



Designation: D8346 – 21a

# Standard Guide for Requirements for Quality Related Professions Within the Cannabis and Hemp Industries<sup>1</sup>

This standard is issued under the fixed designation D8346; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide can provide certification bodies, training providers, employers, and certificate issuers, with best-practice guidance for administering their respective programs for quality-related professions within the cannabis and hemp industries.

1.2 This guide recommends requirements for experience, training, education, and the body of knowledge (BoK) necessary for quality related professions within the cannabis and hemp industries listed in [Table 1](#).

1.3 This guide provides recommendations for articulating professional requirements for training and education or earning certificates. Its content does not supersede requirements for training or earning a certificate defined by jurisdictional entities such as government or other regional regulatory bodies.

1.4 *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.*

1.5 *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:<sup>2</sup>

[D8229 Guide for Corrective Action and Preventive Action \(CAPA\) for the Cannabis Industry](#)

<sup>1</sup> This guide is under the jurisdiction of ASTM Committee [D37](#) on Cannabis and is the direct responsibility of Subcommittee [D37.06](#) on Personnel Training, Assessment, Credentialing.

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[D8308 Practice for Cannabis/Hemp Operation Compliance Audits](#)

[E2659 Practice for Certificate Programs](#)

[E2708 Terminology for Accreditation and Certification](#)

### 2.2 Other Standards:

[21CFR 111 Dietary Supplements<sup>3</sup>](#)

[21CFR 117 FSMA and Food Safety<sup>3</sup>](#)

[21CFR 210 Pharmaceutical Packaging and Holding<sup>3</sup>](#)

[21CFR 211 Pharmaceuticals<sup>3</sup>](#)

## 3. Terminology

### 3.1 Definitions:

3.1.1 *certificate, n*—a document (letter, card, or other medium) awarded to certificate holders that designates the successful completion of a credentialing program's requisites. **E2659, E2708**

3.1.2 *certification agency, n*—the organizational or administrative unit that offers or operates, or both, a certification program. **E2659, E2708**

3.1.3 *certificate program, n*—a non-degree-granting education of training program consisting of (1) a learning event or series of events designed to educate or train individuals to achieve specified learning outcomes within a defined scope, and (2) a system designed to ensure individuals receive a certificate only after verification of successful completion of all program requisites, including but not limited to an evaluation of learner attainment of intended learning outcomes. **E2659, E2708**

3.1.4 *certification, n*—procedure and action by a duly authorized body of determining, certifying, and attesting in writing to the qualifications of individuals, processes, procedures, or items in accordance with application requirements.

3.1.4.1 *personnel certification, n*—procedure and action by a duly authorized body of determining, verifying, and attesting in writing to the qualifications of individuals in a profession, in accordance with application requirements associated with that profession. **E2659, E2708**

<sup>3</sup> Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.

**TABLE 1 Cannabis and Hemp Quality Professions**

	Section
Cannabis and Hemp Quality Professionals	7
Cannabis and Hemp Quality Auditor	7.1
Cannabis and Hemp Quality Control Technician	7.2
Cannabis and Hemp Quality Engineer	7.3
Cannabis and Hemp Preventive Controls Specialist	7.4
Cannabis and Hemp Quality Manager	7.5

3.1.5 *standard guide, n*—a compendium of information or series of options that does not recommend a specific course of action. Guides are intended to increase the awareness of information and approaches in a given subject area.

3.1.5.1 *Discussion*—Guides may propose a series of options or instructions that offer direction without recommending a definite course of action. The purpose of this type of standard is to offer guidance based on a consensus of viewpoints but not to establish a standard practice to follow in all cases (ASTM Form and Style, C15.2).

3.2 *Acronyms:*

- 3.2.1 *ANOVA, n*—analyses of variance.
- 3.2.2 *BoK, n*—body of knowledge.
- 3.2.3 *CAPA, n*—corrective and preventive actions
- 3.2.4 *cGMP, n*—current good manufacturing practices.
- 3.2.5 *DOE, n*—design of experiment
- 3.2.6 *FMEA, n*—failure mode and effects analyses.
- 3.2.7 *FSMA, n*—Food Safety Modernization Act.
- 3.2.8 *HACCP, n*—hazard analyses critical control point.
- 3.2.9 *PPE, n*—personal protective equipment.
- 3.2.10 *QMS, n*—quality management system.
- 3.2.11 *SPC, n*—statistical process control.

**4. Summary of Guide**

4.1 The BoK criteria is itemized in their associated tables and represent the general competency subject matter expertise that practitioners within each profession should demonstrate to meet certificate requirements as guided by Terminology .

4.2 Mastery of said criteria can be demonstrated by many alternative means, including but not limited to passing proctored examinations, attaining educational degrees or training certificates, and the documented completion of apprenticeships or other on-the-job training, as determined by the relevant jurisdiction.

4.3 Section 6 identifies the profession covered in this guide.

4.4 Section 7 includes a subsection for each profession. Each subsection is divided into the following four sections:

- 4.4.1 Profession roles,
- 4.4.2 Experience,
- 4.4.3 Education, and
- 4.4.4 BoK.

4.5 The sourcing of personnel meeting these qualifications may be difficult in an emerging sector. In situations where

post-secondary degreed personnel or post-secondary institutions are not available or applicable, the phasing-in of staff is acceptable in the first three years of employment along with sector training or apprenticeship programs reflecting the content of the profession BoK. The validation process can occur through proctored exams.

**5. Significance and Use**

5.1 As the cannabis and hemp industries expand and their products become more available as consumable products, the following requirements and expectations within the industry become increasingly significant (Practice , Terminology ), requiring:

- 5.1.1 The safety, reliability, and quality of its products;
  - 5.1.2 Worker safety;
  - 5.1.3 Environmental sustainability;
  - 5.1.4 Regulatory compliance;
  - 5.1.5 The need for different levels of qualified professionals;
- and
- 5.1.6 Development of qualified training and certificate programs.

5.2 The primary objectives of this standard are as follows:

- 5.2.1 Provide a general overview of the BoK required for the professions listed in Section 7;
- 5.2.2 Provide recommendations to form the foundation for training and subsequent recognition/certificate systems that enable consumers, employers, organizational management, government agencies, and others who rely upon a skilled workforce to distinguish between qualified and non-qualified workers.

5.2.3 Recommend requirements that agencies can use to develop and document the specific criteria used for training or certificate programs.

5.3 Users of this guide shall document deviations from the recommended requirements to inform their clients of the criteria applied in either the training or the certificate programs offered. As the Cannabis and Hemp industries mature, this guide will be updated to reflect current thinking and requirements.

5.4 The Bok elements are applicable to certificate programs, while the BoK, experiential and educational elements are applicable to certification process requirements

**6. Requirements for Quality Professionals within the Cannabis and Hemp Industries**

6.1 The vocations relative to quality-related professionals within cannabis industry are listed in Table 1. The general requirements, experience, education, and BoK for each profession are provided in the section specified.

6.2 The profession titles used in this guide represent potential titles. The titles used are not intended to replace existing job titles, which fall under the purview of the employing organization. The titles for the certificate and certification programs are determined by the administrating bodies.

**7. Cannabis and Hemp Quality Professionals**

7.1 *Professional Role — Cannabis and Hemp Quality Auditor:*

7.1.1 The Cannabis and Hemp Quality Auditor should:

7.1.1.1 Be a professional who understands the principles of auditing (Practice D8308), has general knowledge of cannabis and hemp operations, and has a working knowledge of applicable audit criteria required to meet the objectives and scope of audits to be performed.

7.1.1.2 Be familiar with operational requirements and criteria as articulated in the BoK.

7.1.1.3 Be able to adjust the audit procedures depending on the type of cannabis and hemp operation such as cultivation, processing, extraction, infused product manufacturing, packaging and labeling, warehousing and distribution, transportation, dispensing and retail, and product testing waste handling, and research and development.

7.1.1.4 Have good communication, coordination, negotiation, and especially questioning and listening skills.

7.1.1.5 Have a good understanding of quality and process management principles and elements required to operate a business in the highly regulated cannabis and hemp industries..

7.1.1.6 Have knowledge and experience of audit planning that expects an auditor to:

(1) Understand the scope and objectives of an audit and understand the different stakeholders and their objectives; and

(2) Know how to translate audit criteria into observation, document and record review, and interview protocols.

7.1.1.7 Know how to plan and coordinate the logistics and developing a plan for conducting the audit.

(1) Understand the techniques and requirements for conducting an audit, including:

(a) Observation, document and record review, and interview techniques;

(b) Proprietary information handling;

(c) Ethical and professional principles;

(d) Questioning, listening, and problem-solving skills to determine if the operation is meeting requirements; and

(e) Methods to identify and classify nonconformities.

7.1.2 Experience:

7.1.2.1 A Cannabis and Hemp Quality Auditor should have had at least one (1) year of experience working in the cannabis and hemp industries.

7.1.2.2 The Cannabis and Hemp Quality Auditor should have at least three (3) years of on-the-job experience as a quality support professional, including auditing responsibilities, experience leading team activities, coordinat-

ing with stakeholders, preparing and presenting plans and results, and tactical problem solving to accomplish team goals and objectives; and

7.1.2.3 They should have familiarity with Good Agricultural Collection Practices (1),<sup>4</sup> or jurisdictional food safety, dietary supplement, and pharmaceutical regulatory requirements such as the Global Food Safety Initiative (GFSI) (2), Safe Quality Foods (SQF) (3), Food Safety Modernization Act (FSMA) (4), 21CFR 111 and 21CFR 117, 21CFR 211, Food Safety Recognition Program (FSRP) (5), or Eudralex Volume 4 (6), etc.

7.1.2.4 If they hold auditor certifications from internationally or regionally recognized auditor certifying bodies such as the ASQ CQA or their international or regional equivalents, they should only require one (1) year or more full-time experience as a quality support individual.

7.1.3 Education:

7.1.3.1 Applicants who have completed a higher education degree (in the fields of chemistry, biology, chemical engineering, mechanical engineering, horticulture, agronomy, and other scientific, manufacturing, or industrial disciplines from an accredited college, university or technical school, or apprentice program) should have part of the experience requirements waived, as follows (only one of these waivers may be claimed):

(1) Diploma, Associates degree or apprenticeship program — one (1) year may be waived.

(2) Bachelor’s degree and higher — two (2) years may be waived.

7.1.4 Body of Knowledge (BoK):

7.1.4.1 A Cannabis and Hemp Quality Auditor should meet the minimum requirements for experience and education and demonstrate proficiency for the topics listed in the BoK as summarized in Table 2.

7.2 Professional Role — Cannabis and Hemp Quality Control Technician:

7.2.1 The Cannabis and Hemp Quality Control Technician is a professional who:

7.2.1.1 Understands quality concepts and quality processes, including basic recordkeeping, sample collection, test methods, and following SOPs.

<sup>4</sup> The boldface numbers in parentheses refer to a list of references at the end of this standard.

TABLE 2 Cannabis and Hemp Quality Auditor Body of Knowledge (BoK)

1 Cannabis and hemp business (processes and materials)	16 Corrective and preventive action (CAPA)
2 Audit concepts and terminology	17 Follow-up of CAPA (Guide D8229) (positive and negative)
3 Audit planning and plan components	18 Audit closure
4 Different audit types and objectives	19 Ethics and professional conduct
5 Audit roles and responsibilities	20 Handling proprietary information
6 Types of audit criteria	21 Recordkeeping and disposition
7 Translating criteria into an audit program	22 Interpersonal skills
8 Elements of an audit program	23 Conflict resolution
9 Audit roles and responsibilities	24 Cultural awareness
10 Communication and coordination	25 Meeting and presentation techniques
11 On-site logistical planning and coordination	26 Observation techniques
12 Conducting an on-site visit(s)	27 Interview techniques
13 Objective evidence collection	28 Basic process improvement methods
14 Analysis and classification of nonconformities	29 Risk management concepts
15 Report preparation	30 Reporting audit results