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Standard Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products[1]

This standard is issued under the fixed designation D8222; 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 guide focuses on the core elements of an effective quality management system (QMS) necessary to optimize consumer and product safety, product quality, and conformance with requirements from industry, governmental agencies, and other authorities having jurisdiction. This guide incorporates basic quality principles, guidelines, and industry best practices necessary to establish a QMS adaptable to all organizations.

1.2 Laws and regulations from authorities having jurisdiction supersede recommendations within this guide.

1.3 *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.*

1.4 *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

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

D8244 Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry

D8250 Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products

D8282 Practice for Laboratory Test Method Validation and Method Development

D8286 Guide for Processing Cannabis Product Complaints

2.2 *ASQ Document:*[3]

Failure Mode and Effects Analysis (FMEA) Brief Summary

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *controlled document, n*—a document with an alphanumeric assignment that is integrated into a QMS and subject to revision and revision tracking.

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

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

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

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

3.1.5.1 *Discussion*—Planned deviations must be approved before execution. Planned deviations should be handled through approved change control procedures.

3.1.6 *recall, n*—a product recall is the process of retrieving defective or potentially unsafe goods from consumers and providing those consumers with compensation.

3.1.7 *removal, n*—a product is removed from the supply chain, but not for health and safety reasons.

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

[1] This guide 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 service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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

3.2 *Abbreviated Terms:*

3.2.1 *BMR, n*—batch manufacturing record

3.2.2 *CAPA, n*—corrective actions/preventive actions

3.2.3 *CPP, n*—critical process parameters

3.2.4 *CQA, n*—critical quality attributes

3.2.5 *FMEA, n*—Failure Mode and Effects Analysis; a process for characterizing and mitigating risks by assigning risk priority numbers

3.2.6 *IQ/OQ/PQ, n*—installation, operational, and performance qualifications

3.2.7 *IPC, n*—in-process controls

3.2.8 *MBR, n*—master batch records

3.2.9 *QA, n*—quality assurance

3.2.10 *QC, n*—quality control

3.2.11 *QMS, n*—quality management system

3.2.12 *SOPs, n*—standard operating procedures

4. Summary of Guide

4.1 This guide encompasses both adult-use and medicinal cannabis/hemp activities associated with processing, packaging, labeling, quality control, and distribution.

4.2 This guide does not cover QMS elements as they relate to laboratory operations (Practice D8282 and Guide D8244).

4.3 The QMS framework includes the core QMS elements as exhibited in Table 1.

5. Significance and Use

5.1 Effective decision-making in a quality systems-controlled environment comes from an informed understanding of quality issues and associated risks. As such, management should monitor and review the performance of the QMS at pre-planned and regular intervals to ensure the system's effectiveness and identify opportunities for improvement of the QMS itself. Management should also provide oversight of the QMS by an independent quality practitioner(s) to assure its effectiveness.

5.2 Moreover, risk-based decision-making encompasses all elements of the QMS and should be at the forefront of each decision. Consumer safety is the top priority, regardless of other considerations.

5.3 Aspects of risk should be considered relative to intended (or unintended) uses of a product to ensure consumer safety. Management should assign priorities and adequate resources to activities or actions based on assessing the risk, including the probability of harm and the potential severity of that harm. It is essential to engage appropriate parties in evaluating the risk. Such parties may include:

5.3.1 Consumers;

5.3.2 Manufacturing personnel;

5.3.3 Marketing personnel; and

5.3.4 Other stakeholders, as needed.

5.4 Implementation of risk management includes assessing the risks, implementing risk management controls commensurate with the level of risk, and evaluating the risk management efforts' results. Risk management assessment is an iterative process and continues when additional information emerges that changes the potential risk's nature.

5.5 Risk management works in conjunction with process understanding to manage and control change and helps drive continuous improvement.

6. Quality Manual

6.1 The quality manual is a document that summarizes the implemented components of the QMS. It provides a general summary of the key elements comprising the content of the QMS.

6.2 The quality manual presents an overview of the functional QMS elements defining the QMS practices within the organization. The quality manual should give short descriptions of all content for the categories found in Table 1.

7. QMS Elements

7.1 *Document Control:*

7.1.1 Controlled documents should be written and reviewed by qualified and authorized personnel whose training and expertise have been documented within the organization's training program.

7.1.2 There should be a standard operating procedure (SOP) defining all document control policies and procedures.

7.1.3 Controlled documents include dynamic documents such as policies, procedures, specifications, work instructions, and other updated and approved documents when corrections or improvements are implemented and static documents that

TABLE 1 QMS Sections and Elements

Section	Element	Section	Element	Section	Element
6	Quality Manual	7.6	Complaints	7.12	Master Batch Records
7.1	Document Control	7.7	Recall/Removal	7.13	Internal Auditing
7.2	Change Management	7.8	Supplier Qualification	7.14	Qualification and Validation
7.3	Deviations	7.9	Facilities/Equipment	7.15	Continuous Improvement
7.4	Corrective and Preventive Actions (CAPA)	7.10	Personnel Qualifications and Training		
7.5	Risk Management	7.11	Records		