

# Regulator's Program Guide

May 2019



**Headquarters:**  
1624 U Street Northwest  
Suite 200  
Washington, DC 20009

**Toll Free:** (888) 929-4367  
**Website:** [americansforsafeaccess.org](http://americansforsafeaccess.org)  
**Facebook:** [facebook.com/safeaccessnow](https://www.facebook.com/safeaccessnow)  
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**Instagram:** [americansforsafeaccess](https://www.instagram.com/americansforsafeaccess)

## Introduction

Since 1996, states have been experimenting with medical cannabis (marijuana) laws and regulations. Patients, health care providers, lawmakers, and regulators now have the tools they need to ensure reliable, high-quality hemp, cannabis, and cannabis products thanks to the 2011 partnership of Americans for Safe Access (ASA), the American Herbal Products Association (AHPA), and the American Herbal Pharmacopoeia (AHP). This unique partnership combines the expertise of ASA, the nation's largest medical cannabis patient advocacy organization, AHPA, the principal U.S. trade association and voice of the herbal products industry since 1982, and AHP, an organization that has developed qualitative and therapeutic monographs on Western herbs since 1994.

AHPA's Cannabis Committee, comprised of cannabis industry leaders from around the country and AHPA staff, has issued a series of Recommendations for Regulators for the cannabis industry. These regulatory guidelines are based on national nutraceutical and botanical standards that contain cannabis-specific guidelines designed to protect the integrity, quality, purity, and consistency of hemp, hemp products, cannabis, and cannabis products. This series provides a comprehensive model of regulations for cannabis standards and quality assurances from seed to consumption. The AHPA Recommendations for Regulators are available in four easy-to-reference documents:

1. Cannabis Cultivation and Processing Operations;
2. Cannabis Manufacturing, Packaging, Labeling, and Holding Operations;
3. Cannabis Laboratory Operations; and
4. Cannabis Dispensary Operations (see appendix).

In December of 2013, the AHP released a Monograph and Therapeutic Compendium for Cannabis. This comprehensive publication serves as a guide for identifying the quality, purity, and potency of the cannabis plant and includes analytical standards to guide cannabis laboratory operations with a baseline for contaminant testing and standardized methodologies for cannabis analysis.

Since the release of the AHPA and AHP guidelines, states have been using them as legislative and regulatory tools to create comprehensive product safety rules and regulations. However, these new regulations will only be effective with proper oversight and enforcement. To aid government agencies in these efforts, ASA has created the Patient Focused Certification (PFC) program. PFC is a non-profit, third-party certification program for the cannabis and hemp industries and the nation's only certification program for the AHPA and AHP standards. PFC is available to all qualifying companies cultivating, manufacturing, or distributing cannabis and hemp products as well as to laboratories providing cannabis and hemp analytic services. PFC offers a comprehensive program that



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includes employee training, compliance inspections, ongoing monitoring, regulatory updates, and an independent complaint process for consumers.

The PFC program is currently offered as a voluntary certification program in all states that permit medical and/or adult-use cannabis and hemp operations. The PFC program:

- ❖ Offers regulators a third-party auditing option to ensure that licensed businesses are meeting standards required under regulation;
- ❖ Is overseen by a Peer Review Board that has over 300 years of collective expertise in USDA food and product safety protocols, federal regulatory development, and medical cannabis research, pharmacology, biochemistry, and industry practices;
- ❖ Provides a logo that lets consumers, policy makers, regulators, community members, and health care providers know that companies are meeting compliance and product safety standard requirements;
- ❖ Monitors violations of regulations as well as complaints from patients, caregivers, health care practitioners, regulators, and community members;
- ❖ Provides trainings that include: Legal Issues, Raid and Robbery Preparedness, Patient Education, Good Neighbor Policies, Safe Handling Protocols, Working with Patient Populations, Understanding Test Results and Delivery Systems, Adherence to Local Laws and Regulations, and Adherence to AHPA and AHP standards;
- ❖ Provides participants with educational materials for patients, caregivers, health care providers, and regulators that describe the certification program.
- ❖ Verifies through independent auditors that companies follow state and local rules as well as AHPA and AHP standards, thereby ensuring patient safety and product quality, purity, and reliability;
- ❖ Offers third-party certification that can help reduce regulatory program cost and oversight burden;
- ❖ Has independent auditors that can be contracted as third-party auditors for regulatory agencies;
- ❖ Provides companies and regulators (if required) with annual Audit Reporting.

## Working with PFC

Working with PFC to provide compliance oversight of the cannabis industry can help close the potential knowledge gap between the industry and regulatory agencies while simultaneously easing financial and staffing burdens on regulators. PFC works directly with regulators and industry trade groups across the country to coordinate the ongoing and evolving development of medical cannabis, adult-use cannabis, and hemp industry regulations and standards. PFC provides regulators with access to some of the industry's best technical experts, delivering consistent services with the highest levels of integrity while providing patients, health care providers,



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and regulators confidence that the program's participants meet the highest levels of product safety and quality available.

## Third-Party Certification Benefits for Regulators and Consumers

In order to reduce the cost and operational burden to regulatory oversight agencies, regulators are increasingly relying on independent third-party declarations of compliance to support their enforcement and monitoring activities. Independent third-party declarations demonstrate compliance with legislation and regulations as well as overall performance against industry benchmarks and performance indicators. Third-party certification ensures that an independent organization has reviewed the quality of the cultivation and manufacturing processes of a product or the management processes of a service, for example, and has determined that the final product complies with specific standards for safety, quality, purity, or performance. This allows the regulatory agency to focus on the development of overall policy requirements or detailed technical requirements while relying on approved third-party certification bodies to ensure a high standard of regulatory compliance. Compliance is demonstrated by the award of a third-party certificate and the ability to add the third party's mark, or seal of approval, to the product or service label.

As with other industries, oversight of cannabis and cannabis products is constantly evolving. PFC verifies compliance with state and local laws as well as the AHPA and AHP standards. In order to ensure ongoing compliance, PFC requires comprehensive staff training, annual inspections, unannounced random inspections, and product testing to ensure that certified companies continue to meet all program standards. PFC is similar to other nationally recognized certification programs including USP, NSF, and ISO.

## AHPA and AHP Standards

Patient Focused Certification standards are established guidelines that provide a system of processes, procedures, and documentation to ensure that hemp, cannabis, and cannabis-derived products have the strength, composition, purity, and identity they represent to possess and that the companies cultivating, manufacturing, and distributing these products are committed to quality and product safety. These standards also provide the foundation of integrity for the PFC program and have been developed through ASA's partnership with the American Herbal Products Association (AHPA) and the American Herbal Pharmacopoeia (AHP). As such, PFC standards represent the consensus of the world's leading experts on cannabis and botanical product regulations. Released in 2013, PFC standards were developed in two parts: 1. AHPA Recommendations for Regulators, and 2. The AHP Monograph and Therapeutic Compendium for Cannabis.

Founded in 1982, AHPA is the oldest non-profit organization specializing in service to the herbal industry. All of AHPA's activities are focused on its mission to promote the responsible commerce of herbal products and are undertaken to maintain and improve market opportunities for companies that sell herbs, herbal and botanical



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products, and other health-related products and ensure that consumers continue to enjoy informed access to a wide choice of goods. In 2010, AHPA established a Cannabis Committee tasked with the development of national recommendations for regulators that would address sensible regulatory practices for hemp, cannabis, and cannabis-derived products from the propagation of plant matter to consumption by the consumer. As such, the AHPA's Cannabis Committee developed a series of guidelines, or Recommendations for Regulators, in the following four areas:

- ❖ **Cultivation and Processing** - Intended to establish a basis for oversight of entities that cultivate cannabis in outdoor, greenhouse, and/or indoor facilities, these guidelines address good cultivation practices, pesticide guidance, facility requirements, management of water resources, recordkeeping, product safety recall systems, adverse event reporting, and information disclosure. This document also establishes best practices and safe handling procedures for operations that provide post-harvest processing of cannabis.
- ❖ **Manufacturing, Packaging, Labeling and Holding** - Intended to establish a basis for oversight of entities that are engaged in the manufacturing of cannabis and cannabis-derived products, these guidelines are modeled after federally recognized Good Manufacturing Practices (GMP's) for botanical and nutraceutical products. These recommendations ensure that GMP's are maintained in manufacturing operations by focusing on personnel, physical condition of the plant and surrounding grounds, manufacturing controls, packaging, holding, and labeling controls, cannabis material acquisition, inventory and recordkeeping, complaints, returns, product safety recalls, and adverse event reporting.
- ❖ **Distribution** - Intended to establish a basis for oversight of entities that provide cannabis and cannabis-derived products directly to compliant individuals through storefront operations, delivery services, direct-from-garden operations, and growing co-op operations, these guidelines focus on personnel, security, product acquisition, record keeping, customer policies, implementable product safety recall systems, adverse event reporting, and other matters that can contribute to best practices in the dispensary setting.
- ❖ **Laboratory Analysis** - Intended to establish a basis for the oversight of entities performing laboratory analysis of cannabis, cannabis-derived products, and hemp products, these guidelines were developed as a complement to existing good laboratory practices and focus on personnel, security, sample handling and disposal, data management, personnel safety and hygiene, and reporting activities that may be unique to laboratories analyzing cannabis, cannabis-derived products, and hemp samples. In addition to the AHPA guidelines, PFC-certified laboratories are also required to adhere to the standards presented in the AHP Cannabis Monograph.



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Established in 1995, the American Herbal Pharmacopoeia (AHP) is a non-profit 501(c)(3) California-based organization with a mission to promote the responsible use of herbal products and herbal medicines. The AHP produces critically reviewed documents called monographs that outline the quality control criteria needed for ensuring the identity, purity, and quality of botanical raw materials. Each document also presents a complete and critical review of the traditional and scientific literature regarding the efficacy and safety of herbal medicines and includes information on specific products such as tinctures and extracts. In 2011, the AHP began the development of a Monograph and Therapeutic Compendium for Cannabis. The first edition was released in 2013 and provides scientifically valid standards for companies engaged in laboratory analysis of cannabis and cannabis-derived products with regards to:

- ❖ Ensuring the identity, quality, purity, and potency of cannabis and cannabis-derived products.
- ❖ Reporting and analytic equipment calibration.
- ❖ Ensuring product safety by identifying safe levels of pesticides, metals, and microbial limits.

Laboratory analysis facilities participating in the PFC program have each successfully calibrated their equipment and implemented protocols in accordance with the AHP Monograph and Therapeutic Compendium for Cannabis, establishing the first standardized testing of cannabis and cannabis products. Through standardized testing, patients and their medical practitioners can now have confidence that the products utilized not only comply with PFC's high quality and safety standards but are also properly labeled and standardized to ensure consistency of quality and effectiveness. Product standardization provides medical practitioners with the confidence necessary to recommend cannabis treatments at the beginning of a treatment cycle, as opposed to a last resort, and provides the foundation for human clinical trials and case studies on cannabis therapeutics.

All PFC companies are required to adhere to these rigid quality standards. Due to the ever-changing and expanding nature of cannabis regulations and cannabis industry innovations, PFC recognizes the need to adopt new standards and guidelines as regulations change and has been developed as a continually evolving program overseen by a Peer Review Board that, along with AHPA and AHP, will oversee and approve the ongoing updating of PFC program standards. Depending on the extent of standard updates, a PFC auditor may be assigned to the affected companies to verify that all necessary compliance updates have taken place. Additional staff training may also be required. The addition of program requirements, determination of corrective actions, and need for additional trainings will be determined by the PFC Peer Review Board.

## PFC Program Oversight

The PFC program is overseen by the PFC Peer Review Board, which is tasked with annually reviewing and updating audit methodologies and program standards, processing and reviewing all certification appeals, and all



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revocation actions. The review board may be asked to weigh in on a company's corrective actions as determined through a scheduled or secondary follow-up audit.

## **Types of Certification Offered by PFC**

Patient Focused Certification is available to hemp companies and to cannabis companies in all states with medical cannabis and/or legal adult-use laws in place and is designed to show the quality commitment of cannabis companies engaged in providing patients with hemp, cannabis, and cannabis-derived products. There are several options for certification available to companies engaged in the PFC program, ranging from single discipline certification to multiple discipline certification options. While all available PFC program certifications verify compliance with local and state laws and regulations as well as AHPA and AHP guidelines, some areas of certification may require additional training and/or additional compliance criteria, such as for companies engaged in manufacturing or laboratory testing operations.

### **Cultivation Certification**

- ❖ Ensures the company is compliant with state and local regulations, including licensing, zoning, and environmental requirements.
- ❖ Demonstrates the safety of products used in the cultivation process.
- ❖ Verifies that the raw cannabis does not contain an unacceptable level of contaminants.
- ❖ Verifies adherence to AHPA and AHP quality standards and that procedures are in place for implementable product recall protocols, adverse event reporting, proper storage, and safe handling protocols.
- ❖ Determines the hazard, risk, and impact of the products used during the cultivation of cannabis, protecting the health and well-being of the environment, employees, and patients.

The Cultivation Certification process includes: comprehensive staff training; a document review; a label review to verify product and marketing claims; a thorough facility inspection; and laboratory testing and contaminant review to ensure there are no unsafe levels of contaminants.

### **Manufacturing, Packaging, Labeling and Holding Certification**

- ❖ Ensures the company is compliant with state and local regulations and licensing, zoning, and applicable environmental requirements.
- ❖ Verifies the identity, purity, quality, and quantity of ingredients declared on the product label.



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- ❖ Demonstrates the product does not contain undeclared ingredients.
- ❖ Verifies that the product does not contain an unacceptable level of contaminants.
- ❖ Verifies adherence to AHPA and AHP quality standards and procedures, including product recall protocols, adverse event reporting, proper packaging, labeling, storage, and handling systems.
- ❖ Determines the hazard, risk, and impact of the products used in the cannabis manufacturing processes to ensure environmental, employee, and patient safety.

The Manufacturing, Packaging, Labeling, and Holding certification process includes: comprehensive staff training; document review; a label review to verify product identity, formulation, and marketing claims; a formulation review to identify and quantify dietary ingredients declared on the product label; a contaminant review and laboratory testing to ensure there are no unsafe levels of contaminants; and a thorough facility inspection.

### **Distribution Certification**

- ❖ Ensures the company is compliant with state and local regulations as well as licensing and zoning requirements.
- ❖ Verifies adherence to AHPA and AHP quality standards and procedures, including product recall protocols, adverse event reporting, and proper storage and handling systems.
- ❖ Determines the hazard, risk, and impact of the processes used in the cannabis distribution operation to ensure community, employee, and patient safety.

The Distribution certification process includes: comprehensive staff training; document review; a label review to verify product formulation and marketing claims; and laboratory testing to ensure there are no unsafe levels of contaminants in products provided to patients.

### **Laboratory Testing Certification**

- ❖ Ensures the company is compliant with state and local regulations, including environmental, licensing, and zoning requirements.
- ❖ Demonstrates the laboratory's commitment to accuracy and integrity.
- ❖ Verifies adherence to AHPA and AHP quality standards and procedures, including proper calibration, storage, and handling systems.
- ❖ Determines the hazard, risk, and impact of the processes used in the medical cannabis laboratory to ensure employee and patient safety.
- ❖ Offers ISO/IEC 17025 accreditation combined with PFC certification through partnership with A2LA.



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The Laboratory Testing certification process includes: comprehensive staff training; document review; equipment and standards review; testing verification; and a thorough facility inspection.

### **Multiple Discipline Certification**

For those companies engaged in multiple types of industry operations, PFC offers multi-discipline certifications. This certification opportunity allows companies engaged in a combination of cultivation, manufacturing, and/or distribution to certify all areas with one PFC seal of approval denoting the combination of disciplines and a commitment to product safety for all aspects of operation. In order to uphold the integrity of PFC independent laboratory testing services and the product safety verification such certified laboratories offer, PFC does NOT allow laboratory operation certification to be combined with other disciplined operations receiving PFC certification. If a PFC laboratory operation wishes to certify in a second discipline, then the certified laboratory facility may NOT be used to satisfy the testing requirements of the secondary discipline.

### **Pre-licensing Certification**

Companies interested in the PFC program but not yet licensed to cultivate cannabis or hemp can engage in the PFC program and begin the audit process prior to license approval. To successfully obtain pre-licensing certification, the assigned PFC auditor(s) must complete a document audit of all of the company's proposed SOPs and employee manuals, and the company must be able to show verification that all staff members identified on the application have successfully completed PFC Training. The assigned PFC auditor(s) will create a detailed audit report for the company outlining any corrective actions necessary for the SOPs to meet the standards of the PFC program. All corrective actions must be successfully implemented prior to receiving PFC approval from the assigned auditor(s). PFC will then provide the company with a letter of intent certifying that the provided documents adequately demonstrate that the company has implementable procedures that comply with local and state laws and regulations and AHPA and AHP guidelines. Companies engaging in this PFC pre-licensing undertaking are held to a rigid timeline for the completion of the certification process upon license issuance.



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## Process for Certification

PFC offers a confidential and supportive certification process that includes:

- ❖ **Introductory call and business review** - the PFC process begins when the licensee or licensee applicant conducts an introductory phone call to review certifications and services and determine what services are needed. That information is then confirmed by a post-call email.
- ❖ **Quote** - using information generated by the introductory call, PFC prepares a price quote and an estimate of time required for completing the certification process.
- ❖ **Contract** - a contract is executed outlining the responsibilities of all parties involved, including financial obligations and acceptance of terms.
- ❖ **Preliminary assessment** (optional) - PFC provides procedures for the audit and questions management about facilities and processes.
- ❖ **Documentation assessment** - an offsite review of company documentation determines if the company's licensing and processes are sufficient to ensure adherence to standards.
- ❖ **Training** - Mandatory training is conducted for all paid and volunteer employees, including all new hires that occur over the course of the certification year. This audit is ongoing; employees must have successfully completed all PFC-required trainings prior to certification approval.
- ❖ **Facility assessment** - trained PFC field inspectors conduct a confidential standard audit and a facility inspection.
- ❖ **Product testing** - PFC tests products for pesticides, molds, and contaminants with an independent, third-party laboratory when available, necessary, and appropriate for certification.
- ❖ **Initial checklist results and corrective recommendations** - the licensee receives the results of the PFC audit and is informed of any corrective actions to be taken.
- ❖ **Secondary audit** - If needed, a secondary audit is conducted to ensure that necessary corrective actions have been taken.
- ❖ **Certification** - the PFC Review Board will issue the licensee's certification once the inspector verifies any required corrective actions were taken and all compliance standards have been met.

### Preliminary Assessment

In many cases, the company seeking certification may request an optional preliminary assessment of their operations. This gives PFC the opportunity to identify in advance any weaknesses that may exist in the company's management systems. A preliminary assessment gives the company sufficient lead time to correct deficiencies



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before audits are conducted and assists PFC in planning for the certification. The scope of the preliminary assessment is determined by the company and may range from a review of documents to a full assessment, including on-site operational observation and assessment. While the preliminary assessment is optional, it is recommended. Ultimately, it may save time and resources by revealing deficiencies that could be corrected before the required audits to avoid the expense of follow-up actions.

## Documentation Assessment

The PFC Independent Auditor(s) assigned to the company will retrieve all local and state licensing documents as well as management system documents and manuals. The auditor(s) will review the documentation to determine whether it meets all local and state regulatory requirements and the AHPA and AHP standards. Documentation should include, at a minimum:

- ❖ **Standards manual(s)** - outlining systems utilized to ensure compliance to state and local laws and regulations as well as the AHPA and AHP guidelines;
- ❖ **Operating procedures** - including detailed descriptions on how to perform system functions;
- ❖ **Work instructions** - defining specific job activities affecting the safety and quality of products and processes; and
- ❖ **Quality documentation** - documents that demonstrate how quality is managed, including charts, files, inspection and testing records, assessment results, implementable product recall procedures, adverse event reporting records, and any other records of objective evidence.

If the documentation fails to meet standards, the deficiencies will be identified in an audit report, and the licensee will be required to take corrective action before certification can be awarded. Once PFC has determined that the documented management systems are satisfactory, a facility audit will be scheduled.

## Training Audit

The PFC auditor(s) assigned to the company will verify that all paid and volunteer staff have successfully completed the required PFC trainings. Successful completion of PFC required courses is documented by passing the corresponding online tests with a score of no less than 70%. All company staff must successfully complete the required trainings prior to receiving certification and all new hires are required to successfully complete the required trainings within 30 days of hire in order for the company to maintain PFC-approved status.



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## Facility Audit

The assigned PFC auditor(s) will complete a thorough on-site assessment of the facility and its operations. An audit agenda will be prepared for the licensee prior to the arrival of the PFC auditor(s), including a daily schedule and any accommodation requests. It is the auditor's (or auditors') responsibility to verify whether the management systems of the company meet all of the applicable standards.

Upon arrival at the facility, the PFC auditor(s) will conduct an introductory meeting followed by a full facility walk-through to observe activities and confirm that the operating procedures outlined in the document audit have been successfully implemented. All PFC auditors reserve the right to obtain samples for the purpose of laboratory testing (if permitted by regulation), conduct private interviews with employees, inspect documents and records, observe work processes, and examine equipment. The objective of the facility audit is to verify technical competency, including statements, documented procedures, records, and written policies.

If deficiencies are found during the course of the audit, the PFC auditor(s) will bring the deficiencies to the licensee's attention and record them as required or suggested corrective actions, depending on the severity of the deficiency in the audit report. The audit report will specifically describe, in detail, what deficiency was observed, the standard or policy to which it relates, and the necessary corrective actions required to remedy the deficiency. PFC audit reports also include a recommended timeline for the company to receive certification. The timeline varies depending on potential corrective actions.

## Product Testing

PFC provides a wide range of comprehensive cannabis product safety testing services, where available. (Services may be limited in some states). PFC's independent laboratory testing services assist certified companies with the establishment of product stewardship by confirming content and purity, identifying problems with contamination, and determining potential for human and environmental exposure risk to ingredients and by-products, including potential allergens, residual pesticides and solvents, heavy metals, and microbiological contaminants. The PFC program specializes in examining product composition and proper packaging, labeling, and storage protocols that ensure public and patient safety. PFC laboratory testing conducted for certification verification is provided by PFC-certified independent labs conforming to AHPA and AHP guidelines as well as all applicable local and state laws and regulations. Laboratory testing for the purpose of certification verification is limited to necessary testing to meet standards. Where allowed by state law, our independent laboratory testing facilities can also provide patients, caregivers, and licensees cannabis analytical services as requested.



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## **Exit Meeting**

Upon completion of the on-site audit, the assigned PFC auditor(s) will conduct an exit meeting. A summary review of the facility audit will be given to management or the primary contact person, and regulators as applicable. If any deficiencies were recorded, they will be described at this time and included in the final facility audit report.

## **Corrective Action**

All PFC applicants with identified deficiencies will be given a reasonable timeframe to implement required corrective actions. PFC requires that all corrective actions be verified and approved by the assigned auditor(s) before certification can be granted. The corrective action response must include objective evidence showing the necessary corrective actions have been completed. PFC may require a follow-up on-site facility audit, limited to the area of concern, depending on the nature of the deficiency. Certification cannot be awarded until any and all deficiencies have been adequately corrected.

## **Final Review, Report, and Appeal Process**

Within 10 business days of the facility audit (if no deficiencies are found), or upon confirmation of completed corrective actions, PFC will issue a confidential report and certification decision. (The report will be provided to regulators if necessary). All documentation will be forwarded to PFC's Review Board, and the Executive Committee will review the application materials and audit documentation prior to issuing a decision on the certification. If the Peer Review Board grants a company certification, they will be notified immediately and the appropriate certification materials will be issued.

In the event that an application for PFC certification is denied, an appeal may be submitted within 10 business days of the issuance of the decision. A Dispute Board that includes at least three members from the PFC Peer Review Board will consider any appeal. Additional dispute board members are selected based on their knowledge of the specific discipline from our network of partner organizations, including the International Cannabis and Cannabinoids Institute (ICCI). Each Dispute Board member must have sufficient knowledge and expertise in the discipline to perform a review of materials and reports and issue an impartial decision. The dispute board will have at least 5 members, and a maximum of 11 members.



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## Certification

Upon the successful completion of PFC-required trainings, audits, and necessary corrective actions, the company will become PFC approved and will receive a PFC-approved materials package. PFC certification materials include:

- ❖ A certificate bearing the certified company's name and the PFC certification logo.
- ❖ A PFC certification window decal.
- ❖ Educational and promotional materials for patients, health care providers, and regulators.
- ❖ PFC website links.
- ❖ A Standards Packet, including applicable AHPA guidelines and an AHP Monograph and Therapeutic Compendium for Cannabis.
- ❖ Verification that copies of the approved certification(s) have been sent to regulators and localities where required by law.

## Annual Audit Reports

The review period begins once certification has been granted, and the company may be subject to random and unannounced audits and/or product testing. An annual recertification process is mandatory for renewal certification(s). Follow-up audits may require document submissions and/or an on-site visit. Consumers, healthcare providers, stakeholder groups, regulators, etc. may submit complaints about a certified company to PFC. PFC will maintain records of complaints about certified companies. Depending on the complaint severity and/or frequency, such complaints may trigger unannounced inspections. If, for whatever reason, certification must be suspended, PFC will notify regulators.

## Certification Process Timeline

The amount of time required to complete the certification process depends on several variables, including the discipline(s), the size of the facility, the number of employees, and the complexity of operations. The amount of time it takes a company to achieve readiness for certification depends on the quality of management systems currently in place. PFC provides optional advisory services to identify and resolve documentation and process deficiencies in advance of the audit process.



**Headquarters:**  
1624 U Street Northwest  
Suite 200  
Washington, DC 20009

**Toll Free:** (888) 929-4367  
**Website:** [americansforsafeaccess.org](http://americansforsafeaccess.org)  
**Facebook:** [facebook.com/safeaccessnow](https://www.facebook.com/safeaccessnow)  
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The speed of the certification process also depends upon timely and complete responses from the applicant. A typical certification timeline is as follows:

- ❖ Introductory phone call and follow-up email
- ❖ Quote generated
- ❖ Contract executed
- ❖ Preliminary Assessment Completion (optional)
- ❖ Documentation Audit – (5-10 business days, upon receipt of documents)
- ❖ Facility Audit/Product Testing – (3-5 business days)
- ❖ Corrective Action Period (if necessary) – (up to 30 days, longer if needed)
- ❖ Final Review, Report and Decision – (5-10 business days)

### **Ongoing Review and Complaint Resolution**

The assigned PFC auditor(s) and PFC staff will monitor certified operations throughout the certification period. In the event of a law or regulation change, or when AHPA or AHP releases updated standards, a review audit may need to be completed. PFC will notify certified companies of any updates to standards and provide an explanation of actions required by the company to comply with such updates, including a required timeframe for compliance. Additionally, if any third-party complaints require an investigation, or if a large number of complaints are received, a review audit may be necessary. PFC will evaluate and respond to all third-party complaints to verify their legitimacy and severity. Certified companies are required to respond to complaints within five (5) business days of notification by an assigned PFC auditor or staff person. When necessary, PFC will require immediate corrective action.

PFC shall investigate complaints related to certified companies, misuse of the PFC logo by certified companies, or use of the PFC logo by non-certified companies. A certified company's failure to cooperate in a complaint investigation will result in the immediate termination of PFC certification.

Parties may lodge complaints by filing a signed PFC Complaint Investigation Request. Complaints will be sent directly to the Program Director, who will track all complaints and investigations. PFC will acknowledge receipt of the complaint, promptly investigate and validate the complaint, and take, or ensure the implementation of, appropriate corrective actions. PFC will notify the complainant of such actions. The certified company will be advised of the complaint at the appropriate time during the investigation as determined by the PFC Program Director. Further, PFC shall determine, together with the certified company and complainant (and regulators where necessary), if the complaint and resolution should be made public.



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Suite 200  
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When a complaint is made by a company, whether PFC certified or not, the complainant agrees to bear the cost of an investigation if the complaint is not verified. If the complaint is substantiated, the certified company shall be responsible for all costs of the investigation. Regulatory authorities, individual consumers, and licensed health care providers are exempt from bearing the costs of any investigation. PFC shall not identify the complainant unless required to do so by law. PFC will treat unsigned Complaint Investigation Requests as informal complaints. PFC may attempt to verify and investigate informal complaints as needed but has no obligation to investigate or respond to them.

## PFC Training

As state cannabis laws and regulations continue to evolve, cannabis-specific trainings have become increasingly required. The District of Columbia and states such as Arizona, Massachusetts, Nevada, Florida, Illinois, and Connecticut have mandated comprehensive training for all staff working or volunteering in government-licensed cannabis facilities. PFC can help state lawmakers and regulators reduce the cost of implementing and operating cannabis training programs by providing qualified third-party certification that includes jurisdiction- and discipline-specific staff training programs.

A leader in cannabis education since 2002, ASA has distributed millions of copies of educational literature to patients, health care professionals, researchers, industry, labor, regulators, and concerned community members and has conducted hundreds of legal and advocacy trainings nationwide.

ASA staff members have over a dozen years' experience in implementing medical cannabis laws nationwide and have helped to develop and improve laws at both the local and state level. ASA staff continue to ensure regulatory compliance of patients and providers by offering a variety of hands-on in-person trainings. Patient Focused Certification's comprehensive staff trainings represent the continuing evolution of this important, ever-expanding work.

The PFC training and education program prepares individuals to understand state and local regulations and to learn required safety and operational protocols while teaching them the basics of cannabis as medicine and common therapeutic uses of cannabis. PFC trainings provide content that will also save businesses time and money, whether they are drafting regulations, applying for a license, or trying to pass numerous state inspections at an existing operation. A full description of each course may be found in Appendix I.

## Training

- ❖ Disciplines (pick 1 or more disciplines to study)
  - Distribution
  - Cultivation and Processing
  - Manufacturing
  - Laboratory



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Suite 200  
Washington, DC 20009

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- ❖ Certification Levels (choose which level is best for you)
  - Staff
  - Verified Professional (recommended for Management-level personnel)
  - Auditor

### **Staff Training Program** (8-10 hours) Requirements:

- ❖ Attend the entirety of required courses
- ❖ Pass tests with a score of 70% or better
- ❖ Courses include:
  - Core Cannabis Training: Cannabis as Medicine (1 hour)
  - Core Cannabis Training: Cannabis Business Operations (2 hours)
  - Core Cannabis Training: Understanding Cannabis Law (1 hour)
  - Core Cannabis Training: State and Local Legal Compliance (2 hours)
  - National Cannabis Standards Training (choose 1 or more of the below disciplines)
    - Distribution Operations (2 hours)
    - Manufacturing, Packaging, Labeling, and Holding Operations (4 hours)
    - Cultivation and Processing Operations (2 hours)
    - Laboratory Operations (2 hours)

### **Verified Professional Training Program** (18-20 hours) Requirements:

- ❖ Attend the entirety of required courses
- ❖ Pass tests with a score of 80% or better (tests can be retaken at additional cost)
- ❖ Courses include:
  - Core Cannabis Training: Cannabis as Medicine (1 hour)
  - Core Cannabis Training: Cannabis Business Operations (2 hours)
  - Core Cannabis Training: Understanding Cannabis Law (1 hour)
  - Core Cannabis Training: State and Local Legal Compliance (2 hours)
  - National Cannabis Standards Training (choose 1 or more of the below disciplines)
    - Distribution Operations (2 hours)
    - Manufacturing, Packaging, Labeling, and Holding Operations (4 hours)
    - Cultivation and Processing Operations (2 hours)
    - Laboratory Operations (2 hours)
  - Enrichment Course: Pesticide Guidance and Integrated Pest Management (2 hours)
  - Enrichment Course: Quality Control / Quality Assurance and Batch Sampling (2 hours)
  - Enrichment Course: Advanced Endocannabinoid System (2 hours)
  - Enrichment Course: Sustainable Cultivation (2 hours)



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Suite 200  
Washington, DC 20009

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- Enrichment Course: Cannabis Extraction and Safety (2 hours)

**Auditor Training Program** (20+ course hours, 2 observed audits, and 2 shadow audits) Requirements:

- ❖ Prerequisites and approved application
- ❖ Attend the entirety of required courses
- ❖ Pass tests with a score of 80% or better (tests can be retaken at additional cost)
- ❖ Complete field requirements
- ❖ Courses include:
  - Core Cannabis Training: Cannabis as Medicine (1 hour)
  - Core Cannabis Training: Cannabis Business Operations (2 hours)
  - Core Cannabis Training: Understanding Cannabis Law (1 hour)
  - Core Cannabis Training: State and Local Legal Compliance (2 hours)
  - National Cannabis Standards Training (choose 1 or more of the below disciplines)
    - Distribution Operations (2 hours)
    - Manufacturing, Packaging, Labeling, and Holding Operations (4 hours)
    - Cultivation and Processing Operations (2 hours)
    - Laboratory Operations (2 hours)
  - Enrichment Course: Pesticide Guidance and Integrated Pest Management (2 hours)
  - Enrichment Course: Quality Control / Quality Assurance and Batch Sampling (2 hours)
  - Enrichment Course: Advanced Endocannabinoid System (2 hours)
  - Enrichment Course: Sustainable Cultivation (2 hours)
  - Enrichment Course: Cannabis Extraction and Laboratory Safety (2 hours)
  - Enrichment Course: Internal and External Auditing for Cannabis Operations (2 hours)

**Additional State Requirements**

As cannabis laws continue to evolve, additional trainings above and beyond the PFC-required trainings are sometimes required by law. Where required, these trainings will cover the specific aspects of the state and local requirements unique to the operation of the cannabis program. These trainings include, but are not limited to, state-specific Best Management Practices, Integrated Pest Management programs for cultivation operations, inventory control systems, workplace safety, and food safety.



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Suite 200  
Washington, DC 20009

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## PFC SERVICES AVAILABLE TO LEGISLATORS AND REGULATORS

PFC staff are always available to help lawmakers and regulatory agencies develop and implement medical and adult-use cannabis and hemp programs through the following services.

**Legislation and regulation development:** Since 2002, Americans for Safe Access has been working with lawmakers to adopt and improve medical cannabis legislation and regulations, including the adoption of model legislative language and the submission of comments to assist in the development of regulations. ASA continues to facilitate support for medical cannabis in Congress and administrative agencies and has organized many prestigious advisory boards to assist policymakers and other stakeholders with the science of cannabis.

**Sensible regulations based on the AHPA and AHP guidelines:** These comprehensive guidelines serve as a tool, to be used in sections or in whole, for the sensible regulation of the cannabis and hemp industries. Together, these guidelines inform cannabis and hemp regulations from plant propagation to product sale. Local and state governments have increasingly utilized these guidelines as the foundation for sensible regulatory development.

**Staff training:** PFC's comprehensive training program can be utilized in a multitude of ways, from assisting regulators in the training of regulatory staff and state inspectors to providing consistent and reliable regulator-mandated educational programs for staff working in the cannabis industry.

**In-depth training on the AHPA and AHP guidelines:** This in-depth training is designed to educate attendees on compliance with the AHPA and AHP guidelines and provide comprehensive training on handling practices, implementable product recall protocols, adverse event reporting, security, and best practices for industry operations.

**Compliance and auditor training:** PFC's compliance and auditor training serves functions beyond the training of PFC independent auditors. It is also a valuable tool for governments, one that provides an opportunity for regulatory agencies to train department auditors in the specifics of auditing cannabis operations in a thorough and knowledgeable manner. Additionally, PFC independent auditors can be made available to assist regulatory and other government agencies fulfill audit requirements.

**Certified training management:** PFC offers a comprehensive array of ready-to-use training programs designed for industry staff, health care practitioners, government employees, auditors, and consumers in a variety of subjects pertaining to cannabis. Two accessible formats are available: in-person training is conducted by a PFC-certified instructor, and online training is available through [www.pfctraining.org](http://www.pfctraining.org). PFC courses are continually updated to meet or exceed each state's requirements.



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Suite 200  
Washington, DC 20009

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**Instructor training services:** PFC's Certified Instructor Training program has trained and certified instructors in across the country who are available to offer PFC trainings on a national level. By working with the PFC Certified Instructor Training program, state governments can bridge the knowledge gap between industry and regulators and have confidence in the knowledge that all training programs required by law meet or exceed state requirements and are conducted in a consistent and professional manner.

**Program oversight:** The PFC program verifies state and local compliance protocols as well as product safety and quality standards through the PFC training programs and the PFC independent auditor services. By working with the PFC program, government and regulatory agencies can reduce the oversight burden and cost of implementing medical cannabis programs.

**Compliance protocols:** PFC's seal of approval confirms that cannabis operations are compliant with all local and state laws and regulations as well as the AHPA and AHP guidelines. By mandating PFC certification for qualifying businesses, government and regulatory agencies can focus on the development and updating of cannabis laws and regulations and leave compliance verification to third-party auditors.

**Audit services:** PFC Auditor Training programs provide a comprehensive training opportunity for qualified individuals interested in becoming PFC independent auditors, as well as for government and regulatory agency staff requiring cannabis specific auditor training. Government and regulatory agencies can also engage PFC independent auditors to conduct compliance audits in all disciplines of the medical and adult-use cannabis industries and hemp industry.



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1624 U Street Northwest  
Suite 200  
Washington, DC 20009

**Toll Free:** (888) 929-4367  
**Website:** [americansforsafeaccess.org](http://americansforsafeaccess.org)  
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### **About ASA, AHPA, and AHP**

Founded in 2002, **Americans for Safe Access** (ASA) is the largest organization of patients, medical professionals, scientists, and concerned citizens promoting safe and legal access to medical cannabis for therapeutic uses and research. ASA works with our grassroots base of over 100,000 members to effect change using public education and direct advocacy at the local, state, and federal level. ASA trains and educates patients, advocates, health care professionals, and other stakeholders. ASA also provides direct legal support and uses impact litigation to protect and expand patients' rights.

As patient advocates, ASA has worked to create laws and regulations that foster the rights of patients and ensure access to safe and legal medical cannabis. Patients, caregivers, health care practitioners, and regulators can rest assured that PFC-certified cannabis or cannabis products have been produced in a manner that is not only compliant with local and state laws but also with a commitment to product safety. See more at: [www.safeaccessnow.org](http://www.safeaccessnow.org).

The **American Herbal Products Association** chartered a Cannabis Committee in 2010 to meet the needs of those of its members that grow, manufacture, or distribute cannabis in accordance with state law and companies that market industrial hemp products. AHPA has been the principal U.S. trade association and voice of the herbal products industry since 1982. AHPA promotes the economic health of the herbal products industry and promotes high quality herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life. See more at: [www.ahpa.org](http://www.ahpa.org).

The **American Herbal Pharmacopoeia** was formed in 1995 to promote the responsible use of herbal products and herbal medicines. AHP is a worldwide network of botanists, chemists, herbalists, medical doctors, pharmacists, pharmacologists, and other experts in medicinal plants. AHP has published monographs for 38 different botanicals, including Aloe Vera Leaf, American Ginseng Root, and Echinacea. The organization expects to eventually publish more than 300 monographs, covering the most widely used western, Ayurvedic, and Chinese botanicals. See more at: [www.herbal-ahp.org](http://www.herbal-ahp.org).

For more information:

Heather Despres  
Patient Focused Certification Director  
[heather@safeaccessnow.org](mailto:heather@safeaccessnow.org)  
202.857.4272 x6



**Headquarters:**  
1624 U Street Northwest  
Suite 200  
Washington, DC 20009

**Toll Free:** (888) 929-4367  
**Website:** [americansforsafeaccess.org](http://americansforsafeaccess.org)  
**Facebook:** [facebook.com/safeaccessnow](https://facebook.com/safeaccessnow)  
**Twitter:** [@SafeAccess](https://twitter.com/SafeAccess)  
**Instagram:** [americansforsafeaccess](https://www.instagram.com/americansforsafeaccess)

## Appendix I

### PFC Course Descriptions

**Core Cannabis Training (CCT)** - CCT provides the foundation for all PFC educational programs and is the prerequisite for any additional trainings. The CCT program is taught in sections, providing a well-rounded understanding of the history of medical cannabis laws, cannabis as medicine, cannabis science and research, and running a safe cannabis business.

- ❖ **Core Cannabis Training: Cannabis as Medicine (1 hour)**
  - The course gives participants an overview of the most current cannabis research, how cannabis works in the body, different varieties of cannabis and cannabinoids, and the various cannabis-based pharmaceuticals currently available.
- ❖ **Core Cannabis Training: Business Operations (1 hour)**
  - The course teaches how to deliver the best quality of care to customers, how to handle interactions with Federal law enforcement, what to do in an emergency situation, and how to ensure the safety of cannabis products.
- ❖ **Core Cannabis Training: Understanding the Law (1 hour)**
  - The course is an overview of federal cannabis laws, the history of medical cannabis laws, which states have medical cannabis laws, and the conflict between state and federal laws. The course also includes a Federal law enforcement interaction and raid preparedness training component.
- ❖ **State-Specific Compliance Training (SSCT) (2 hours)**
  - These courses are designed to give individuals a comprehensive foundation of knowledge of the laws pertaining to Cannabis businesses as well as the regulations that govern day-to-day operations. The SSCT course is broken into two components: state and local laws & state and local regulations.
- ❖ **National Cannabis Standards Training (NCST) (2-4 hours/discipline)**
  - NCST is designed to educate industry professionals about the particulars of compliance specific to the AHP Cannabis monograph and AHPA guidelines. The NCSTs are available in four cannabis industry disciplines, including: cultivation and processing; manufacturing, packaging, labeling, and holding; distribution; and laboratory analysis.
- ❖ **National Cannabis Standards Training: Cultivation and Processing Operations (2 hours)**
  - This course is designed to educate industry professionals about the particulars of compliance specific to the AHPA Recommendations for Regulators. Learn the skills necessary to implement Good Agricultural Practices, including pesticide guidance, facility requirements, water resource management, recordkeeping, product safety recall systems, adverse event reporting, and information disclosure.
- ❖ **National Cannabis Standards Training: Manufacturing, Packaging, Labeling, and Holding Operations (4 hours)**



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Suite 200  
Washington, DC 20009

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- This course is designed to educate industry professionals about the particulars of compliance specific to the AHPA guidelines. The training is designed for individuals engaged in the manufacturing of cannabis and cannabis-derived products and provides the tools necessary to comply with Good Manufacturing Practices.
  
- ❖ **National Cannabis Standards Training: Laboratory Operations (2 hours)**
  - This course is designed to educate industry professionals about the particulars of compliance specific to the AHP Cannabis Monograph and AHPA guidelines. This training is designed for individuals performing laboratory analysis of cannabis and cannabis-derived products. The training will examine Good Laboratory Practices and facility security, sample handling and disposal, data management, personnel safety and hygiene, and reporting activities that may be unique to laboratories analyzing cannabis, cannabis-derived products, and hemp samples.
  
- ❖ **National Cannabis Standards Training: Distribution Operations (2 hours)**
  - This course is designed to educate industry professionals about the particulars of compliance specific to the AHPA guidelines. In this training you will learn the skills necessary to implement Best Management Practices relating to the distribution of cannabis and cannabis-derived products directly to compliant individuals through storefront operations, delivery services, direct-from-garden operations, and growing co-op operations.

## **PFC Enrichment Courses (PFCEC)**

PFCEC offer individuals specialized cannabis industry education ranging from Pesticide Guidance and Integrated Pest Management to QA/QC and Representative Sampling. PFC Enrichment Courses can be utilized to fulfil continuing education requirements for staff and are part of the required courses for PFC Verified Professionals and PFC Accredited Auditors seeking to achieve and maintain accreditation.

- ❖ **Enrichment Course: Pesticide Guidance and Integrated Pest Management (2 hours)**
  - This course offers individuals specialized cannabis industry education that includes key definitions pertaining to pesticides and how to properly read a pesticide label. The trainings explore the importance and function of tolerance thresholds, major chemical families, Restricted-Entry Intervals (REIs), and Personal Protective Equipment (PPE) as well as employee safety and employer responsibilities. You will also learn the key components to developing a successful Integrated Pest Management (IPM) program. This course is highly recommended for all cultivation and processing management personnel.
  
- ❖ **Enrichment Course: Sustainable Cultivation (2 hours)**
  - Designed to help cultivators reduce their impact on the environment, this course provides tools for reducing the carbon footprint of cultivation operations as well as information on the use, recycling, and reuse of mediums. In addition, this course discusses appropriate nutrient use, the consequences of mined and imported materials, and the proper storage of chemicals. Water source development, use, storage, and reduction techniques are also addressed in this course, as is the proper tracking of materials used during the cultivation process.



**Headquarters:**  
1624 U Street Northwest  
Suite 200  
Washington, DC 20009

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- ❖ **Enrichment Course: Quality Control/Quality Assurance and Batch Sampling (2 hours)**
  - This course offers individuals specialized education that includes developing and implementing Quality Assurance (QA) and Quality Control (QC) systems, including method validation and Good Manufacturing Practices (GMPs) as they relate to QA/QC topics. Additionally, this guide will explore “representative sampling” techniques and how to apply them to cultivation, processing, and manufacturing operations to ensure consistent product purity and quality as well as accurate labeling. This course is strongly recommended for management working in a Cannabis business.
  
- ❖ **Enrichment Course: Advanced Endocannabinoid System (2 hours)**
  - This course offers individuals specialized education that covers how cannabis works in the human body and an in-depth look at current research. The course covers how THC, CBD, and other substances stimulate the endocannabinoid system and is recommended for people with a base of knowledge in medical cannabis and in areas such as manufacturing, marketing, education, product development, laboratory operations and management, and health care.
  
- ❖ **Enrichment Course: Internal and External Auditing for Cannabis Operations (2 hours)**
  - This course offers individuals specialized education, including: audit protocols; how to administer checklists, questionnaires, and document reviews; guidelines for conduct; and travel tips. The course also covers etiquette and appropriate protocols for interacting with staff and management at the location being audited as well as organizational techniques necessary for writing a final audit report.
  
- ❖ **Enrichment Course: Cannabis Extraction and Laboratory Safety 101 (2 hours)**
  - This course is designed as a comprehensive review of current methodologies and best practices in the extraction and processing of cannabis. Participants will learn: the latest developments in extraction and analysis technologies; guidance on how to comply with standards; regulations; and how to operate safely.
  
- ❖ **Enrichment Course: Cannabis Care Certification Patient Education (2 hours)**
  - This course offers guidance on speaking with patients about medical cannabis and is recommended for all individuals interacting with patients.



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