Designation: D8477 – 22

Standard Practice for Cannabis or Hemp Supplier Lifecycle Management[1]

This standard is issued under the fixed designation D8477; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice provides cannabis or hemp operations, or both, with methods, procedures, responsibilities, and criteria for supplier management practices to reliably receive supplies that meet specifications. Effective supplier management includes clear concise communication and comprehension between departments and business functions, that is, marketing, finance, operations, supply requirement analysis, supplier assessment or audits, supplier selection, backup suppliers, and supply/supplier information management.

1.2 In this practice, the term cannabis can be substituted with the term hemp. This practice applies to industrial hemp operations, CBD operations, and as referred to by several authorities having jurisdiction, licensed marijuana operations.

1.3 This practice provides a process for supplier management in Section 5 and criteria for supplier evaluation in Section 6.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D8222 Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products

D8229 Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry

D8270 Terminology Relating to Cannabis

D8286 Guide for Processing Cannabis Product Complaints

D8308 Practice for Cannabis/Hemp Operation Compliance Audits

D8320 Practice for Implementing an Information Security Program in a Cannabis Operation

3. Terminology

3.1 *General*—Definitions are in accordance with Terminology D8270 unless otherwise indicated.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *critical supplies, n*—supplies and services provided by other companies that present an unacceptable level of risk if not available in the quantity, quality, or time required.

3.2.1.1 *Discussion*—When applicable, the term critical supplies includes critical services.

3.2.2 *operation, n*—any entity or individual licensed/permitted by an authority having jurisdiction to grow, process, handle, package, store, distribute, or sell, or combinations thereof, a cannabis plant, its parts, or products, or combinations thereof.

3.2.3 *operations, n*—the active functioning and processing to keep a business running.

3.2.4 *operator, n*—an individual or individuals with the responsibility to manage an operation.

3.2.5 *supplier audit, n*—the process of evaluating a supplier's quality management system and ability to meet the operation's supplier requirements.

3.2.6 *supplies, n*—tangible goods, equipment, material, or services that are provided by sources external to the operation.

[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.

Current edition approved Oct. 1, 2022. Published October 2022. DOI: 10.1520/D8477-22.

[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 Document Summary page on the ASTM website.

3.2.6.1 *Discussion*—In this practice, the term supply or supplies may refer to services.

3.2.7 *surveillance audit, n*—a periodic audit performed to ensure that a supplier continues to meet the operation's supplier requirements.

3.3 *Acronyms:*

3.3.1 *CAPA*—corrective action and preventive action

3.3.2 *QMS*—quality management system

4. Significance and Use

4.1 This practice is intended to be used by cannabis or hemp operators, or both, to establish good supplier lifecycle management practices.

4.1.1 Without proper oversight, the quality and reliability of supplied materials, equipment, parts, software, or services can degrade. This can create issues that directly impact the operation's performance and remain undetected until customers experience a problem.

4.1.2 Early identification and mitigation of risks within the supply chain are crucial to controlling costs and minimizing potential impacts on operations, customer experience, and business reputation. In general, costs are reduced when issues are prevented early and upstream in the supply chain.

4.2 This practice applies to the cannabis or hemp horticulture, agriculture, processing, manufacturing, testing, and distribution operators and the many suppliers that provide materials, equipment, parts, software, or services to these operations.

4.3 This practice provides operations and consultants supporting operations with the actions required to implement good supply and supplier management practices.

4.4 Any supply chain operator can use this practice to conduct an internal gap assessment and risk analysis to identify opportunities for improvement.

4.5 Certification bodies can use the standard to develop supplier audit programs.

4.6 Section 5 provides details on the supplier lifecycle management process that includes the following seven activities:

4.6.1 Supply and supplier information management.

4.6.2 Supply identification and specifications.

4.6.3 Supplier options, evaluation, and selection.

4.6.4 Supplier onboarding.

4.6.5 Supplier performance and risk management.

4.6.6 Supplier relationship management.

4.6.7 Supplier offboarding.

4.7 To implement supplier management, follow the process in Sections 5 and 6. Start by applying the principles in this practice to a few supplies and suppliers and work through all of the steps in the process. Then repeat the process for more supplies or refine the details on supplies that are already addressed.

4.8 This practice applies to critical supplies that require rigorous management and non-critical supplies that don't. It applies to large multi-location operations with a large staff and complex communication needs, and small single facility operations with a small staff where communication is simple. The key to applying this practice is documenting the operation's procedures and specific methods along with a valid justification when a step is modified or simplified to meet the intent of a step in Sections 5 and 6 as it applies to a small operation or a non-critical supply.

5. Supplier Management Process

5.1 *Supply and Supplier Information Management:*

5.1.1 The operator shall establish a system to maintain and readily access supply and supplier information. The key elements of the system shall be documented. The description of the supply and supplier information management methods should be included in the operator's quality manual or similar documentation. Refer to Guide D8222 for guidance on quality manuals.

5.1.2 The operator shall document policies and procedures for the supplier information management system.

5.1.3 The supplier information management system can be manual, partially automated, or fully automated. The details of an effective and secure information management system are not addressed in this guide. Information security is covered in Practice D8320.

5.1.4 The operator shall establish and document a frequency for routine review of the supplier management policies, procedures, policy, and training material and update them as needed to reflect current practices. Annual reviews are recommended and shall be performed at least once every three years.

5.1.5 Document the supply and supplier management policies, procedures, and the supplier information system. Follow change control procedures as improvements are made to these documents.

5.2 *Supply Identification and Specifications:*

5.2.1 The operator shall identify supplies and services required for reliable operations, product quality, safety, and to meet the operation's delivery schedules.

5.2.2 The operator shall rate each supply from critical to noncritical based on the risk potential/impact to the operation if the supply suddenly does not meet requirements or is suddenly unavailable, and is not readily available from multiple suppliers. The operator should consider the potential for various global supply chain failure events and the impact on the operation.

5.2.3 Initially, critical supplies shall have documented descriptions and specifications. The goal should be to document all supplies and services used in an operation. The operator can reference industry-recognized specification standards. The specification should include the following:

5.2.3.1 Purpose or objective of the supply,

5.2.3.2 Availability and alternative sources,

5.2.3.3 List of alternative options,

5.2.3.4 Quantity typically ordered,

5.2.3.5 Anticipated order frequency,

5.2.3.6 Anticipated lead time,

5.2.3.7 Inventory to be held, and

5.2.3.8 Other supply information useful to the organization.

5.2.4 The operator may choose to organize critical supply specifications in a table or spreadsheet, by maintaining a document for each supply item, or by using a supply resource management system.

NOTE 1—When identifying supplies, consider specifying the purpose and requirements of a supply rather than a specific type or brand. Example: For indoor grow operations identifying the specific requirements of grow-medium rather than selecting a specific grow-medium will allow for more options that meet the requirements.

5.2.5 The operator shall establish a policy and specify a schedule to review and update supply specifications.

5.3 *Supplier Options, Evaluation, and Selection:*

5.3.1 The operator shall document its supplier selection procedures.

5.3.2 Determine and document the level of supplier due diligence appropriate for each supply item based on the risk assessment for the particular supply as described in 5.2.2.

5.3.3 Decisions to deviate from the rigor of the following steps for supplies that are low risk, are readily available from multiple suppliers, or for other reasons shall be documented in the supplier information system.

5.3.4 For each supply, research and identify available options for the supply and suppliers.

5.3.5 Determine and rank the criteria that will be used to evaluate suppliers.

5.3.5.1 This may include cost, product quality, delivery capacity, use of QMS methods and procedures, certifications, availability of alternative suppliers, value, safety, supplier reputation, support, education and communication skills, social responsibility, convenience, risk, changing technology, supplier agility, ability to provide multiple supplies, and the ability to develop a mutual relationship and trust with the supplier.

5.3.5.2 Specific regulations and standards related to a supply item will vary depending on the authority having jurisdiction and the standards that a specific supplier chooses or is required to conform with.

5.3.6 Identify and research available options for the supply and suppliers. Use internet queries, operator recommendations, or industry contacts to select supplies and suppliers.

5.3.7 Consider supply needs for all phases of operations. For example, different solutions may be required to control the humidity of cannabis flower during different phases (processing, sampling, testing, storing, transporting, bulk packages, product packages, etc.).

5.3.8 Send a supplier questionnaire to help shortlist the suppliers. Ask potential suppliers what unique criteria sets them apart from competitors. Use questions that touch on unique risks present in the cannabis or hemp industry. For example, a supplier that is a grower may talk about the importance of pesticide handling and their post-harvest humidity control or consider an equipment manufacturer's parts and service policy and response time. Use a documented consistent questionnaire and shortlisting process to narrow the list of potential suppliers, typically two to four suppliers.

5.3.9 Depending on the nature of the supply item and the shortlisted suppliers either:

5.3.9.1 Provide a questionnaire or perform an assessment that is more in-depth than the initial questionnaire applied in section 5.3.8 and optionally include an on-site visit, or

5.3.9.2 Perform a rigorous audit of each shortlist supplier.

5.3.9.3 To perform a rigorous audit, the operator shall develop or acquire a rigorous supplier audit program. The audit program could be built upon digital documents, spreadsheets, or a fully-featured online audit platform. Practice D8308 provides details on audit protocols and conducting audits. Appendix X1 provides an audit protocol that can be used as a template to develop a specific audit.

5.3.10 Select a primary and backup supplier by reviewing evaluation results. The selected suppliers should satisfy the most important selection criteria.

5.3.11 The operator shall verify that the selected supplier can meet the supply specifications and requirements for a given duration. For critical supplies, if the initial supplier assessment was not extensive, a complete supplier audit should be conducted on the selected supplier to validate the selection. A supplier audit checklist is provided in Appendix X1. In some cases evaluating the supplier history, ratings from other customers and employees, or other evaluation means can be sufficient.

5.3.12 Select a backup supplier in case a day comes when the selected supplier can't perform temporarily or permanently. Periodically confirm that the backup supplier continues to be a viable option.

5.4 *Supplier Onboarding:*

5.4.1 The operator shall execute a written contract with all key suppliers (see Note 2) that:

5.4.1.1 Contain supply specifications as outlined in 5.2.3, as well as acceptable delivery times, corrective action expectations, notification requirements if a plan to discontinue a supply item emerges, and other requirements. Refer to Guide D8229 for guidance on corrective and preventive action.

5.4.1.2 Contain standard contract language such as name, address, and responsibilities for each party; pricing and payment details including schedule and invoicing process; performance criteria and frequency of periodic supplier reviews or audits; confidentiality clauses, refunds, and compensation terms; level of after-sales service required, and other common contractual terms and conditions such as failure to perform, dispute resolution, renewal or termination of the contract.

NOTE 2—Key suppliers provide supplies that are critical to the operation.

5.4.2 The operator shall maintain an approved supplier list, sometimes referred to as an approved vendor list.

5.4.3 The operator shall gather and retain supplier-related information which may include supply specifications, product manuals, selection criteria, supplier audit reports, contracts, confidentiality agreements, safety data sheets, access permissions, and other pertinent information and records.

5.4.4 To build a good working relationship with suppliers, the operator should:

5.4.4.1 Facilitate introductions with key personnel for both parties such as billing and finance, primary contacts, delivery

and receiving personnel, top management. The contact information should be documented and available to personnel with a need-to-know.

5.4.4.2 Ensure the payment method is established and make timely payments.

5.4.4.3 Discuss and understand lead times for orders and special requests.

5.4.4.4 Establish procedures for reporting and resolving issues.

5.4.4.5 Request feedback from the supplier to identify ways to improve the mutual relationship.

5.4.4.6 Onboarding activities often continue throughout the life of the supplier relationship. Changes in staff, procedures, product details, and other details will require attention.

5.4.5 The operator shall maintain records to support future supplier off-boarding activities. Examples of this type of information are:

5.4.5.1 Access granted to information and information systems. Examples: the issuance of user accounts, transmitted proprietary information.

5.4.5.2 Access granted to the physical property and buildings. Examples: the sharing of combinations, the issuance of badges, access cards, keys, and parking credentials.

5.4.5.3 Supplier owned equipment and materials located at the operator's location.

5.4.6 The operator shall document and periodically review and update the supplier onboarding procedure to reflect current practices.

5.5 *Supplier Performance and Risk Management:*

5.5.1 Operators shall monitor supplier performance using measurement and analysis methods and address performance issues throughout the contract period.

5.5.2 The operator shall document the operation's performance monitoring practices. These practices should include but are not limited to the following activities.

5.5.2.1 Categorize each supplier as critical or non-critical to the operation and identify the inherent risk level, usually on a tiered scale such as low, moderate, or high risk.

5.5.2.2 Maintain a log of supply/supplier issues, including date, description of the issue, evidence such as photos, the person reporting the issue, supplier coordination, and issue resolution in order to identify ongoing trends. Preferred suppliers should have and follow documented CAPA procedures.

5.5.2.3 Inform suppliers of issues in a timely manner and set an appropriate timeline for completion of CAPA activities, typically 30 to 60 days.

5.5.2.4 Address issues at the product or service level and focus on processes, not individuals. An individual's mistakes are often the failure of a process such as change management, document control, communication, training, or corrective action.

5.5.2.5 Determine, document, and follow the appropriate level and frequency of surveillance for each vendor to evaluate ongoing supplier performance and risk management practices. A test or calibration laboratory or sampling body that is ISO/IEC 17025 accredited by a reputable ILAC-MRA (see Note 3)[3] signatory may not require extensive surveillance but there are exceptions.

NOTE 3—ILAC-MRA, International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement. This means that the accreditation body that assessed the test or calibration lab or sampling body to the requirements of ISO/IEC 17025 is also accredited themselves and found that their ISO/ IEC 17025-accredited labs' results are acceptable across economies.

5.5.3 An audit program with consistent assessment protocols and scoring mechanisms shall be used for surveillance audits. Section 6 and Practice D8308 provide information on audits.

5.5.4 The operator shall periodically conduct surveillance audits as defined in 5.5.2.5. Surveillance audits may require less time than the initial selection and onboarding audit. Surveillance audits are used to:

5.5.4.1 Review the previous audit results and previously collected documentation,

5.5.4.2 Identify changes, improvements, or new issues,

5.5.4.3 Assess new customer complaints, recalls, and CAPA activity,

5.5.4.4 Visit the supplier's site to verify that the daily practices, facility maintenance, and equipment calibration and maintenance continue to meet expectations.

5.5.4.5 Identify ongoing trends of nonconformance using data from previous audits.

5.5.5 When nonconforming conditions or trends are noted the supplier shall be notified and provided a specific time frame to correct the issues. The corrections shall be verified and noted in the audit report. Ongoing nonconformance trends may lead to the termination of the supplier relationship.

5.5.6 Minor nonconformance items and improvement suggestions shall be noted in the audit report and may be addressed over time and verified in a future surveillance audit depending on the nature and risk of the issue.

5.5.7 The audit reports should be consistent and provide clear statements about positive and negative observations, required corrective actions, and suggested opportunities for improvement.

5.5.8 An audit program should provide risk-based scoring to inform the supplier of higher risk priority issues.

5.5.9 The operator should stay abreast of regulations that apply to their suppliers and adjust their supplier risk assessment protocols as necessary.

5.6 *Supplier Relationship Management:*

5.6.1 Supplier relationship management is a process to develop mutually beneficial long-term relationships with strategic suppliers. The goal is to deliver greater levels of innovation and competitive advantage than could be achieved by operating independently or through a traditional, transaction purchasing arrangement. The operator needs to actively monitor and manage supplier information, compliance, risk, and performance and build mutual trust to accomplish these goals.

5.6.2 The operator shall document their supplier relationship policy and goals.

[3] See https://ilac.org/ ilac-mra-and-signatories/

5.6.3 The operator shall identify their strategic suppliers and describe why a supplier is considered strategic.

5.6.4 Supplier relationships begin with onboarding activities as described in 5.4.4.

5.6.5 Surveillance assessments and supporting the supplier's CAPA activities display your interest and commitment to suppliers that pursue a culture of quality products and services.

5.7 *Supplier Offboarding:*

5.7.1 The operator shall identify and fulfill contractual agreements.

5.7.2 The operator shall revoke access to systems and information. Examples: consultants, legal counsel, IT contractors.

5.7.3 The operator shall revoke physical access. Examples: custodial firms, security firms, delivery, consultants.

5.7.4 The operator shall return supplier-owned equipment, property, or both to the supplier.

5.7.5 The operator shall provide final payments.

5.7.6 The operator shall update the supplier status in the information system.

5.7.7 The operator should seek legal counsel to identify other risks not mentioned in this practice.

5.8 *This practice does not purport to address all risks or legal responsibilities related to supplier relationships or contracts.*

6. Supplier Audits (2nd Party Audits)

6.1 After selecting a supplier, the operator shall perform a due diligence activity as specified in 5.3.11 to ensure the supplier does not create an unacceptable risk to the operation.

6.2 There are various means of assessing the operational quality of a supplier. These activities include:

6.2.1 Sending questionnaires.

6.2.2 Performing an audit.

6.2.3 Contracting with or accepting an audit by an independent audit body.

6.2.4 Accepting a certification or accreditation issued by an independent and accredited body.

6.3 To develop supply-specific criteria and audit questions:

6.3.1 Ask potential suppliers what unique risks and criteria should be used to select a good supplier.

6.3.2 Include criteria that apply to all suppliers such as organizational structure, having current standard operating procedures, document control, preventing unauthorized change, deviation handling, complaints, recall, and other QMS type topics. Appendix X1 provides a basic audit checklist for these topics.

6.3.3 Remove or add criteria from the checklist in Appendix X1 that are specific to each type of supplier. For example, proper handling of pesticides does not apply to security firms, and the proper training for the use of firearms most likely does not apply to an indoor grow-light supplier.

6.3.4 Develop open-ended interview questions to learn how communication, training, and changes are deployed, how issues and suggestions are reported, and if quality concepts are practiced as a culture throughout the organizational structure. Ask open-ended questions during the audit such as, what risks are unique to your industry that must be properly controlled and managed, and how do you control and handle each of these risks?

6.3.5 During industry conventions and conferences, ask the vendors what criteria are important when selecting a supplier in their industry and add the criteria to your audit program.

6.3.6 Search online for industry-specific checklists and assessments.

6.3.7 Acquire industry-specific audit programs from commercial providers.

6.4 Supplier audits can be time-consuming. Consider using an audit platform to streamline this activity.

6.5 The platform should:

6.5.1 Allow the user to customize their own audits.

6.5.2 Support multiple question and answer types such as multiple-choice, all-that-apply, text, numbers, and others.

6.5.3 Provide references and links to online information to embed knowledge into the audit process to guide and educate the auditor.

6.5.4 Provide references and links to the same knowledge information in the audit reports.

6.5.5 The ability to attach documents and directly take photos.

6.5.6 Support remote auditing to reduce travel costs.

6.5.7 Allow online collaboration with the supplier to:

6.5.7.1 Provide preliminary information,

6.5.7.2 Attach documents for review,

6.5.7.3 Respond to corrective action requests, and

6.5.7.4 Attach evidence of corrections made in the form of photos or documents.

6.5.8 Automatically generate standard reports with executive summaries.

6.5.9 Provide scoring and graphs to identify and visualize gaps and risks.

6.5.10 Provide easy access to previous audit results and attached documents to streamline surveillance audits and identify nonconformance trends.

6.5.11 Securely store and control access to audit results and attachments.

6.5.12 Offer common industry audits based on standards and regulations.

6.6 Information obtained during a supplier audit can be proprietary and confidential. Good audit practice is to treat all information as confidential unless otherwise specified or known to be available in public.

6.7 For more information on creating audit programs, conducting audits, and other audit details refer to Practice D8308.

7. Keywords

7.1 cannabis; cannabis audit; GACP; GAP; GLP; GMP; good manufacturing practice; hemp; risk management; SLM; supplier audit; supplier management; suppliers; supply chain