

Designation: D8347 - 21a

Standard Guide for **Requirements for Analytical Laboratory Related Professions** Within the Cannabis and Hemp Industries¹

This standard is issued under the fixed designation D8347; 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 can provide certification bodies, training providers, employers, and certificate issuers, with best-practice guidance for administering their respective programs for supporting analytical laboratory-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 analytical laboratory 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:²

E2659 Practice for Certificate Programs E2708 Terminology for Accreditation and Certification

2.2 Other Standards:

21CFR 111 Dietary Supplements³

21CFR 117 FSMA and Food Safety³

21CFR 210 Pharmaceutical Packaging and Holding³

21CFR 211 Pharmaceuticals³

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories⁴

3. Terminology

- 3.1 Definitions:
- 3.1.1 biosafety level 2, n—a biosafety level classification pertaining to laboratories that work with agents associated with human diseases (that is, pathogenic or infections organisms) that pose a moderate health hazard.
- 3.1.2 certificate, n—a document (letter, card, or other medium) awarded to certificate holders that designates the successful completion of a credentialing program's requisites.

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- 3.1.3 certification agency, n—the organizational or administrative unit that offers or operates, or both, a certification program.
- 3.1.4 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**,

3.1.5 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.

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

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.

TABLE 1 Cannabis and Hemp Supporting Analytical Laboratory
Professions

	Section	
Cannabis and Hemp Laboratory Professionals	7	
Cannabis and Hemp Sampling Technician	7.1	
Cannabis and Hemp Laboratory Technician	7.2	
Cannabis and Hemp Laboratory Analytical Chemist	7.3	
Cannabis and Hemp Microbiologist	7.4	
Cannabis and Hemp Laboratory Manager	7.5	

- 3.1.5.1 *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.

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- 3.1.6 *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.
- 3.1.6.1 *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 BoK, n—body of knowledge.
 - 3.2.2 *cGMP*, *n*—current good manufacturing practices.
 - 3.2.3 FSMA, n—food safety modernization act.
 - 3.2.4 PPE, n—personal protective equipment.
 - 3.2.5 *QC*, *n*—quality control.
 - 3.2.6 *QMS*, *n*—quality management system.
 - 3.2.7 *R&D*, *n*—research and development.

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 Practice E2659.
- 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 covering all elements of the specific BoK for that position as determined by the relevant jurisdiction.
- 4.3 Section 6 identifies the professions 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 Professions 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 professional 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 E2659, Terminology E2708), 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 guide are as follows:
- 5.2.1 Provide a general overview of the BoK required for the professions listed in Section 6 (Table 1); and
- 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. Vocational Requirements for Analytical Laboratory Professionals within the cannabis and hemp Industries

- 6.1 The cannabis and hemp analytical laboratory-related professions 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.