

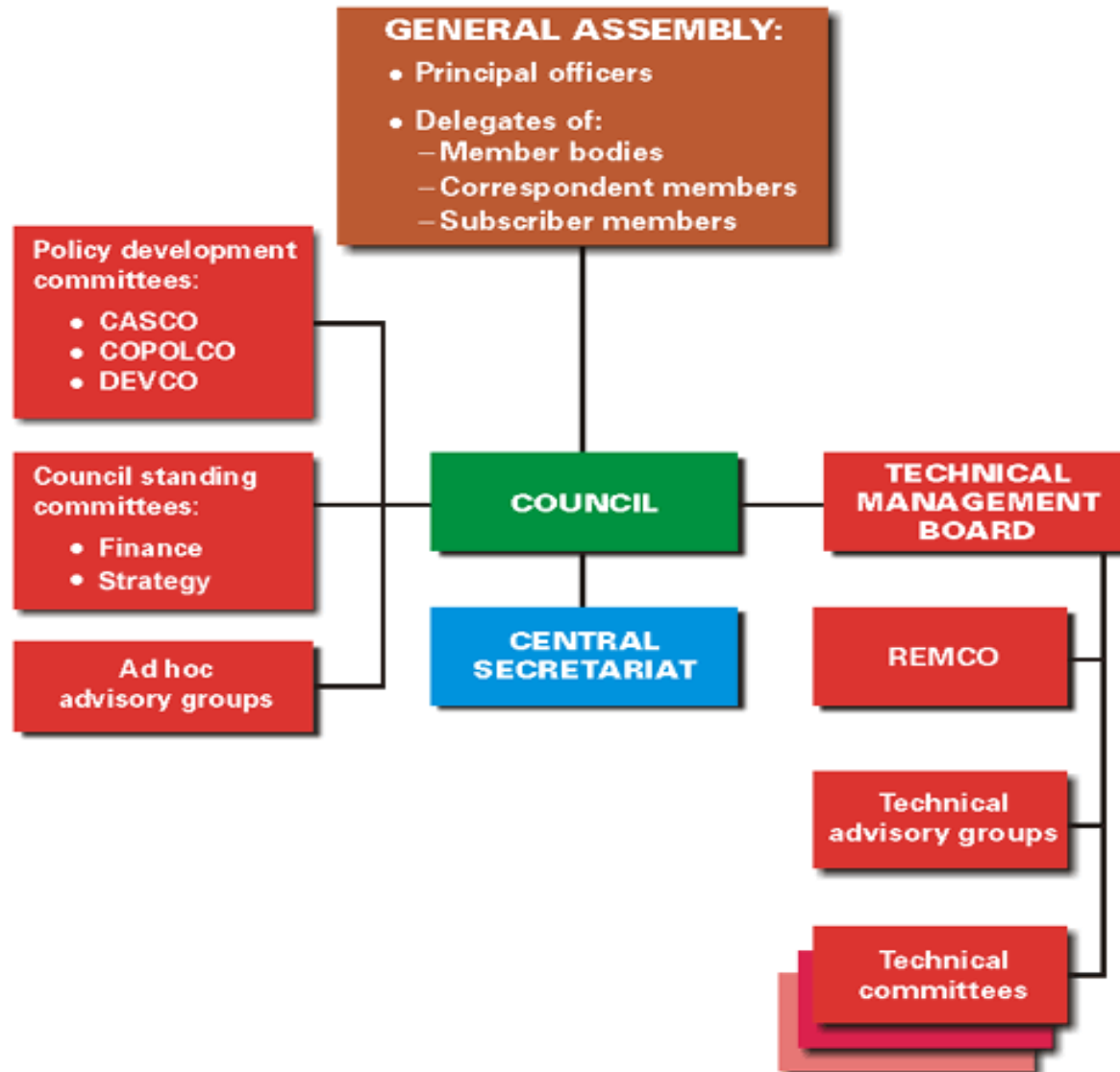
# WELCOME to the ISO World

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# About ISO

- ISO (International Organization for Standardization) is the world's **largest developer** and publisher of **International Standards**.
- ISO is a **network** of the national standards institutes of **162 countries**, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.
- ISO is a **non-governmental organization** that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.
- Therefore, ISO enables a **consensus** to be reached on solutions that meet both the requirements of business and **the broader needs of society**.

# ISO STRUCTURE



# ISO Organization

- CASCO (Conformity Assessment Committee)
- COPOLCO (Consumer Policy Committee)
- DEVCO (Committee on Developing Country Matters)
- REMCO (Committee on Reference Materials)

# CASCO Membership

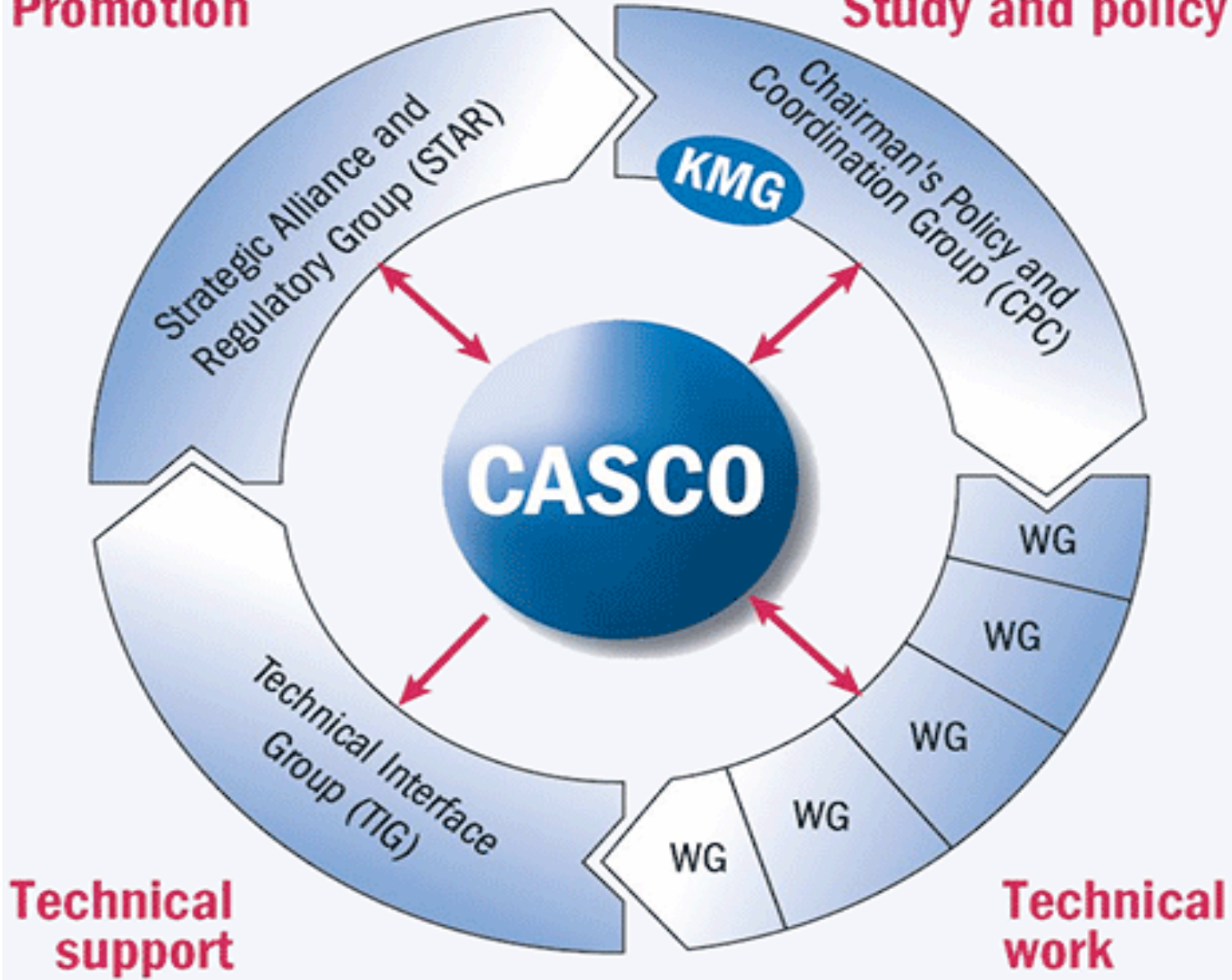
- P = Participation membership
  - ANSI is the P member for the United States on ISO CASCO
- O = Observer membership
- CASCO Liaisons
  - A (Organizations that work with technical committee or subcommittees)
  - D (Organizations that make technical contributions to working groups, maintenance teams, or project team)

# CASCO Policy Groups

- CPC = CASCO Chairman's Policy & Coordination Group
  - Ileana Martinez (NIST) represents the United States in this group
- STAR = CASCO Strategic Alliance & Regulatory Group
- TIG = CASCO Technical Interface Group
  - Carl Kircher (The NELAC Institute) represents the United States in this group

**Promotion**

**Study and policy**

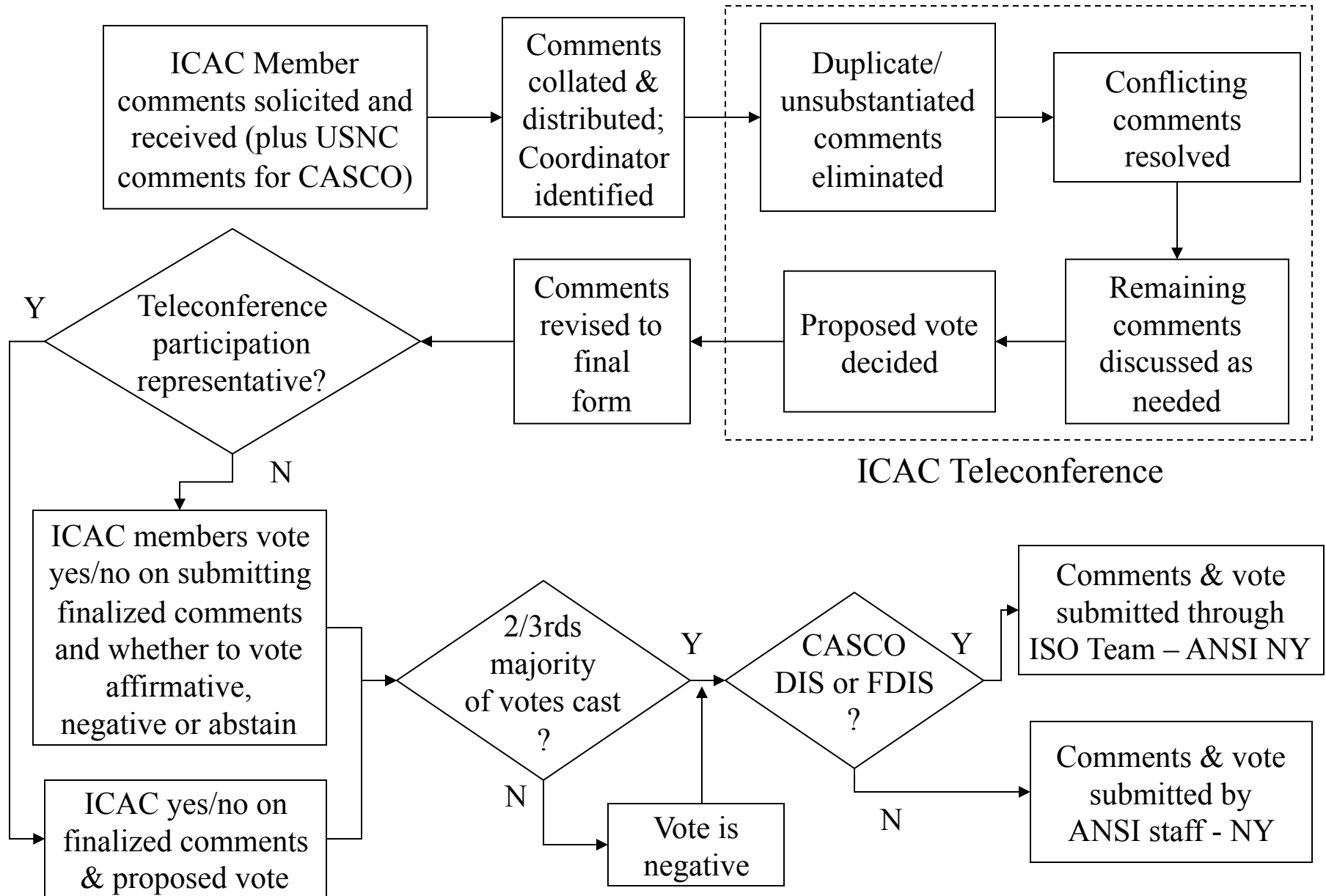


# Some Important Terminology

- ISO = International Organization for Standardization
- IEC = International Electrotechnical Commission
  - IEC has a CAB (Conformity Assessment Board), which corresponds to CASCO in ISO
- WG = Work Group
  - where CASCO's technical work is principally accomplished
- TC = Technical Committee
- SC = Subcommittee
- AB = Accreditation Body
- CB = Certification Body
- CAB = Conformity Assessment Body
- NMC = National Mirror Committee
  - ANSI ICAC (International Conformity Assessment Committee) is the NMC for the United States

# ANSI ICAC Process

ICAC 10-013  
11 Feb 2010



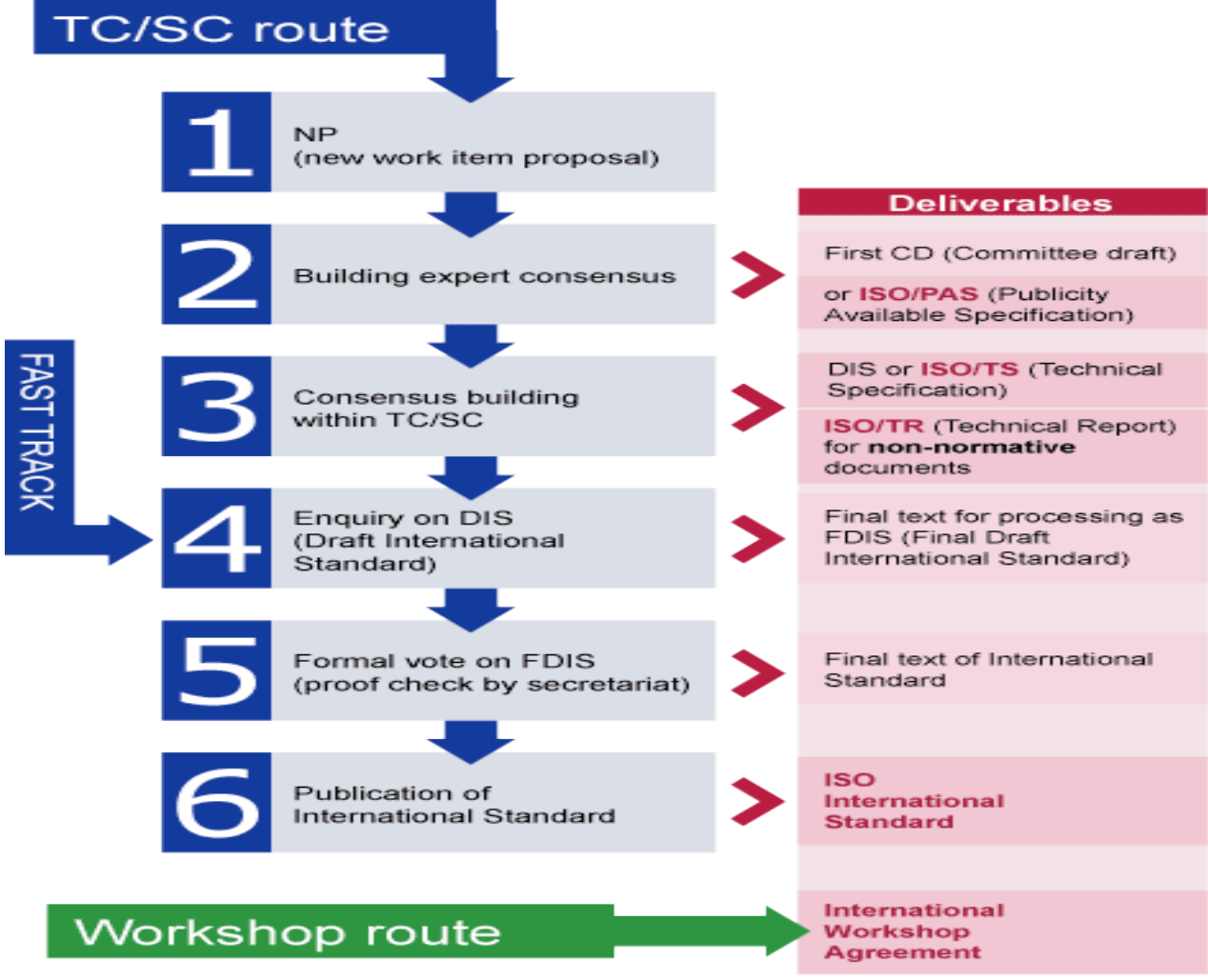
# Important ISO Standards

- ISO 9000-series (Quality Management Systems)
- ISO 14000-series (Environmental Management Systems)
- ISO 17000-series (Conformity Assessment Standards)
- ISO 22000-series (Food Safety Management Systems)
- ISO 27000-series (Information Technology Security Techniques)

# CASCO Toolbox

- Vocabulary, Principles, & Common Elements of Conformity Assessment
  - ISO/IEC 17000 & ISO PAS 17001-17007
- Code of good practice (ISO Guide 60)
- Testing and Calibration (ISO 17025 & 17043)
- Inspection (ISO 17020)
- Supplier's declaration of conformity (ISO 17050)
- Product Certification (ISO Guides 23, 28, 53, 65, 67; to become ISO 17065 & 17067)
- Peer Assessment (ISO 17040)
- Mutual Recognition Arrangements (ISO Guide 68)
- Accreditation (ISO 17011)
- Marks of Conformity (ISO 17030)
- System Certification (ISO 17021)
- Certification of Persons (ISO 17024)

# How to Make an ISO Standard



# More Terminology

- NWIP = New Work Item Proposal
- WD = Working Draft
- CD = Committee Draft
- DIS = Draft International Standard (ISO)
- FDIS = Final Draft International Standard
- Publication stage (ISO/IEC standard)

# ISO Neutrality Policy

- ISO/CASCO has a neutral policy with regard to the application of standards by 1st, 2nd, or 3rd parties
- There have been exceptions to this policy (financial planners)
- The application of 1st, 2nd, or 3rd party should be decided on by the client (regulator) based on a risk assessment and associated costs and benefits.
- 3rd party (certification) often is associated with significant risk
- 3rd party can be required by technical regulation (mandatory certification) or can be voluntary.
- Regulator can also require use of accredited facilities (laboratories and certification bodies)
- CASCO sets the basis consensus requirements, but the regulator can then add to these should the circumstances require it.
- Objective of CASCO is to ensure that wherever Conformity Assessment is used, it is used and applied in a consistent manner and the rules are the same.

# CASCO Internal Liaisons

- TC34 (Food Products)
- TC46/SC 11 (Archives / Record Management)
- TC69 (Application of Statistical Methods)
- TC85 (Nuclear Energy)
- TC176 (Quality Management & Quality Assurance)
- TC207 (Environmental Management)
- TC212 (Clinical Lab. Testing & In Vitro Diagnostic Test Systems)
- TC242 (Energy Management)
- TC243 (Consumer Product Safety)
- TC248 (Sustainability Criteria for Bio-energy)

# Some Important CASCO External Liaisons

- IAF (International Accreditation Forum)
- ILAC (International Laboratory Accreditation Cooperation)
  - IAF/ILAC/ISO MoU (Memorandum of Understanding)
  - IAF-ILAC-ISO JWG (Joint Working Group)
- UNFCCC (United Nations Framework Convention on Climate Change)

# CASCO Current Activities

- ISO Strategic Plan 2011-2015
  - CASCO Balanced Scorecard
    - Customer quadrant
    - Financial quadrant
    - Process quadrant
    - Learning & Growth quadrant
- CPC Composition
- CASCO Satisfaction Surveys
- CASCO Communication strategy
- CASCO systematic review of standards
  - ISO 17011 & 17043 up for review in 2013
  - ISO 17025 up for review in 2015
- CASCO Interpretation Process
- CASCO Workshops on special topics (e.g., risk assessment)

# Now... Some TNI Standards Applications

- Get the TNI Standards &  
**READ THEM ---**

**CAREFULLY !!!!!!!!!!!!!!!**

# True or False?

- Second-sources are no longer needed for Chemistry analyses.

# FALSE!

- Even though no longer needed for IDOC, second-source standard is still needed anytime an initial instrument calibration is performed (TNI V1M4, 1.7.1.1(d)).
  - Depending on the lab. written procedures, second-source standard may be needed for titration methods (one source for the LCS for batch acceptance, and the other source to verify the titrant normality)

# TRUE OR FALSE?

- If the sample source is not suspected to contain chlorine, then Microbiology samples no longer need to be checked for the absence of chlorine at the laboratory.

# FALSE!

- All samples must be checked for the absence of chlorine until the sample site has a “demonstrated history of acceptable preservation,” then Microbiology samples from that source are checked for the absence of chlorine on one sample per month (TNI V1M5, 1.7.5(b))
  - Samples from new clients or new sources are considered “unknown sources” where chlorine usage is suspected.
  - The laboratory must show that the received sample containers are from its laboratory.

# TRUE OR FALSE?

- In a membrane filtration series of fewer than 10 samples, only one beginning and one ending method blank are required, even though the filtration series may include multiple filtration units.

# True!

- TNI V1M5, 1.7.3.1(a)(i)
- NOTE: For laboratory-sterilized funnels, a sterility check is required on one funnel per sterilization batch.

# TRUE OR FALSE?

- A NELAC-specified certification statement is no longer necessary to document each initial demonstration of capability.

# True, BUT ...

- The following information must be readily available for each affected employee:
  - Analyst(s) involved in preparation and/or analysis
  - Matrix
  - Analyte(s), Class of Analyte(s), or Measured Parameter(s)
  - Identification of the Test Method(s) performed
  - Identification of the laboratory-specific SOP used for analysis, including Revision Number
  - Date(s) of Analysis
  - Summary of Analyses

# True or False?

- If a CCV fails the first time, corrective action is performed, and the CCV passes the second time, then you can proceed to analyze the samples.

# FALSE!

- TWO consecutive CCV's are required after corrective actions, and BOTH attempts must pass (otherwise instrument must be recalibrated).
  - TNI V1M4, 1.7.2(e)

# True or False?

- If the pH meter is calibrated with pH 4 & 7 or with pH 7 & 10 standard buffers, that is good enough.

- True!
  - IF the pH meter is being used as support equipment (e.g., check Microbiology media, sample pH adjustments)
- False!
  - If the pH meter is a measurement & test equipment (e.g., for SM 4500H+ B), THREE standards minimum are needed (TNI V1M4, 1.7.1.1(j))
- Questions!
  - For other tests, does the CB or blank count as one of the standards?
  - Do I need a second-source ICV if each calibration standard is from a different lot?

# Remember the Hierarchy

- Minimum requirements
  - Laboratory quality system
  - The NELAC Institute's standards
  - Test Method requirements & specifications
  - Regulatory requirements from US EPA & FL-DEP
  - **CLIENTS!!**
- Most stringent requirements

# The NELAC Institute (TNI) is a Conformity Assessment System

- If you are dues-paying members of TNI, then you are the Scheme Owners of the following Accreditation Schemes:
  - TNI National Environmental Laboratory Accreditation Program (NELAP)
  - TNI Proficiency Testing Program (includes accredited PTP's & PTPA's)
  - TNI Stationary Source Audit Sample Program (SSAS)
  - TNI National Environmental Field Activities Program (NEFAP)
- WELCOME TO THE ISO WORLD !!