

A Systematic Approach to Methods Development and Validation

William A. Telliard
USEPA (retired)



ASTM

- Organized in 1898
- Independent, private sector, not-for-profit
- Over 12,000 standards published annually
- 30,000+ members
- 128 countries
- 90 industrial sections represented
- 2,200+ Subcommittees



D19 Committee on Water

- As of 2012, it is 80 years old
- 325 members
- 348 standards
- 9 technical subcommittees
- 28 countries represented



Breakdown of D19 Standards

- 19 new works items in progress (2012)
- 1 Standard specification (cyanide)
- 4 terminology standards (topic specific)
- 41 standard guides
- 89 standard practices
- 213 standard test methods

- 367 total standards in D19



Coverage

- Metals
- Organics
- Microbiology
- Radiochemistry
- Inorganics
- Flow measurement
- Sediment
- Treatment technologies (ozone and disinfection)



Technical Committee Organization

- Technical Committees are formed to address specific industry needs
- Subcommittees are established to address subsets of specialized subject matter
- Subcommittees organize their expertise into Task Groups in write standards



Technical Committees

- Technical Committees are “classified” and “balanced”
- Committee members are “classified”
“as one of the following:
 - Producer
 - User
 - General Interest, or
 - Consumer
- Only one official vote is assigned per company



Life of a Standard

- Begins as a work order from a committee, subcommittee, or task group
- Can be new technology
- Review of existing standard (required every 5 years)
- Revision to an existing practice

New Technology

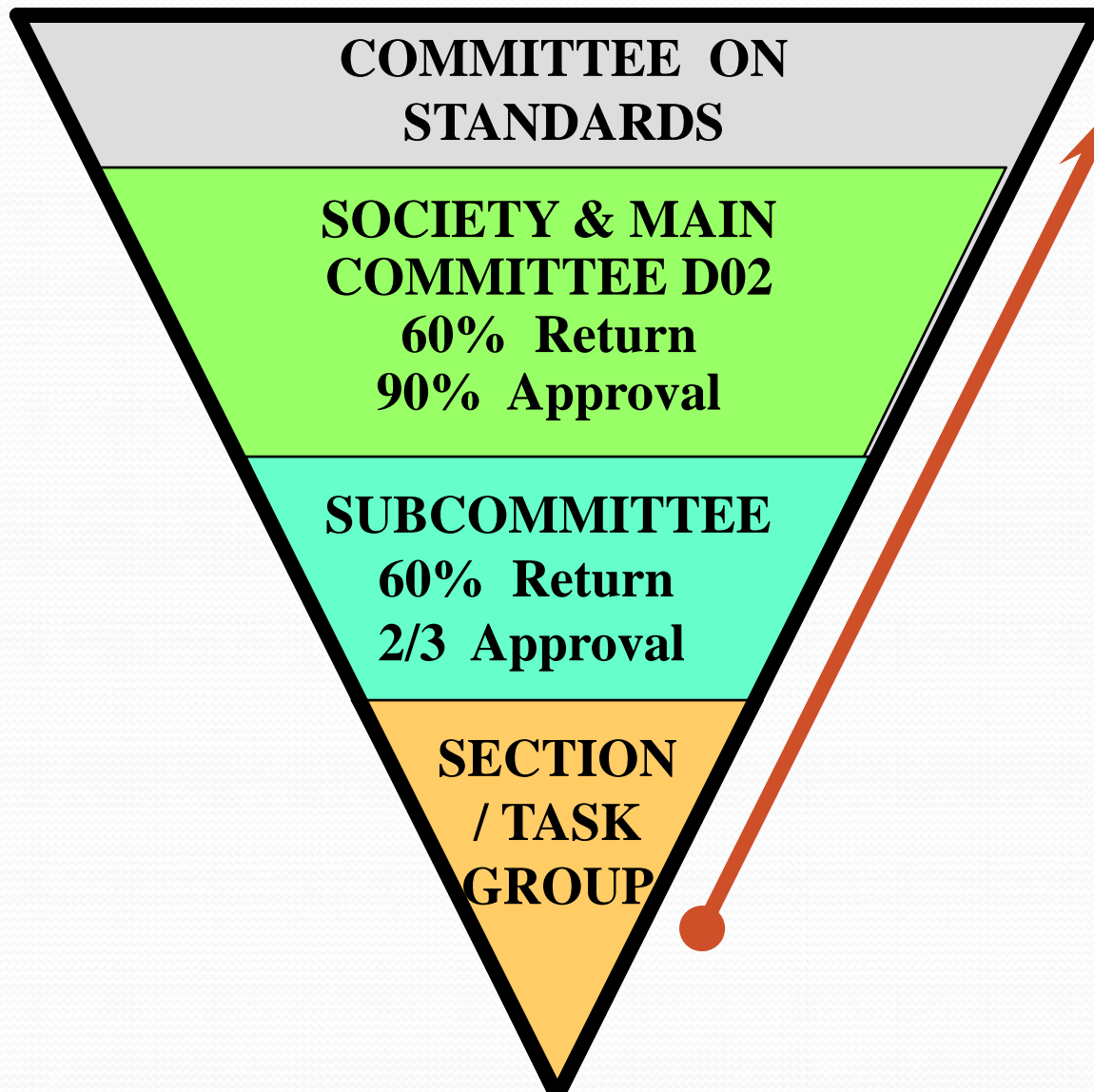




Validation

- The standard for developing precision and bias data in D2777
- The standard EPA QA/QC requirements are added to all ASTM methods in 1999
- Prior to validation, the study plan is reviewed and approved by a study coordinator, for either a single-lab or multi-lab study
- The coordinator will generate the statistics from the study results (e.g., precision and bias)

ASTM Balloting Process



The ASTM standards development process is driven from the bottom up, by the technical experts.

In the balloting process extensive consideration is given to negative votes. Standards are not approved until all negatives are resolved.

Ballot Response

- Affirmative
- Affirmative with comment
- Negative **Must have written reason!**
 - Preferably not editorially based
- Abstention
- Abstention with comment

Resolving Negatives

- Withdrawn by voter
- Withdrawn with Editorial change – D19 Editor approval required
- Not related (2/3 hand count required – voting members). *Must become a new business item*
- Not Persuasive (2/3 hand count required)
 - SC must supply reasoning for motion in adjudication documentation



Appeal of Not Persuasive

- Negative voter options on Main Committee Ballots
 - If not persuasive, voter may request a confirming ballot on his/her Main Committee negative vote
 - Must be within 30 day of receiving notification of vote
 - Electronic ballot conducted to sponsoring subcommittee
 - No comments on ballot (yes, no, or abstain vote)
 - Appeal to COS
 - Response based on basis of Due Process, not technical



Not Persuasive Negatives

- Negatives determined Not Persuasive on Subcommittee Ballots attached to ballot item for rest of approval process, includes
 - Copy of negative
 - Copy of subcommittee response
 - Vote count totals
- Committee on Standards (COS)
 - Reviews all Not Persuasive ballot actions on Main Committee/Society Ballots for due process. No technical issues considered

Ballot Comments

- All comments must be considered
- Options
 - Editorial changes
 - Cannot be substantive. If in doubt consult with editorial staff
 - New work item
 - Not related to ballot item

Ballot Not Required

- Editorial changes
 - Correct typographical errors
 - Correct editorial style
 - Change non-technical information
 - Reduce ambiguity

Ballot Required

- Substantive
 - Specification limits
 - Changes to
 - Procedure
 - Equipment
 - Precision statement
 - Scope
 - Significance & Use
 - Any other significant change
 - Summary of Change Section addition
 - Contents change automatically when changes are balloted

ASTM Proxy

Proxy: Votes for a voting member at Subcommittee or Main meeting

- **Voting member:**
 - Contacts the proxy
 - Completes form in its entirety and SIGNS it
 - Sends form to the Chairman prior to action
 - Separate form required for each individual meeting
 - **Proxy:**
 - Ensures Chairman holds a copy
 - Cannot hold more than one proxy at a meeting
- NO SOLICITATION!**

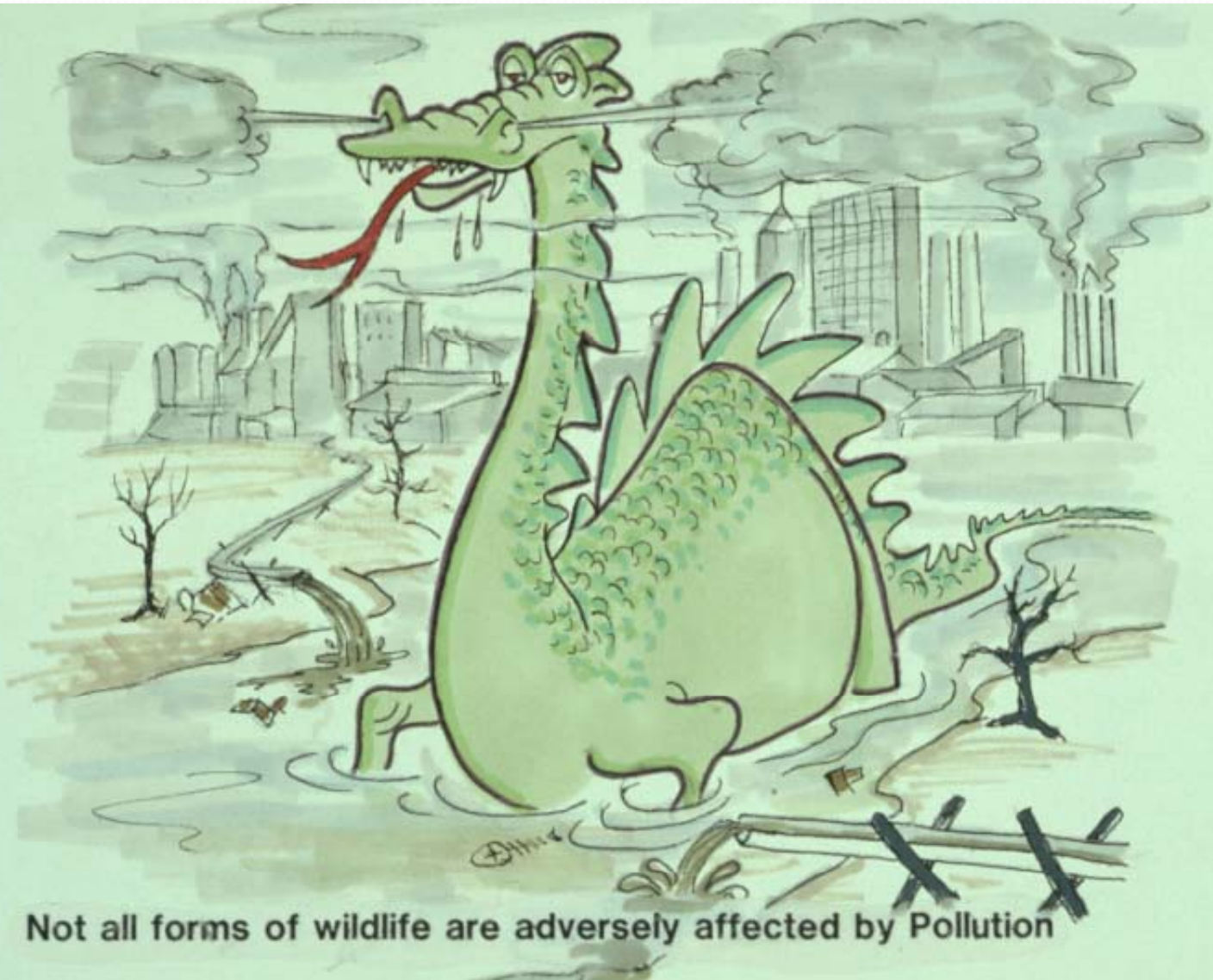


NTTAA 1995

- National Technology Transfer and Advancement Act
- D19 standard is forwarded to EPA's Office of Water
- EPA has an opportunity to review the standard and either accept or deny its use for compliance monitoring (WW and/or DW)
- If denied, EPA must provide a written response to OMB and Congress

Federal Review





Not all forms of wildlife are adversely affected by Pollution