

ASTM INTERNATIONAL Helping our world work better

D37 Cannabis ASTM Background & Overview

ASTM International 2017 Update

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About ASTM Overview and Process

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What is ASTM?



A Proven and Practical System

- Established in 1898
- 147 Committees & 12,500+ Standards
- 32,000 members
 - 8,000+ International Members from 135 countries
 - 5,100 ASTM standards used in 75 countries
- Accreditation: American National Standards Institute (ANSI)
- Process complies with WTO principles: Annex 4 of WTO/TBT Agreement
- Development and delivery of information made uncomplicated
- A common sense approach: industry driven
- Market relevant globally
- No project costs



Important. Every Day.



The Role of ASTM Standards

- Ensures safety, quality and reliability
- Emerging Industry Support: Standards are a foundation to build upon
- Responsive: innovations, new challenges, new technology and new markets
- Industry Lead: Effective and relevant across diverse markets
- Built on Consensus: 90% approval; balanced and equal
- Helping Everyone: all stakeholders involved directly impacts content
- Voluntary until Referenced: contracts, regulations, codes, and laws around the world.



Over a Century of Openness



How We Work

Provide Infrastructure and Tools

 Templates, Online balloting, Online collaboration areas, meetings support, managers, administrative support, editors, promotional support

- Industry comes Together:

- Exchange expertise and knowledge
- Participating in a transparent process open to anyone, anywhere
- Staff does not write standards, remain neutral



ASTM: The Power of Partnership



- All stakeholders involved
 Neutral forum
- Consensus-based procedures
- Private and public sector cooperation
- Every member has equal say
 - ✤ 1 vote per interest



EXAMPLE

- Manufacturers
- Federal agencies
- Design professionals
- Professional societies
- Trade associations
- Financial organizations
- Academia

Balance of Interest





Technical Committees are balanced. No excess influence by any interest group. Ensures market relevance of the content of standards.

Technical Committee Structure





Time Frame for Developing Information





Average Standards Approval: 18 months New Standards Activities: 7 months Revisions: 6 months

Complexity of the job

Urgency of needs

Time devoted by members

Utilization of new informational technologies ASIA

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Standards in Industry and Regulation What role do they play?

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How Are ASTM Standards Used?

Developed voluntarily and used voluntarily Cited in a contract

Government agency reference them in codes, certification, regulations, and laws, supports P.L. 104-113

Used by tens of thousands of individuals, companies, and agencies globally



National Technology Transfer and Advancement Act of 1995 (NTTAA)

- Requires federal government agencies to use standards developed by voluntary consensus standards organization when possible
- Encourages federal government agencies to participate in standards development organizations

OMB Circular No. A-119

- Reinforces goals of National Technology Transfer and Advancement Act
- Discourages federal agencies from using government-unique standards

"A voluntary consensus standards body is defined by the following attributes: (i) Openness. (ii) Balance of interest. (iii) Due process. (vi) An appeals process. (v) Consensus"

Usage and Acceptance



State Utilization

- State labs
- State cannabis programs
- Green codes / Building codes
- Sustainability

Global Application:

- International Codes
- Open Participation ensuring global acceptance
- Support and Facilitate Trade
- Accredited by SCC

ASTM Complies with the WTO principles

for international standards development



WTO / TBT Principles	ASTM Principles	
Transparency	Transparency	
Openness	Openness	
Impartiality and consensus	Impartiality and consensus	
Effectiveness and relevance	Effectiveness and relevance	
Coherence	Coherence	
Consideration of developing	Consideration of developing	
nations	nations	

ASTM Program and Services

Pre-standardization

- > Workshops
- > Symposia's
- Roadmapping

Post-Standardization

- Product Certification, Labeling
- Interlaboratory Study Programs
- Laboratory Proficiency
- Personnel Training (Certificate and Certification)
- Compass
- Standards as Digital Data
- Supplemental Products (software, samples, and more)

Strengthened by Partnerships

- Formal and informational
- Co-branding, collaborations
- Centers of Excellence, Consortiums, Innovation Centers
- Databases



Solutions

through

Standards



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D37 on Cannabis Formation and Structure

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Formation of an Activity



✓ Stage one: Exploratory level:

- ASTM contacted about possible development of an activity
- Period of due diligence to gather information about the industry and the need for standards
- A few diverse stakeholders are contacted (often from opposite sides of the issue), to see if there is enough support to proceed.

✓ Stage two: Planning level.

- Meeting of key stakeholders in the given area average number of attendees is 10-20 people.
- ASTM-facilitated meeting
- Agenda to determine if there is support for the standards development activity, areas in which standards needed, and if ASTM is an appropriate venue.

✓ Stage three: Organizational level.

- ASTM-facilitated meeting
- An open meeting is held where all relevant stakeholders are invited to attend and provide input.
- Formal motions to approve a title, scope, and structure for the activity.
- · Final motion to organize a new activity within ASTM

Background of Request



2005 Request from Hawaii

- Regulatory Climate
- Stakeholder buy-in

> 2015 Request from In Grown Farms, Larry Kiest

- Global Regulatory Climate evolved
- State legislation progressed, Global initiative progression

Existing Members Drive

- Ralph Paroli, NRC Canada
- E55 Manufacture of Pharmaceutical and Biopharmaceutical Products

Stage one: Exploratory level:



- ✓ ASTM contacted about possible development of an activity
- Period of due diligence to gather information about the industry and the need for standards
- A few diverse stakeholders are contacted (often from opposite sides of the issue), to see if there is enough support to proceed.

February 2016 – September 2016

Identified 50+ organizations

- Government Representatives
- Industry Associations
- Academia
- Laboratories
- Cultivation Centers
- Suppliers

Stakeholder Outreach and Results

- 1. Scattered research and efforts
- 2. Product safety & evaluation
- 3. Standardized Test Methods
- 4. Product Specifications
- 5. Recommended Practices
- 6. Quality Control and Assurance
- 7. Labeling Requirements
- 8. Laboratory Proficiency

Stage two: Planning level.



- Meeting of key stakeholders in the given area average number of attendees is 10-20 people.
- ✓ ASTM-facilitated meeting
- Agenda to determine if there is support for the standards development activity, areas in which standards needed, and if ASTM is an appropriate venue.

Planning Meeting

January 2017 Hosted by American Public Health Association Washington, DC

13 Representatives:

state laboratories, standards developers, research institution, academia, cultivation centers, auditors and software compliance providers

Resulted In:

4 Target Areas identified40 Specific Standards

- Expand Outreach to other organizations
- Explore Partnerships for Harmonization
- Hold organizational meeting

Stage three: Organizational level.



- ASTM-facilitated meeting
- An open meeting is held where all relevant stakeholders are invited to attend and provide input.
- ✓ Formal motions to approve a title, scope, and structure for the activity.
- ✓ Final motion to organize a new activity within ASTM.

Organizational Meeting Details:

Held at ASTM International HQ February 28, 2017

65 attendees, representing 58 voting interests from:

- Associations
- Academia
- Laboratories
- Supplier
- Cultivation Centers
- Government
- Transportation Services
- Software Providers
- Accreditation bodies

Organizational Meeting Results:

Unanimous vote to form D37 on Cannabis

Scope: The development & maintenance of standards and guidance materials for cannabis and its products and processes.

D37.01 Indoor and Outdoor Horticulture and Agriculture D37.02 Quality Management Systems D37.03 Laboratory D37.04 Processing and Handling D37.05 Security and Transportation D37.06 Personnel Training, Assessment, Credentialing D37.90 Executive D37.91 Terminology

D37 on Cannabis



Overview

Formed in 2017; 65 participants

Title: Cannabis

Scope: The development & maintenance of standards and guidance materials for cannabis and its products and processes.

D37.01 Indoor and Outdoor Horticulture and Agriculture
D37.02 Quality Management Systems
D37.03 Laboratory
D37.04 Processing and Handling
D37.05 Security and Transportation
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Represented by

- Associations
- Academia
- Laboratories
- Supplier
- Cultivation Centers
- Government
- Transportation Services
- Software Providers
- Accreditation bodies

Collaborating to Develop Robust Solutions Toolbox

Areas for Consideration



Indoor and Outdoor	Laboratory	Processing &	Personnel Training,
Horticulture and		Handling	Assessment,
Agriculture			Credentialing
 Integrated pest management Imputs Seed and/or plant material selection Genetic modifications Selection of water, Processing of water, Quality considerations, Water cultivation practices Water system mgmt Environmental site assessments Biodiversity Sustainability Indoor/outdoor cultivation Bulk sampling Supply chain due diligence Energy usage and mgmt. Waste Mgmt Harvest drying and curing 	 3rd party attestation / verification Sampling – overall Bulk Laboratory specifics Stability testing Extraction – plant extraction and Purity testing Contaminant – testing, removal and permissible levels, levels based on patient Analytical methods Validation methods Laboratory proficiency testing GLP GMP QMS (ASTM E11) Laboratory specific Critical control testing - process/final product 	 Security & Transportation Harvest drying and curing Harvest trimming Exposure management Waste Management Product storage Temperature/moisture management Stability Labeling requirements / recommendations Recall traceability Packaging – including specifications during all stages Shipping Data mgmt. / integrity / security Risk assessment and mitigation Occupational health & safety Environmental health & safety Product remediation 	 Lab technicians PPE / clean room Engineering controls Qualifications Background checks Cultivator training QA inspectors/auditors Code officials (all levels) First responders and law enforcement Occupational health & safety Environmental health & safety Patient education Physician education

Supporting Resource Experts



Primary

- E35 Pesticides, Antimicrobials, and Alternative Control Agents
- E55 Manufacture of Pharmaceutical and Biopharmaceutical Products
- **D10 Packaging**
- E11 Statistics
- E50 Environmental Assessment, Risk Management and Corrective Action
- **D19 Water**
- **E29 Particle and Spray Characterization**

Secondary

- C16 Thermal Insulation
- D18 Soil and Rock
- **D20 Plastics**
- D34 Waste Management
- D35 Geosynthetics
- E13 Molecular Spectroscopy and Separation Science
- **E30 Forensic Sciences**
- **E41 Laboratory Apparatus**
- E60 Sustainability
- E61 Radiation Processing
- **F02 Primary Barrier Packaging**
- **F23 PPE**



- 1.ASTM provides the infrastructure so you can focus on technical aspects
- 2. Standards are built upon consensus (90%)
- 3. Standards respond and evolve to meet scientific and technological advancements
 - Change faster than Regulations (6months vs 5years+)
- 4. Standards set the baseline and allow for innovation / minimum requirements
- 5. Standards can be for products, processes, services, or personnel
- 6. Standards can be for required or recommended practices (practices/guides)
- 7. ASTM Standards are voluntary until referenced by regulation as a MOC.
- 8. Normatively reference don't reinvent the wheel
- 9. Standards stay around even after we aren't
- 10.ASTM's process allows YOU to determine what you have to meet

Questions?



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