

**PH&S & ASTM INTERNATIONAL**

The Public Health & Safety/ASTM Cannabis Certification Initiative

Presented to the Attorney General Alliance (AGA) Cannabis Project

## **The Public Health & Safety/ASTM Cannabis Certification Initiative**

### **TABLE OF CONTENTS**

#### Section I: Executive Summary

- a. Phase One Overview - Financial Institutions
- b. Phase Two Overview - Operations
- c. Summary of Findings

#### Section II: Phase One: Financial Institution Certification Pilot Description

- a. CASE STUDY: U.S. Eagle Federal Credit Union in New Mexico

#### Section III: Phase Two: Operations Certification Pilot Description

- a. CASE STUDIES

#### Section IV: Conclusion

#### Section V: Organizational Background

#### Section VI: Evidence of Certification

#### Section VII: Secure Portal

#### Section VIII: Appendix

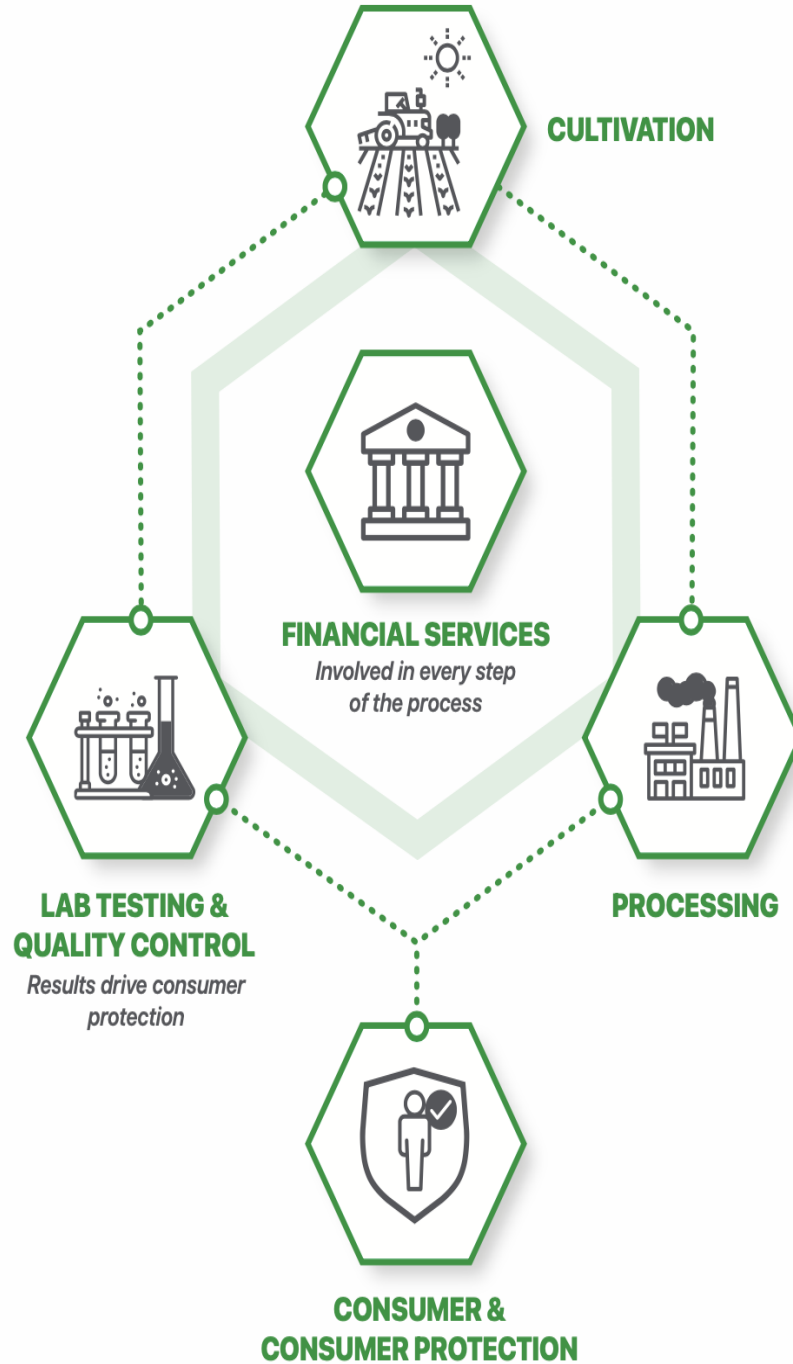
## **EXECUTIVE SUMMARY**

The Policy Center for Public Health & Safety (PH&S) and ASTM International have completed a two-part collaborative pilot, called “The Public Health & Safety/ASTM Cannabis Certification Initiative” (Initiative), observed by the American Trade Association for Cannabis & Hemp (ATACH). The Initiative assessed the following type of operations, which encompass the end-to-end cannabis and hemp production supply chain (from seed to final product), including two critical ancillary components:

1. Financial Institutions
2. Operations (including the following functions):
  - Laboratory Testing Facilities
  - Cultivation Operations
  - Production Operations
  - Extraction Operation
  - Commercial Scale Manufacturing & Research & Development of Hemp Derived Ingredients

# LIFE CYCLE OF CERTIFICATION VALIDATION

*How the ASTM & PH&S Certification Program ensures public health and safety and diversion during all stages of the cannabis supply chain*



ATACH initially engineered the collaboration and PH&S is running the dual program based upon feedback and support from law enforcement. The Public Health & Safety/ASTM Cannabis Certification Initiative is the only cannabis industry certification available with input from law enforcement.

The Initiative will assist law enforcement as well as companies who participate in distinguishing compliant entities from noncompliant. It also has the potential to become part of a larger risk avoidance strategy for cannabis & hemp operators in the heat of a public health crises stemming from questionable production practices.

For these reasons, there is incentive for cannabis and hemp operators to participate in the Initiative. Further, this certification trips the “compliance switch.” As rules and regulations evolve, certified companies completing this Initiative will be better positioned from a regulatory and operating perspective. It is a key transition point which justifies voluntary participation in a compliance protocol effort.

Additionally, financial institution certification is key as there will come a time that financial institutions will require certification as a fundamental requirement to access cannabis banking even if federally legalized.

## **PILOT PROJECT PHASE ONE FINANCIAL INSTITUTIONS**

Part one of the Initiative assessed financial institutions based upon demonstrable criteria such as;

- (1) Implementation of anti-money laundering protocols and
- (2) Proof of compliance with state and federal regulations & protocols for banking of cannabis funds

The rationale behind the Initiative is two-fold.

First, industry accountability begins with the integrity of sources of funds utilized in cannabis operations. Without validation of funds entering the US regulated financial institutions, the system breaks down. Hence, the need for financial institutions is not only understanding but in executing robust cannabis compliance protocols.

Further, identifying legal from illicit operations is key.

The foundation of accountability in the cannabis industry is in following the money. The potential for abuse and money laundering with legacy funds is a legitimate issue. While a company may appear to be compliant – if the authenticity of its financial base cannot be validated – the US monetary system is at risk from untraceable funds. The certification of financial institutions (as our Program allows for) will drive accountability and allow state attorneys general, law enforcement and regulators to be able to identify legal from illicit as well as compliant from non-compliant operations.

As more financial institutions are certified, a clear standard will emerge for interacting with cannabis companies, driving accountability by the financial institutions choosing to serve the cannabis and hemp sectors. With the realistic possibility of a Safe Banking Act or similar legislation passing in US Congress at some point, more entities will enter the cannabis banking business. As a result, standardization of operational protocols will only become more critical to proactively addressing safety and security issues relating to the US financial system.

Credit unions participating in this Initiative and engaged in cannabis banking were audited. Those who met our standards were certified.

## **PILOT PROJECT PHASE TWO OPERATIONS**

PH&S and ASTM International are strategic partners in implementing this Initiative.

ASTM is an internationally recognized 120-year old standards development organization. With over 1,000 members across 30 countries, its Committee D37 on Cannabis has developed over 28 consensus-approved standards that cannabis businesses are certified against. Certification to these standards indicates a level of integrity and product safety built into their operational culture that state regulations do not assess. It provides confidence that operational best practices, aligned with globally recognized Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) are in place, mitigating the risk that processes may result in adverse consumer health and safety events.

In this part of the Initiative, an operational component was selected as it relates to the production & supply chain which ultimately interfaces with the consumer. All audited operations have been identified and audited as key components in chain of custody protocols.

Specifically, the following types of operations were identified and audited as key components in the chain of custody flow:

- Marijuana and hemp cultivations (grow operations both indoor and outdoor)
- Marijuana and hemp processing facilities (manufacturers, extractors, and packagers)
- Lab testing facilities

Tying consensus standards to legitimate lab testing protocols, which are assessed during an on-site audit and review of testing records, can assist in mitigating the problem of "lab shopping." Unscrupulous cannabis operators often "shop" for a lab that will give them the most desired outcome, i.e. high potency or no detection of uncompliant substances.

From a policy perspective, the combination of raising production standards with credible and rigorous audit processes results in a robust program that ensures credibility across the entire supply chain - from "seed-to- sale."

Every time an exchange of hands occurs, there is a risk for diversion or adulteration. In turn, these best practices translate to improved public health and safety protocols.

## **SUMMARY OF FINDINGS**

Upon the completion of this pilot Initiative, we learned several important items of importance to state attorneys general:

- There is a large span of operators and how they conduct business.
- The biggest risks and gaps we identified include:
  - Lack of formal documented programs to ensure traceability
  - Lack of management commitment and "buy-in" to support the necessary fundamental programs to ensure products are safe and compliant

- Lack of records to support adherence to these programs;
- Diversion risks are much HIGHER in the hemp/CBD space than cannabis. The real risk, as expected, is the continued lack of any oversight following on from the passage of the 2018 Farm Bill, which has enabled a multi-billion-dollar market to flourish including novel products with high levels of contamination through unsafe synthetic processes (e.g. Delta-8). These products are available at gas stations, convenience stores, and head shops in nearly every state.
- Risk to consumer health and safety on THC side (product quality) is Medium. Diversion risk is LOW, as states have robust systems in place to track the actual cannabis product. Risk to consumer health and safety on the CBD side (product quality) is Medium to High. Diversion risk is HIGH.

The Public Health & Safety/ASTM Cannabis Certification Initiative provides a best practices system that creates a path to successful implementation for which financial institutions, regulators and law enforcement can utilize. The certification Initiatives provide core program elements, leaving little room for nefarious activities that result in substandard compliance, unsafe products, and an exposed financial system.

This Initiative serves as an effective early warning system and can verify initial assumptions of risks. It reduces diversion risk, provides monitoring and alerts relating to product quality issues wherein certified companies go from high or medium consumer health risk to low risk. In turn, certified operations move from a high risk of diversion activities to low risk based upon production standards and protocols.

While the ASTM certification can conduct stand-alone audits to be certified, in order to be certified under the PH&S ASTM banner, the participating company must adhere to two conditions:

1. That it becomes part of a resource base available to state attorneys general for review of the outcomes of the certification process.
2. Financial institution (FI) relationships must be disclosed to determine if that FI has a legitimate anti-money laundering program in place.

Findings from the Initiative confirm many of the assumptions and concerns that led to its development, primarily:

1. State cannabis programs vary widely in their program requirements including a major absence of best practices (e.g. Good Manufacturing Practices – GMPs) that protect public health and provide consumer protection.
2. In states where requirements for Good Manufacturing Practices to be adhered to exist, the language is vague and has resulted in the execution of programs that are inadequate to address the complex nature of the cannabis product types.
3. The gaps in oversight of the Hemp/CBD market, enabled through the 2018 Farm Bill has resulted in a complete absence of oversight to ensure products are produced legally and safely.
4. The gaps in oversight of the Hemp/CBD market have also resulted in opportunities for unscrupulous producers to create unique products that place consumers at great risk - including the vape market and proliferation of Delta-8 products – which has prompted FDA and CDC warnings.
5. Testing laboratories are challenged by the rapid evolution of unique cannabis product types that require meticulous method development and validation to ensure reliable testing and detection of contaminants (pesticides, heavy metals, residual solvents, etc.) as well as accurate reporting of cannabinoid content which further increases the risk to public health.

Throughout the pilot Initiative process, 360-feedback with the participants has reinforced that we have developed the framework for a robust Cannabis Certification Initiative that addresses the challenges and gaps identified above. It is clear that state cannabis and hemp programs need to be more consistent in requiring quality GMP programs that are fit for purpose based on the unique risk profiles of the cannabis industry and the diversity of product types (e.g. smokable flower, tinctures, edibles, topicals) using consensus-based standards.

The Public Health & Safety/ASTM Cannabis Certification Initiative is the only program that provides this solution and addresses the four pillars that state attorneys general are focused on protecting:

- Public health & safety
- Consumers
- Anti-money laundering
- Rule of law

Ultimately, the marketplace including regulators, consumers, and industry producers will all be beneficiaries with increased confidence in consistent operational guidance that protects all. As the Initiative opens up to the broader marketplace, and ASTM Committee D37 continues to develop consensus industry standards, the Initiative will continue to grow alongside the industry, resulting in greater protections and opportunities for the consumer.

It is relevant to note the following:

- All audited operations were randomly selected based upon position in the marketplace or recommendations by third parties.
- None of the operations audited had a relationship with the Policy Center for Public Health & Safety (PH&S).
- As this certification Initiative rolls out on a commercial basis in the future, there will be no requirement of membership nor contribution to PH&S.
- PH&S is not a membership organization nor is it ever intended to be.
- PH&S is an advocacy organization whose mission is to focus upon anti-money laundering, public health and safety, consumer protection and the rule of law.

Going forward, post our pilot Initiative, all audits will be a fee-based initiative payable to the PH&S Foundation, a 501c3. In turn, no one on the foundation board is allowed to have direct business affiliations with the operations being audited



## **Section II**

### **PHASE ONE: Financial Institution Certification Pilot Project**

A daunting challenge for financial institutions to serve the marijuana and hemp market is managing risk; companies must demonstrate compliance to be able to access the financial system in a lawful manner.

PH&S has undertaken a certification pilot project that will certify financial institutions' ability to serve marijuana and hemp operators. The implementation of a legitimate certification Initiative will set the stage for validating compliant financial institutions in the marketplace who are serving marijuana and hemp companies

No other entity in the United States is currently providing such evaluation and analysis to the industry and to law enforcement.

As the PH&S financial certification pilot expands to the cannabis and hemp industry operations, those that cannot comply with or be banked by a certified financial institution, will be ineligible for certification and recorded for review by law enforcement and regulators.

### **Financial Services Background**

Whether they know it or not, many financial institutions across the country have accounts from cannabis businesses and have potential compliance issues banking hemp-related transactions. Given this fact, there is a responsible role for banking to play. This role is not about accommodating the cannabis industry. Rather, it is about preserving integrity in the US monetary system, eliminating money laundering, and doing so in a methodical manner consistent with state and federal law.

In certifying a financial institution, transparency is paramount, financial institutions must utilize programs and procedures that are sufficient to both bank and monitor the industry and these protocols and processes must be sufficient to avoid Bank Secrecy Act (BSA)/Anti-Money Laundering (AML) issues surrounding cash management and black-market activities.

### **Highlights Include:**

- Transparency on business structure and ownership; avoiding any use of shell light companies to obtain access to the system without full disclosure.
- Transparency with the larger financial sector to ensure the safety of the financial system overall.
- Proper and thorough disclosure to financial service providers.
- Validation of the source estimation and movement of funds within the financial system.
- Proof of adhering to laws on licensing, transporting, purchasing and selling a product.
- Regular submission of annual certification licenses and financial records.
- Disclosure of business clients for the business is done as well as processes to ensure clients are compliant with state and local laws.
- Management of cash funds to ensure the safety of the entity and community.
- Sufficient financial processes and training to avoid bank secrecy act and anti-money laundering issues surrounding cash management and black-market activities.

### **The Problem**

Financial service operations including traditional banks must quickly identify if licensed cannabis industry players are compliant and promptly relay that information to law enforcement.

Financial institutions must know they are following appropriate protocols and won't be subject to regulatory scrutiny based on a disagreement over vague regulatory language. A recent cease-and-desist order to a Michigan credit union for failure to follow guidelines when banking the cannabis industry highlights the reality of the problem.

More so, state attorneys general and regulators must have confidence and independent validation that financial institutions are servicing marijuana and hemp businesses in a compliant manner. Such criteria cannot be self-regulated or industry managed and must be conducted by a third-party to ensure legitimacy.

To date, many financial institutions in the banking sector have ignored the needs of the cannabis and hemp industries. As political insiders anticipate the continued expansion of legalization initiatives across the US and the toppling of federal marijuana prohibitions, many financial institutions that are contemplating banking the industry are unprepared for the looming banking challenges, responsibilities, and potential liabilities.

### **The Solution**

The Public Health & Safety/ASTM Cannabis Certification Initiative independently certifies financial institutions. Certification signals to both law enforcement and senior management of the institutions their ability to comply with the law and proactively detect compliant or nefarious activity.

The PH&S certification Initiative is uniquely structured to not only assist a financial institution in clarifying its functions and responsibilities, but to allow regulators, law-enforcement, and insurers to assess the legitimacy and compliance of institutions involved in cannabis banking. No other entity in the United States is currently providing such evaluation and analysis to the industry and to law enforcement.

The certification Initiative comprehensively audits a financial institution's background, Bank Secrecy Act/Anti-Money Laundering activities by that institution, implements cannabis related account monitoring protocols, develops internal policies involving cannabis banking and BSA, and identifies other high-risk activities the institution may be involved in such as virtual currency. The result is a comprehensive view and analysis of whether a financial institution is effectively managing and executing a compliant cannabis banking operation.

State attorneys general are the logical audience to present this pilot initiative insofar as these offices are involved with policy advocacy. This is particularly so in the absence of clearly defined federal policies.

### **The Financial Certification Pilot - Best Practices**

With the pilot Initiative currently completed, the overarching goals have been:

- To address a need which exists relating to these multibillion-dollar industries
- To be self sustaining
- To be independent of the industry itself
- To have legitimacy & credibility

The current state-of-play is being driven by the states.

The foundation of the Initiative's best practices related to financial institutions, serving high-risk cannabis and hemp businesses, is based upon the Partner Colorado Credit Union protocols.

Safe Harbor Private Banking ("SHPB") is a division of Partner Colorado Credit Union doing business under Safe Harbor Private Banking, which was specifically created to manage the complex nature of banking in the cannabis industry. SHPB was established in 2015 and has methodically built a cannabis banking program that has withstood the scrutiny of 15 Federal and State Regulatory Exams.

Partner Colorado has created a reliable standard composed of tried and true best practices which creates a path to the successful implementation of a cannabis banking program upon which financial institutions, regulators, and law enforcement can rely. The result is a standard of core programs that encompass this certification program; leaving little room for 'cost cutting' measures that result in substandard compliance and an unprotected financial system.

## **CERTIFICATION PROCEDURES**

Following are the steps undertaken in this Initiative pilot to certify financial institutions. This is an actual audit conducted by PH&S and Colorado Partner Credit Union, both entities that have championed financial institution programs and protocols to achieve transparency and accountability in the cannabis sector.

1. Complete the PH&S financial certification affidavit/questionnaire.
2. Deliver the completed affidavit and supporting documentation to a review committee for initial findings and recommendations.
3. The Committee looks for responses that might trigger red flags surrounding Anti-Money Laundering and the Bank Secrecy Act.
4. A formal call is convened with auditors and the financial institutions to review questions surrounding the affidavit/questionnaire and the financial institutions will be asked to demonstrate compliance. This is to verify that these critical objectives are in process. The areas that will be reviewed are included but not limited to: Onboarding Process, Validation, BSA reporting/tracking and ongoing monitoring.
5. The analyzed application is sent back to the financial institution review committee for any final concerns or observations following the applicant call.
6. Awarded an approval or denial.
7. Certificate with approval and how to use the certificate letter. i.e., send a copy to any 3rd party service provider that is part of their monetary system (i.e. The Federal Reserve, Federal Home Loan Bank, Insurer, Correspondent banks, etc.)
8. Notice is sent when a certificate is about to expire re: 'time to re-apply.'

## **The Financial Certification Pilot - Desired Outcomes**

The foundation of accountability in the cannabis industry is in following the money. The potential for abuse and money laundering with legacy funds is a real issue. While a company may appear to be compliant, if the authenticity of its financial base cannot be validated, the U.S. monetary system is at risk from these untraceable funds.

With the certification of financial institutions, there are several outcomes that will drive accountability and allow state attorneys general, law enforcement and regulators to be able to identify compliant from non-compliant operations.

Further, as more financial institutions are certified, a clear standard will emerge for interacting with cannabis companies, driving accountability by the financial institutions choosing to serve the marijuana and hemp sector.

With the realistic possibility of a Safe Banking Act passing Congress in the future, more entities will enter the banking business, and as such, standardization of operational protocols will only become more critical to proactively address safety and security issues relating to the US financial system.

## **CASE STUDY**

### **U.S. Eagle Federal Credit Union in New Mexico**

U.S. Eagle Federal Credit Union is New Mexico's first member-owned credit union. Founded in 1935, U.S. Eagle offers a full suite of financial products and services and has ten locations in Albuquerque, Bernalillo, Farmington, and Santa Fe. With assets of more than one \$1B, more than 80,000 members.

U.S. Eagle created a division that specializes in cannabis industry banking. The division, Aery Group, is built on the highest standards of accountability, transparency, monitoring, reporting, and risk mitigation measures to ensure that all BSA Obligations and FinCEN guidance on banking Cannabis Related Businesses (CRB) are being met.

With the New Mexico cannabis market at \$200 million in patient sales in 2020, any cannabis money that is not in a secure banking system (and therefore contributing to the black market) - can pose a risk to our members and the community.

This is the institution's first and primary reason for engaging in cannabis banking; keeping money in the system where it can be tracked. The secondary result of banking the industry is the law enforcement benefit whereby banking contributes to community safety by effectively 'weeding out' the bad players in the industry.

Unbanked funds cannot be monitored for non-compliant activities.

Credit unions were chartered to serve the unbanked/underserved population. The cannabis industry has been unbanked and underserved for years, resulting in many negative repercussions within these communities to include:

- Robberies of cannabis related facilities resulting in the use of firearms and death.
- Wrongful entry into homes that are not even related to cannabis business but the robber has selected the wrong family; resulting in family trauma and death.
- Shootings resulting in death of security guards, employees and innocent consumers.
- Backpacks of cash at the grocery store being exchanged for money orders; resulting in public safety issues to all those just grocery shopping.
- Hidden bank accounts resulting in unmonitored cannabis related transactions that could involve money laundering, tax evasion and other non-compliant activities.
- Criminal Banking behavior resulting in structured transaction federal reporting and the decreased law enforcement effectiveness
- Cash payrolls place the risk of robbery on tens of thousands of employees working for the industry.
- Lack of business transparency / accountability makes it difficult for law enforcement to pinpoint non-compliant activities from tax evasion to money laundering.
- Cash carriers move money throughout a community in vehicles; placing consumers nearby at risk for robbery, violent crimes and death.

**The Aery Group's cannabis banking compliance program, consistent with certification requirements, has resulted in evidence of implementation of the following elements which are required of all certification applicants.**

- The highest level of compliance standards that will meet the expectations of BSA and the FinCEN guidelines – understanding that any program will need to evolve with this emerging market.
- Mainstream depository options for cannabis related entities, including both plant touching and ancillary service providers, ensuring accountability, transparency, and reporting of the industry.
- Monitoring of internal activities of all personnel involved in the compliance program to ensure full compliance with processes that will protect U.S. Eagle.

- Monitoring cannabis clients to ensure they are internally prepared to prevent or implicate any enforcement priorities previously recorded in the Cole Memo and still referenced in the Financial Crimes Enforcement Network (FinCEN) Guidelines.
- Creating a transparent environment of all activities with examiners, auditors, and other third parties that work with the financial institutions to build comfort and understanding; ultimately improving processes in the long term.
- Joining a network of cannabis banking financial institutions that share and develop best practices surrounding cannabis banking and using this shared network to assist each other with safety and soundness.
- Maintaining safety and soundness of the U.S. Eagle while closely managing concentration and risk levels acceptable to regulators.
- Digitizing financial transactions to the highest level possible to increase transparency.
- Ensuring records are thorough, easily navigated, and readily available to fulfill law enforcement demands such as subpoenas, inquiries, etc.

Further, the US Eagle/Aery Group follows the model developed by Safe Harbor which is the cornerstone of the certification process and is accepted by state and federal agencies as the standard of compliance and in implementing general risk mitigating strategies.

Specifically, those include:

- Need-to-know approach: To keep the potential competitive advantages AND to keep employees out of ANY compromising position, information associated with Aery Group members will be shared on a need-to-know basis only.
- Isolate associated risks by limiting service to cannabis related companies ONLY at a designated location.
- Utilize a private business banking service model that will allow for:
  - Personal/Private banking for each company; limiting client-to-banker ratio based upon company size and/or complexity.
  - Regular monitoring of businesses with frequency determined by a BSA Risk Score assigned annually during the annual review.
- Employee level of expertise: Higher level employees with a compliance focus to ensure necessary skills can be learned and implemented pertaining to BSA and the cannabis industry:
  - Ability to create Account Analysis, Pattern Establishment -Business Plan Familiarity
  - Ability to do annual due diligence on businesses
  - Ability to suspend services and accounts without hesitation
  - Consistently and thoroughly validate transactions
- Code of ethics to include confidentiality of all processes and procedures, non-socializing with any client understanding that a breach of any ethical standard or established policy will result in immediate termination. Staff will follow U.S. Eagle's personnel manual with respect to appropriate staff/client interactions.
- BSA Certification: All employees managing cannabis related accounts will maintain BSA Certification as standard requirement and re-certify as required by regulations. In addition to the BSA certifications, Aery staff also hold CAMS certifications (Certified Anti-Money Laundering Specialist), and NCBSO (NAFCU Bank Secrecy Officer) certifications. This ensures the highest level of attention and awareness is placed upon proper reporting and monitoring of accounts.
- Compliance Managers and Monthly Reviews: Compliance Managers are employed to monitor bankers and their assigned clients, limiting manager-to-banker ratio based upon company size and/or complexity. Each Compliance Manager will accomplish tasks listed below in general:
  - Ensure Reviews are accomplished timely
  - Review Annual Documentation

- Review Employee Transactions
  - Review Employee Reporting requirements
  - Approve Employee analysis of account activities
- BSA Officer: As Aery Group members and volume increased, the company dedicated a BSA Officer to provide program oversight.
- Malicious Insider Activity – in accordance with BSA obligations – by segregating accounts and locking down accounts so information is limited to a need-to-know approach and non-compliant requests from external sources are limited or unavailable.
- Specialize in regulatory monitoring and reporting required for this industry:
  - Utilize high level software monitoring to track transactions and assist with identifying money laundering/non-compliant activities.
  - Track business performance and trends; validating financial trends against strategic growth of the businesses.
  - Incorporate higher level BSA processes to include specialized third parties for additional reviews and recommendations.
  - Validate depository transactions against reported sales transactions and state/federal tax reporting; always looking for a minimum of two points of validation.
- Audit outgoing payments for suspicious activity.
- Engage a separate internal audit process to monitor Aery Group components monthly to start and quarterly once established.
- Effective cash management processes:
  - Deposit by courier only to courier location.
  - Limit depository activities by contract and banker approvals.
  - Digitize transactions at retail locations (ACH, POS, etc.).
- Extra security measures involve:
  - Transactions by appointment only.
  - Specific compliant documents to complement present agreements; ensuring more flexibility and higher levels of client performance.
  - Accounts by referral and/or recommendation only; selected prospective members vetted first by SHS and then reviewed and approved by internal management.
  - Extensive web services to collect and monitor business activities include Google alerts and searches, Facebook and Linked-In monitoring, Lexus-Nexis and background verifications.
  - Lock down of locations in which private bankers are located.
  - Secure drop box for check deposits.
- Physical security requirements:
  - Separation of business from consumer business.
  - Separate facility as size of business merits.
  - Use of multiple electronic-entry doors to deter risk, cameras, and high-level security access as required.
  - Access to operations by appointment only with their assigned personal banker.
  - Access by account owners and appointed corporate personnel only.
  - No walk-in traffic.

### **Section III**

#### **PHASE TWO: Operations Certification Pilot Description**

This Initiative is the result of a collaboration of over 1,000 cannabis and hemp industry leaders and organizations, with ASTM International at the center, brought together to provide industry stakeholders, including state and global regulators with a venue for the development of standards and related best-in-class, value-added programs that will ultimately lead to safe and reliable cannabis products and processes.

With an increasing number of stakeholders coupled with complex state and global regulations, it has never been more important to have a comprehensive program available for cannabis and hemp organizations and businesses to verify that best practices are being adhered to and to promote activities that foster end user public health and safety.

From a policy perspective, the combination of raising production standards with credible and rigorous audit processes, literally create an identifiable trail from “seed-to-sale” as it relates to the safe and consistent production and sale of cannabis and hemp derived products. In turn, this represents a complete chain of custody which targets everything that will impact the ultimate delivery of these regulated products to the consumer. Every time an exchange of hands occurs, there is a risk for diversion or adulteration. This Initiative provides proactive monitoring and mitigation of these risks through the utilization of the approved ASTM International voluntary consensus standards. More importantly, these best practices and highest standards provide the necessary safeguards to identify and protect impacts to public health and safety.

ASTM and PH&S launched the pilot Initiative in December 2020. Since conducting the first pilot Initiative audit, ASTM has promoted the Initiative to its members and interest groups. The response received has been positive with operators across the United States interested in seeking certification to differentiate themselves as producers of best in-class safe and reliable cannabis products.

#### **The Problem**

The regulated global cannabis market is valued at nearly \$10 billion dollars with an expected compound annual growth rate of 25 percent. This unprecedented market explosion has resulted in a patchwork of regulations across state and national markets. This challenges law enforcement, places consumers at risk, and continues to plague the industry with inconsistent expectations regarding how to maintain a legally compliant business. Now, more than ever, there is a need for programs that can reduce risk for consumers, owners of cannabis companies, operators, investors, and ancillary businesses.

Currently 37 states, the District of Columbia, Puerto Rico, Guam, and the US Virgin Islands have implemented medical cannabis programs. Of those, 18 states plus the District of Columbia, Commonwealth of the Northern Mariana Island, and Guam have also legalized adult use cannabis programs. This is despite cannabis still being illegal at the federal level as a Schedule 1 drug on the Controlled Substances list.

Further, the Farm Bill of 2018 enabled the legal cultivation of cannabis plants containing not more than 0.3% delta-9-THC (the psychoactive component of the cannabis plant). These plants are typically high in CBD, a non-psychoactive cannabinoid. However, the Farm Bill failed to implement provisions to regulate the production or sale of consumer facing products derived from these plants – creating a gray market for CBD and CBD derived products that have virtually no oversight by state or federal agencies.

## **CASE STUDIES: Cannabis Operations Certification**

The ASTM Cannabis Certification Program's team of qualified auditors assessed five operations over a period of five months that spanned the entire supply chain of cannabis and hemp operations, representing cultivation, extraction and processing, and laboratory testing operations. The operations included both hemp (low-THC) and cannabis/marijuana (high-THC), from small (<10,000 square foot) operators to a large multi-state operator.

### **Findings of the Pilot Initiative**

All operations had findings (referred to as non-conformances) which ranged in scope and severity, summarized below. It is typical for even established and mature operators in other industries to have findings. Audit programs help industries evolve, improve, and keep pace with new technology and industry advancements.

The top findings that were consistent across all participants were in the following areas:

- Deviations and reporting/tracking
- Complaint logging and handling
- Management reviews (which include a careful review of deviations and complaints to summarize, identify, and take action to mitigate potential risks within their operation that lead to process deviations/failures and end user complaints.
- Labeling and traceability
- Environmental monitoring

All aspects of the audit – which evaluates operators quality management systems and Good Manufacturing Practices (GMPs) program will lead to improved quality, establish strong operating procedures, reduce the risk of unsafe products entering the marketplace, and ensure facilities adhere to required safety regulations. When companies consistently evaluate these aspects and address non-conformances, effectively, they produce higher quality products and build consumer confidence.

### **Non-conformances are categorized as either Minor or Major**

The definitions of these two categories are defined here to provide context and clarity:

Minor – A single quality management system failure or a lapse in conformance with a requirement that does not show the absence or complete breakdown of an element of the quality management system.

Major – The absence of or complete breakdown of a management element specified in the quality system or a nonconformance that would result in failure of the quality system or a nonconformance that would result in a failure of the quality management system or reduce the systems' ability to assure controlled processes.

It is important to clarify that findings do not mean that there is an imminent risk to public health and safety. Rather, it signifies there is a lack of control which increases the risk of processes leading to adverse consequences, product failures, etc.

Below is a summary of the non-conformances found during the pilot Initiative certification audits.



Operator description	Scope of operation	Audit Performed	Summary of findings	Certified
Large east coast multi-state operator (MSO)	Marijuana cultivation	December 2020	51 Major 35 Minor	No
	Marijuana processor	December 2020	47 Major 36 Minor	No
Colorado producer	Hemp processor	February 2021	8 Major 16 Minor	Yes
Oregon producer	Hemp processor	February 2021	7 Major 32 Minor	Yes
Oregon cultivator	Hemp cultivation	February 2021	Not applicable	Yes
State-approved Colorado testing laboratory	Hemp testing laboratory	April 2021	3 Major 17 Minor	Yes

### Large East Coast Multi-State Operator (MSO)

With the added challenge of a global pandemic, extensive precautions were taken before, during, and after travel and we are pleased to report that no auditors or operator staff and support teams contracted COVID.

While the large east coast multi-state operator (MSO) accepted the findings of non-conformance, they were unable to prioritize and provide a plan for resolution, a requirement to achieve Certification. The audit findings triggered additional senior level conversations within the organization that led to the need for them to perform additional due diligence/research on the business case as they have multiple facilities, are rapidly expanding and lack an overarching corporate quality program. This highlights the complexity and challenges that larger operators face by not having a Quality Program to mitigate major operational risks.

This operator had a general GMP certification in place as required by their state cannabis commission. Our findings reinforce the reality that not all GMP programs are created equal – and need to be carefully evaluated to ensure they effectively evaluate cannabis industry specific needs and risks. The ASTM & PH&S program was developed with cannabis specific standards with strict auditor qualifications that also include hands-on knowledge of the cannabis industry. As evidenced by the number of findings during our audit, **it is clear that there is a need for cannabis specific programs to ensure the safety and consistency of products.** Furthermore, the continued increase in recalls by state health agencies due to heavy metal contaminants, labeling errors, and moldy products reaffirm the risks to consumer health as long as the industry lacks a cannabis certification program that includes Good Manufacturing Practices.

### Colorado Hemp Processor

The Colorado producer also had a third-party GMP certification. During the closing audit meeting, it was stated by the quality manager that in comparison to their other third-party audit, the cannabis industry knowledge combined with the GMP audit expertise resulted in a much more valuable experience for them as we uncovered findings that went unnoticed by the cannabis inexperienced auditor.

### **Oregon Producer and Cultivator**

The Oregon processor was initially chosen only as a major supplier to the Colorado processor. Based on the experience in Colorado, this processor ultimately decided to be on-boarded as an official participant. This team benefitted from having a management team with decades of food quality and agricultural experience, which we largely attribute to their success in rapidly resolving the non-conformances identified.

### **State-Approved Colorado Testing Laboratory**

Throughout the process of auditing the cultivators and processors, it was also clear that major gaps existed in the third-party testing laboratory requirements. The State-approved Colorado testing laboratory was included to uncover the potential extent and need for a program that goes above and beyond the standard ISO 17025 accreditation scheme which the majority of states require testing laboratories to meet.

Similar to how we uncovered gaps that were not discovered during the other participants' GMP audits, our findings support the need for a more robust program that addresses the unique challenges of testing cannabis product types.

Cannabis products are diverse and require very specific methodologies and different test preparations in order to confidently report on contaminants as well as potency. By example, a variant of THC that is the primary constituent of marijuana, Delta-8 THC has emerged as a lucrative synthesized product from CBD that is derived from hemp. D8-THC produces almost half of the 'high' as Delta-9 THC found naturally in marijuana, yet the perceived lack of clarity between the 2018 Farm Bill and the Analogues Act, combined with a lack of any oversight, poses a major health and security risk. Many laboratories lack the qualification and expertise to consistently identify this unique compound in the wide variety of cannabis products on the marketplace.

For law enforcement officials, the landscape surrounding cannabis and hemp is constantly changing. As producers develop new products, unless laboratories are informed of the potential new ingredients, solvents, or final product types, what does not get tested does not get reported. This has been highlighted by the recent emergence of Delta-8 THC and other synthetically derived cannabinoids.

### **Delta-8 THC Complicates Regulators, Law Enforcement, and Compromises Consumer Safety**

Delta-8 THC produced from hemp operates in an unregulated market with products being sold in gas stations and on the internet. Products such as Delta-8-THC produced outside of regulated state programs are problematic. Inside the regulated market, product testing, labeling, and good manufacturing practices are routinely employed. This certification effort aids in allowing law enforcement and consumers to know the source of products and cut down the channel and demand for unsafe and unregulated products.

The isomers of THC (e.g. Delta-8 and Delta-10) are not found in sufficient quantities in the cannabis plant and thus are synthetically created using dangerous chemicals that place consumers at considerable

health risks. A certified lab can serve as an early warning detection system for law enforcement to turn to as certified labs will have the capacity to legitimately test emerging products for the presence of contaminants and isomers that have not been shown to be safe for human consumption. A more detailed summary of the issues surrounding Delta-8-THC were highlighted in a [recent white papers](#) published by [ASTM International](#) and the [United States Pharmacopeia's Cannabis Expert Panel](#).

### **Benefits To The Industry: Validation**

This third-party, independent certification designation will likely become an integral part of a larger risk avoidance strategy for cannabis and hemp operators when encountering a public health crisis stemming from questionable production practices. Proof of production standards become verifiable and legitimately defend embedded production protocols and standards.

For these reasons, there is a great incentive for cannabis and hemp operators to participate in this certification program. Further, this specific certification trips the compliance switch which as rules and regulations evolve, certified companies will be better positioned from a regulatory and operating perspective. It is a key transition point which justifies voluntary participation in a compliance protocol effort.

### **Benefits To Law Enforcement: Access To Information**

A secure portal with information that is only available to the Attorney General Alliance (AGA) and its representatives will be maintained. This secure portal will allow the state attorneys general to view:

- A list of all marijuana and hemp operators and financial institutions that have been audited
- The result of audits (pass/fail)
- Dates of certification and expiration

Each participant in the certification process will be required to sign a disclosure allowing this information to be shared with law enforcement.

The ultimate objective is to provide information to law enforcement allowing them to identify compliant from non-compliant operations as well as confirm compliance with public health and safety production protocols.

Precedents for this system exist globally. Producers of life-critical protective equipment (e.g. [NIOSH respirators](#)), sporting goods and more are certified and listed on [SEI's Certified Product list](#). The European Medicines Agency maintains and operates the [EudraGMDP database](#) providing a list of all GMP certificates, statements of non-compliance, import authorization holders and more for all manufactures of drugs and drug components. These portals provide critical information to stakeholders resulting in consumer confidence and a robust supply chain.

Further, there will be a general portal with availability for vendors, insurers and financial institutions to determine if a company is certified. Thus, informed business decisions can be made based upon the credibility of the entity being looked at for some sort of relationship or coverage.

With the establishment of:

- Credible processes and protocols
- Audit procedures
- Recurring review

- Revocation authority
- Information access to law enforcement
- Tying every operation to financial integrity and transparency

This initiative creates a tool for law enforcement which is a further step toward building industry accountability and knowledge consistency.

## **Section IV: CONCLUSION**

The comprehensive The Public Health & Safety/ASTM Cannabis Certification Initiative overseen by the PH&S, in partnership with ATACH and ASTM International, demonstrates an effective solution for law enforcement to have trust in the \$20 billion dollar cannabis and hemp marketplace that lacks traditional federal oversight.

The PH&S Certification Initiatives cover the supply-chain from end-to-end, from the raw material production to retail distribution, including financial and product testing oversights. As every change of hands in a complex and evolving marketplace such as cannabis and hemp represents an opportunity for product adulteration or diversion, risk mitigation strategies and safeguards that this program provides is paramount.

Third-party programs have been utilized successfully in dozens of marketplaces, including the [FDA for foreign food facilities](#) and [medical devices](#), to ensure the safety of [children's products and toys by the CPSC](#). At the core of the The Public Health & Safety/ASTM Cannabis Certification Initiative is ASTM International's globally recognized voluntary consensus standards development process which has resulted in thousands of ASTM standards being incorporated by reference into US law as well as [globally](#).

In the short term, businesses that achieve Certification can be recognized by regulators, law enforcement, and industry alike as trusted providers of safe quality products. In the long-term, this Initiative can serve as a trusted solution to the complex interface between state and federal agencies, as cannabis has quickly become a global commodity that has unique benefits and risks that have failed to be addressed within current national and global frameworks for policy.

At the end of the day, standards and certification mechanisms to demonstrate conformance against such standards exist in an ecosystem that is able to evolve with changes in technology and new scientific discoveries, while providing the protection and safeguards that are critical to governments and will uphold the credibility and fabric of our society.

## **Section V: ORGANIZATIONAL BACKGROUND**

**ABOUT PH&S:** The Policy Center for Public Health & Safety (PH&S) is a public policy and education organization which collaborates closely with state Attorneys General and law enforcement. The organization was developed to formalize work PH&S has conducted on behalf of AG organizations for the past 6 years and was founded with input from and the perspective of the states, policy makers and regulators. PH&S approaches cannabis and hemp from the following four policy pillars: which are of fundamental importance to law-enforcement and attorneys general: Anti-money laundering, public health and safety, consumer protection and rule of law. These are part of the constitutional charges of state Attorneys General.

The Policy Center is involved with facilitating dialogue and policy discussion surrounding the conflicting aspects of the legalization efforts, the recent impacts of the 2018 US Farm Bill addressing hemp and CBD production and distribution. The PH&S Foundation was established to administer the certification initiative and to demonstrate its independence from PH&S.

**ABOUT ASTM:** ASTM International is one of the oldest and most respected consensus-based standards development organizations in the world, formed in 1898 as the American Society for Testing Materials. In 2017, ASTM International approved the formation of "Committee D37" to develop standards for cannabis and hemp, its products and processes. The activities are focused on meeting the needs of the cannabis industry, consumers, and regulators, addressing quality and safety through the development of voluntary consensus standards. Subcommittees focus on the development of test methods, practices and guides for cultivation, quality assurance, laboratory considerations, packaging and security. Through ATACH's MOU with ASTM International, and PH&S' MOU with ATACH, this creates a unique certification opportunity with an emphasis on involvement from law enforcement. D37 has grown to nearly 1000 members across 30 countries, including businesses, laboratories, associations, governments, regulators, and others.

**Section VI: EVIDENCE OF CERTIFICATION**



**ASTM International  
CANNQ/HEMPQ Certification Program  
for Test Laboratories**

**Certificate of Certification**



Certified Test Laboratory

**This quality GLP certificate is issued to:**

**Laboratory Name**

**Laboratory City, State**

Issue Date: XX.XX.XXXX

For participation in the ASTM International CANNQ/HEMPQ certification program managed by the Safety Equipment Institute. The program encompasses the successful completion of an annual SEI quality assurance and good laboratory practice audit to the conformance requirements of the SEI Certification Program Manual and ASTM Cannabis Certification Program. This laboratory has demonstrated good practice quality guidelines that will contribute to consumer protection and public health and safety.

Tricia Hock  
Safety Equipment Institute  
Director, Certification Operations

Timothy Brooke  
Safety Equipment Institute  
President

Fred Niehaus  
Policy Center PH&S  
Chairman



Let it be known that \_\_\_\_\_ is CERTIFICATED by the Policy Center for Public Health and Safety (PH&S).

The company has been certified by PH&S as to adhering to and practicing the highest standards in providing financial services, practices & protocols in compliance with federal anti-money laundering guidelines and statutes set forth by the US Treasury Dept and FinCen.

Let it further be recognized that this certified institution has successfully completed & committed to a rigorous process in providing financial services to the cannabis & hemp industries.

As a condition of certification, The Financial Institution hereby certified has committed to the following:

- Creation of an ongoing program to assist law enforcement track, find and eliminate activities related to money laundering, illicit drug activity, human trafficking, terrorist activities, transfers to sanctioned territories and illegal funds from the black market.
- Protecting the US Financial System from entrance of illicit dollars and to embrace & implement best practices and regulatory requirements to meet Bank Secrecy and Anti-Money Laundering obligations.
- Eliminating illegitimate, black-market businesses utilizing enhanced Due Diligence and annual monitoring best practices to eliminate Illicit Organizations from accessing the financial system.
- Validating funds entering the financial system to ensure all sales are legally earned, officially reported and properly taxed.
- Monitoring industry participants to ensure licenses are maintained and the highest standard of operations are in place to prevent implicating enforcement priorities.

Let it be known that notice of this Certification shall be sent to office of the state attorney general, regulators overseeing licensed operations and the relevant State Banking authorities.

The Certification issued by PH&S recognizes responsible industry excellence in providing financial services to the cannabis and hemp industries in a lawful and legitimate manner.

By virtue of obtaining this PH&S Certification, \_\_\_\_\_ Company may display this Seal of Best Practices in facilities so long as it remains in good standing as to the integrity of the certification requirements provided.

SIGNATURE \_\_\_\_\_ Date \_\_\_\_\_  
Policy Center for Public Health and Safety Representative

Notarization of Certified Operation \_\_\_\_\_  
Official Witness





## Policy Center Public Health & Safety



Whereas the integrity of the United States monetary system is of the highest priority;

Whereas the multi state legalization of cannabis products has created a market and regulatory need for enhanced anti-money laundering protocols;

Whereas cannabis legalization continues to expand, more financial institutions will enter the cannabis banking market place requiring those institutions to embrace robust anti-money laundering enterprise risk management protocols specifically certified to mitigate money laundering and other illicit activities;

Whereas since the inception of such cannabis banking, Partner Colorado Credit Union ("PCCU") is one of the pioneers to openly develop comprehensive and credible cannabis enterprise risk management systems and protocols designed to mitigate money laundering and other illicit activities;

Whereas CEO Sundie Seefried has been the instrumental force in the development of these risk management systems and protocols;

Whereas since 2015, PCCU through its Safe Harbor Private Banking Division, has built a cannabis banking program that has withstood the scrutiny of 15 State and Federal Regulatory examinations;

Let it be known that PCCU is being recognized as the preeminent entity in development of one of the first cannabis banking training protocols in the United States. Such development of practices which have, in the public interest, been translated into a nationally recognized financial institution protocol which establishes the highest standards of compliance with federal anti-money laundering guidelines and statutes set forth by the United States Treasury and the Federal Financial Crimes Enforcement Network;

Let it further be known that PCCU is certificated by the Policy Center for Public Health & Safety ("PH&S") for exemplary development of anti-money laundering training practices for the financial services industry;

Consequently, companies being certified by the PH&S are recognized as following the highest standards of enterprise risk management systems and customer due diligence relating to anti-money laundering and cannabis banking which will positively impact the US monetary system as a result of implementing and embracing the standards set forth by PCCU;

Therefore let it be recognized and acknowledged that the certified cannabis banking initiative has successfully been developed and financial institutions seeking certification have committed to a rigorous process in providing financial services to the cannabis and hemp industries;

Specifically such commitments encompass the following:

- Creation of an ongoing program to assist law-enforcement track, find and eliminate activities related to money laundering, illicit drug activity, human trafficking, terrorist activities, transfers to sanctioned territories and illegal funds from the illicit market;
- Certifying financial institutions through a rigorous multi-stage auditing process that includes a detailed questionnaire with accompanying affidavits, discussions with auditors about responses and potential red flags on AML and BSA violations;
- Assisting in the protection of the US financial system from the entrance of illicit dollars and to embrace and implement best practices and regulatory requirements to meet Bank Secrecy Act and anti-money laundering obligations;
- Assisting in the elimination of, illicit market businesses through robust enterprise risk management systems including enhanced customer due diligence and annual monitoring best practices to mitigate illicit organizations from accessing the financial system;
- Validating funds entering the financial system to facilitate legally earned sales, that are officially reported and properly taxed; and
- Monitoring industry participants to ensure licenses are maintained and the highest standards of operations are in place to prevent implicating enforcement priorities;

This certification by PH&S recognizes responsible industry excellence in providing financial services training and programs to the financial services industry in a lawful and legitimate manner;

By virtue of obtaining this PH&S certification, PCCU and its subsidiary Safe Harbor Financial may display this Seal of Best Practices in all of its facilities.

## Section VII: Secure Portal

## Section VIII: Appendix

Participants in the ASTM Certification Initiative are required to adhere to the ASTM Certification Program Manual, a summary of this is provided below. There are three program schemes for the **ASTM CANNQ/HEMPQ Certification Program**:

- Cultivating Facility and Cannabis Flower Program
- Producer (Extracting) Facility Program
- Test Laboratory Program

An application form is completed for all initial and surveillance certification audits for review. The information provided is reviewed to determine the quality audit plan and sample selection plan for certification testing.

Participants will submit their Quality Manual and supporting documentation to the auditor for a Document Review prior to the on-site audit. The document review audit is conducted to review key controlled documents prior to scheduling the on-site audit.

The on-site audit is focused on the participant's **Quality GMP/GLP System** which shall be audited initially and annually. The participant shall have a quality assurance GMP/GLP program that meets the SEI requirements detailed in the ASTM Certification Program Manual: Core Requirements. In addition, cannabis program participants shall meet the following Quality Management System Requirements related to Good Manufacturing Practices (GMPs) and Good Laboratory Practices (GLPs).

For cultivators and producers (including extractors), **Good Manufacturing Practices (GMPs)** are minimum requirements that provide an additional layer of assurance that products are produced in a manner that results in consistent batch-to-batch quality that is fit for their intended use. Having an effective quality management system (QMS) is required to provide the assurance that GMPs will be effective.

The ten core principles of GMP that are evaluated ensure:

1. The **facility and equipment are designed and constructed properly**. This includes:
  - a. A facility layout that reduces the chances of cross-contamination and product mix-ups.
  - b. Established air, water, lighting, ventilation, temperature, and humidity specifications that are maintained to reduce environmental contamination.
  - c. Equipment that are designed, located, and maintained to suit its intended use.
2. **Processes and equipment are validated** to prove that they can consistently do what they are supposed to do, and that changes that may affect validation are documented and approved.
3. **Standard Operating Procedures (SOPs) are written** and followed for all activities that may impact the final quality of the product.
4. Personnel have clear roles and responsibilities documented in **job descriptions** with an organizational chart to delineate responsibilities.
5. **Records** are generated and maintained that enable you to track all activities performed during production – from the receipt of raw materials through final release and distribution (if applicable). Records provide evidence that SOPs and Specifications are continually adhered to.
6. **Good hygiene and sanitation practices** are established and validated to ensure they do not contaminate products.

7. **Quality is designed into the entire product lifecycle** and final QC testing is not relied on as the primary determining factor in whether a batch is safe for release. This includes:
  - a. Control and approval of all raw materials entering the facility
  - b. Controlling the manufacturing process through validated SOPs and record keeping
8. An effective **training program** for both initial and on-going training of staff is in place.
9. **Facilities and equipment are maintained effectively**. This includes:
  - a. Scheduled maintenance programs for facilities and equipment with records of all scheduled and unscheduled maintenance and cleaning.
  - b. A calibration program is in place and kept up to date for all equipment requiring calibration.
10. Regularly assess the effectiveness of the Quality and GMP program through a **self-auditing** program. Findings from self-audits as well as external audits are corrected through an effective Corrective Action Preventive Action (CAPA) system.

For testing laboratories, **Good Laboratory Practices (GLPs)** are minimum requirements that provide an additional layer of assurance that testing is being conducted in a manner that promotes uniformity, consistency, reliability, reproducibility, quality, and integrity of products. Having an effective quality management system (QMS) is required to provide the assurance that GLPs will be effective.

The ten core principles of GLP that are evaluated ensure:

1. **Quality assurance programs**
  - a. Personnel have clear roles and responsibilities documented in **job descriptions** with an organizational chart to delineate responsibilities.
2. **The facility and equipment are designed and constructed properly**. This includes:
  - a. A facility layout that reduces the chances of cross-contamination and product mix-ups and provides a clear separation for designated activities.
  - b. Established air, water, lighting, ventilation, temperature, and humidity specifications that are maintained to reduce environmental contamination.
  - c. Equipment that are designed, located, and maintained to suit its intended use.
  - d. A facility that is designed with the proper safety equipment and procedures.
3. **Laboratory instrumentation, apparatus, material, and reagents are qualified / certified** to prove that they can consistently do what they are intended to do, and that changes that may affect qualification / certification are documented and approved.
4. Validated **Analytical / Microbiological Test Methods**
5. **Handling and storage** of test and reference substances
6. **Standard Operating Procedures (SOPs)** are written, followed, and managed through proper change control for all activities that may impact the final quality of the product.
7. Documentation of **laboratory analysis**
8. **Data Integrity** and reporting of results
9. Storage, retention and archival of **records and materials**. Records provide evidence that SOPs and specifications are continually adhered to.
10. Control of **non-conforming work and out of specification (OOS)** results

Consensus standards provide the foundation for the Certification Program. A non-exhaustive list of ASTM International's approved cannabis standards utilized in this Initiative include the following:

- ASTM D8197 Standard Specification for Maintaining Acceptable Water Active (aw) Range (0.55 to 0.65) for Dry Cannabis Flower
- ASTM D8196 Standard Practice for Determination of Water Activity (aw) in Cannabis Flower

- ASTM D8205 Standard Guide for Video Surveillance System
- ASTM D8217 Standard Guide for Access Control System
- ASTM D8218 Standard Guide for Intrusion Detection System (IDS)
- ASTM D8219 Standard Guide for Cleaning and Disinfection at a Cannabis Cultivation Center
- ASTM D8220 Standard Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry
- ASTM D8222 Standard Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products
- ASTM D8229 Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry
- ASTM D8244 Standard Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry
- ASTM D8245 Standard Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products
- ASTM D8250 Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products
- ASTM D8282 Standard Practice for Laboratory Test Method Validation and Method Development
- ASTM D8286 Standard Guide for Processing Cannabis Product Complaints
- ASTM D8308 Standard Practice for Cannabis/Hemp Operation Compliance Audits
- ASTM D8334/D8334M Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses

Upon successful completion of the audit and issuance of the certification letter, the official certification mark may be used. The participant shall use the certification mark on approved product packaging and marketing materials to demonstrate the cannabis facility has met the applicable standard(s) and has been verified by the Quality Auditor to meet the quality assurance requirements.

###