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How to Remain Objective and Open;
Overview of the Consensus Standard Development Process

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August 2020

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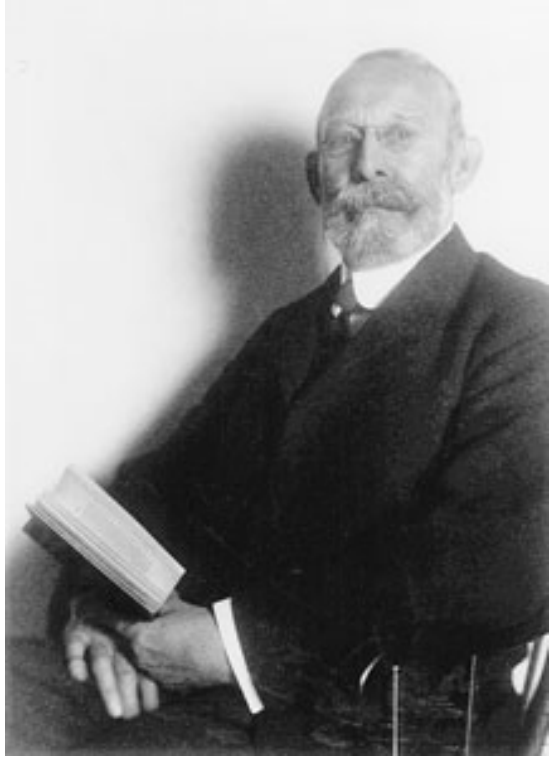
In the beginning - Charles Benjamin Dudley formed the ASTM and began the concept of consensus standards

- ASTM established in 1898 to bring together suppliers and customers in Technical Committees
- Committees provide representatives of every interested party
- Specifications and Methods established by consensus
- Created periodic review, revisions and updates as part of the process



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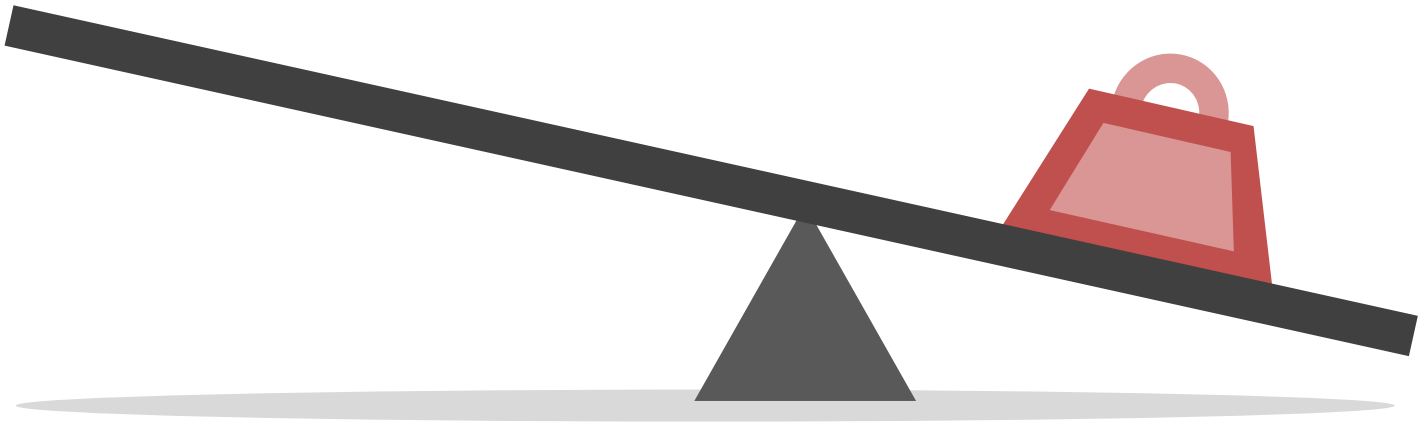
In 1908, ASTM set rules regarding committee balance, 2/3 majority vote, and weighting of negatives. Most SDOs follow these today



The basic structure of checks and balances, designed to ensure fairness of standards, is still in place today

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The NBS, established in 1901, met great resistance with industry because no one wanted forced national standards

Americans “loved” setting standard specifications, and methods based on consensus of all stakeholders.

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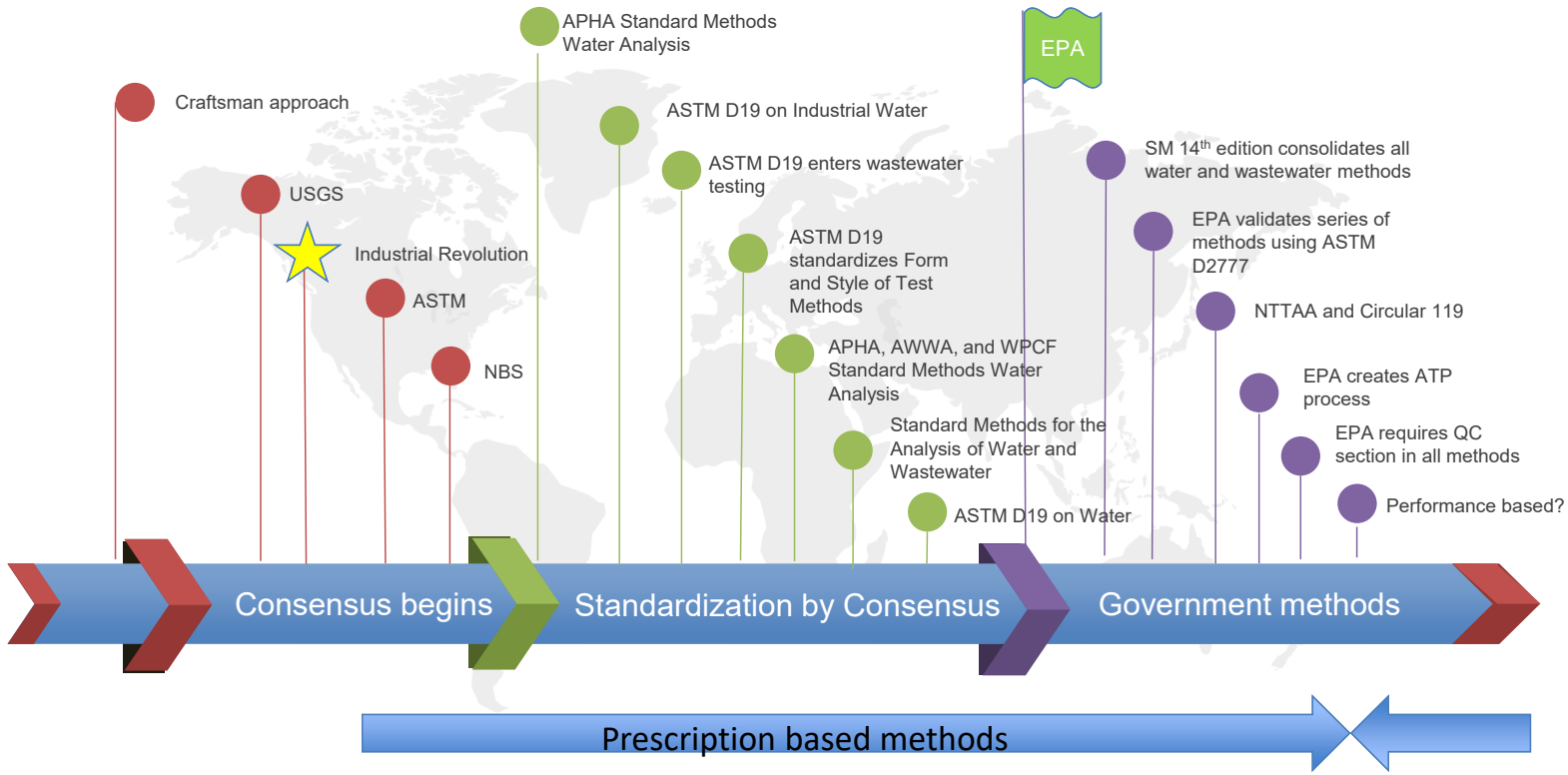
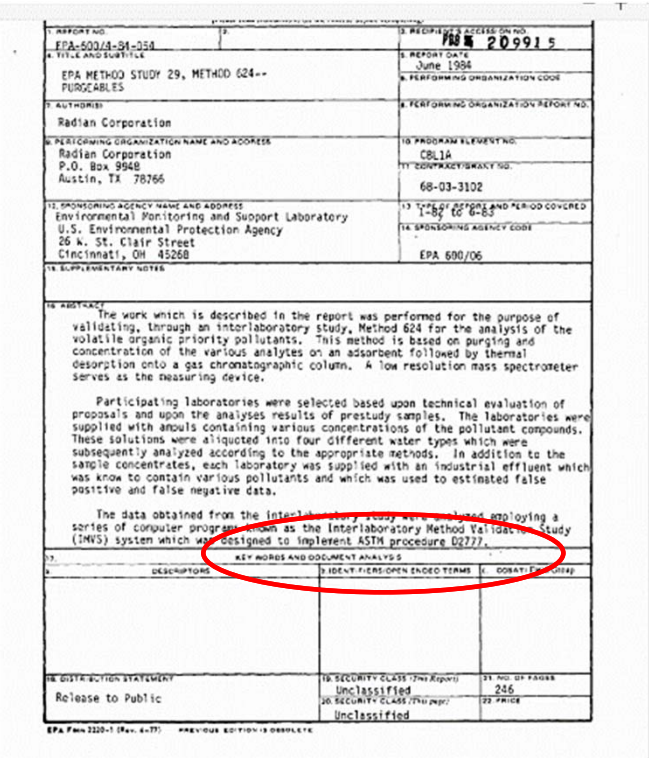
In 1970, the EPA was established and due to litigation a system of federally developed methods was created



At first EPA and consensus standard development organizations collaborate freely in method validation and sharing data



1. REPORT NO. EPA-600/4-84-054	3. RECIPIENT'S ACCESS ION NO. PB84 209915
4. TITLE AND SUBTITLE EPA METHOD STUDY 29, METHOD 624-- PURGEABLES	5. REPORT DATE June 1984
7. AUTHOR(S) Radian Corporation	8. PERFORMING ORGANIZATION REPORT NO.
9. PERFORMING ORGANIZATION NAME AND ADDRESS Radian Corporation P.O. Box 9948 Austin, TX 78766	10. PROGRAM ELEMENT NO. CBL1A 11. CONTRACT/GRANT NO. 68-03-3102
12. SPONSORING AGENCY NAME AND ADDRESS Environmental Monitoring and Support Laboratory U.S. Environmental Protection Agency 26 W. St. Clair Street Cincinnati, OH 45268	13. TYPE OF REPORT AND PERIOD COVERED 1-82 to 6-83 14. SPONSORING AGENCY CODE EPA 600/06
15. SUPPLEMENTARY NOTES	

16. ABSTRACT

The work which is described in the report was performed for the purpose of validating, through an interlaboratory study, Method 624 for the analysis of the volatile organic priority pollutants. This method is based on purging and concentration of the various analytes on an adsorbent followed by thermal desorption onto a gas chromatographic column. A low resolution mass spectrometer serves as the measuring device.

Participating laboratories were selected based upon technical evaluation of proposals and upon the analyses results of prestudy samples. The laboratories were supplied with ampuls containing various concentrations of the pollutant compounds. These solutions were aliquoted into four different water types which were subsequently analyzed according to the appropriate methods. In addition to the sample concentrates, each laboratory was supplied with an industrial effluent which was know to contain various pollutants and which was used to estimated false positive and false negative data.

The data obtained from the interlaboratory study were analyzed employing a series of computer programs known as the Interlaboratory Method Validation Study (IMVS) system which was designed to implement ASTM procedure D2777.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group

18. DISTRIBUTION STATEMENT Release to Public	19. SECURITY CLASS (This Report) Unclassified	21. NO. OF PAGES 246
	20. SECURITY CLASS (This page) Unclassified	22. PRICE

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samples for trace elements to D19.05.04 for use in conducting a round robin study on inductively-coupled plasma (ICP) methodology.

However, as was suggested, the recent completion by U.S. Environmental Protection Agency (USEPA) of a very comprehensive collaborative study on trace metals by ICP, provides a large data base for your consideration. I am enclosing a copy of the very extensive report. Please review it and if the study meets your needs, feel free to utilize the statistics or reference any part of the report.

Our agency is very pleased to work with D-19 and other American Society for Testing and Materials (ASTM) committees and to search out common methodologies, in the spirit of Office of Management and Budget (OMB) Circular A-119.

Good luck in review of the data. If you have any questions, don't hesitate to call.

Sincerely yours,

John A. Winter
Chief
Quality Assurance Branch

Attachment (1):
As Stated

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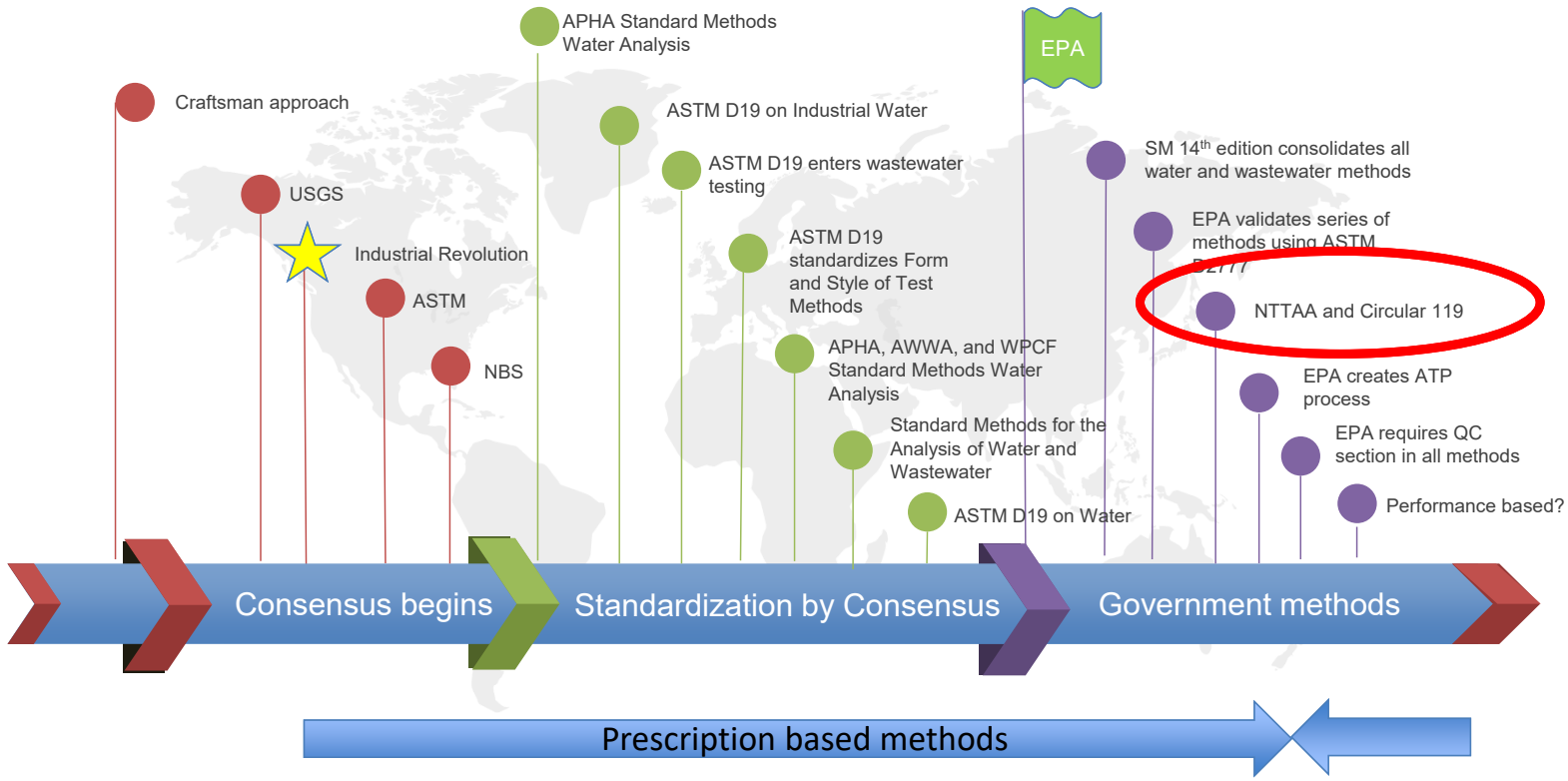
But due to litigation, a large number of federally developed and mandated methods became the norm



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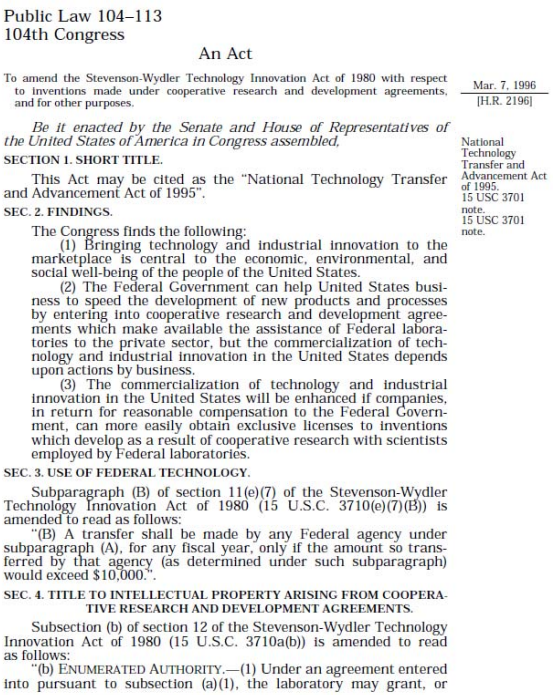
The National Technology Transfer and Advancement Act (NTTAA) "tells" EPA and other federal agencies to do what was done before



Public Law 104–113
104th Congress

An Act

To amend the Stevenson-Wydler Technology Innovation Act of 1980 with respect to inventions made under cooperative research and development agreements, and for other purposes.

Mar. 7, 1996
[H.R. 2196]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National Technology Transfer and Advancement Act of 1995.
15 USC 3701 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Technology Transfer and Advancement Act of 1995".

15 USC 3701 note.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Bringing technology and industrial innovation to the marketplace is central to the economic, environmental, and social well-being of the people of the United States.

(2) The Federal Government can help United States business to speed the development of new products and processes by entering into cooperative research and development agreements which make available the assistance of Federal laboratories to the private sector, but the commercialization of technology and industrial innovation in the United States depends upon actions by business.

(3) The commercialization of technology and industrial innovation in the United States will be enhanced if companies, in return for reasonable compensation to the Federal Government, can more easily obtain exclusive licenses to inventions which develop as a result of cooperative research with scientists employed by Federal laboratories.

SEC. 3. USE OF FEDERAL TECHNOLOGY.

Subparagraph (B) of section 11(e)(7) of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710(e)(7)(B)) is amended to read as follows:

"(B) A transfer shall be made by any Federal agency under subparagraph (A), for any fiscal year, only if the amount so transferred by that agency (as determined under such subparagraph) would exceed $10,000.".

SEC. 4. TITLE TO INTELLECTUAL PROPERTY ARISING FROM COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS.

Subsection (b) of section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a(b)) is amended to read as follows:

"(b) ENUMERATED AUTHORITY.—(1) Under an agreement entered into pursuant to subsection (a)(1), the laboratory may grant, or

1995 – NTTAA encourages formal adoption of National Consensus Standards for American regulatory agencies.

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OMB Circular A-119 emphasizes the NTTAA and says “use VCSBs”

- **Use Voluntary Consensus Standards in lieu of government-unique standards**
- **Provides guidance for agencies participating in VCSBs**
- **<u>Reduce</u> reliance by agencies on government standards**

BACKGROUND

1. **What Is The Purpose Of This Circular?**

This Circular establishes policies to improve the internal management of the Executive Branch. Consistent with Section 12(d) of P.L. 104-113, the "National Technology Transfer and Advancement Act of 1995" (hereinafter "the Act"), this Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the Act. The policies in this Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards. These policies do not create the bases for discrimination in agency procurement or regulatory activities among standards developed in the private sector, whether or not they are developed by voluntary consensus standards bodies. Consistent with Section 12(b) of the Act, this Circular directs the Secretary of Commerce to issue guidance to the agencies in order to coordinate conformity assessment activities. This Circular replaces OMB Circular No. A-119, dated October 20, 1993.

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But what is a Voluntary Consensus Standard Body (VCSB)?

- A VCSB operates according to:
  - Openness
  - Balance of Interest
  - Due Process
  - Appeals Process
  - Consensus

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VCSB methods are the only way, other than EPA developing a method, to get new methods into regulation. Do you have a say?

VCSB's include:

1. Standard Methods
2. ASTM
3. AOAC

TABLE IB - LIST OF APPROVED INORGANIC TEST PROCEDURES

Parameter	Methodology [58]	EPA [57]	Standard methods	ASTM	USGS/AOAC/other
1. Acidity, as CaCO3, mg/L	Electrometric endpoint or phenolphthalein endpoint		2310 B-2011	D1067-11	I-1030-85. [2]
2. Alkalinity, as CaCO3, mg/L	Electrometric or Colorimetric titration to pH 4.5, Manual		2320 B-2011	D1067-11	973.43, [3] I-1030-85. [2]
	Automatic	310.2 (Rev. 1974) [1]			I-2030-85. [2]
3. Aluminum - Total, [4] mg/L	Digestion, [4] followed by any of the following:				
	AA direct aspiration [36]		3111 D-2011 or 3111 E-2011		I-3051-85. [2]
	AA furnace		3113 B-2010.		
	STGFAA	200.9, Rev. 2.2 (1994)			
	ICP/AES [36]	200.5, Rev 4.2 (2003); [68] 200.7, Rev. 4.4 (1994)	3120 B-2011	D1976-12	I-4471-97. [50]

Incorporation by reference is used primarily to make privately developed technical standards Federally enforceable

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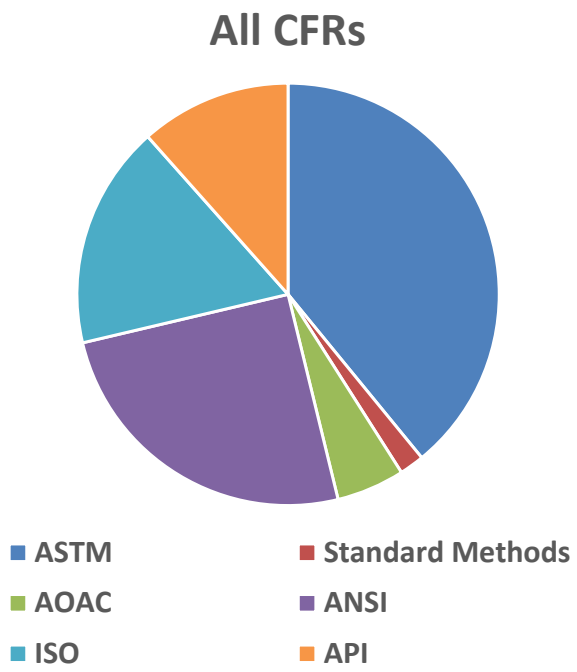
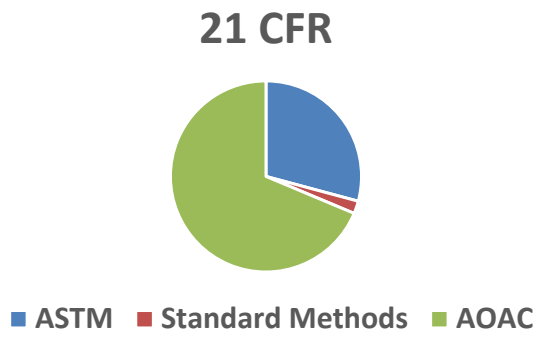
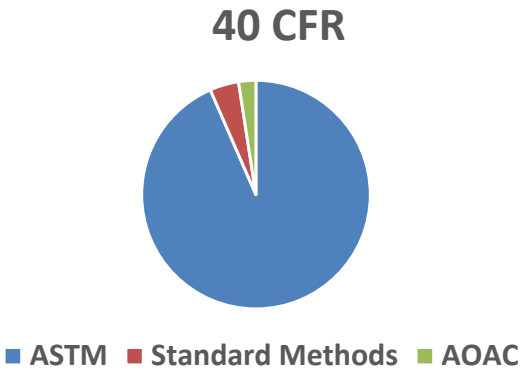
Many people do not realize that there are thousands of VCSBs incorporated in Federal Regulations







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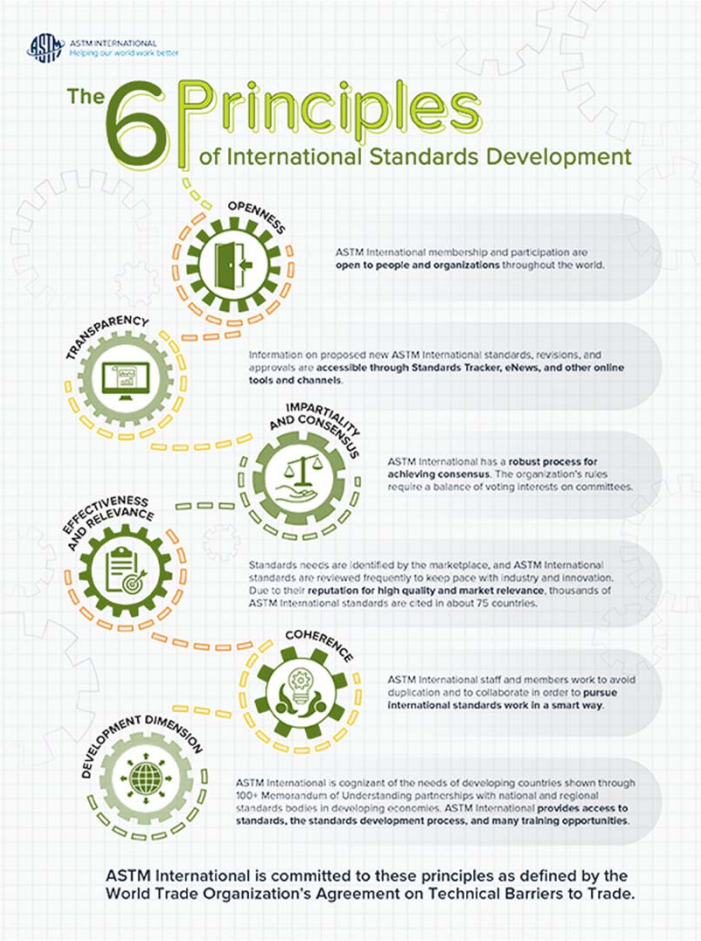
The World Trade Organization (WTO) adopted a set of principles to which VCSBs (SDO) must comply to be considered International Standards



- Openness
- Transparency
- Impartiality and Consensus
- Effectiveness and Relevance
- Coherence
- Development Dimension

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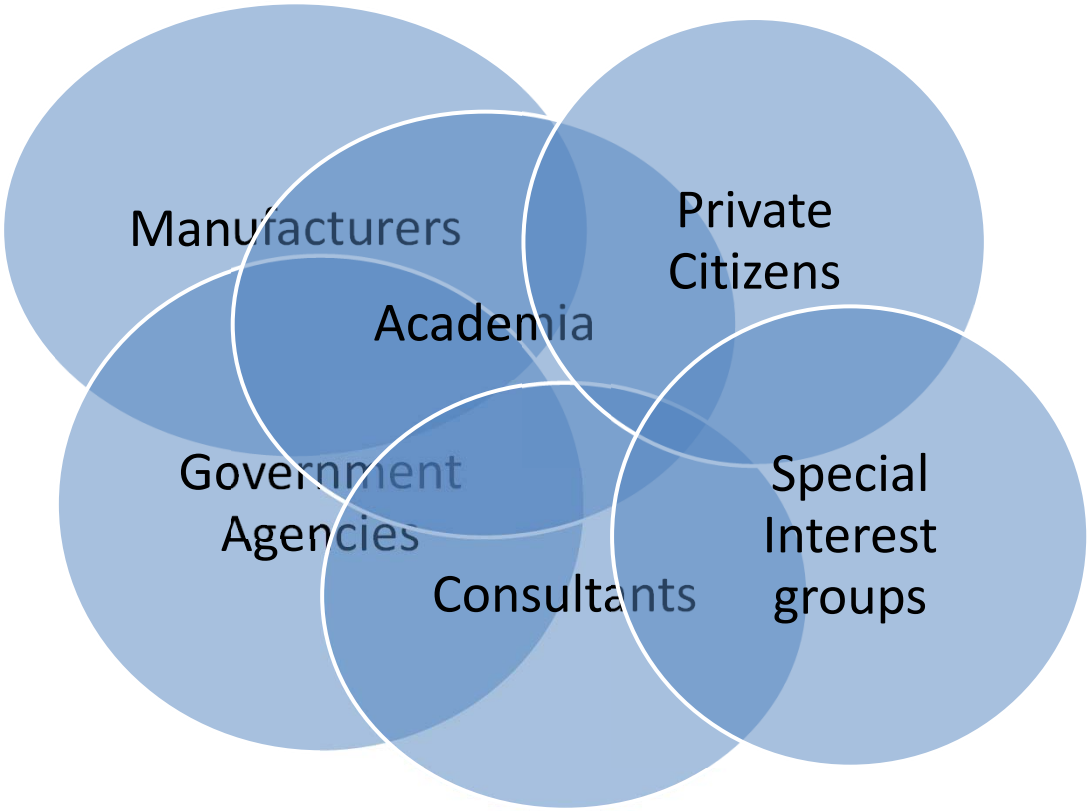
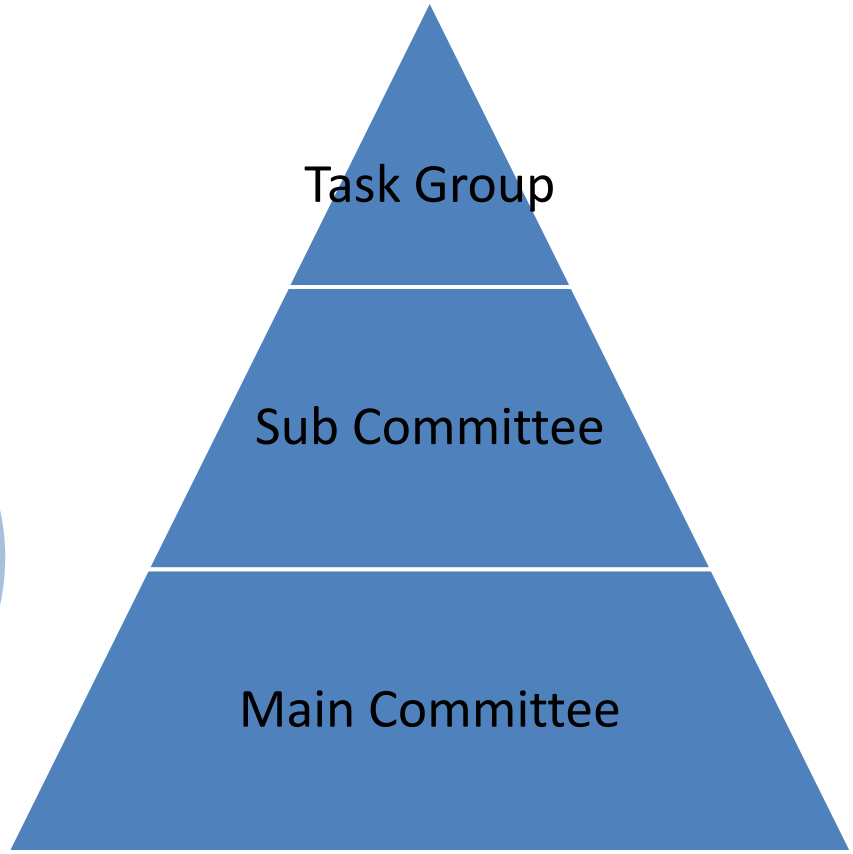
Openness means everyone is involved and guarantees participation to those who are directly or indirectly affected





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Transparency – all information under consideration and final results are easily accessible during method development to all interested parties

Proposals for new standards are readily available

Activity made public

Anyone may participate

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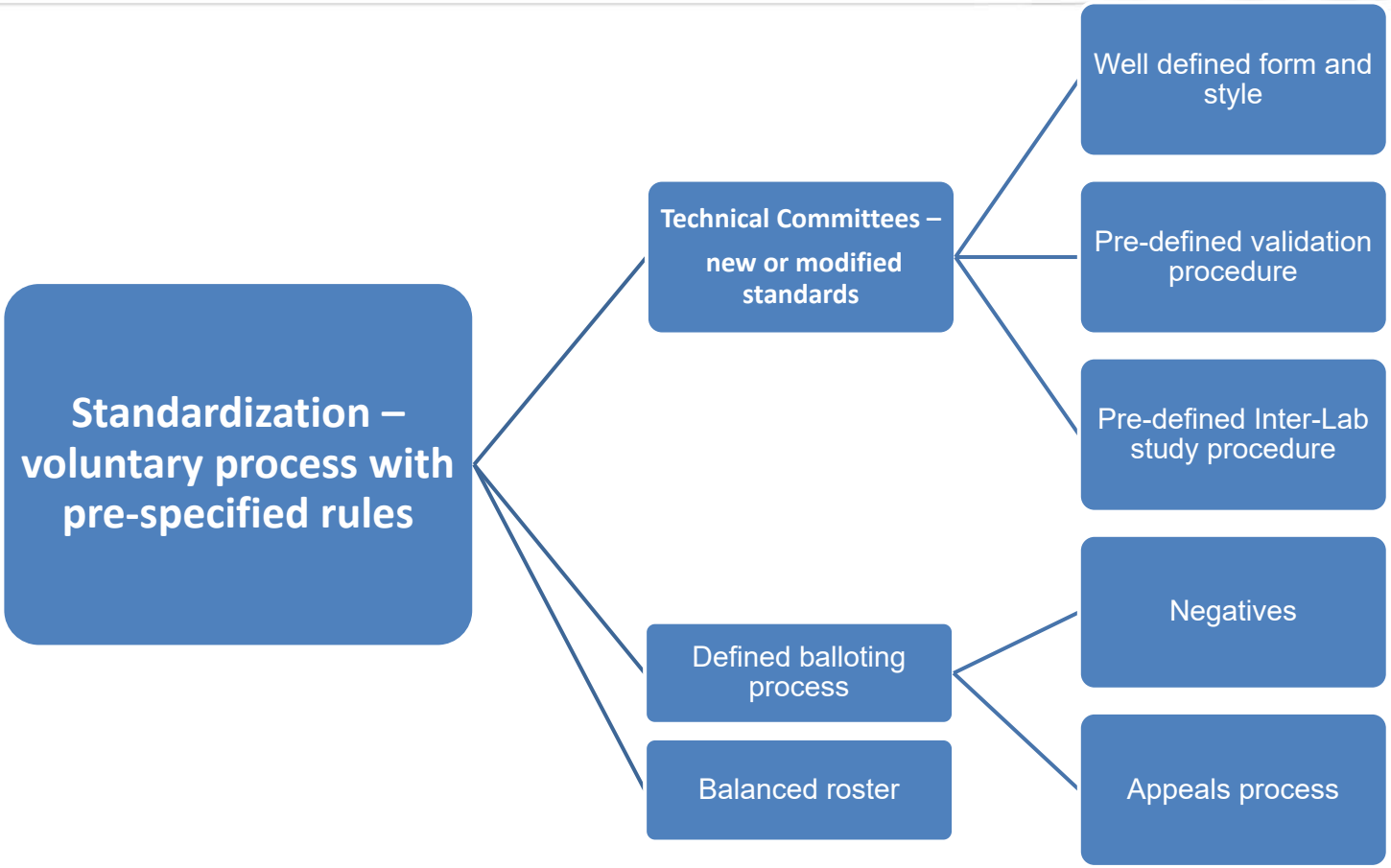
Impartiality and Consensus – no privileges to any one group



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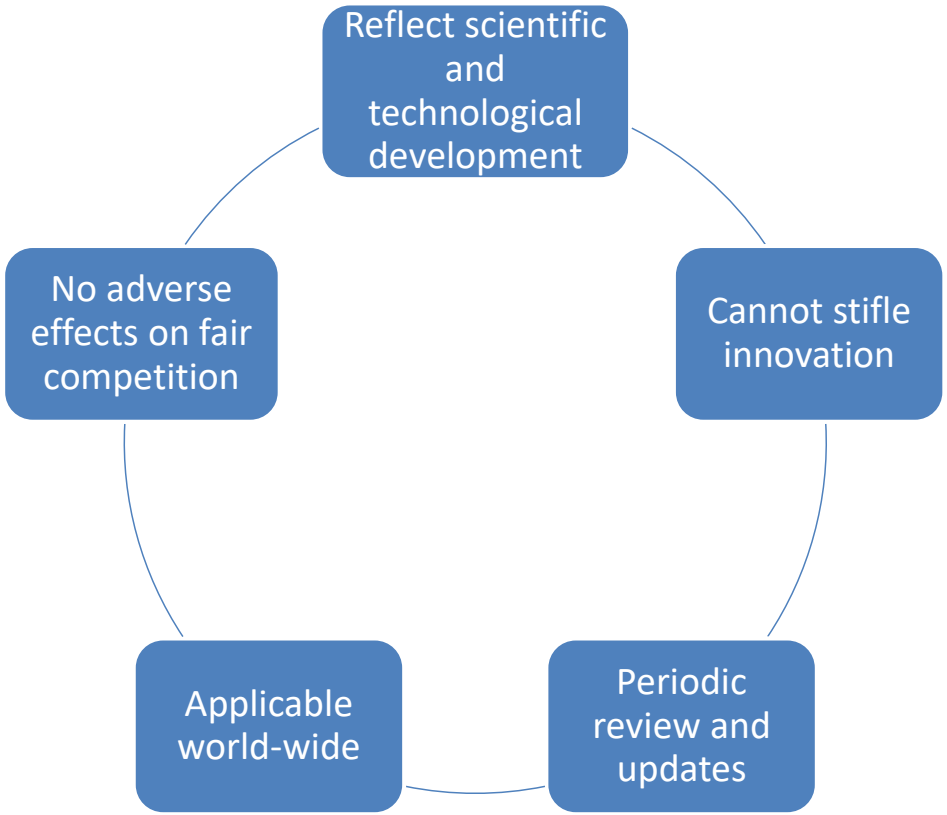
Standards are developed to respond to regulatory and market needs



Many designed to meet UN sustainability goals

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Coherence means SDOs avoid duplication, overlap, or collaborate with other SDOs

- Collaborate with other committees within the SDO
- Collaborate with other SDOs
  - Formal liaisons and written agreements

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SDO's work with developing countries and share expertise, ensuring they have availability to new standards

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A brief description of Standard Methods for the Examination of Water and Wastewater method development process

- Part 1000 Quality Assurance
- Part 2000 Physical and Aggregate Properties
- Part 3000 Metals
- Part 4000 Inorganic Nonmetallic Constituents
- Part 5000 Aggregate Organic Constituents
- Part 6000 Individual Organic Compounds
- Part 7000 Radioactivity
- Part 8000 Toxicity
- Part 9000 Microbiological Examination
- Part 10000 Biological Examination

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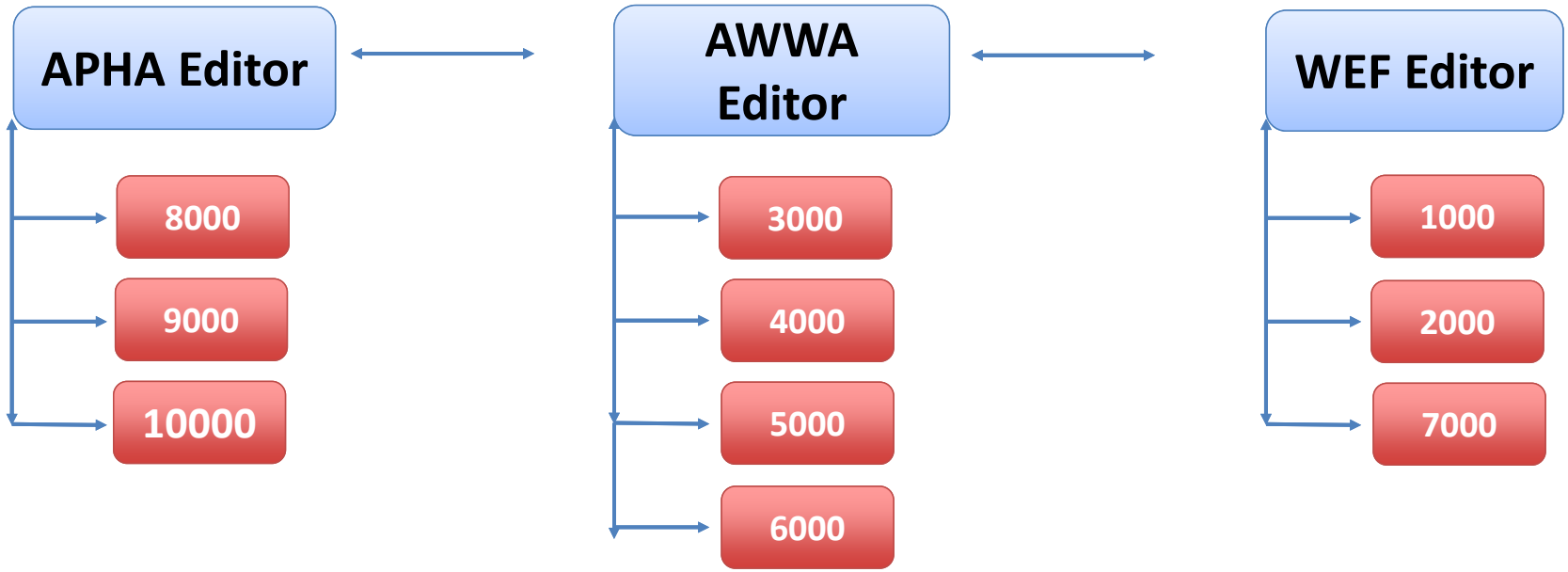
The Standard Methods Organization

American Public Health Association (APHA)

American Water Works Association (AWWA)

Water Environment Federation (WEF)



Standard Methods Manager acts as secretary to the JEB and a Managing Editor.

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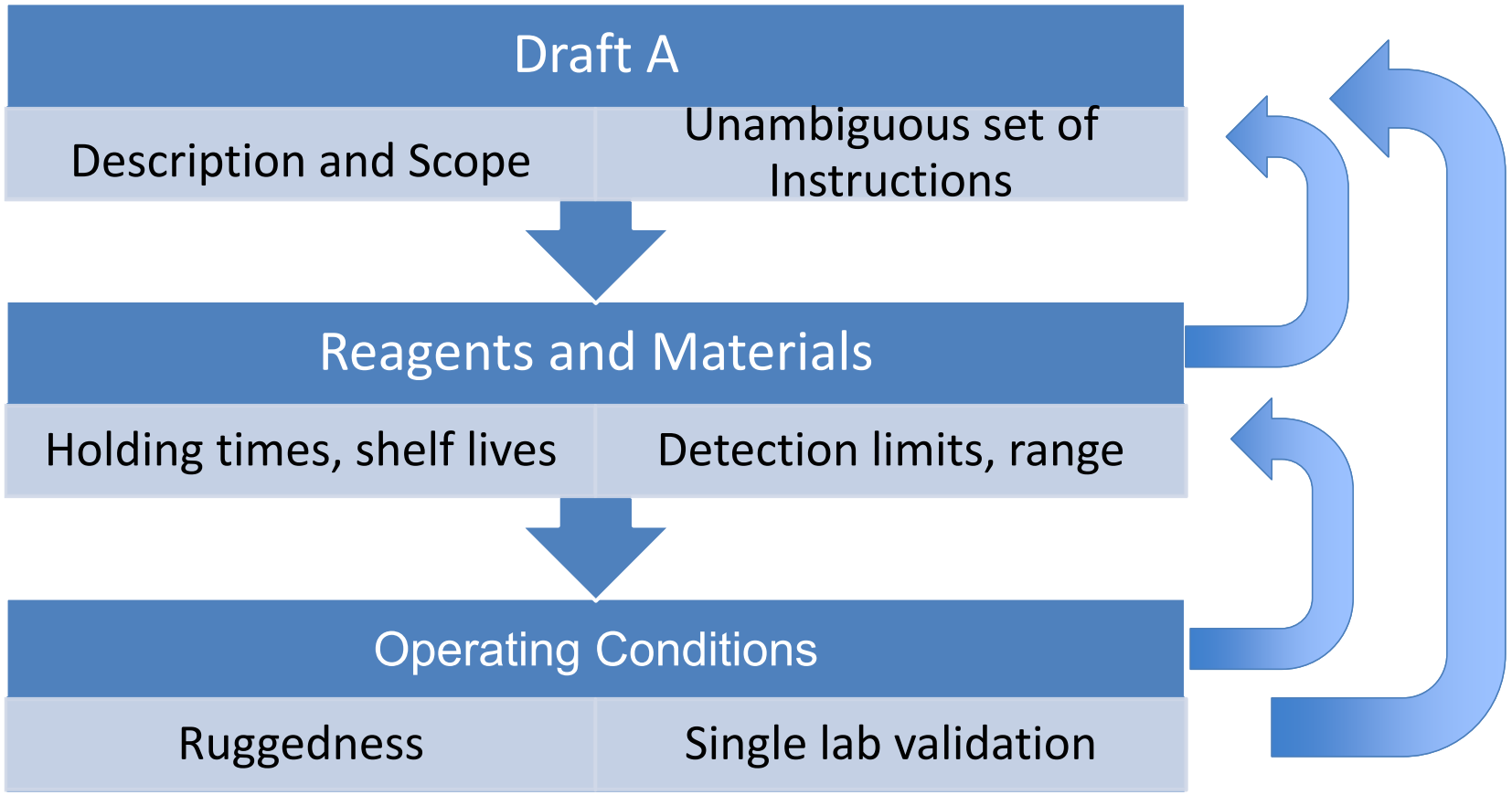
The JTG develops a method and writes Draft A



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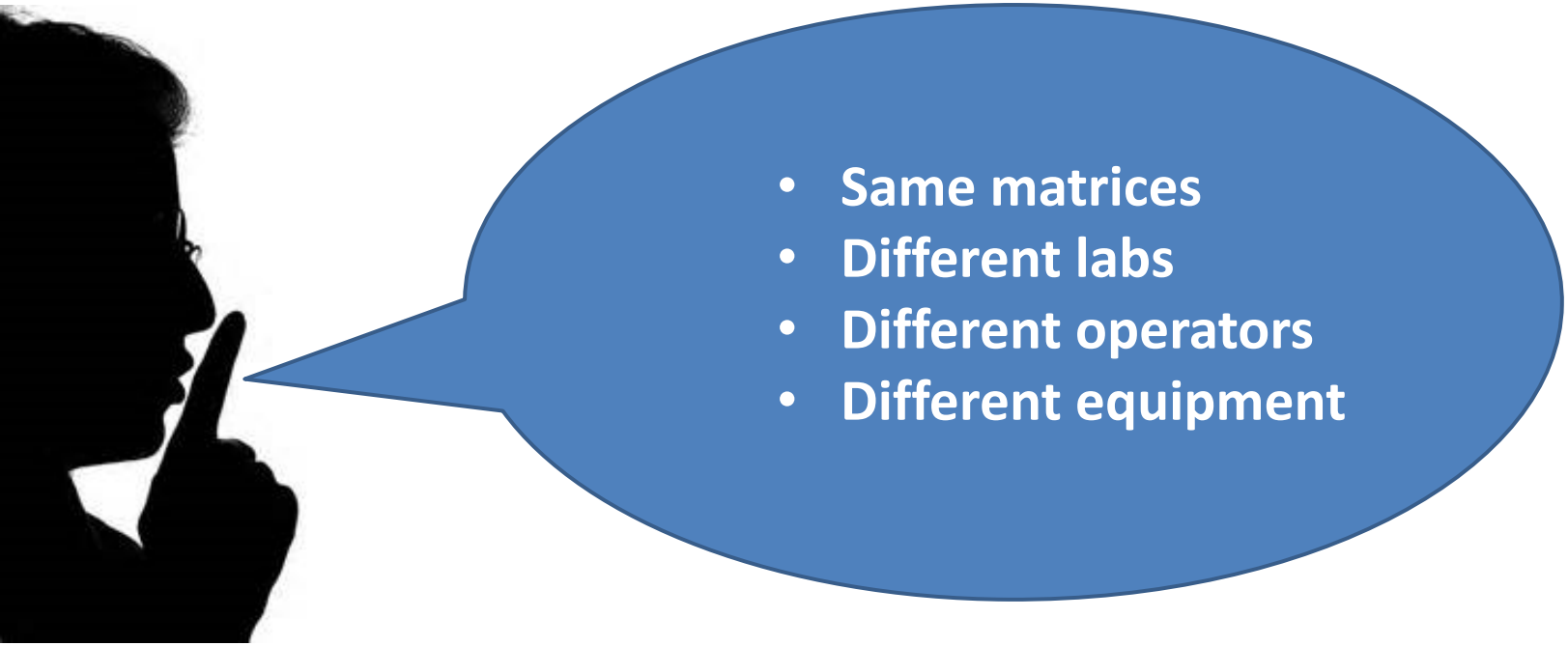
The multiple lab study is described in SM 1040 B, and is similar to AOAC, ISO and ASTM procedures.



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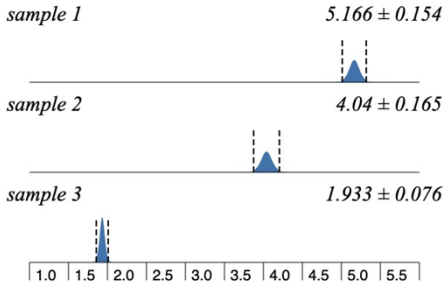
The main purpose of the collaborative study is to confirm the method is "transferable" and provide between lab variability

At least three labs

Different Apparatus

Three or more matrices

Three or more concentrations



Example = 5 labs, 4 concentrations in triplicate

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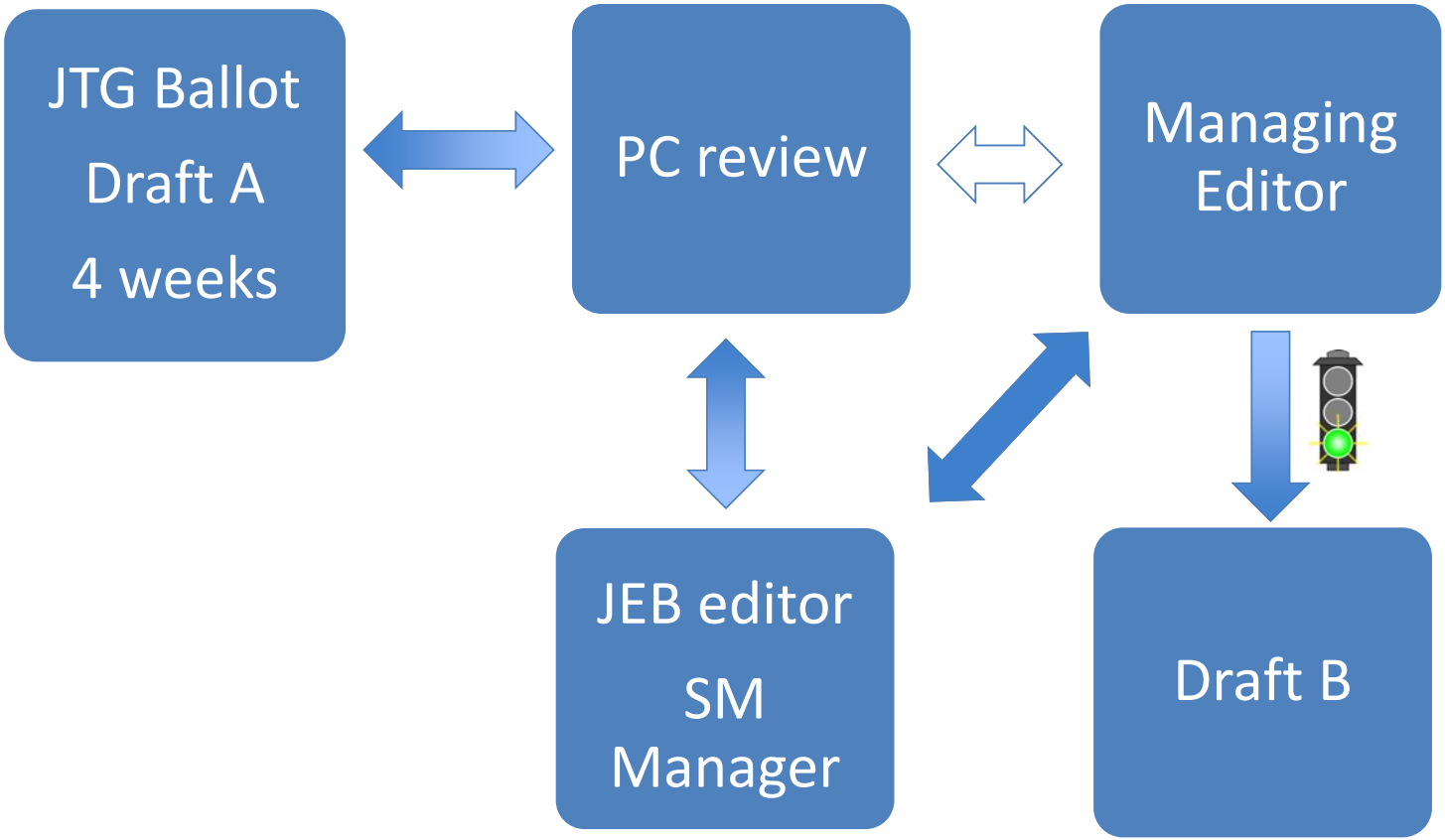
JTG Draft balloted and then passed through the PC to the JEB editor



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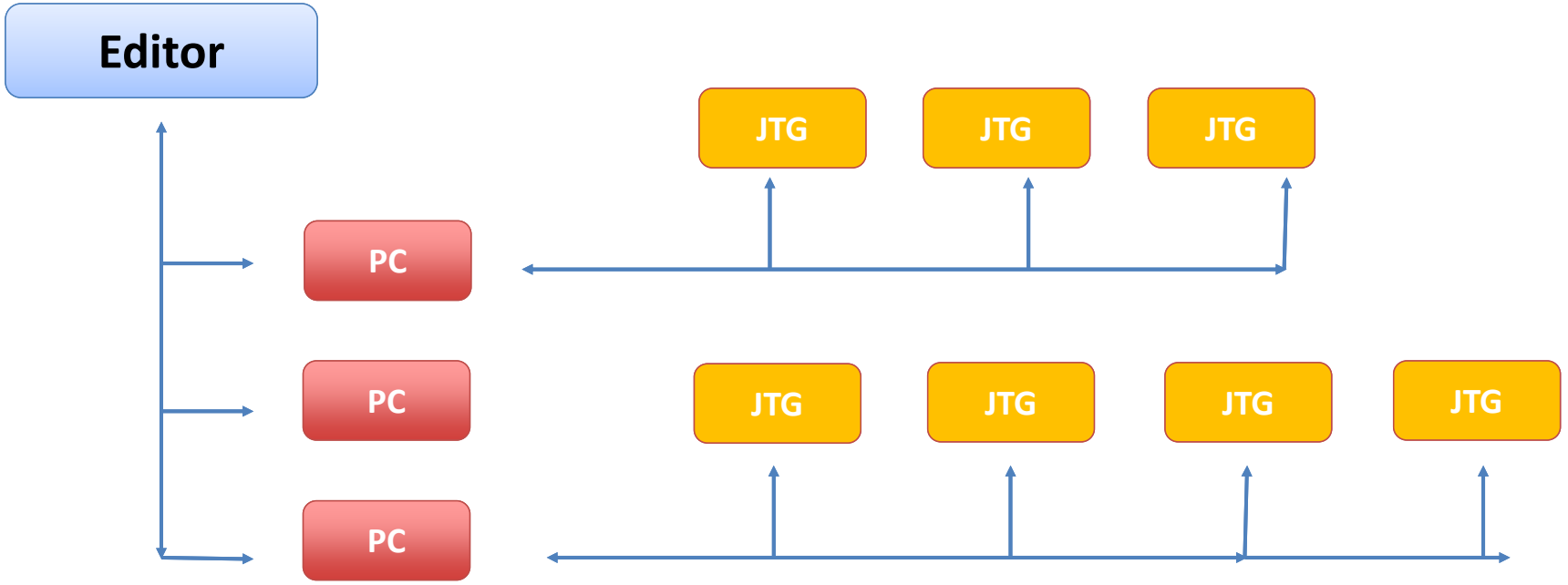
There may have numerous JTGs at the same time, in various stages of completion



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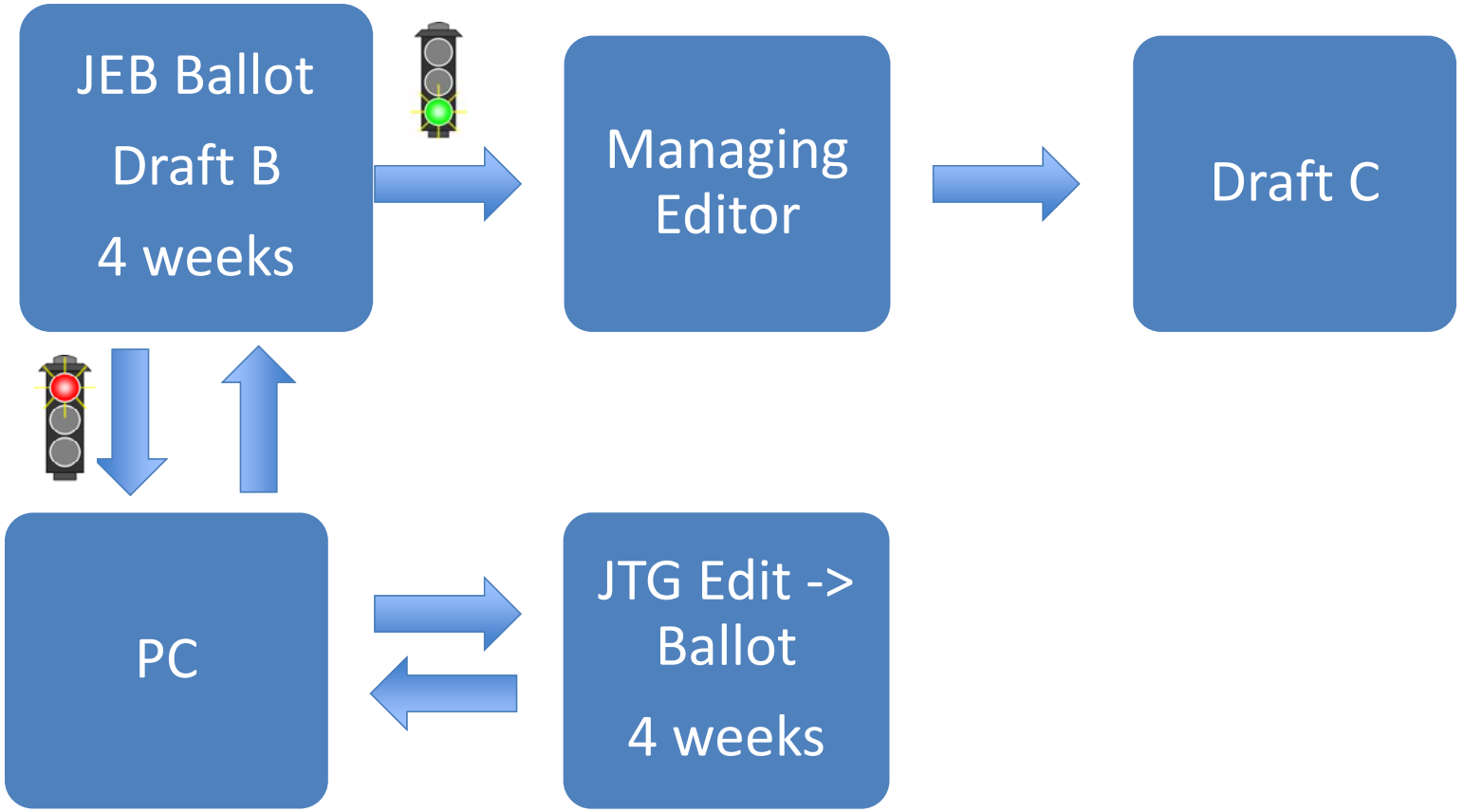
The JEB votes on Draft B



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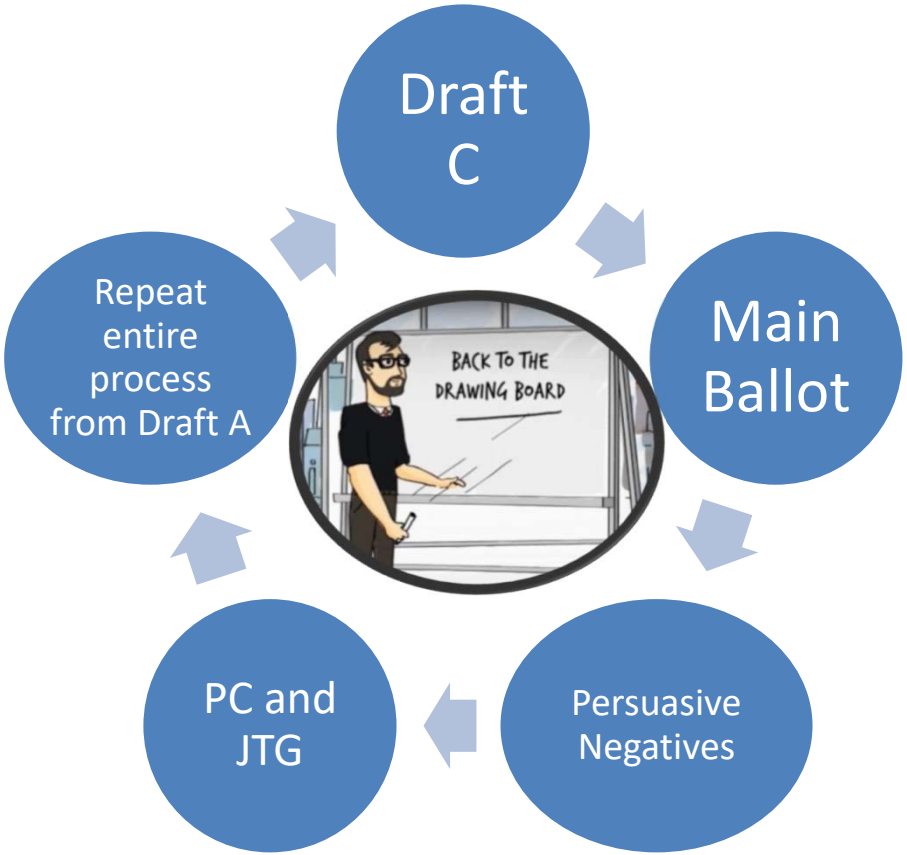
Draft C is then balloted at the main Committee, negatives go back to PC and JTG



- **Negatives must have a comment**
- **All negatives addressed**
- **Persuasive negatives**
- **May re-ballot with just negatives**

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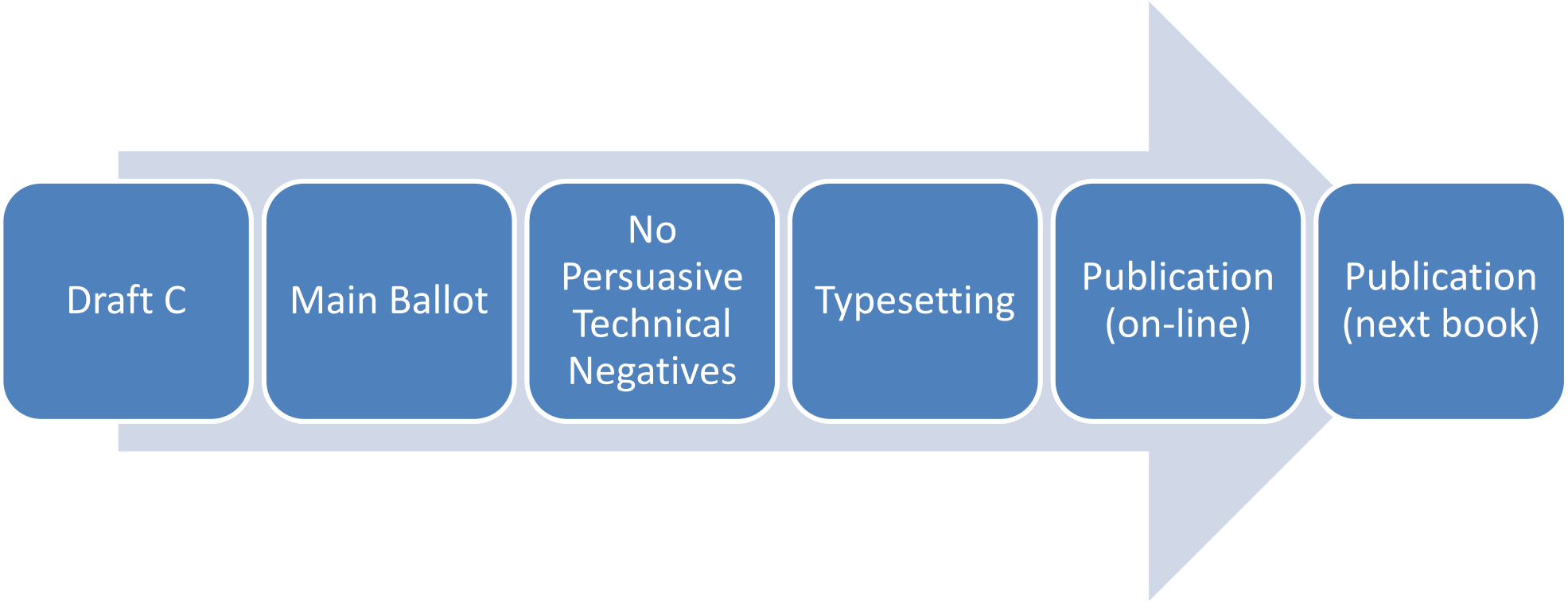
A Draft C ballot with no technical negatives is considered complete



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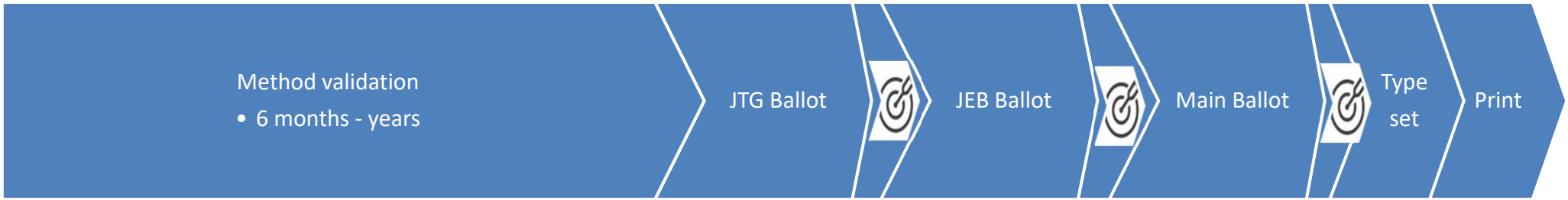
Example of the timeline – method development is a detailed process explaining why details matters

Depending on complexity of method, and motivation of task group, a new method could take years



Any Questions?

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