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Standard Practice for Requirements of a Quality Management System for Cannabis and Hemp Operations¹

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1. Scope

1.1 This practice covers a concise set of requirements for the elements of an effective quality management system (QMS) for the cannabis industry's agriculture, processing, and testing operations. Related ASTM guides and practices are available or are being written for each of the QMS elements. The available guides and practices are referenced throughout this practice. Guide [D8222](#) provides guidance for establishing a quality management system.

1.2 Understanding the significance and use of these requirements in Section [4](#) is important to properly meet the requirements.

1.3 This practice applies to all types of operations from cultivation, processing, testing, distribution, and other related operations. If some QMS elements do not apply to a specific type of operation it shall be documented in the operations quality manual as described in [6.2](#).

1.4 Laws and regulations from authorities having jurisdiction supersede requirements within this practice.

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

- [D8220](#) Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry
- [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
- [D8250](#) Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products
- [D8270](#) Terminology Relating to Cannabis
- [D8286](#) Guide for Processing Cannabis Product Complaints
- [D8308](#) Practice for Cannabis/Hemp Operation Compliance Audits
- [D8346](#) Guide for Requirements for Quality Related Professions Within the Cannabis and Hemp Industries
- [D8347](#) Guide for Requirements for Analytical Laboratory Related Professions Within the Cannabis and Hemp Industries
- [D8348](#) Guide for Requirements for Transportation and Logistics Related Professions Within the Cannabis and Hemp Industries
- [D8398](#) Practice for Management Responsibilities in Managing a Quality Management System (QMS)
- [D8452](#) Guide for Medical-related Professionals within the Cannabis and Hemp Industries
- [D8477](#) Practice for Cannabis or Hemp Supplier Lifecycle Management

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

2.2 Other Standards:

ASQ Document Failure Mode and Effects Analysis (FMEA) Brief Summary³

ISO 9001-2015 Quality management systems – Requirements⁴

3. Terminology

3.1 Definitions:

3.1.1 *General*—Terms used in this practice are in accordance with Terminology D8270, unless otherwise defined in Practice D8477.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *assessment*, *n*—an opinion, judgment, or evaluation about somebody or something that has been thought about carefully but is not conducted with the systematic rigor or the third party independence requirement of an audit.

3.2.2 *audit*, *n*—a systematic, documented, and objective assessment to evaluate conformance relative to predefined criteria.

3.2.2.1 *Discussion*—The term audit applies to several types of audits, such as an internal self-assessment, a supplier audit, or an independent third party audit. Refer to Practice D8308 for information on audits and the different types of audits.

3.2.3 *batch record (BR)*, *n*—a record of the actual manufacturing methods, materials, procedures, instructions, and controls associated with manufacturing and testing a specific product batch.

3.2.4 *controlled document*, *n*—a document that provides value to the operational integrity and product quality and is identified to be subjected to the operation's document control practices.

3.2.4.1 *Discussion*—Controlled documents include dynamic documents such as, but not limited to, policies, procedures, responsibilities, job qualifications, specifications, work instructions, and master batch records; and external documents such as standards, regulations, equipment manuals, licenses, permits, supplier contracts, and material safety data sheets.

3.2.5 *deviation*, *n*—a departure from an approved instruction, procedure, specification, or standard.

3.2.6 *document*, *n*—short for controlled document.

3.2.6.1 *Discussion*—The noun document refers to documentation that is updated to represent current operational information such as a procedure, policies, and training programs. An obsolete document may be retained as a record of past operational practice.

3.2.7 *document*, *v*—record something in written, photographic, or other form.

3.2.8 *documentation*, *n*—written information that is useful for the functioning of the operation.

3.2.8.1 *Discussion*—Documentation includes, but is not limited to, procedures, manuals, guides, diagrams, and records.

3.2.9 *equipment*, *n*—non-expendable, tangible moveable property needed for the performance of a task or useful in effecting an obligation.

3.2.10 *gap assessment*, *n*—an assessment to identify non-conformities.

3.2.10.1 *Discussion*—A gap assessment may follow audit methods provided in Practice D8308 but does not require an independent party to conduct the assessment.

3.2.11 *inculcate*, *v*—to instill (an attitude, idea, or habit) by persistent instruction.

3.2.12 *instrumentation*, *n*—equipment capable of performing measurements used to generate analytical data (GC-MS, IR, NMR, balances, etc.).

3.2.13 *master batch record (MBR)*, *n*—a document that defines the manufacturing methods, materials, procedures, instructions, and controls associated with the manufacture and testing of a specific product.

3.2.14 *must*, *v*—used to express that it is necessary or very important that something happens in the present or future.

3.2.14.1 *Discussion*—The term “must” is used in some QMS element descriptions to present concepts and are not intended to be specific requirement statements.

3.2.15 *nonconformity*, *n*—conditions that do not meet documented expectations or criteria.

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

3.2.16.1 *Discussion*—This practice does not differentiate between different operation structures such as a small single facility, a multi-facility operation, or a large multi-state operation. The user of this practice is responsible for defining the proper context of scale.

3.2.17 *periodic*, *adj*—a set period of time.

3.2.17.1 *Discussion*—In this practice, periodic is used to specify a set period of time to perform certain recurring activities.

3.2.18 *planned deviation*, *n*—pre-approved variation from the current operational document or system, covering a specified period or number of batches.

3.2.19 *practice*, *n*—a definitive set of instructions for performing one or more specific operations that do not produce a test result.

3.2.20 *practice*, *v*—performing daily operational activities.

3.2.21 *production*, *n*—the value-added activities required to produce a product, provide a service, or both.

3.2.21.1 *Discussion*—The term production is used to apply to agricultural production, curing, processing, manufacturing, transportation, testing, distribution, and other value-added activities.

3.2.22 *qualified individual*, *n*—an individual who meets applicable skill, experience, education, or other requirements of an employment position that they hold or seek and can perform the job's essential functions with or without reasonable accommodation.

³ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

⁴ Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <https://www.iso.org>.

3.2.23 *recall, n*—the process of reducing the probability that defective or potentially unsafe goods are consumed.

3.2.24 *record, n*—static documentation of events, decisions, results, authorizations, permits, certificates, and other information that is retained as historical evidence.

3.2.25 *removal, n*—a product is voluntarily removed from the supply chain for reasons other than health and safety.

3.2.26 *standard operating procedure (SOP), n*—established or prescribed methods to be followed routinely to perform designated operations and respond to defined situations.

3.2.26.1 *Discussion*—The term SOP may be used herein to refer to one or more documented procedures.

3.2.27 *supplier, n*—a person or entity that provides needed materials, products, or services.

3.2.28 *unplanned deviation, n*—a state of nonconformance from the designed systems or procedures at any manufacturing stage, packaging, testing, holding, or storage of the product.

3.2.29 *vendor, n*—a person or company offering something for sale.

3.3 Abbreviations:

3.3.1 *BR*—batch record

3.3.2 *CAPA*—corrective actions and preventive actions

3.3.3 *CQI*—continuous quality improvement

3.3.4 *FMEA*—failure mode and effects analysis; a process for characterizing and mitigating risks by assigning risk priority numbers

3.3.5 *GACP*—good agriculture and collection practices

3.3.6 *GLP*—good laboratory practices

3.3.7 *GMP*—good manufacturing practices

3.3.8 *MBR*—master batch records

3.3.9 *QMS*—quality management system

3.3.10 *SOPs*—standard operating procedures

4. Significance and Use

4.1 Having a concise set of QMS requirements allows users of this practice to understand "what" needs to be established, consistently practiced, monitored, maintained, and improved.

4.2 Guidance on "how" and "why" to implement the QMS elements are provided in the referenced guides and practices for each element.

4.3 These QMS requirements can be used as the basis for gap assessments, internal and external audits, training programs, certification programs, an implementation checklist, or a combination of these uses.

4.4 As the regulated cannabis industry moves forward, authorities having jurisdiction are adopting good practice protocols and quality management system requirements. QMS principles are a foundation for good manufacturing practices (GMP), good agricultural and collection practices (GACP), and good laboratory practices (GLP). This practice does not focus on a particular type of cannabis operation. It provides QMS requirements incorporating requirements specific to GMP, GACP, and GLP that can be applied to these operations.

4.5 Each type of operation may need to adapt a requirement to meet certain GACP, GMP, or GLP requirements by documenting the requirement and how it is adapted to meet the specific requirement.

4.6 When a QMS requirement is not applicable to an operation, the operation shall document the reason a requirement is not applicable. By doing this, each requirement is addressed and if the reason is justifiable the operation can be considered in full compliance with these requirements.

4.7 This practice provides an internationally recognized set of requirements that can be used by:

4.7.1 Operations that grow, harvest, process, test, package, or distribute adult-use and medicinal cannabis and hemp to voluntarily implement quality practices;

4.7.2 State and national regulatory agencies to inform good practice and quality-related regulations; and

4.7.3 Third-party training, consulting, and certification bodies to base their services on.

5. Summary of the QMS Elements

5.1 A list of QMS elements follows below. A brief description of each element is provided in the first paragraph for each element in Section 6. Three appendixes provide optional information.

5.1.1 **Appendix X1** provides a listing of the element descriptions.

5.1.2 There is a significant level of interaction and integration among all the elements of a robust QMS system. A relationship diagram is provided in **Appendix X2**, with a general description of these interactions.

5.1.3 **Appendix X3** provides a general implementation sequence of the QMS elements presented in Section 6.

5.2 Guide **D8222** provides information for establishing a QMS.

5.3 The elements addressed in Section 6 are:

- 6.1 Management Responsibilities
- 6.2 Quality Manual
- 6.3 Document Control
- 6.4 Change management
- 6.5 Documentation
- 6.6 Internal Audits
- 6.7 Risk Management
- 6.8 Continuous Quality Improvement (CQI)
- 6.9 Deviation Handling
- 6.10 Corrective Action and Preventive Action (CAPA)
- 6.11 Complaint Management
- 6.12 Personnel Qualification
- 6.13 Equipment, Instrumentation, and Utensils
- 6.14 Buildings and Grounds
- 6.15 Recall and Withdrawal
- 6.16 Supplier Management

6. QMS Element Requirements

6.1 *Management Responsibilities:*

6.2 *Quality Manual:*

6.2.1 The quality manual is the operation's top QMS document. It documents the operation's goals, general policies, context, and a roadmap of the operation's QMS elements.

6.2.2 Revision to the quality manual shall be approved by the quality manager and a chronolog

revision log. An entry shall be added to the revision log for the top management review and approval.

6.2.3 The quality manual shall include an overview of the operation's Quality Management System.

6.2.4 The quality manual shall include a high-level description or diagram or both of the production systems.

6.2.5 The quality manual shall include or reference the documented QMS policy, goals, and strategies. It should contain or reference related policies, goals, and strategies.

6.2.6 For each QMS element, the quality manual shall include the following:

6.2.6.1 A short overview of the element and related practices. If an element is not applicable or implemented, it should be stated as such with a brief explanation of why it is not applicable or when it will be implemented,

6.2.6.2 The owner or approval authority of each element. This could be a simple statement that the quality manager is responsible for all the aspects of the QMS, if applicable and accurate,

6.2.6.3 A reference to the controlled document inventory as described in 6.3, and

6.2.6.4 Any additional information can be included in the quality manual, such as organizational structure, documentation framework, high-level concepts from the QMS elements, short-term goals, initiatives, or other important information. It is desirable to minimize having the same information in multiple documents as it increases maintenance efforts to avoid obsolete information.

6.2.7 The quality manual shall be a living document, dynamic, and routinely updated to reflect the operation's current QMS goals, strategies, specifications, organization, and other criteria. The quality manual should include helpful information that routinely provides criteria to inform and guide management decision-making.

6.3 Document Control:

6.3.1 Document control ensures that various forms of the operation's policies, procedures, records, and other forms of knowledge are documented, up to date, securely stored, and accessible to inform and ensure that daily practices are correctly performed.

6.3.2 The operation shall document a policy and maintain a standard operating procedure (SOP) for document control. This SOP shall address company-authored documents, external documents, and records that apply to production activities and the following requirements.

6.3.3 The operation shall maintain an inventory listing of its controlled documents for company-authored documents, external documents, and types of records that apply to production activities.

6.3.4 The inventory listing of the company-authored documents shall include the document ID, title, document owner, latest revision date, revision number, approval authority, distribution, date of the last review, and the date for the next review. Applicable external documents shall list similar information as applicable.

NOTE 1—The inventory information for a document shall be updated when a new version becomes available.

6.3.5 The inventory listing of production records shall include records required by QMS requirements, authorities having jurisdiction, legal consideration, and records required to support an audit trail for root cause analysis activities.

6.3.6 Information about each record should include:

6.3.6.1 Process name or title relating to the type of record,

6.3.6.2 Retention storage system or location,

6.3.6.3 Record type such as public, confidential, proprietary, or other helpful information,

6.3.6.4 The reference to the procedure that defines the content and recording practices or a short description of such,

6.3.6.5 The retention duration, and

6.3.6.6 Any special disposal requirements such as shred or delete backups.

6.3.7 The document control SOP shall describe the facilities, equipment, systems, off-site backup, amendment methods, and practices to prevent damage, deterioration, alteration, and loss.

6.3.8 Record procedures shall require that the documentation of observations, activities, data, and calculations required are recorded by the person responsible for performing the task when the task is performed.

6.3.9 Records shall be protected from alteration but may be amended by recording additional or corrective information.

6.3.10 There shall be a single master copy of a document or record. Documents and records and the retention systems may be paper, digital, stored locally, on cloud systems, or a combination of these.

6.3.11 Records shall be retained for a defined duration and shall be disposed of according to the operation's procedures that should consider legal, privacy, and security risks.

6.3.12 The operation shall have quality standards for company-authored documents, activity record logs, and forms that specify required content, structure, and style, such as, but not limited to, requirements for title page content, page numbering, fonts, mandatory sections, revision history, use of images and references, approvals.

6.3.13 The operation shall periodically review the inventory listings of documents and records.

6.3.14 Changes to controlled documents shall follow change management procedures to ensure that changes are properly and completely implemented.

6.3.15 Controlled documents should be updated in a timely manner as changes emerge.

6.3.16 Each controlled document shall be periodically reviewed and updated to reflect current operations at least once every twelve months. Obsolete documents shall be noted.

6.3.17 All obsolete copies of controlled documents shall be made inaccessible for production activities. A copy of an outdated document can be identified as obsolete and retained as a historical record in a manner that prevents accidental production use.

6.3.18 Competent and authorized personnel shall approve all new, revised, and disposal of controlled documents.

6.3.19 A revision log shall be maintained for changes to each company-authored document. The log can be part of the document or an external record.