all states and at that time a national testing laboratory accreditation program will be desirable.

Third party accreditation represents best practice for all regulatory testing laboratory oversight programs. This approach is widely applied in construction material, electronic, pharmaceutical, clinical, environmental, and food safety testing lab accreditation programs operated in all states.



ACIL ENCOURAGES LABORATORIES AND STATE AGENCIES INVOLVED IN THIS EFFORT TO ENSURE THE SPECIFIC STATE PROGRAM DOES NOT ADD REDUNDANCIES, EFFORT, OR COSTS OVER THOSE CURRENTLY EXPERIENCED BY LABORATORIES.

CANNABIS LABORATORY PROFICIENCY TESTING

Proficiency testing (PT, PT Sample) is a testing industry practice that allows comparison of test results on identical samples tested by multiple labs during the same time period. Reported test results are compared to determine interlaboratory accuracy. Error rates, testing precision and uncertainty data are derived from statistical analysis of reported results.

"Uncertainty" is the error range around which measurements can be considered identical. Typically, uncertainty results are presented scientifically as a number with a second number expressing the range within which the result could be considered accurate, e.g., 10 +/- 1. In this expression, the test result indicates the true value for the material tested was somewhere between 9 and 11 with 10 as the most probable result. As such, the result would be 10, the uncertainty 1. Political polls and surveys of voters use similar statistics to describe the uncertainty of their polling results.

Food safety, environmental, electronic, construction materials and other types of testing labs rely on periodic proficiency testing analyses to demonstrate the acceptability of the labs results when compared to other laboratories performing the same sorts of tests. Participating laboratories are expected to process the proficiency testing sample, and determined measurement values should be similar and within an acceptable margin of error or uncertainty.

Proficiency tests allow laboratories to identify failures within their systems and procedures and specifies process improvement needs and goals. Proficiency testing allows regulators and accreditation bodies means to identify underperforming laboratories that may pose a risk to human health and safety in their jurisdictions.

Due to the prohibition on interstate transportation of small amounts of cannabis for testing purposes, the testing industry has no knowledge of the uncertainty between labs around the United States.

Proficiency testing samples must be uniformly prepared and standardized to ensure the participating laboratories are analyzing material consistent with their typical samples that is both uniform and of known value with respect to the test parameter. PT samples must be prepared under international standards (ISO/IEC 17043) to be recognized by laboratories and ABs as being sufficient to conduct these sorts of tests.

A single source of controlled reference samples prepared and analyzed according to ISO/IEC 17043 is not available for use by C-labs in the US. Therefore, the results of these labs cannot be truly known, thus compromising tremendous amounts of data generated at large expense with potential enormous use to the public.

Ideally, states should set requirements and procedures for interlaboratory proficiency testing and each cannabis testing facility licensed in the state should be required to participate.

Lab standards of practice, such as CanNaLAP, typically specify how frequently proficiency testing should occur, which types of samples should be used for PTs, and what types of results should be considered outliers. Retesting, physical inspection, and methodological re-validation can be required for laboratories that report outliers during round-robin proficiency testing.

INTERSTATE SHIPMENT OF SMALL QUANTITIES FOR TESTING PURPOSES

ACIL supports legislation to correct the prohibition against the shipment of small quantities of cannabis containing materials for testing purposes. We have experience crafting language and can send well qualified experts to inform writing of legislation to this end.

ACIL-Federal Agency Partnerships for Advancing Cannabis Testing

ACIL seeks to develop relationships and to become a resource to federal agencies responsible for cannabis testing to ensure the protection of public health and safety through the application of test and measurement sciences.

FDA, DEA, and USDA are working to develop a collaborative regulatory framework to deal effectively with the emerging uses of cannabis. Additionally, members of Congress are responding to these uses by advancing legislative proposals that will eventually address cannabis' Schedule 1 designation. In the interim, ACIL will continue to advocate for and support informed sound testing, along with federal regulatory and legislative policies, which will properly address the nascent cannabis industry at the national and international levels.

More specifically, ACIL seeks to educate all federal agencies, along with the DEA, on the importance of interstate testing procedures for cannabis products, which is rooted in the premise that testing laboratories need reference, calibration, and performance evaluation materials from suppliers in other states. These materials contain cannabis and are essential to ensuring accurate test results. Having test results from multiple states will only enhance the quality and reliability of future cannabis public health studies.

Currently, there is a process for testing labs to get a DEA registration to test cannabis products shipped from outside their state. ACIL reports that (1) DEA is not issuing those registrations, and (2) those registrations do not cover cannabis products. Current law allows DEA to do both these things. ACIL seeks to consult with Congress and the DEA to explore options to improve this situation in the interest of public health and safety.

Commercial testing laboratories are unable to test cannabis under the current DEA policies and regulation; thereby, ACIL intends to work diligently with DEA to identify changes that will support DEA's mission and improve public health and safety through effective recreational and medicinal cannabis product testing under federal law.

ACIL SEEKS TO EDUCATE ALL FEDERAL AGENCIES ON THE IMPORTANCE OF INTERSTATE TESTING PROCEDURES FOR CANNABIS PRODUCTS.

PRODUCT SAFETY & CONSUMER PROTECTION

Establishing regulations to govern a product safety testing program is incredibly complex in any industry. The task is substantially more difficult for the cannabis industry because it is rapidly evolving from an illegal to a legal market and the products, safety and efficacy remain to be determined over a broad population of American citizens.

ACIL will collaborate with existing federal agencies responsible for product safety, efficacy and consumer product inspection services such as USDA-FSIS, FDA & DEA to develop standards and protocols for sampling, handling, inspecting and testing cannabis products for human and veterinary uses.

There are long lasting laboratory standards of practice available to inform and leverage best practices for testing laboratories. Federal and international standards exist upon which to base the testing protocol, practice, procedures and quality systems necessary to support a rigorous safety and efficacy testing regimen.

ACIL can provide industry experts for legislators, regulators, and other state officials who are forced to make decisions on complex technical and policy issues related to testing that are outside their scope of expertise.

USDA inspections at meat, poultry, swine, and other food processing facilities under its Food Safety and Inspection Service directorate have been a key component for ensuring food safety in the United States for more than 100 years. Similarly, FDA has been protecting the nations' food supply by testing randomly, and for enforcement, both domestic and imported foodstuffs for pesticide and bacteriological contamination as well as other disease or toxic agents.

USDA draws its legislative authority under FSIS from the Federal Meat Inspection Act of 1906. Practices can be applied to cannabis cultivation and manufacturing by directing cannabis or hemp regulatory enforcement officers to identify potential sources of contamination and randomly select products for testing.

Currently many cannabis production facilities are regularly inspected by state government officials, similar to field investigations conducted by public health officials charged with mitigating risks for infectious diseases or food and water borne pathogens.

Standardized procedures for state and local officials inspecting systematic or randomly selected cannabis production facilities should be developed by consensus with regulators and industry representatives seeking best practices for facility or product audits. Field investigators for regulatory agencies can be trained to identify potential sources of contamination in addition to regulatory violations.

Procedures for conducting test procedures, potency assays, microbial and other testing and the associated quality control criteria, including batch sizes, number and type of QC samples, to satisfy regulatory testing requirements are appropriately determined by consensus agreements between industry and regulators. Recognition for the validity of these procedures and practices can be included within the CanNaLAP laboratory accreditation standard.

Early indications suggest USDA is evaluating delegating their sampling and testing responsibilities under the recent Farm Bill to state public health laboratories. **The appropriate role of public laboratories is to provide services unavailable in the private sector in basic science, investigations, or forensic projects.** Private sector labs have a long and successful history performing high quality cost effective routine test and measurement services. ACIL favors the use of commercial laboratories over state owned laboratory assets because: 1) use of commercial laboratories puts the financial burden of cannabis testing on the cannabis industry rather than the public, 2) most states have zero experience performing cannabis testing and the lead time to establish competency will be both costly and time consuming; 3) state public health labs, unlike commercial laboratories, are frequently both unaccredited and unable to effectively and efficiently process the huge volume of sampling and testing required to adequately address their responsibilities to protect public health and safety, and; 4) private laboratories currently possess requisite expertise and infrastructure to perform such work.

ACIL will remind USDA, FDA, and DEA policy makers of the substantial capabilities and capacity of the commercial testing laboratories. We will ask agency policy makers to change their thinking from exclusively funding and expanding public sector labs to considering commercial testing options. We will be communicating a model for routine regulatory testing to be performed at commercial laboratories while investigatory and forensic testing are performed in state and federal laboratory facilities.

The value of independent testing performed at industry expense by accredited and commercial laboratories for testing cannabis and its products exceeds anything provided or contemplated by state or federal laboratories. ACIL intends to support USDA's recognition of the ILI's CanNaLAP Accreditation program to establish the competency of private labs providing these testing activities for public health and safety.

The 2018 Farm Bill has handed Hemp Testing oversight to the USDA. ACIL seeks to engage with the statutory rule-making process to draft and comment on regulatory language to implement the Hemp Clause in the Farm Bill. ACIL will work with the USDA to allow the shipment of hemp samples and products across states' borders for testing purposes. We will also work with USDA to set clear, appropriate regulatory levels for hemp ingredient and contaminant testing that correspond to product labeling requirements. ACIL will support USDA requiring hemp testing laboratories be accredited to the CanNaLAP standard and otherwise specify the CanNaLAP scheme document for implementation of their program nationally. ACIL will collaborate with USDA to address the above and other goals of mutual interest.

ACIL is currently unaware of any plans at FDA to develop a cannabis product testing policy. This is understandable, as cannabis is a Schedule 1 drug. There is very if any little flexibility or incentive under law allowing FDA to address its regulatory responsibilities to ensure the health and safety of the country's pharmacopeia. ACIL stands ready to assist, inform, and otherwise work with FDA to promote a comprehensive testing program for medical and recreational cannabis products. ACIL will advocate CanNaLAP or similar consensus standard based program for recognition of competency for all public and private sector laboratories conducting routine testing of cannabis products.

ACIL seeks to provide guidance, information and support to DEA, USDA and FDA as they are tasked with adopting new regulations governing cannabis testing. Also, ACIL seeks to ensure new cannabis regulations are based on input from stakeholders with varying subject matter expertise toward developing best policies and testing practices.

As Congress considers legislation related to cannabis use, ACIL will opine that few areas of cannabis testing policy should be established in statute. Experience with environmental and product testing legislation have taught ACIL that testing policy and procedures may best be handled at the agency level by implementation of broader legislative policy. ACIL supports cannabis legislation that delegates testing policy to regulatory agencies.

Specifically, ACIL recommends agencies such as DEA, FDA, and USDA consider policies that address frequency of testing, application requirements for laboratories and samplers, and required types of analyses. Statute could authorize state agencies to adopt policies governing the entities that will sample, audit, and test cannabis.

ACIL would consider federal legislative proposals on providing legal protections to DEA licensed laboratories to test cannabis through defining prohibited acts for issues unrelated to the science of cannabis testing, such as multi-license and cross-license ownership limitations for cannabis testing laboratories. Additionally, ACIL would support legislative proposals that would direct state public health and scientific agencies to provide support to the federal agencies that oversee cannabis testing within their legal regulatory responsibilities.

Currently, the process for establishing cannabis regulations is governed by state administrative procedure acts, which are designed to resolve technical issues with a significant economic impact by providing timelines for public notice, opportunities for debate, and legal rights for judicial review. However, ACIL supports continued flexibility in approaching procedures governed by test and measurement science, along with allowing cannabis testing policy be deliberated in stakeholder forums that provide subject matter experts such as ACIL a voice as necessary components of good lawmaking.

ACIL supports technical testing terms defined in regulation and definitions in federal law and international standards, which will allow state regulation to seamlessly integrate with eventual, if not inevitable, federal oversight. Additionally, on regulatory issues related to cannabis science or testing policy, ACIL would work to provide recommendations and support information such as sampling procedures, permissible levels of contamination, types of pesticides required for testing, and procedures for proficiency testing.

When creating official policy and/or regulations, ACIL highly recommends members of Congress and regulators reference existing federal and internationally recognized standards whenever possible. This practice prevents conflicting and duplicate requirements and the process of requiring cannabis standards to conform to existing national and international requirements will ease the process of eventual, if not inevitable federal regulation. Consequently, in the absence of established standards, ACIL will continue to assist the cannabis industry in developing and creating their own consensus methods and process requirements.

Issues for Statute

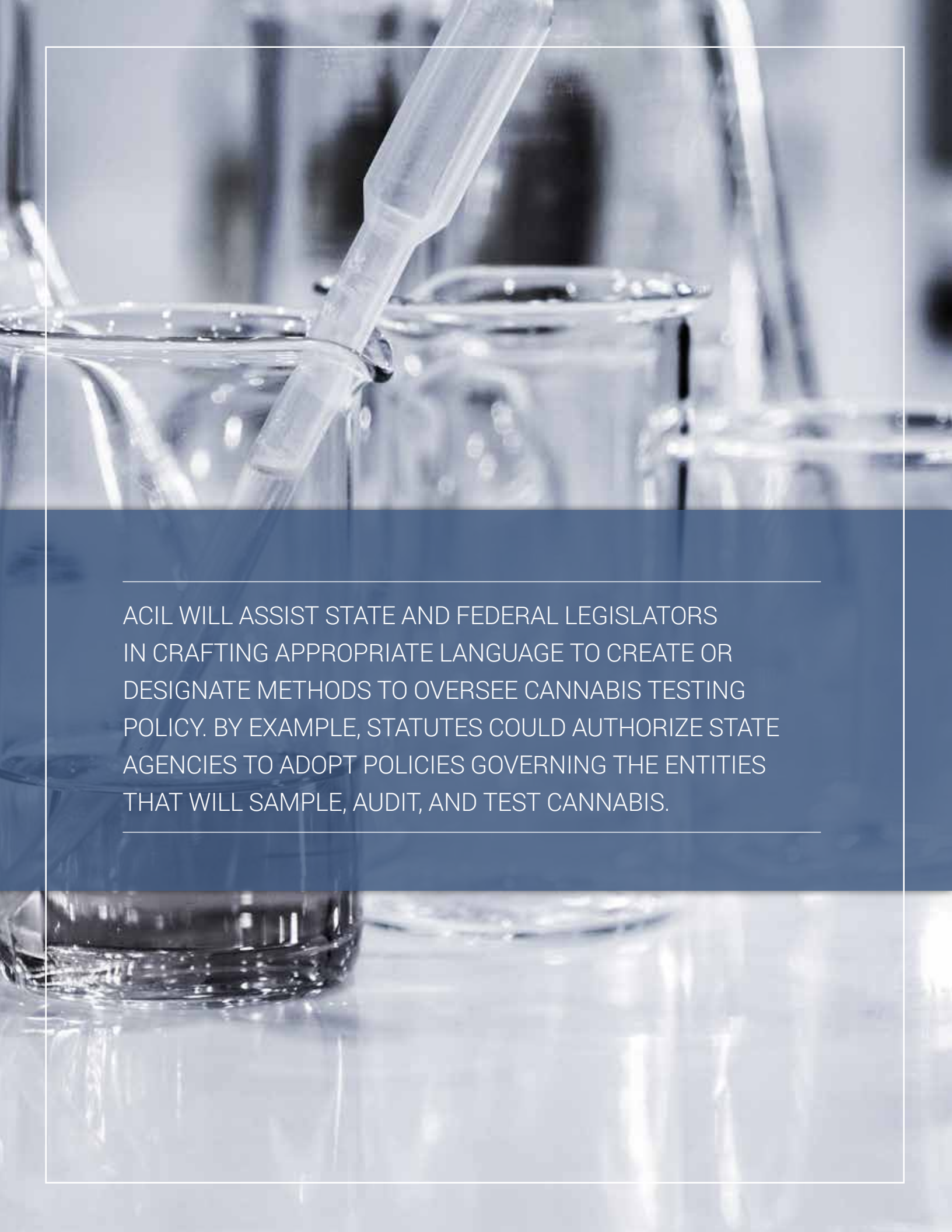
- Reassessment of Schedule 1 designation for cannabis
- Creation of a third-party sampler permitting program(s)
- Multi-license ownership limitations for cannabis testing laboratories
- Legal protections and prohibited acts for testing labs, employees, and samplers

Issues for Regulation

- Accreditation requirements for public and commercial testing laboratories
- Batch testing: size, frequency, compositing
- Contaminants to be tested
- Cannabinoids, terpenes, and flavonoids to be tested
- Retesting and remediation process for failed tests
- Permissible sources of cannabis for proficiency testing
- Definitions for required and/or optional testing
- Laboratory testing record and sample retention requirements
- Educational and experience requirements for laboratory personnel
- Criteria laboratory auditing and conformity assessments
- Sample waste disposal requirements and recordkeeping
- Definitions of technical testing terms used in regulation

Policy Issues

- Permissible contaminant levels, including solvents and manufacturing by-products
- Policy for accreditation of public and commercial laboratories performing regulatory testing, Canna-LAP and ISO/IEC 17025 accreditation
- Lists and limits for Crop Protection Agents required to be tested
- Procedures for sample collection and laboratory acceptance
- Requirements for developing and validating standardized test methods for regulatory purposes
- Specifications for equipment calibration and recording inspection data
- Procedures for laboratory proficiency testing
- Sampling procedures: representativeness, composites, and sample preparation
- Permissible methods for remediating contaminated or impacted materials in supply chain



ACIL WILL ASSIST STATE AND FEDERAL LEGISLATORS IN CRAFTING APPROPRIATE LANGUAGE TO CREATE OR DESIGNATE METHODS TO OVERSEE CANNABIS TESTING POLICY. BY EXAMPLE, STATUTES COULD AUTHORIZE STATE AGENCIES TO ADOPT POLICIES GOVERNING THE ENTITIES THAT WILL SAMPLE, AUDIT, AND TEST CANNABIS.

ACCESS TO TESTING LABS

Cannabis represents a disruptive approach to long-established, well-controlled if not highly regulated marketing, production, and distribution of pharmaceutical agents used by the public. Consumers in states where cannabis is legal are allowed to grow plants and produce their own cannabis products. The access to testing laboratories for these growers and producers is critical if the products produced by individuals is for the efficacious use of cannabis products for therapeutic or recreational purposes.

Denying the public, and possible criminal enterprise, access to commercial testing labs for the purposes of providing quality control for an otherwise illegal drug marketing operation is a keystone of DEA testing lab policy.

Cannabis is different from other Schedule 1 drugs in that it has known therapeutic and safe recreational uses. Generally, cannabis use poses far less harm than the other agents listed in Schedule 1. Regardless of whether one views cannabis' Schedule 1 designation as merited or not, it remains undeniable that the Schedule 1 classification of cannabis is causing, through DEA policy implementation, serious harm to the health and safety of the American public by restricting and/or inhibiting all cannabis testing and research.

Legislators and the American people deserve to learn facts about the risks posed by use of cannabis by the public caused by decriminalization and legalization at the state level. These facts can only come out through accelerating the pace of cannabis testing and research, which requires the changes advocated in this document.

ACIL supports regulation that allows appropriately accredited laboratories to accept cannabis samples from the general public, home cultivators, patients, journalists and others involved in the industry. ACIL supports allowing accredited cannabis testing laboratories to perform other types of testing, such as Food Safety, Product Safety, and Pharmaceutical Environmental. This will expand the reach and benefits of cannabis testing to the public by allowing public access to testing resources to support product development, safe/responsible uses, and health outcomes.

ACIL will assist state and federal legislators in crafting appropriate language to create or designate methods to oversee cannabis testing policy. By example, statutes could authorize state agencies to adopt policies governing the entities that will sample, audit, and test cannabis.

Statute could provide legal protections to licensees and define prohibited acts for these regulated entities that are sensitive issues unrelated to the science of cannabis testing, such as multi-license and cross-license ownership limitations for cannabis testing laboratories.

Statute could direct public health and state agencies to support cannabis testing program oversight. When regulatory issues cover areas of cannabis science or testing policy, ACIL will provide recommendations and supporting information to help regulators make decisions grounded in research and existing best practices.

SAMPLING AND TESTING WITHIN THE CANNABIS PRODUCT SUPPLY CHAIN

ACIL seeks to ensure that sampling for regulatory purposes is independent, representative, and consistent with scientific best practices as established through consensus standards generated by professional scientific organizations including AOAC, USP, ASTM, and within the constructs of agency partners who implement government mandated product testing programs.

The distinction between process control testing, conducted by growers or producers of cannabis products, and regulatory testing conducted for the purposes of demonstrating product safety, should be preserved. Regulatory testing is costly. Programs designed to ensure product safety including tests for crop protection, mold metabolites, bacteria, residual solvents, and other agents posing health risks need to be conducted primarily on products anticipated for consumption. Alternatively, testing can be performed on product ingredients if no further testing is anticipated prior to product release.

Specifying the locations in the supply chain requiring regulatory testing is best left to professionals with experience in pharmaceutical product safety and risk management. The consequence of an overbearing sampling and testing scheme for regulatory purposes is the furtherance of the "black market" for illegal cannabis products due to the existence of onerous costs of regulatory compliance.

Policy makers should mandate independent testing to protect public health and safety in the cannabis product supply chain by ensuring that potency is accurately labeled and production practices result in safe products for consumers.

Most state cannabis programs mandate third-party testing from a licensed cannabis laboratory. While this may appear to guarantee objectivity and impartiality, it affronts an industry that is equally required to develop and support resources and procedures for in-house testing for quality control purposes. Mandating independent testing of all cannabis products anticipated for human consumption is adequate to satisfy regulatory requirements for public health and safety. Legislative flexibility to allow cannabis growers and producers to test ingredients and "intermediates" for quality control purposes should be unfettered by laws mandating independent testing.

To maintain the integrity of an independent system and prevent conflicts of interest, states typically prohibit any shared ownership interest between a testing lab and other licensed cannabis businesses.

Most states actually prohibit licensed cannabis testing facilities from testing non-cannabis products or cannabis products from patients or individuals of legal age; thereby reducing the size of the overall testing market.

Many non-cannabis testing laboratories service clients across multiple states and industries to maximize volume and reach profitability. Federal law makes this interstate testing impossible for cannabis laboratories. ACIL recommends policy makers consider economic balance when mandating independent testing. States and the country need a profitable, competitive cannabis testing market. To achieve this end, ACIL advances the following recommendations:

- Ensure an adequate definition of independence and impartiality are included in legislation requiring independent testing for regulatory purposes.
- Allow cannabis laboratories to participate in basic research and new product development activities while testing cannabis products for human or veterinary consumption for regulatory purposes, provided the laboratory meets the criteria for independence to test those products.

MANY STATE CANNABIS TESTING PROGRAMS REQUIRE PRODUCTS BE TESTED MULTIPLE TIMES PROVIDING VERY LITTLE VALUE TO CUSTOMERS AND LITTLE IMPROVEMENT IN PUBLIC HEALTH OUTCOMES.

- Allow cannabis laboratory owners to own minority, non-controlling interests cannabis businesses to ensure the financial success of the organization.
- Permit licensed cannabis testing facilities to engage in testing activities unrelated to cannabis testing, such as food safety, environmental, pharmaceutical, and/or industrial hygiene and/or indoor air quality testing activities.

After identifying which products need to be tested, what they need to be tested for, and how frequently testing should occur, policy makers must then determine where along the supply chain cannabis products should be tested. Many state cannabis testing programs require products be tested multiple times prior to sale, providing very little value to customers and little improvement in public health outcomes.

Certain states require that an edible cannabis product be tested three separate times by a third-party for potency during the production process – the raw cannabis plant material, the cannabis concentrate infused into the product, and finally the product itself. Only the potency of the final edible product is relevant to a consumer and public health. Although there may be business reasons to test the inputs for potency, there are no substantial public safety risks to justify government mandated independent third-party testing for product "intermediates".

Frequently, policy makers have assumed that "over-testing" is harmless and only creates negative impacts on a cannabis business's bottom line. This assumption is false. Rigorous nonscientific "over-testing" damages public safety by shifting resources away from compliance initiatives that protect public safety and increasing the competitiveness of black-market actors. Policy makers can improve public safety by increasing the efficiency of cannabis testing and eliminating duplicative testing.

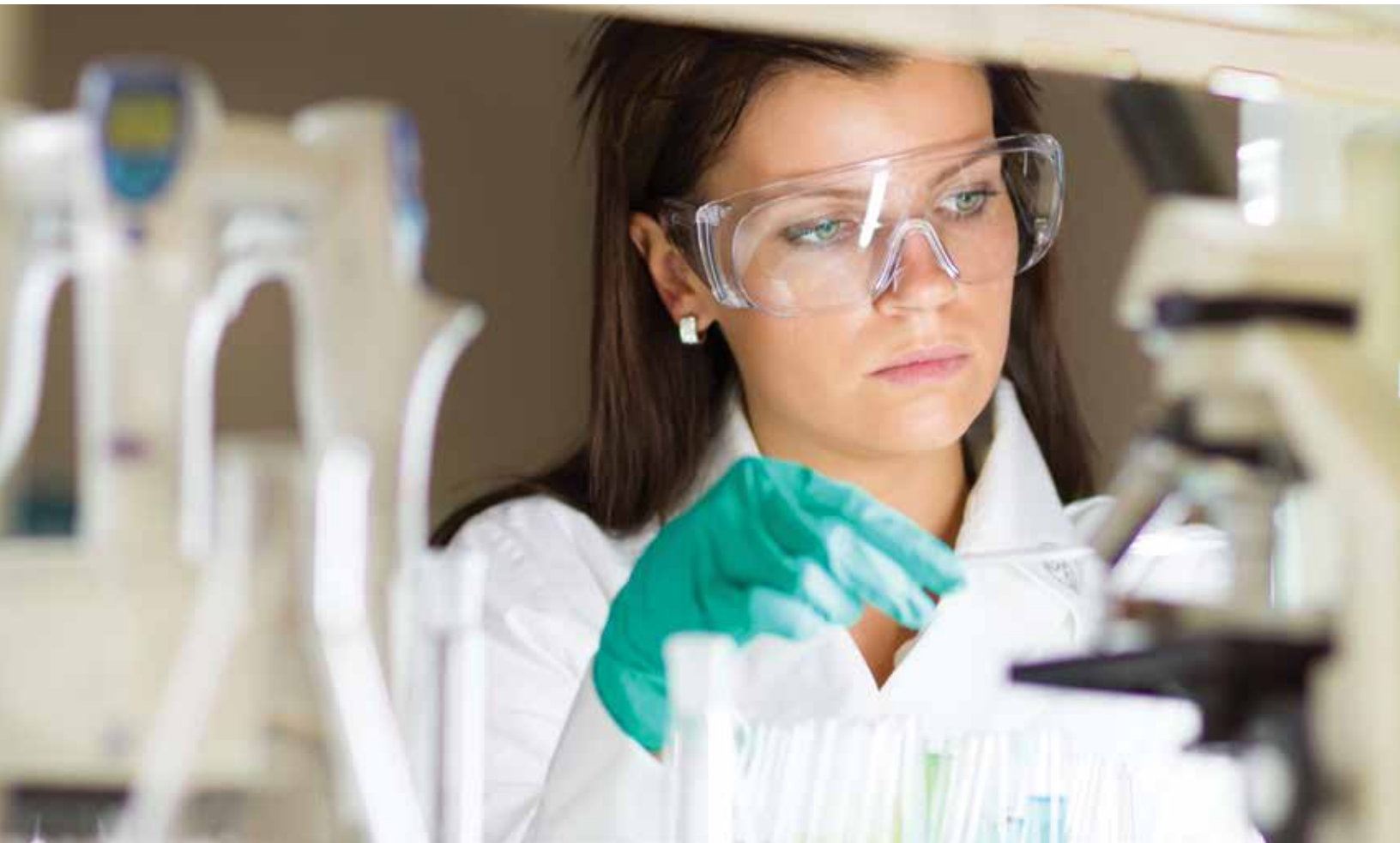
States should mandate independent third-party testing for cannabis products in their final form, prior to transfer to a retailer or a customer. Intermediate cannabis products intended for further manufacturing that will not be sold to consumers without further processing should be exempt from mandatory testing requirements. Testing at the final stage guarantees that the products tested are representative of the products consumers will purchase, while leaving testing further up the supply chain for businesses to decide on their own. Many responsible businesses will still conduct potency and contaminant testing of intermediate products; however, such testing can be conducted internally for process control purposes.

CONCLUSION

The federal government shares many of the same goals as the private sector in the conformity assessment arena. Government should leverage that expertise, knowledge, and capability when developing regulations and administering agency programs. ACIL believes that public-private partnerships drive sound policy and enable more efficient and cost-effective use of resources. The government should approach and engage the private sector on initiatives such as cannabis testing policy, practice and regulation, as well as other areas where goals align. ACIL is a "go to" resource for knowledge and expertise in testing and conformity assessments.

ACIL supports government proactively seeking the views of the private sector in advance of regulatory rulemaking to leverage available research and data and to promote transparency.

ACIL members are committed to upholding the best practices of scientific leadership. The membership supports well-formulated policies which mitigate bias and promote scientific rigor and integrity. The ACIL network of resources fosters idea exchange to promote professional growth and opportunities to address business challenges. ACIL encourages members to participate and cultivate relationships with fellow members and within the wider stakeholder community. ACIL delivers value through its network of resources which assist idea exchange to promote professional growth and opportunities.



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