D37 Cannabis
ASTM Background & Overview
ASTM International
2017 Update

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www.astm.org
What is ASTM?

A Proven and Practical System

- Established in 1898
- 149 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) and Standards Council of Canada (SCC)
- 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.

6,788
ASTM standards have been adopted, used as a reference, or used as the basis of national standards outside the USA
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

- Activities are Industry-Driven
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
Time Frame for Developing Information

- Complexity of the job
- Urgency of needs
- Time devoted by members
- Utilization of new informational technologies

Average Standards Approval: 18 months
New Standards Activities: 7 months
Revisions: 6 months
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
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 ANSI & SCC
ASTM Complies with the WTO principles
for international standards development

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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
D37 on Cannabis

Formation and Structure

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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 identified
40 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

Launching
Formed: February 2017
Roster: 145+ Members
First Meeting: 11-12 June 2017, Toronto, Canada

Future Meetings:
10-11 October 2017 – Workshop in Cologne, Germany, TBD
21-22 January 2018 – Full Meetings, New Orleans, USA
October 2018 – Full Meetings, Amsterdam – Dates TBD

Since Organizational Meeting:

Approvals
• Committee on Technical Committee Operations (COTCO) Approval
• Board of Directors Approval
• Bylaws drafted, anticipated June ballot

Elected Officers
• Chairman: Ralph M. Paroli, National Research Council Canada
• Vice-chairman: Jeremy Applen, Canopy Systems
• Recording Secretary: Kathleen May, MP Consulting, LLC
• Membership Secretary: Susan Audino, S.A. Audino & Associates, LLC

Subcommittee Chairman Appointments
• Underway
## A Sneak Peak

### Cultivation
- Pest Mgmt.; Environmental Site Assessment
- Seed / Plant Material Selection; Water Selection & Processing

### Quality Management Systems
- Manufacturing & Product Quality; Risk Assessment & Mitigation
- Sampling; Recall Traceability

### Test Methods and Proficiency
- Analytical and Validation; Sampling and Extraction
- Purity and Contaminants

### Product and GMP
- Occupational and Environmental Health & Safety; Labeling
- Harvesting; Exposure Mgmt.; Waste Mgmt.

### Products, Transport, and Dispensaries
- Product Storage and Shipping; Stability
- Moisture Mgmt.; Risk Mgmt.; Data Mgmt.

### Training, Assessment, Credentialing
- All interfacing personnel (inspectors, codes officials; technicians, dispensaries….)
- Engineering controls, PPE, clean room, Occupational and Environmental Health & Safety
D37 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
D13 Molecular Spectroscopy and Separation Science
E30 Forensic Sciences
E41 Laboratory Apparatus
E60 Sustainability
E61 Radiation Processing
F02 Primary Barrier Packaging
F23 PPE

Collaborating to Develop Robust Solutions Toolbox
ASTM Overview: Key Takeaways

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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