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Standard Practice for Cannabis/Hemp Operation Compliance Audits[1]

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1. Scope

1.1 *Purpose*—This practice identifies the minimum requirements for the planning, conduct, and reporting of compliance audits of a cannabis/hemp business. It provides information on terms, procedures, and responsibilities.

1.2 *Intent*—The intent is to provide specific instruction needed to develop reliable audit programs and procedures that are used to conduct audits that produce credible, consistent, and objective evidence and findings related to compliance with one or more standards, regulations, policies, best practices, or quality specifications. This practice can be used internally for pre-audit assessments to identify and correct operational gaps.

1.3 *Organization*—This practice is organized in the following manner:

1.4 Nothing in this practice shall preclude observance of federal, state, or local regulations which may be more restrictive or have different requirements.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

[1] This practice is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.02 on Quality Management Systems.

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2. Referenced Documents

2.1 *ASTM Standards:*[2]
D8229 Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *action plan, n*—a plan to correct negative audit findings and close ~~compliance~~ gaps.

3.1.2 *audit, v*—see *compliance audit*.

3.1.3 *audit authority, n*—the entity that authorizes, or initiates, the audit process.

3.1.3.1 *Discussion*—
The audit authority may be internal to the audited entity, such as ~~a department manager, a CEO, or the board of directors,~~ senior management not involved with the day-to-day operations of the operation/area(s) being audited; or external, such as a financial stakeholder, a business customer, or a government authority having jurisdiction.

3.1.4 *audit criteria, n*—the set of requirements that are applicable to the objective and scope of an audit. Examples include standards, regulations, laws, policies, best practices, quality specifications, and industry best practices.

3.1.5 *audit data, n*—data collected during an audit to support the audit findings. Examples: Photos, notes, documents, records, forms, and answers.

3.1.6 *audit finding, n*—a statement of the audited entity's conformity against the audit criteria at the time of the audit.

3.1.6.1 *Discussion*—
The audit finding is the good/bad, conformity/nonconformity statement that results from an evaluation of the audit data collected. It can also be the collective conformity/nonconformity of each question or criteria. The audit finding(s) is not the audit data that supports the audit finding.

3.1.7 *audit objective(s), n*—broad statement(s) of what the audit intends to accomplish.

3.1.8 *audit plan, n*—documentation that describes the objective, scope, specific responsibilities, schedule, logistics, deliverables, completion requirements and other plan details for a particular audit.

3.1.9 *audit program, n*—an auditing body's procedures, protocols, methods, and techniques for conducting an audit.

3.1.10 *audit program supplier, n*—an entity that develops and provides a program of audit procedures and protocols that can be used repeatedly by auditing bodies to conduct consistent and reliable audits.

3.1.11 *audit protocol, n*—standard methods for the collection of audit data. Examples: Checklist or questions used during on-site inspections, guides that define the types of records and documents required to provide objective evidence, and interview questions and techniques.

3.1.12 *audit report, n*—a written summary that provides the context or objectives of the audit, relevant background information, the audit findings, and objective audit data that provides evidence to support the findings.

3.1.13 *audit scope, n*—a description of what is to be audited.

3.1.13.1 *Discussion*—
The audit scope should include a description of the period under review, the audited entity, the audit criteria, and the elements being audited, such as facilities, security, procedures, product packaging/labeling, and operational practices.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the ~~standard's~~standard's Document Summary page on the ASTM website.

3.1.14 *audit team, n*—one or more auditors responsible for conducting an audit. The audit team may be supported by technical experts and auditors-in-training.

3.1.15 *audited entity, n*—a facility, organization, or part thereof, that is the subject of an audit.

3.1.16 *auditing body, n*—the organization that plans and conducts an audit, and provides the audit report.

3.1.16.1 *Discussion—*

For an internal audit of a small operation, a single person might take on the responsibilities of the auditing body, the lead auditor, the audit team, and the auditor. For a large external audit, it could be a large audit firm.

3.1.17 *auditor, n*—a person qualified to conduct an audit. A member of an audit team.

3.1.18 ~~*authority*~~*authorities having jurisdiction, n*—~~an~~ external ~~organization, office,~~organizations, offices, or ~~individual~~individuals responsible for enforcing the requirements of a code or standard, or for approving equipment, materials, an installation, procedures, or ~~procedures.~~products.

3.1.18.1 *Discussion—*

In the context of this ~~standard,~~practice, this is typically ~~a government department or agency.~~one or more government departments or agencies. In most cases, multiple authorities are involved such as cannabis agencies, food, fire, building, worker, and consumer health and safety agencies. Requirements from city, state, and country agencies may apply and multiple jurisdictions that have authority over international and cross-border trade may apply.

3.1.19 ~~*cannabis*~~*cannabis/hemp operation, n*—a person, group of persons, non-profit entity, or business entity that cultivates, processes, manufactures, tests, distributes, stores, dispenses, sales, or otherwise handles cannabis/hemp, or products containing cannabis/hemp.

3.1.20 *compliance audit (audit), n*—a comprehensive, systematic, documented, and objective assessment of an audited entity to evaluate and report objective evidence of compliance relative to predefined and mandated laws, regulations, standards, or policies audit criteria.

3.1.20.1 *Discussion—*

In this ~~standard,~~practice, the term "audit" refers to ~~compliance~~ audits that ~~may or may not include an audit for the accuracy of financial books and records or the accuracy of information technology records.~~are based on mandatory or voluntary criteria.

3.1.21 *compliance gap, n*—a condition that does not ~~meet the requirements~~ conform to a mandatory criteria of one or more ~~applicable standards, regulations, policies, best practices, or quality specifications.~~mandated laws, regulations, standards, or policies.

3.1.21.1 *Discussion—*

In this practice, the term "gap" is used to refer to nonconforming conditions based on either mandatory or voluntary criteria.

3.1.22 *documents, n*—written policies, processes, procedures, plans, standards, specifications, and other written information that governs the conduct of a business. Documentation also includes records.

3.1.22.1 *Discussion—*

Records are a form of documentation. It is not uncommon to use the term document to refer to records. The special characteristic of a record is that it documents that some action or event has occurred, or been witnessed. A record does not change since it reflects past events. Documentation such as plans and procedures can be changed but previous versions may be retained as a record.

3.1.23 *independence, n*—a condition characterized by organizational standing where an auditor is free to conduct an audit without being controlled or influenced by others.

3.1.24 *lead auditor, n*—an auditor designated to lead and manage the audit.

3.1.25 *objective evidence, n*—information collected that someone when reviewing an audit report can inspect and evaluate for themselves.

3.1.25.1 *Discussion—*

Objective evidence included in an audit report allows others to substantiate that the audit was actually performed as indicated, that the criteria for the audit were upheld by a proper assessment, and that the findings are valid.

3.1.26 *objectivity, n*—a condition characterized by the absence of bias, influences, and conflicts of interest that affect or have the potential to compromise audit findings.

3.1.27 *open audit issue, n*—a potentially negative audit finding that cannot be verified or resolved without additional time and information.

3.1.28 *period under review, n*—the time interval over which conditions at the audited entity are evaluated against audit criteria.

3.1.29 *physical inspection, n*—first-hand observation and assessment of the audited entity conditions.

3.1.30 *records, n*—an audited entity's documentation and other forms of recorded information. ~~Examples: Inventory records, point of sale records, maintenance logs, pesticide application logs, usage logs, incident reports, batch records, and training records.~~

3.1.30.1 *Discussion—*

Records are information about events or conditions at a point in time. A procedure is a document that can be changed and updated. The previous unchanged version of the procedure can be saved as a record. Other examples include inventory records, point of sale records, maintenance logs, pesticide application logs, usage logs, incident reports, corrective actions, preventive actions, root cause analysis, batch records, and training records.

3.1.31 *working papers, n*—paper, electronic documentation, or both developed or collected by the auditing body and its auditors relating to an audit. Examples: Planning and preparation background information, responses to checklist and questions, photos and other media, copies of documents and records, and notes and descriptions about the audit findings. Audit data is a subset of working papers.

4. Significance and Use

4.1 *Intended Use*—This practice is intended for use by parties who either develop, plan, and conduct internal or external audits, or are interested in the audit process since they are the subject of compliance audits or they mandate such audits to occur.

4.2 *Audits*—Audits are conducted by an auditor or audit body that is independent of the entity being audited. Individuals that conduct an assessment of an operation or product that they are directly involved with or have a vested interest in, is technically not an audit. These assessments might be a pre-audit or gap assessment. This practice can be used for these types of activities and the rigor of a true audit may not be as critical.

4.3 *Terms and Concepts*—The definition of terms in Section 3 and the perspectives on scale, objectives, and types of audits in Annex A3 provide concepts that help clarify the different roles involved in an audit, the various elements of an audit, and how this ~~standard~~practice applies to different situations. This ~~standard~~practice is written in terms that accommodate audits for different objectives and sizes.

4.4 *Application*—Compliance audits are used to identify gaps between some criteria and the actual operational conditions. Knowledge of ~~compliance~~ gaps are used to assess various risks, guide corrective ~~action and~~ action, preventive action, root cause analysis, improvement efforts, prevent fines and penalties, or provide stakeholders an objective evaluation of an operation and its potential safety, financial, or other risks. A user of this practice should understand and adapt the audit concepts, process, and responsibilities in this practice to their specific organizational structure and situation.

4.5 *Audit Scale*—The scale of an audit can range from an internal audit of a small single operation with fewer than ten employees to an external audit of a large corporation with facilities at multiple international locations. In either case, large or small, the principles in this practice shall be followed to produce objective and credible results.

4.6 *Audit Criteria*—As the ~~cannabis~~cannabis/hemp industry develops globally and continues to gain acceptance, both new and previously established standards, regulations, policies, and best practices are being developed, adopted, evolving, and applied to this industry. Due to this evolving nature, diligent attention is needed by auditing bodies to maintain up-to-date audit criteria and protocols.

5. Audit Process Overview

5.1 An audit involves a minimum of three activities: audit preparation, conducting the audit, and reporting findings. In addition, it is in the audited entity's best interest to address and resolve ~~compliance~~ gaps and have a follow-up audit conducted.

5.2 *Preparation*—Prior to conducting an audit the auditing body plans, coordinates, organizes, and communicates the activities for conducting an effective and efficient audit.

5.3 *Conducting the Audit*—The audit is conducted per plan by the audit team member(s) to assess the operation by collecting objective evidence, working papers, and audit findings. The audit activities can occur remotely, during an on-site visit, or both as specified by the audit plan.

5.4 *Reporting*—The audit findings, objective evidence, and working papers are organized to produce a clear and concise audit report. Depending on the objectives and scope, the audit report is shared with the audit authority, the audited entity, or others as defined in the plan. Reporting the audit findings occurs after conducting the audit is completed; however, preparatory reporting may occur earlier in the process.

5.5 ~~*Follow-up*~~*Follow-Up Audit*—In most cases the objective of an audit is to identify and execute corrective/preventive actions to address ~~compliance~~ gaps and reduce various risks. A follow-up audit can be conducted to verify that such actions have resolved the gaps.

5.6 Section 7 provides the details of the audit process. A diagram of the audit process data flow between the process elements and an activity flowchart is provided in Annex A4.

6. Audit Programs

6.1 An audit program is the procedures, protocols, methods, and techniques for conducting an audit. An auditing body may develop a unique audit program for a single use, develop a repeatable audit program, or acquire a repeatable audit program from an audit program supplier. An audit program can be paper based or a software application.

6.2 *Audit Program Credibility*—The credibility of an audit report starts with the quality of the audit program used along with the skill of the auditor(s) to conduct the audit and produce a useful report. The purpose and objectives of an audit program shall be clear in order to ensure it is used in alignment with the objectives of a particular audit.

6.3 *Consistency*—A well-designed audit program brings consistency to the methods and techniques used to conduct audits, report findings, ~~and conduct follow-up audits.~~ coordinate corrective and preventive actions, and conduct follow-up audits to confirm the corrective actions resolve the issues reported.

6.4 *Audit Criteria*—An audit program is based on criteria from one or more standards, regulations, policies, best practices, or quality specifications. ~~The authority and version of the criteria used by the program shall be clearly stated.~~Sources of criteria can be from but not limited to:

(1) Internal policy, procedure, specification;
(2) Standard bodies;
(3) Customer specification;
(4) One or more authorities having jurisdiction for local operational requirements; and
(5) One or more authorities having jurisdiction where products are shipped to and further processed or marketed.

When conflicts exist between the criteria from different sources, document the decision and rationale for the audit criteria used in the audit plan and in the audit report if not otherwise provided to the recipients of the report. The authority and version of the criteria used by the program shall be clearly stated.

6.5 *Audit Protocols*—Audit criteria are used to develop audit protocols. The audit criteria are interpreted and converted into question or checklist protocols that guide the collection of objective evidence during visual inspections, interviews, and the review of documents and records. The quality of an audit is dependent on the depth and specificity of these protocols. To illustrate this

point, the question "*does management care about worker safety?*" can result in a simple and subjective yes or no answer. It should be replaced with several questions that draw out objective evidence of the actions taken by management that have led to worker safety.

6.6 *Program Procedures and Guidelines*—The procedures and guidelines to use the program in a manner that produces accurate and credible results shall be documented. These procedures and guides are especially important for newer auditors. The guides can include but are not limited to objective evidence collection guides, instructions to collect data sources such as the times or shift that the observations were made, locations, departments, special conditions, and names of people interviewed, interview techniques, observation techniques, and document and record review methods. Audit bodies that develop their own programs may consider these procedures and guides as proprietary information.

6.7 *Qualifications and Training to Use the Audit Program*—The qualifications and training required for an auditor to perform audits following the framework of an audit program shall be defined, documented, and provided to auditors that use the program. The time required to prepare, conduct, and report results can be wasted if a quality audit program is not used or the audit is conducted poorly.

7. Audit Process

7.1 *Audit Initiation:*

7.1.1 An audit ~~requires resources. Audits are~~ is initiated and approved by ~~someone.~~ someone that can provide the resource for the audit and define alignment with business objectives. It may be a manager, the CEO, a board of directors, or a ~~stakeholder.~~ stakeholder that is typically not involved with the day-to-day operations of the entity being audited. In this practice, this role is referred to as the *audit authority*. An authority having jurisdiction may mandate an audit but this does not make them the audit authority. The request to have an audit conducted may come in different forms and may or may not be clearly communicated in which case the audit body will need to gain clarification of the request for an audit and its objectives.

7.1.2 The audit authority or their delegate selects the audit body that will prepare and conduct the audit.

7.2 *Audit Preparation:*

7.2.1 Someone is going to plan, coordinate, organize, and communicate the activities for conducting the audit. This is primarily the responsibility of the *auditing body*, but others are involved. Depending on the scope and scale of the audit, the auditing body may be an internal auditing department, a single employee, an external audit contractor, or a large audit firm. Typically the *lead auditor* will perform or lead the preparation activities. The result of the preparation activities is an audit plan.

7.2.2 An audit plan shall be developed and documented or an existing plan refined that addresses:

(1) ~~the~~The objective and scope of the audit;
(2) ~~identification~~Identification of stakeholders;
(3) ~~background information;~~Identification of applicable authorities having jurisdiction;
(4) Identification of applicable audit criteria;
(5) Background information;
(6) ~~description~~Description of the audit program to be used;
(7) ~~audit~~Audit process and procedures;
(8) ~~audit schedule;~~Audit schedule and timeframes;
(9) Audit logistics;
(10) Audit resources;
(11) Corrective action and follow-up plans;
(12) Personnel responsibilities;
(13) Documentation and records to be produced; and
(14) ~~audit logistics.~~Suggested improvements to the audit process and plans.

Each of these plan elements is covered in the following sections. The sequence presented below does not imply a sequence to be followed. As the plan details emerge the elements should be enhanced and updated.

7.2.2.1 *Objective and Scope of the Audit*—Understanding the objective of an audit is important in order to select applicable criteria and develop or acquire appropriate protocols. An objective to identify ~~compliance~~ gaps to drive corrective/preventive actions may require different protocols than an objective to show evidence of investment risk for potential investors. In cases where there is not a clear and established mandate, it may be necessary to coordinate with the *audit authority* to understand or even help develop the purpose and objectives of the audit. Any intent to conduct corrective action and perform a follow-up audit, or not, shall be understood and included in the plan objectives. The audit scope should include a description of the period under review, the audited entity, the audit criteria, and the focus of the audit such as facilities, security, food safety, quality management systems, information security, occupational safety, product packaging/labeling, fire safety. The risk associated with the business case for performing an audit should be described. The level of risk can inform the type, level of detail, and frequency of the audit and follow on audits.

7.2.2.2 *Identification of Stakeholders*—The stakeholder(s) that will receive a copy of the audit report shall be noted as well as others involved such as the audit authority, audited entity, auditing body, audit team, audit leader, and other team members.

7.2.2.3 *Identification of Applicable Authorities Having Jurisdiction*—This is typically one or more government departments or agencies. In most cases, multiple authorities are involved such as cannabis/hemp agencies, food, fire, building, worker, and consumer health and safety agencies. Requirements from city, state, and country agencies may apply and multiple jurisdictions that have authority over international and cross-border trade may apply.

7.2.2.4 *Identification of Applicable Audit Criteria*—Include a list of the audit criteria. The criteria are determined by the purpose and scope of the audit and can include government laws and regulations, industry recognized standards, criteria established by certification bodies, company policies and procedures, or other defined criteria.

7.2.2.5 *Background Information*—Background information can be useful to understand the scale, scope, and nature of the pending audit when developing the audit plan. Background information may consist of records, documents, site descriptions, operation and maintenance manuals, compliance inspection reports, previous audit reports, notices of violations, and other relevant information.

7.2.2.6 *The Audit Program*—An audit program can be developed by the auditing body, acquired from an *audit program supplier*, or a combination of both. In either case, the program needs to be understood and be applicable to accomplish the objectives of the audit. Section 6 covers the requirements of an audit program. The plan shall include a description of the audit program to be used including the authority and version of the criteria that the audit program is based on. Any procedural details that impact the planning, schedule, coordination, or logistics of the audit plan shall be documented. Any audit program methods and techniques that are proprietary to the auditing body ~~do~~does not have to be included in the plan.

7.2.2.7 *Audit Process and Procedures*—To ensure a smooth and efficient audit process, include procedures in the audit plan that guide the actions of the auditing body, the audit team, the audited entity, and other stakeholders. Proprietary procedural details that are used internally by the auditing body do not have to be included in the plan.

7.2.2.8 *Audit Schedule*—A schedule of audit activities shall be developed and documented including major preparation and reporting activities. The schedule shall clearly document the expected timeframes and timeline between the auditing body and the audited entity with respect to the audit execution, reporting audit findings, corrective action, any follow-up audits, and closure as applicable.

~~7.2.2.6 *Background Information*—Background information can be useful to understand the scale, scope, and nature of the pending audit when developing the audit plan. Background information may consist of records, documents, site descriptions, operation and maintenance manuals, compliance inspection reports, previous audit reports, notices of violations, and other relevant information.~~

7.2.2.9 *Audit Logistics*—Issues such as identifying site contacts, scheduling site visit(s), site security and access authorization, use of safety equipment, lodging, transportation, on-site workspace, internet access, special communication situations, on-site meals, and other details should be addressed and documented in the plan.

7.2.2.10 *Audit Resources*—The resources required to conduct the audit shall be listed in the plan. Consider the labor required, time, material, the cost for lodging, transportation, and other logistical needs.

7.2.2.11 *Corrective Action and Follow-Up Plans*—The plan and schedule for activities after conducting the audit and reporting the findings. These activities can include corrective and preventive actions, root cause analysis, and a follow-up audit or assessment.

7.2.2.12 *Personnel Responsibilities Plan*—Documentation of the key roles and responsibilities of stakeholders and personnel involved with the successful outcome of the audit process.

7.2.2.13 *Documentation and Records Plan*—An inventory of the documentation and records that will be produced as a result of the audit process and the plans for delivery, security, retention, and disposal of these documents and records.

7.2.2.14 *Suggested Improvements To the Audit Process and Plans*—Address and incorporated as applicable improvement ideas that were captured during a previous audit. 7.7.1 specifically includes an activity to capture improvement suggestions. An audit body that regularly performs audits should establish key performance indicators (KPIs) and collect performance data to guide the audit process and planning improvements.

7.2.3 *Audit Plan Approval*—Prior to conducting the audit, the plan shall be presented to the audit authority to obtain agreement that the audit, as planned, will accomplish their intent and presented to the audited entity to ensure that they support the audit plan.

7.2.4 *Audit Team Formation and Preparation*—As required by the scale and scope of the audit, assemble the audit team. Team members may or may not be called upon to support preparation activities. Prior to conducting the audit, the team should be briefed on the objectives, procedures, logistics, schedule, and other plan details. Any training on methods and techniques shall be completed.

7.3 *Conducting the Audit:*

7.3.1 *Opening Meeting*—An opening meeting should be held, to ~~bringing~~bring together and introduce the *audit team* to members of the *audited entity* staff that will be involved or support the audit and when available the audit authority. This meeting should also share the audit plan and scope. The meeting should facilitate the subsequent collection of information by the audit team and encourage discussion of any questions or concerns. The *audited entity* should provide an overview of the facility operations for the audit team during this opening meeting.

7.3.2 *Data Collection Protocols*—The audit team shall utilize the audit program protocol standards to ensure consistency in collecting audit data. Auditors should have access to reference specific audit criteria, and access to subject matter experts to clarify their understanding of unique situations as they conduct an audit using the protocol checklists and questions. The collected audit data shall be evaluated by the audit team to verify that it provides objective evidence that supports the audit findings to meet the audit objective. The primary audit protocols to use during the audit are:

7.3.2.1 *Physical Inspections*—Physical inspections and site-visits of the audited entity shall be based on checklists or questions designed to address pertinent requirements of the audit criteria.

7.3.2.2 *Interviews*—Interviews should be conducted to obtain information on audited entity daily practices and procedures. Appropriate management, employees and, if applicable, contractors, should be interviewed. Interview questions shall be designed to address pertinent requirements of the audit criteria with consistency.

7.3.2.3 *Document and Records Review*—Applicable documents and records shall be reviewed by the audit team. This review shall be conducted in a manner that complies with privacy and proprietary information regulations and policies. Documents and records may include items such as but not limited to standard operating procedures, maintenance manuals, company policies, service contracts, reports submitted to an authority having jurisdiction, information on physical conditions of the audited entity, equipment certifications, training records, visitor logs, maintenance logs, surveillance and access control system outage reports, incident logs, safety data sheets, production records, prior audit reports, transaction records, testing logs and records, and advertising records.

7.3.3 *Collecting Data*—Collecting objective evidence to support the audit findings is critical. Evidence of compliance can be as important as evidence of non-compliance depending on the objective of the audit. Electronic or paper copies of the audited entity's records and documents, photos, or other forms of media are necessary to support audit findings. These are considered audit data and shall be treated and handled as proprietary information.

7.3.4 *Team Meeting(s)*—Meetings of the audit team should be conducted to share information, review initial audit findings, identify open audit issues and coordination to ensure timely, accurate, and consistent completion of the audit.

7.3.5 *Closing Meeting*—At the conclusion of the site visit, a closing meeting should be held to discuss draft audit findings and audit status. The closing meeting provides an opportunity for the audited entity personnel to discuss and question draft audit findings. Post-visit procedures should be discussed at the closing meeting including a process for resolving challenged audit findings and for closing or reporting any open audit issues.

7.4 *Audit Reporting:*

7.4.1 *Documentation*—Audit protocols should be completed, or explanations provided for open findings, in accordance with the audit plan.

7.4.2 *Finalizing Audit Findings*—Final audit findings shall be based upon the most recent verifiable audit data from the period under review. Audit findings and ~~compliance~~ gaps that are resolved within the period under review shall be included as audit findings in the audit report and be noted as resolved.

7.4.3 *Preparing the Audit Report*—An audit report shall be prepared that presents audit findings. Providing objective evidence with clear and concise comments in the audit report allows others to understand and act upon the findings efficiently.

7.4.4 *Draft Audit Report*—A draft audit report should be developed for review and comment. Comments on a draft audit report should be made in a timely manner. Reviewers' failure to provide comments shall not prevent the issuance of the final audit report.

7.4.5 *Final Audit Report*—A final audit report shall be issued.

7.4.6 *Presenting the Audit Report*—The audit report shall be presented as defined in the audit plan.

7.5 ~~*Corrective/preventive*~~*Corrective/Preventive Actions:*

7.5.1 In most cases, the purpose of an audit is to identify and execute corrective/preventive actions to address ~~compliance~~ gaps. Planning and implementing corrective/preventive actions follow but are not part of the audit process. A corrective and preventive action plan that assigns responsibilities, describes the actions required to close the ~~compliance~~ gaps, and sets completion target dates should be developed to guide these activities. Refer to Practice D8229 on corrective and preventive action.

7.6 ~~*Follow-up*~~*Follow-Up Audit:*

7.6.1 A follow-up audit can be conducted to verify that corrective actions have resolved the gaps. A follow-up audit can occur

immediately after the corrective actions are completed in which case it is typical to only assess the negative finding(s). In cases where periodic audits are conducted such as quarterly or annually a follow-up audit to verify the resolved gaps can be incorporated into the next periodic audit. A follow-up audit does not preclude the audit team from finding other non-complaint conditions.

7.7 *Closing:*

7.7.1 As appropriate, conduct a final closing meeting or coordinate with the audit authority to ensure they are satisfied with the conduct and reporting of the audit results. Any open items should be taken care of promptly and suggestions for improvement noted and incorporated to improve future audits.

8. Record Management

8.1 *Records*—Records collected by audit protocols are considered either audit data or working papers and shall be securely managed. Records may be but are not limited to physical items or documents, copies of such items or documents, and electronic data of various forms and media such as photos and videos.

8.2 *Confidentiality*—The content of all records, whether audit data or working papers, shall be considered confidential to the entity to which the content or data belongs unless otherwise specified in the audit plan. Securing audit findings and reports should not be taken lightly. Negative findings in the hands of the wrong people can have serious consequences.

8.3 *Record Management*—Record management shall include the following:

8.3.1 Policies for record handling, retention, and the retention period;

8.3.2 Procedures for storage, handling, disclosure, and disposal of confidential records; and

8.3.3 As appropriate by documented in the audit plan.

8.4 *Working Papers*—Working papers include electronic forms of information. In addition to the requirements for records, management of working papers shall include the following additional requirements:

8.4.1 A system to facilitate working paper review with a means to prevent tampering; and

8.4.2 A system for managing corrections and revisions of working papers.

9. Keywords

9.1 cannabis; cannabis assessment; cannabis audit; cannabis best practices; cannabis compliance; cannabis internal audit; hemp; marijuana

ANNEXES

(Mandatory Information)

A1. ROLES AND RESPONSIBILITIES

NOTE A1.1—This annex lists responsibilities grouped by role. A summary diagram is provided in Annex A4.

A1.1 *Audit Authority Responsibilities*—The audit authority shall:

A1.1.1 Determine the need for and initiate an audit;

A1.1.2 Specify or approve the audit objectives;

A1.1.3 Select the auditing body; and

A1.1.4 Support the audit process.

A1.2 *Auditing Body Responsibilities*—The auditing body shall:

A1.2.1 Provide or acquire a valid audit program;

A1.2.2 Provide qualified auditors;

A1.2.3 Select a lead auditor;

A1.2.4 Coordinate with the audit authority;

A1.2.5 Provide quality assurance and quality control of their audit procedures, auditor qualifications, auditor effectiveness, and audit reports;

A1.2.6 Provide support for the management and accountability of the audit working papers, collected data, audit findings, and audit reports; and

A1.2.7 Disclose to the audit authority, issues that compromise the auditing body, or audit team objectivity.

A1.3 *Lead Auditor Responsibilities*—The lead auditor shall:

A1.3.1 Ensure the audit process is efficient and effective;

A1.3.2 Develop or lead the effort to develop the audit plan and coordinate with the audit authority as needed to meet the audit objectives;

A1.3.3 Gather appropriate background information from the audited entity to support audit preparation and planning;

A1.3.4 Communicate with the audited entity and manage audit plan issues. For example, schedule, logistics, access, availability of audited entity staff to interview, operating conditions, audit team needs, and health and safety precautions;