

Objectives



Introduce ASTM International



Committee D37

Who is ASTM International?



Operating Globally

- One of the world's largest Standards **Developing Organizations**
- Established in 1898
- 30,000 members over 150 countries
- 148 technical committees



8,700+ citations of **ASTM** Standards in 75 nations

12,800+ ASTM standards operate globally

ASTM International Recognition



2021 OECD Report







WTO/TBT Principles

Transparency

Openness

Impartiality and Consensus

Effectiveness and Relevance

Coherence

lopment Dimension

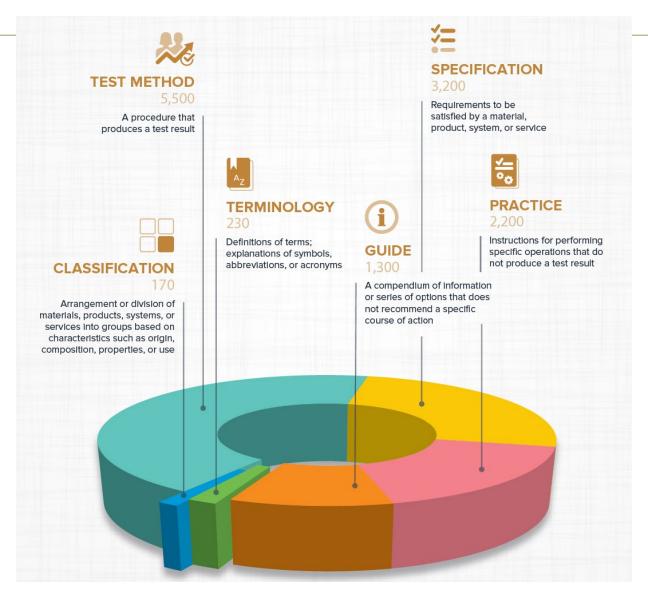


ASTM International is "Quick to react to emerging areas in need of standardisation action, notably around key new production technologies." — OECD

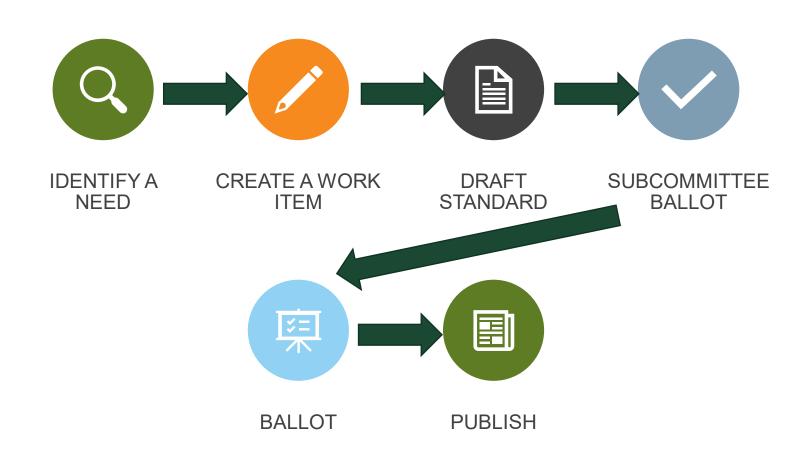
08

Many types of ASTM Standards



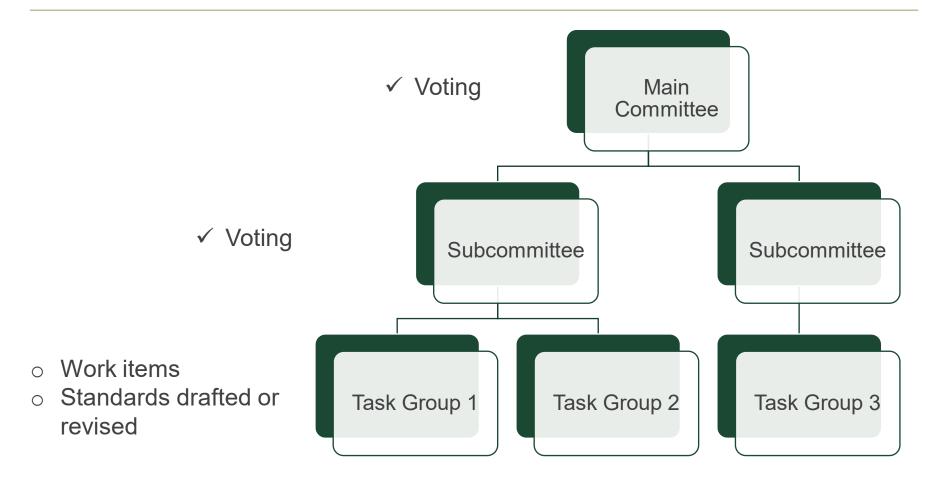


The birth of an ASTM standard



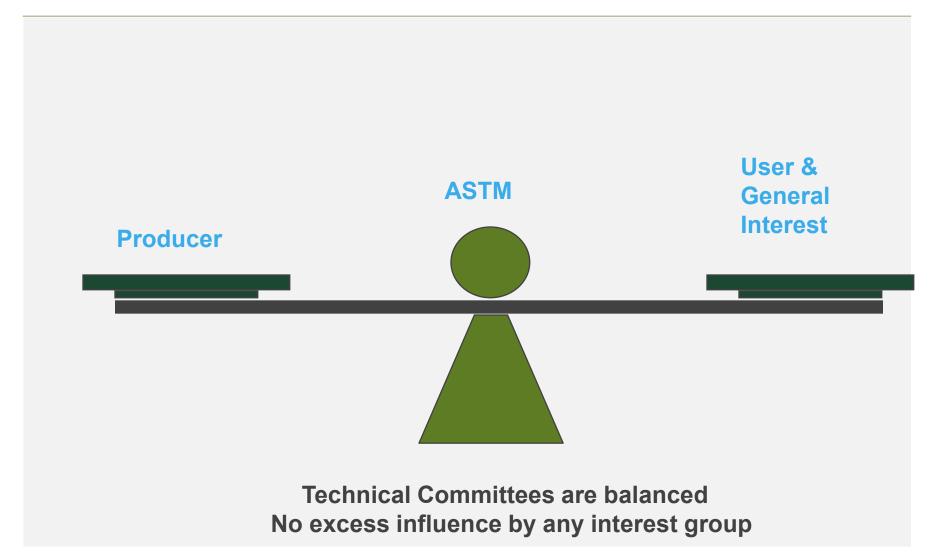
A standards journey through the Committee





Voting: A Balance of Interest





Committee D37 on Cannabis



Formed in 2017

1200+ members, 30+ countries 10 technical subcommittees

48 approved standards as of December 2022

Meet twice a year in person – January and June

Next – San Antonio, TX, USA Jan 23-25, 2023

Represented by

- Academia
- Laboratories
- Farms and Agriculture
- Government
- Extractors
- Packaging companies
- Accreditation bodies
- ... and more



Designation: D8197 - 21



Standard Specification for Maintaining Acceptable Water Activity (a_w) Range (0.55 to 0.65) for Dry Cannabis Flower Intended for Human/Animal Use¹



NLT 0.55 NMT 0.65

- D37's first standard specification
- Safety and quality
- Referenced by USP expert panel

Examples of useful Cannabis standards





Designation: D8309 - 21

Standard Guide for Stability Testing of Cannabis-Based Products¹

2.2 ICH Documents:³

Q1A(R2) Harmonised Tripartite Guideline – Stability Testing of New Drug Substances and Products

Q1B Harmonised Tripartite Guideline – Stability Testing: Photostability Testing of New Drug Substances and Products

3. Terminology

Designation: D8250 – 19

Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products¹



Designation: D8439 – 22

Standard Specification for Medicinal-use Cannabis Inflorescence



TABLE X1.1 Quality Attributes for Medicinal-Use Cannabis Inflorescence

	Quality Attribute
Identity	Macroscopic & Microscopic Analysis Cannabinoids
Phytochemical Profile	Cannabinoid Profile
	Terpene Profile

mable milere.	
	Pesticides
	Elemental Impurities
Contaminants	Microorganisms and Mycotoxins
Other Quality Attributes	Water Activity (a _w)
	Foreign Organic Matter
	Total Ash
	Total Insoluble Ash





Designation: D8450 - 22



Standard Specification for **Environmental Conditions While Packaging Cannabis/Hemp** Flower¹



packaging operations. Outdoor operations are outside the scope of this specification and are not addressed.

1.5 This specification is to be followed by licensed opera-tors in the cannabishemp space who move the cased cropso into consumer or non-consumer packaging used for distribu-

1.4 Security of the cumultis/berrip flower during the packaging process is not within the scope of this specification.

1.5 This specification is intended to remain valid until the packaged cannabis/hemp flower is placed in storage or transit. 1.6 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 appropriors safety, health, and environmental practices and deter-nion the applicability of regulatory limitations prior to ass. 1.7 This international standard was developed in accor-

dence with internationally recognized principles on standard. expressed as (I).3

Corpor relation approved May 1, 2822. Published July 2022. DOI: 18.15309 DM-10-22.

Intended for Hamos/Animal Use D8270 Terminology Relating to Cannabia

3.1 Definitions: 3.1.1 General—Definitions are in accordance with Terminology D6270, unless otherwise indicated.

3.2 Deferitions of Terms Specific to This Standard:

3.2.1 environmental conditions, n—the atmosphere immedi-nicly surrounding the cannabiothemy flower as it is transferred from drying/ouring to packaging, whether controlled within the immediate vicinity in which the flower is contained, or in the larger space surrounding the puckaging operation of the flower

3.2.2 nesso kinetic temperature, m-a simplified way of expressing the overall offect of temperature fluctuations during storage or transit of perishable goods.
3.2.2.1 Directors—The MKT is widely used in the pharmacolor

miceutical industry. The mean kinetic temperature can be

For referenced AETH standards, visit the AETM syrbolis, www.astm.org, or contact.AETM Conteners Service as acriscott summary. For Annual Stool of AETM Datachads scheme information, self-or in the anadora? Information Services appage on the AETM within.

"The boldler conducts as parcelleses refer to the list of references at the end of

$$\begin{split} T_{\mathcal{S}} &= \Delta H W \cdot \ln[t_1 \, e^{iABST_i)} + t_2 \, e^{iABST_i)} + \ldots \\ &+ t_n \, e^{iABSL_i/c} (t_1 + t_1 + \ldots + t_n) \end{split}$$

4.1. The cannabis/herry industry, from seed to consumption, is undergoing a transition and modernization. Thus, standards for emering safety, quality, and weight stabilization during key steps of the cannabis/hemp flowers sejourn are in order.

4.2 This specification is intended to ensure safety, quality, and weight stabilization of cornobischerap flower during indoor

4.3 This specification is intended to be used by pursupors who move the cered coap to consumer or non-consumer packaging used for distribution.

5. Appearation

5.1 Montester Equipment

 5.1.1 Temperature—Device or devices capable of measuring temperature to ensure specifications of this standard are met. Monitoring and tracking may be automated or manual.

5.1.2 Relative Themship—Device or devices capable of measuring relative hamility to ensure specifications of this standard are not. Monitoring and tracking may be automated

6. Record Keeping

6.1 Records shall be maintained to ensure that the specifications of this standard are met. Record keeping can be automated or manual.

7. Specification for Environmental Conditions While

where:

Is a mean kinetic temperature in kelvim (K),

MI = activation energy (in k) and T_s,

Is a go constant (in 1 and K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant (in 1 and K K K).

Is a go constant of the constant of the parkaging operation of contributions of the constant of the prediction of the parkaging operation of constant of the parkaging operation of the parkaging operation of constant of the parkaging operation of the parkaging operation of constant of the parkaging operation of

7.3 Light exposure (visible and ultraviolet (UV)) of the canodischeray flower shall be limited to the minimum necessary for sofe and effective packaging operation.
7.3.1. When possible. UV filters should be used with thorocord light fixtures. LEID light fixtures are preferred as these do not prefuse UV radiation.

R. Special Considerations

R.1 Adherence to this specification can be verified by the means defined in 5.1 situated near the locations of the cannabischerup flower as it is being puckaged.

mental conditions; hence, hence flower; humidity; industrial hence, modd, physical damage; preservation; quality; safety; temperature; water activity; water content; weight stabilization

TABLE 1 Temperature and Relative Hambilly of Pockaging

Seropesaura of Factorging Stransportant, "C	Relative Humbly of Factoring Environment, fo RM
25 to 50	60 ± 5
21 to 25	58 ± 5
18 to 20	10 + 1
11 to 15	54 x 5
610.18	58 + 5

Problem: Cannabis plant is not homogenous!





Designation: D8334/D8334M - 20

D8334/D8334M – 20

complicated arrangement of branches. Morphologically, it is the modified part of the shoot of seed plants where flowers are formed.

4. Summary of Practice

4.1 This standard provides best practice procedures and protocols for sampling cannabis harvest batches to collect representative samples used for laboratory testing that are representative of an entire harvest batch that is intended for

- 4.2 Harvest batch size for batches of inflorescence shall have a maximum weight of 6.8 kg [15 lb], unless local jurisdiction has alternative requirements for maximum batch size.
- 4.3 The sampling protocols in this standard:
- 4.3.1 Apply to harvest batches of cannabis grown indoor or outdoor:
- 4.3.2 Attempt to minimize harvest lot variation;
 4.3.3 Requires that all material in a harvest batch comes

Standard Practice for Sampling of Cannabis/Hemp Post-Harvest Batches for Laboratory Analyses¹

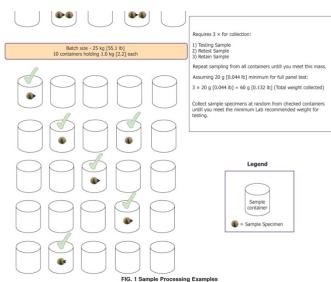
Builds off existing knowledge





Hop Inspection Handbook





ASTM D8441/8441M, Specification for an International Symbol for Identifying Consumer Products Containing Intoxicating Cannabinoids



– Scope

- Establishes international symbol for all consumer products containing intoxicating cannabinoids at a defined quantity
- Finished products intended for consumer use including topical, ingestion, inhalation, or other adsorption method on or in the body of a human or animal.

- Significance & Use

- Uniformity in identifying health and safety hazards of a substance that may cause mind altering effects.
- Visual clarity and consistency improve recognition and comprehension for end user.

ASTM International Intoxicating Cannabinoid Product Symbol (IICPS)



Light Background



Dark Background

Personnel and Credentialing – Who is qualified to do what?

Designation: D8452 – 22

Standard Guide for Requirements for Medical-related Professionals within the Cannabis and Hemp Industries¹

TABLE 2 Cannabis and Hemp Medical Professional Body of Knowledge (BoK)

ВоК	Section ^A
Legal Landscape of Cannabis and Hemp	A1.1
History of Cannabis and Hemp in the World	A1.2
The Endocannabinoid System	A1.3
Cannabinoids, Terpenes, and Opioids	A1.4
Delivery Systems for Medical Cannabis and Hemp	A1.5
Patient-centered Dosing	A1.6
Laboratory Testing	A1.7
Clinical Practice and Broad Therapeutic Uses	A1.8
Cannabis and Opioids	A1.9

^A Details for each BoK topic are provided in Annex A1.



Designation: D8469 - 22

Standard Test Method for Analysis of Multiple Elements in Cannabis Matrices by Inductively Coupled Plasma Mass Spectrometry (ICP-MS)



Designation: D8375 - 22

Standard Test Method for Determination of Cannabinoid Concentration in Dried Cannabis and Hemp Raw Materials using Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS)¹

ASTM D8442-22 (i)

Standard Test Method for Determination of
Cannabinoids in Cannabis Raw Materials and Resin
Cannabis Products by Gas Chromatography and Flame
Ionization Detection

Much more in development



Test Methods

 84190 - Test Method for Determination of THC Isomers in Hempseed Products Intended for Animal Feed and Ingredients by Gas Chromatography and Flame Ionization Detection (84190)

Sampling and Process Methods

- Guide for The Sampling of Field and Bulk Harvest Lots of Cannabis and Hemp for Laboratory Analyses (80447)
- Guide for Cleaning and Disinfecting Water and Fertigation Systems in Cannabis Cultivation Facilities (82019)
- Guide for Indoor/Outdoor Cannabis Cultivation Space Entry Protocols (81375)
- Guide for **Process Validation** Requirements in the Cannabis Industry (73764)
- Practice for Decontamination of LP Cylinders used in Biomass Extraction (81376)
- Specification for Restricted Substances used or contained in Materials to manufacture Herbal Product Vaporizers (76669)



Converging for quality and safety



Problems demand solutions

- We have a wide breadth of standards
- Leverage ASTMs robust process
- All with an interest in cannabis standardization are invited to participate



ASTM International Committee D37 on Cannabis

THANK YOU!

David Vaillencourt, M.Sc.

Vice-Chair ASTM Committee D37

CEO, The GMP Collective

david@gmpcollective.com

For more information about ASTM Committee D37 and how to join, visit www.astmcannabis.org