National Commission on Forensic Science
http://www.justice.gov/ncfs
NCFS Meeting 5
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Standards Training & Discussion

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National Institute of Standards and Technology
Standards Coordination Office

Introduction to this Panel

- Acting NIST Director Willie May offered NIST support for explaining standards further to the Commission at the last meeting (October 29, 2014) following questions raised
- A request for topics to cover was made on November 12, 2014 to Commissioners
- **Based on responses received, the following material was put together by NIST**
- This material was originally planned for a webinar but Commission leadership felt the topics were important enough to cover as part of this meeting
  - especially given the **Draft Recommendation on Universal Accreditation** being brought by the Subcommittee on Accreditation and Proficiency Testing

Acknowledgments and Disclaimer

- Slides prepared by John Butler and the presenters

- Input on information to cover:
  - Cecelia Crouse, Ted Hunt, Pam King, Marc LeBeau, Peter Neufeld, Linda Jackson, Patricia Manzolillo, Robin Jones, Willie May

Points of view in this presentation are those of the presenters and do not necessarily represent the official position or policies of the U.S. Department of Justice or the National Institute of Standards and Technology. Certain commercial equipment, instruments, and materials are identified in order to specify experimental procedures as completely as possible. In no case does such identification imply a recommendation or endorsement by the National Institute of Standards and Technology, nor does it imply that any of the materials, instruments, or equipment identified are necessarily the best available for the purpose.

NIST Efforts in Forensic Science
Measurement Standards & Research

Current Programs and Research Focus Areas:

1. DNA
2. Digital (computer) Forensics
3. Ballistics & Toolmarks
4. Statistical Interpretation

- **Forensics@NIST 2014** meeting was held December 3-4 with >50 presentations (including the keynote address by Judge Jed Rakoff)
  - See http://www.nist.gov/forensics/forensics-at-nist-2014.cfm

Presentation Overview

- Gordon
  - Standards, Federal Policy, SDOs
  - International Standards for Conformity Assessment and Accreditation
- Warren
  - ISO/IEC 17025 overview and requirements
  - Laboratory accreditation process
- Karen
  - OSAC plans for standards and guidelines
  - Role of Code of Practice

Six ISO standards will be passed around during the presentations for Commissioners to view

Time after presentations for Questions and Discussion (~1 hour)

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Part of NIST Planning Team designing OSAC

NIST Standards Coordination Office

- Mission: SCO provides U.S. stakeholders with standards and conformity assessment tools, information and solutions to stimulate innovation, foster competitiveness, and support government objectives

- SCO insight has shaped standards and conformity assessment in critical areas such as homeland security, electronic health records, cloud computing and consumer product safety

Types of Standards

physical (measurement) standards

Certified reference material to aid with calibration of measurements

documentary (technical) standards

INTERNATIONAL STANDARD

ISO/IEC 17025

Second edition
2005-05-15

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Specific requirements for the operation of a laboratory related to management system and competence

Federal Standards Policy

- The National Technology Transfer and Advancement Act, and
- Office of Management and Budget Circular A119:
  - Establishes a preference for federal agency use of voluntary consensus standards over government standards
  - Encourages federal participation in standards development
  - Authorizes the National Institute of Standards and Technology to coordinate conformity assessment activities of the agencies working with state and local government and the private sector

http://www.whitehouse.gov/omb/circulars_a119/

Voluntary Consensus Standards Process Attributes

(i) Openness
(ii) Balance of interest
(iii) Due process
(iv) An appeals process
(v) Consensus *

* general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

Standard Developing Organizations (SDOs)

- **International Standards Organizations**
  - ISO (International Organization for Standardization) – founded 1947
  - IEC (International Electrotechnical Commission) – founded 1906
  - ITU (International Telecommunication Union) – founded 1865

- **ANSI** (American National Standards Institute) – founded in 1918
  - Coordinator of U.S. private sector led standards system
  - Organizes U.S. representation to ISO and IEC
  - Publishes *Essential Requirements for Due Process*
  - Operates a voluntary program to provide confidence that standards are developed via a consensus process

- Hundreds of SDOs exist in the U.S. producing thousands of standards in many diverse areas

Example of SDOs with Efforts Intersecting the Forensic Sciences

Standards Developing Organization (SDO)	Activities in Forensic Science
ASTM International http://www.astm.org/COMMITTEE/E30.htm	Formed Committee E30 on Forensic Sciences in 1970; currently 685 members from 15 countries; 51 standards developed so far (each updated every five years); meets in Feb each year in conjunction with AAFS meeting
American Dental Association (ADA) http://www.ada.org	ANSI/ADA Standard No. 1058 for Forensic Dental Data Set – ADA 1058-2010D ($98); dental XML data transmission standard that is used in disaster victim identification efforts

ASTM INTERNATIONAL
Helping our world work better

ADA American Dental Association®
America's leading advocate for oral health

Types of Conformity Assessment and ISO/IEC Standards

- Supplier's Declaration of Conformity (SDoC)
- Inspection
- Personnel Certification
- Laboratory Testing
- Certification
- Registration
- Accreditation

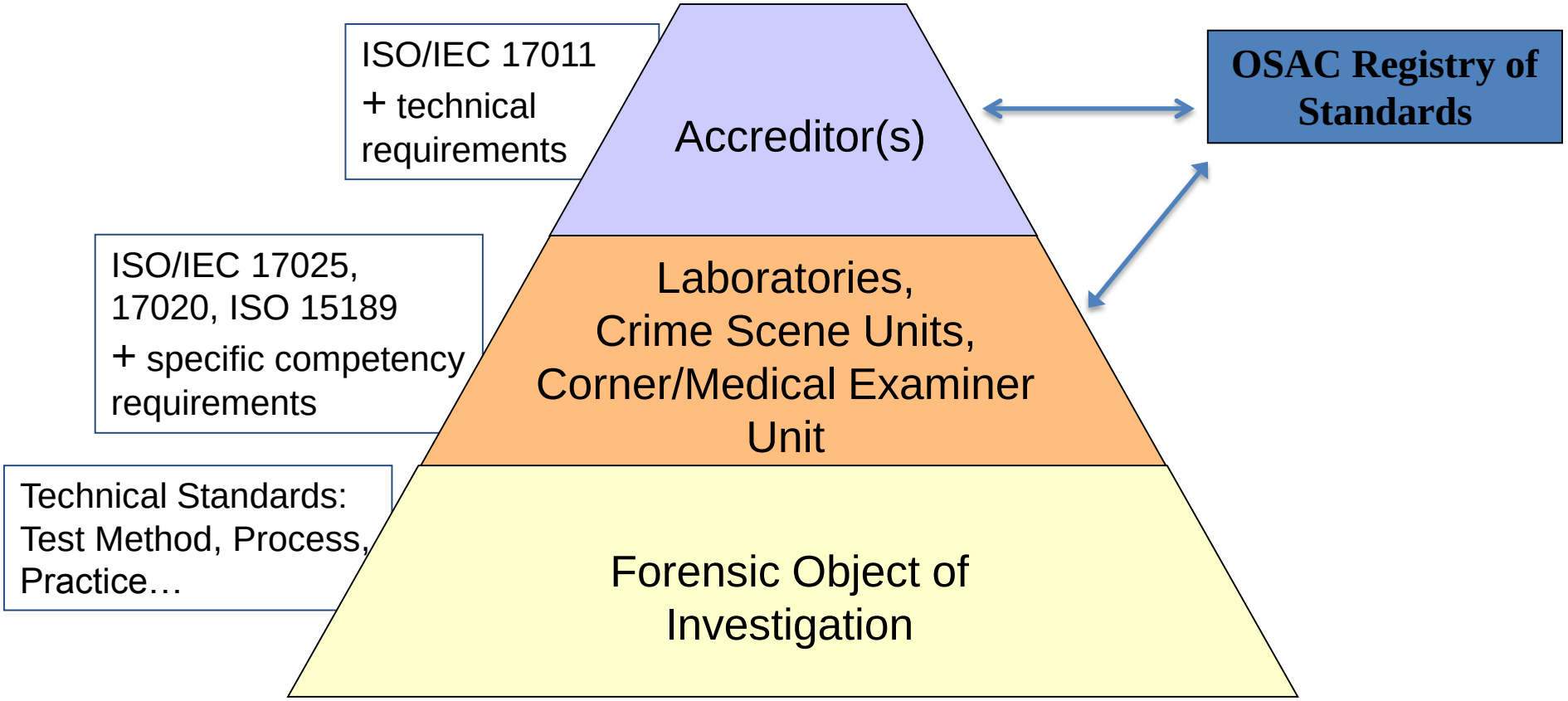
- ISO/IEC 17050 parts 1 and 2
- ISO/IEC 17020
- ISO/IEC 17024
- ISO/IEC 17025
- ISO/IEC 17065
- ISO/IEC 17021
- ISO/IEC 17011

Primary conformity assessment standards of interest to the forensic science industry

ISO/IEC Standard*	Title of Standard
15189:2012	Medical laboratories -- Requirements for quality and competence
17011:2004	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
17020:2012	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
17024:2012	Conformity assessment – General requirements for bodies operating certification of persons
17025:2005	General requirements for the competence of testing and calibration laboratories
17043:2010	Conformity assessment – General requirements for proficiency testing

*15189:2012 is ISO only and not a dual ISO/IEC standard

Accreditation Hierarchy



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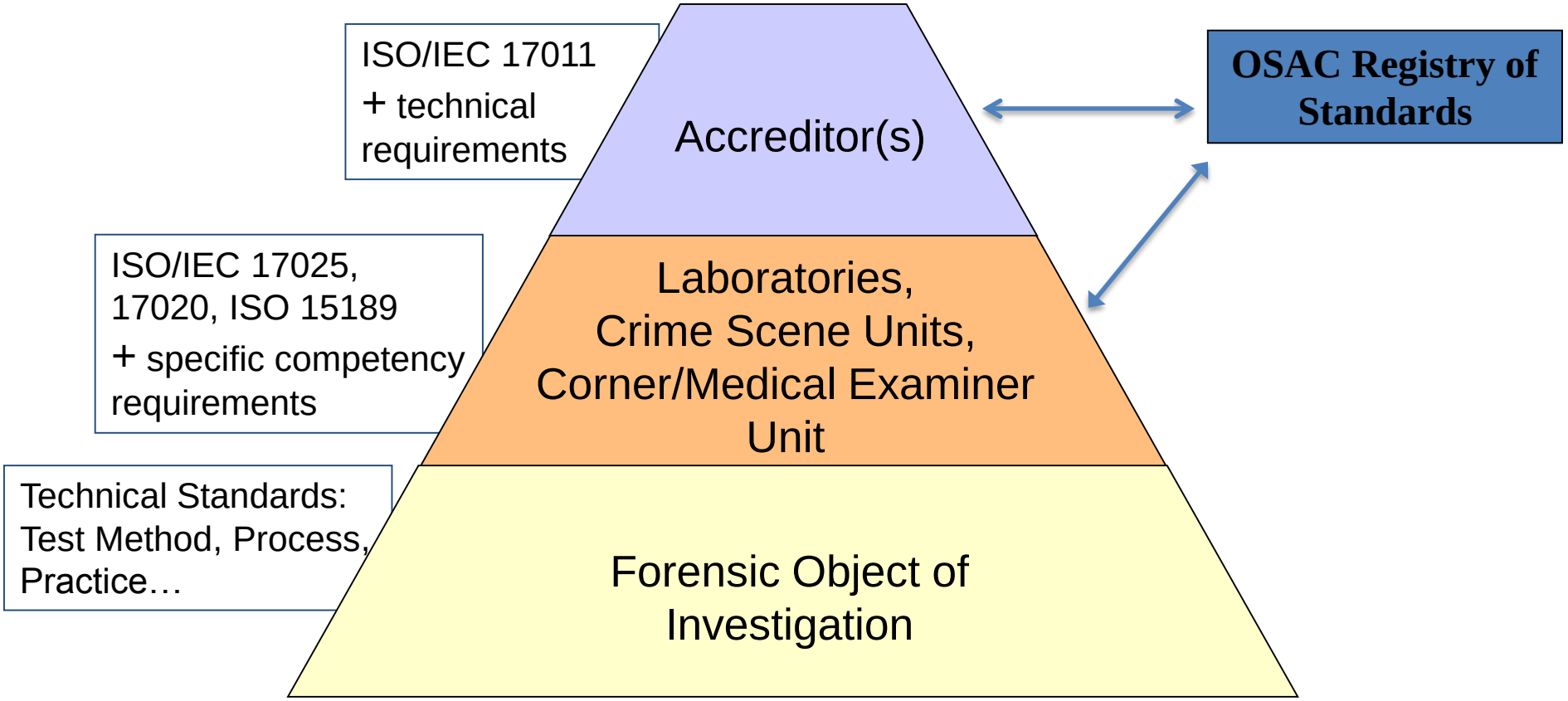
Convener of working group on revision of ISO/IEC 17025

Accreditation Hierarchy



Contents of ISO/IEC 17025:2005

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
5. Technical requirements

Annex A (informative) Nominal cross-reference to ISO 9001:2000

Annex B (informative) Guidelines for establishing applications for specific fields

1. Scope [Paraphrased]

1.1 General requirements for competence
- Tests and/or calibrations, including sampling
- Standard, non-standard, laboratory-developed methods

1.2 Applicable to all organizations performing tests and/or calibrations
- Intended to be applied to all types of laboratories, accredited or not
- First-, second-and third-party laboratories

1.3 Notes provide clarification, examples, guidance; not requirements

1.4 Standard is for use in developing a laboratory management system, but not for certification of that system

1.5 Standard does not cover regulatory or safety requirements

1.6 Compliance with ISO/IEC 17025 meets the principles of ISO 9001:2000

4. Management Requirements

4.1 Organization
4.2 Management system
4.3 Document control
4.4 Review of requests, tenders and contracts
4.5 Subcontracting of tests and calibrations
4.6 Purchasing services and supplies
4.7 Service to the customer
4.8 Complaints
4.9 Control of nonconforming testing and/or calibration work
4.10 Improvement
4.11 Corrective action
4.12 Preventive action
4.13 Control of records
4.14 Internal audits
4.15 Management reviews

5. Technical Requirements

5.1 General
5.2 Personnel
5.3 Accommodation and environment
5.4 Test and calibration methods and method validation
5.5 Equipment
5.6 Measurement traceability
5.7 Sampling
5.8 Handling of test and calibration items
5.9 Assuring the quality of test and calibration results
5.10 Reporting the results

Key differences between ISO/IEC 17020 and ISO/IEC 17025

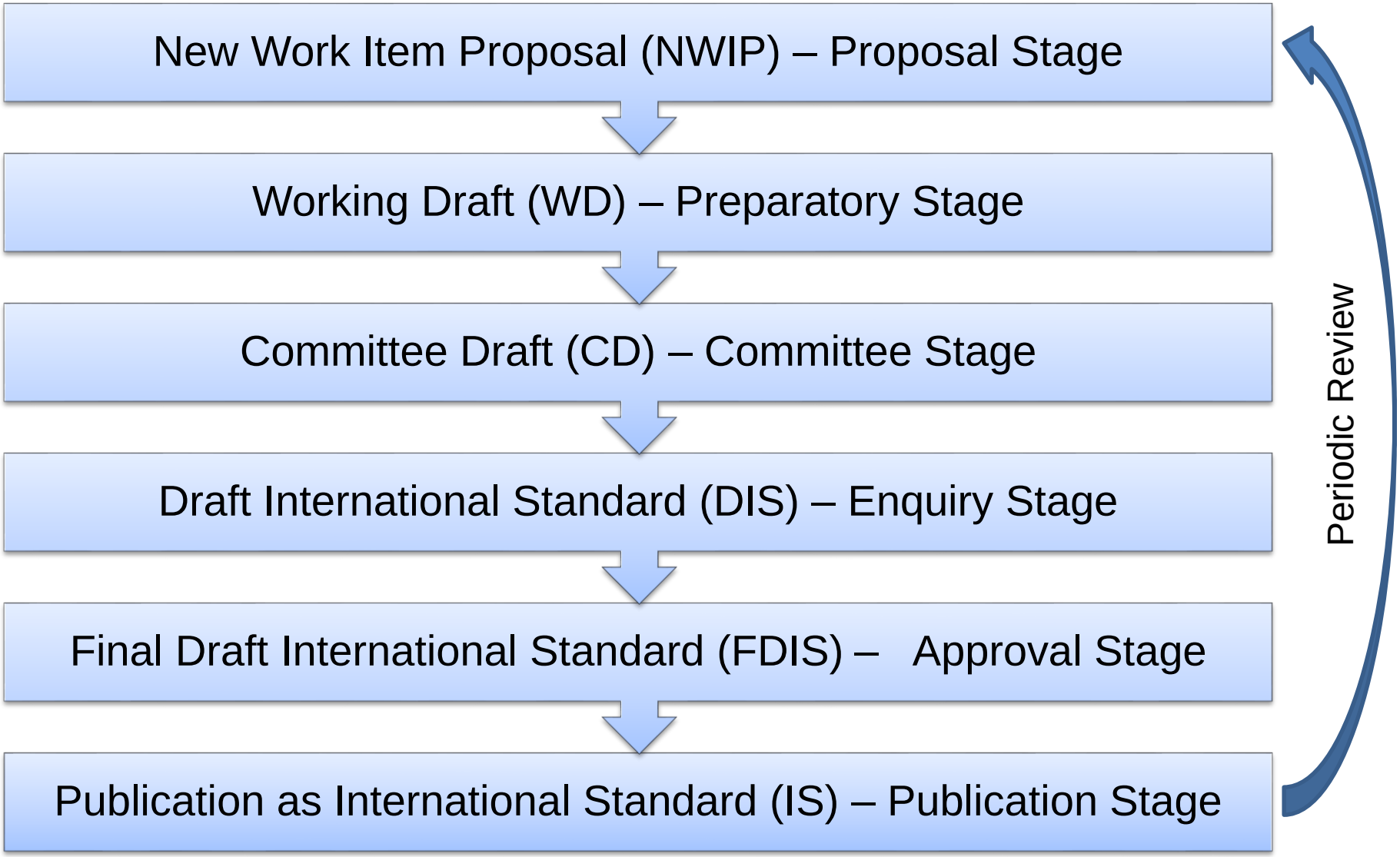
- Scope
  - ISO/IEC 17025: testing or calibration of items
  - ISO/IEC 17020: inspection of products, processes, services, or installations

- Professional judgment
  - ISO/IEC 17025: opinions and interpretations possible, but limited to items tested or calibrated
  - ISO/IEC 17020: requires professional judgment when determining conformity with general requirements

ISO Conformity Assessment Committee, CASCO

- Develops conformity assessment standards
- CASCO is a policy committee and standards developer
- CASCO has authority to develop standards and follows ISO Directives
- CASCO has working groups to develop standards (no Technical Committees or Subcommittees)

ISO Standards Development



ISO Standards Review Process

- All standards are subject to a 5-year Systematic Review process
- 5-month inquiry to confirm, revise or withdraw
- ISO/IEC 17025:2005 confirmed in 2010
- Due in 2015 for regular Systematic Review
- Revision started earlier because a New Work Item Proposal was submitted

What is Laboratory Accreditation?

- Independent, third party assessment of laboratory technical competence
- Based on international standards
  - **ISO/IEC 17025 for laboratories**
  - ISO/IEC 17011 for accreditation bodies
- Assessment by peer technical experts for a specific scope of accreditation
- Periodic surveillance and reassessment

What to Expect from an Accredited Laboratory

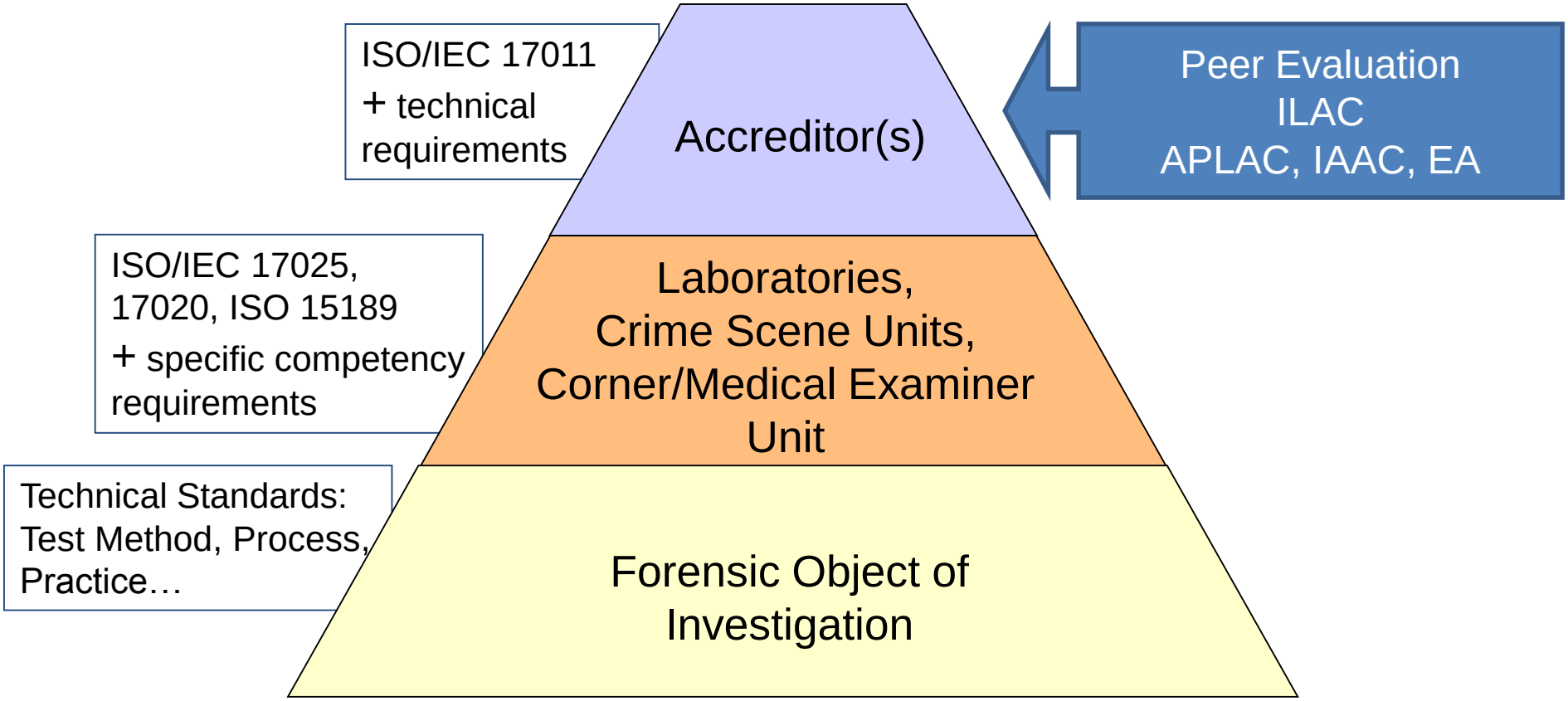
Technical competence

- ✓ Qualified to perform methods identified on the Scope of Accreditation
- ✓ Report results in accordance with requirements

Accountability

- ✓ Contract review between laboratory and customer to clearly identify scope and objectives of work
- ✓ System for handling feedback and complaints
- ✓ If laboratory's system fails to address any concerns, can pursue with accreditation body

Accreditation Hierarchy



International Recognition of Accreditation Bodies (ABs)

- Laboratory accreditation bodies can demonstrate competence via recognition by an international accreditation cooperation
- Based on peer evaluations against ISO/IEC 17011 and additional requirements

  - **ILAC**: International Laboratory Accreditation Cooperation www.ilac.org
  - **APLAC**: Asia Pacific Laboratory Accreditation Cooperation www.aplac.org
  - **IAAC**: Inter American Accreditation Cooperation www.iaac.org.mx

What is Required by ISO/IEC 17011 for Accrediting Bodies?

- ISO/IEC 17011 includes requirements for operation of an accreditation program
  4. Structure
  5. Management system
  6. Human resources (including assessors)
  7. Accreditation process
  8. Responsibilities of AB and accredited entities

- Recognition involves joining a regional accreditation cooperation (e.g., IAAC) and undergoing peer evaluation

International Recognition of Accreditation Bodies (ABs)

- ABs that successfully complete the evaluation process sign the associated Recognition Arrangement
- Signatories' accreditations are considered to provide equivalent outcomes with respect to those requirements
- Regulators or other users of accredited laboratories can specify ILAC recognition when developing conformity assessment schemes
- Regions and/or ILAC develop requirements beyond ISO/IEC 17011 for ABs
- Also develop guidance or requirements to be used in specific sectors to supplement ISO/IEC 17025

Supplemental Accreditation Requirements

Expand upon the general requirements in ISO/IEC 17025

- Can be generated by:
  - Individual accreditation bodies
  - Accreditation cooperations
  - Standards development organizations
  - Other stakeholder groups (e.g., OSAC)

When comparability among ABs or across borders is important

- Example: ILAC-G19:08/2014, *Modules in a forensic science process*
  - Developed by a working group of the ILAC Accreditation Committee
  - Additional guidance for application of ISO/IEC 17025 and/or ISO/IEC 17020

Current Hierarchy of Standards
for Accrediting Bodies to Use in Auditing U.S. Forensic DNA Laboratories

International Laboratory Accreditation Cooperation (ILAC)
G19:08/2014 Modules in a Forensic Science Process

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

The FBI Quality Assurance Standards (2011) serve as supplemental materials to ISO/IEC 17025 for DNA audits

SWGDAM guidelines (interpretation, validation, etc.) provide further information but are not audited against

Accreditation Assessors

- Assessors are selected based on qualifications, technical experience, and personal attributes
- ABs are required to ensure that assessors have undergone relevant training
- Conflicts of interest avoided; laboratories can object to assignments
- Some ABs or programs require specific credentials, levels of experience, and/or training
- Assessments conducted on site
  - Covers management system and technical activities
  - Number of assessors and duration depend on proposed scope of accreditation
- Report is generated and used by AB for its decision making process

Accreditation Cycles

- ISO/IEC 17011 allows some flexibility in surveillance and reaccreditation process
  - If based on reassessment visits alone, maximum interval is 2 years
  - If combination of reassessment and surveillance, maximum interval is 5 years for reassessments, 2 years between surveillance visits
- Accreditation fees vary among ABs
  - Generally an annual fee
  - Cost associated with assessments

Proficiency Testing

- Evaluation of participant performance against pre-established criteria by means of interlaboratory comparison
- Part of the planned quality assurance activities required by ISO/IEC 17025; can be used by inspection bodies
- Recognized that PT is not possible for all areas of testing, calibration, or inspection
- ILAC policy for minimum participation:
  - Satisfactory participation prior to accreditation
  - Ongoing activity appropriate to the Scope of Accreditation

Issues to Consider

- Consistency in accreditation is linked to the standards to which the testing laboratory (or inspection body) is held
  - ISO/IEC 17025 contains general requirements, providing a fundamental basis for determining competence
  - Specific technical issues addressed in supplemental requirements and test methods
- Accreditation is not conditional upon the characteristics of the applicant
  - Single-person or large systems
  - First, second, or third party laboratories

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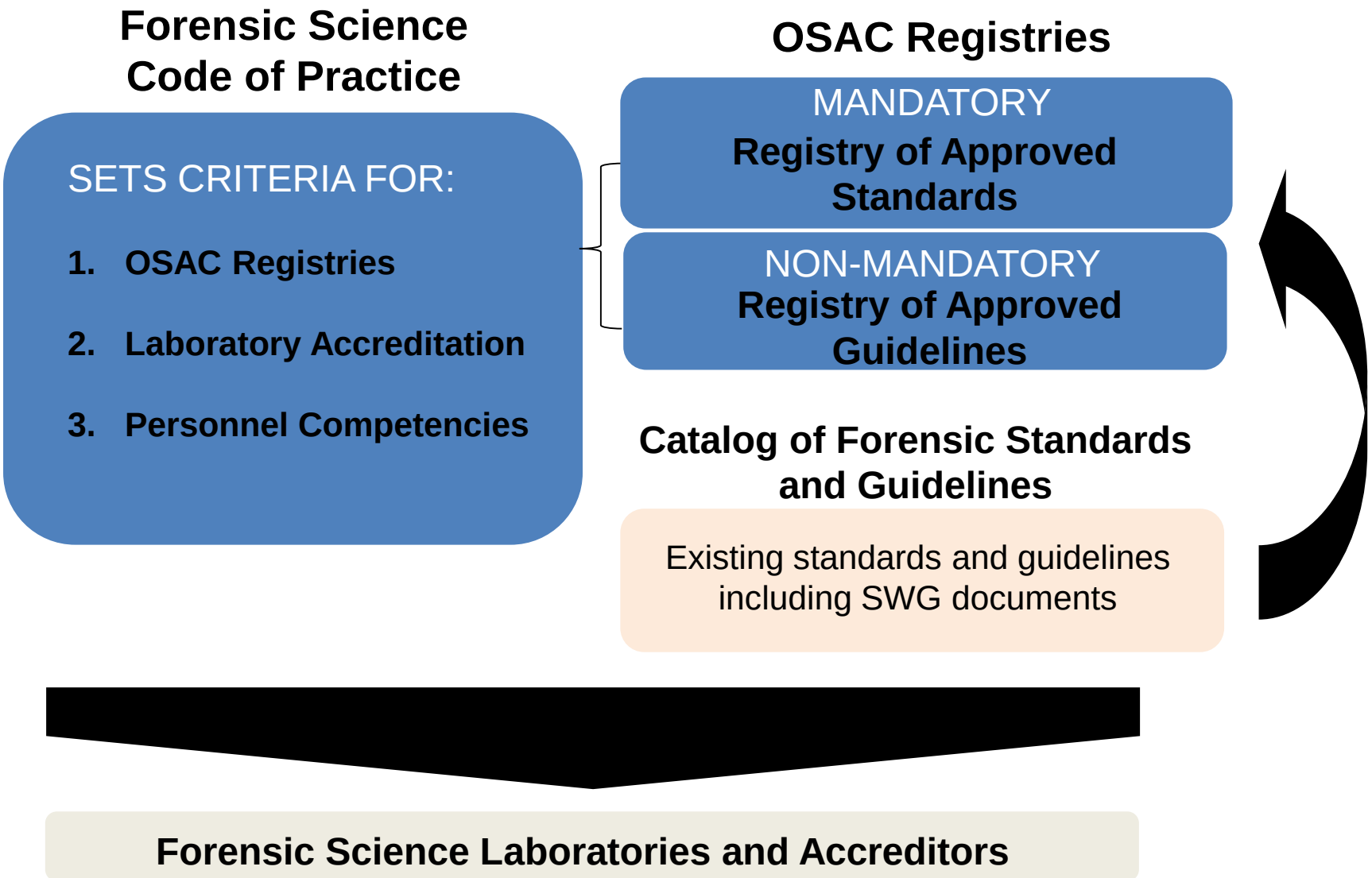
Chair, OSAC Quality Infrastructure Committee

A Framework for a Quality Infrastructure



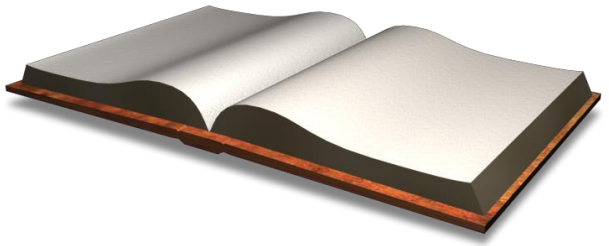
What is the Code of Practice?

Documents the minimum requirements for:

1. Standards and guidelines used in forensic science
2. Accreditation of laboratories and investigative units supplying forensic science services

   Discipline specific requirements to supplement international standards developed in a consensus
3. Competencies of forensic science practitioners

   Implemented in forensic science service organizations' management systems



What Goes on the OSAC Registries?

Documentary standards and guidelines that have demonstrated:

- **Technical merit**
  - Detailed Scope
  - Fitness for purpose
  - Uncertainty measurement and potential bias
  - Method validation, as appropriate
- **Reasonable standards development process**
  - Due Process
  - Consensus
  - Openness
  - Transparency
  - Freedom from undue influence
  - Balance of interests
- **Approved standards may come from 3 sources:**
  - Adoption of an existing SDO publication
  - Catalyzation with an existing SDO
  - Development by an OSAC Subcommittee using the Canvass Method

Building on Existing Work

- Documents produced by the 21 Scientific Working Groups (SWG)
- Published standards and guidelines; international in scope
- Technical reports and papers from forensic science associations and organizations

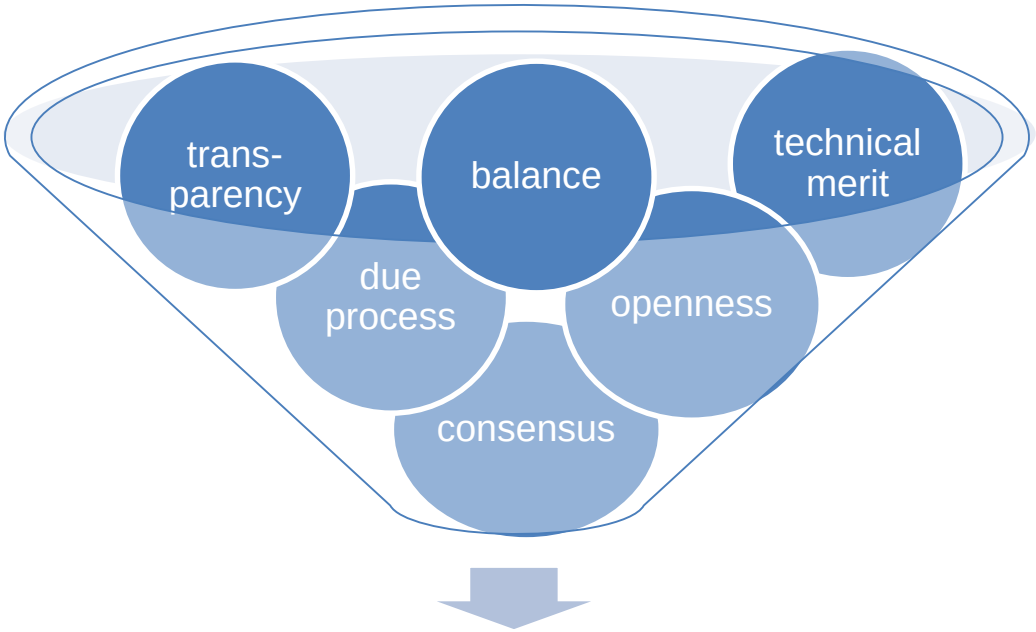
Catalog of Current Standards Documents Relating to Forensic Science Released

- NIST Forensic Science Program staff members have **compiled an inventory of existing documents (standards and guidelines)** in order to build upon the previous work of independent scientific working groups (SWGs), standards developing organizations (SDOs), and professional organizations for use by the forensic science community

- **729 standards, guidelines and related documents**
  - with web addresses for documents that are available online
  - available to download (since Dec 12, 2014) as a sortable Excel spreadsheet file
  - intended to serve as a resource to the forensic science community and a foundation for the future work of the Organization of Scientific Area Committees (OSAC)
  - Produced from scanning all known forensic science organizations, associations and standards development organizations, in addition to the results of a data call to each of the 21 SWGs

http://www.nist.gov/forensics/osac/standards-guidelines-catalog.cfm

Approved Standards vs. Guidelines



OSAC Registry of Approved Standards

Standard

- Specifies uniform methods, actions, practices, or processes, protocol
- Compliance recommended to be mandatory and modified only under unusual circumstances
- Approved by FSSB

OSAC Registry of Approved Guidelines

Guideline

- Suggested methods, actions, practices, or processes to consider in absence of applicable standards
- Best practices that are strongly recommended but not required
- Approved by SAC

OSAC Standards/Guidelines Process Overview

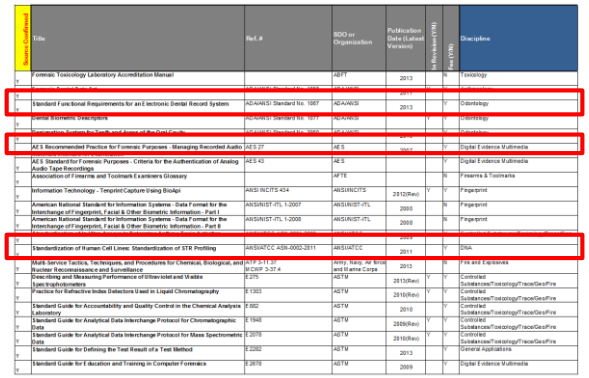
STAGES

ACTIVITIES

COMMITTEE

Prioritization Stage

OSAC Priorities Identified; Catalog used as a starting point



Source Confirmed	Title	Ref. #	SDO or Organization	Publication Date (Latest Version)	Re-Released (Y/N)	Part (Y/N)	Discipline
Y	Forensic Toxicology Laboratory Accreditation Manual		ABFT	2013		N	Toxicology
Y	Standard Functional Requirements for an Electronic Dental Record System	ADA/ANSI Standard No. 1067	ADA/ANSI	2013		Y	Odontology
Y	Dental Biometric Descriptors	ADA/ANSI Standard No. 1077	ADA/ANSI			Y	Odontology
Y	AES Recommended Practice for Forensic Purposes - Managing Recorded Audio	AES 27	AES			Y	Digital Evidence Multimedia
Y	AES Standard for Forensic Purposes - Criteria for the Authentication of Analog Audio Tape Recordings	AES 43	AES			Y	Digital Evidence Multimedia
Y	Association of Firearms and Toolmark Examiners Glossary		AFTE			N	Firearms & Toolmarks
Y	Information Technology - TenprintCapture Using BioApi	ANSI INCITS 434	ANSI/INCITS	2012(Rev)	Y	Y	Fingerprint
Y	American National Standard for Information Systems - Data Format for the Interchange of Fingerprint, Facial & Other Biometric Information - Part 1	ANSI/NIST-ITL 1-2007	ANSI/NIST-ITL	2000		N	Fingerprint
Y	American National Standard for Information Systems - Data Format for the Interchange of Fingerprint, Facial & Other Biometric Information - Part II	ANSI/NIST-ITL 1-2008	ANSI/NIST-ITL	2008		N	Fingerprint
Y	[illegible]	[illegible]	[illegible]	[illegible]		Y	[illegible]
Y	Standardization of Human Cell Lines: Standardization of STR Profiling	ANSI/ATCC ASN-0002-2011	ANSI/ATCC	2011		Y	DNA
Y	Multi-Service Tactics, Techniques, and Procedures for Chemical, Biological, and Nuclear Reconnaissance and Surveillance	ATP 3-11.37 MCRP 3-37.4	Army, Navy, Air Force and Marine Corps	2013		N	Fire and Explosives
Y	Prescribing and Measuring Performance of Ultraviolet and Visible Spectrophotometers	E 275	ASTM	2013(Rev)	Y	Y	Controlled Substances/Toxicology/Trace/Gen/Fire
Y	Practice for Reflective Index Detectors Used in Liquid Chromatography	E 1303	ASTM	2010(Rev)	Y	Y	Controlled Substances/Toxicology/Trace/Gen/Fire
Y	Standard Guide for Accountability and Quality Control in the Chemical Analysis Laboratory	E 882	ASTM	2010		Y	Controlled Substances/Toxicology/Trace/Gen/Fire
Y	Standard Guide for Analytical Data Interchange Protocol for Chromatographic Data	E 1948	ASTM	2009(Rev)	Y	Y	Controlled Substances/Toxicology/Trace/Gen/Fire
Y	Standard Guide for Analytical Data Interchange Protocol for Mass Spectrometric Data	E 2078	ASTM	2010(Rev)	Y	Y	Controlled Substances/Toxicology/Trace/Gen/Fire
Y	Standard Guide for Defining the Test Result of a Test Method	E 2282	ASTM	2013		Y	General Applications
Y	Standard Guide for Education and Training in Computer Forensics	E 2678	ASTM	2009		Y	Digital Evidence Multimedia

Approval Stage

OSAC Approves recommended Standards/Guidelines

Path 1
- Review and adoption of existing standard/guideline

Path 2
- Development of a standard/guideline within an external SDO

Path 3
- Development of a standard/guideline within OSAC

Registry Listing Stage

Standards/Guidelines are listed on the OSAC Registry of Approved Standards/Guidelines

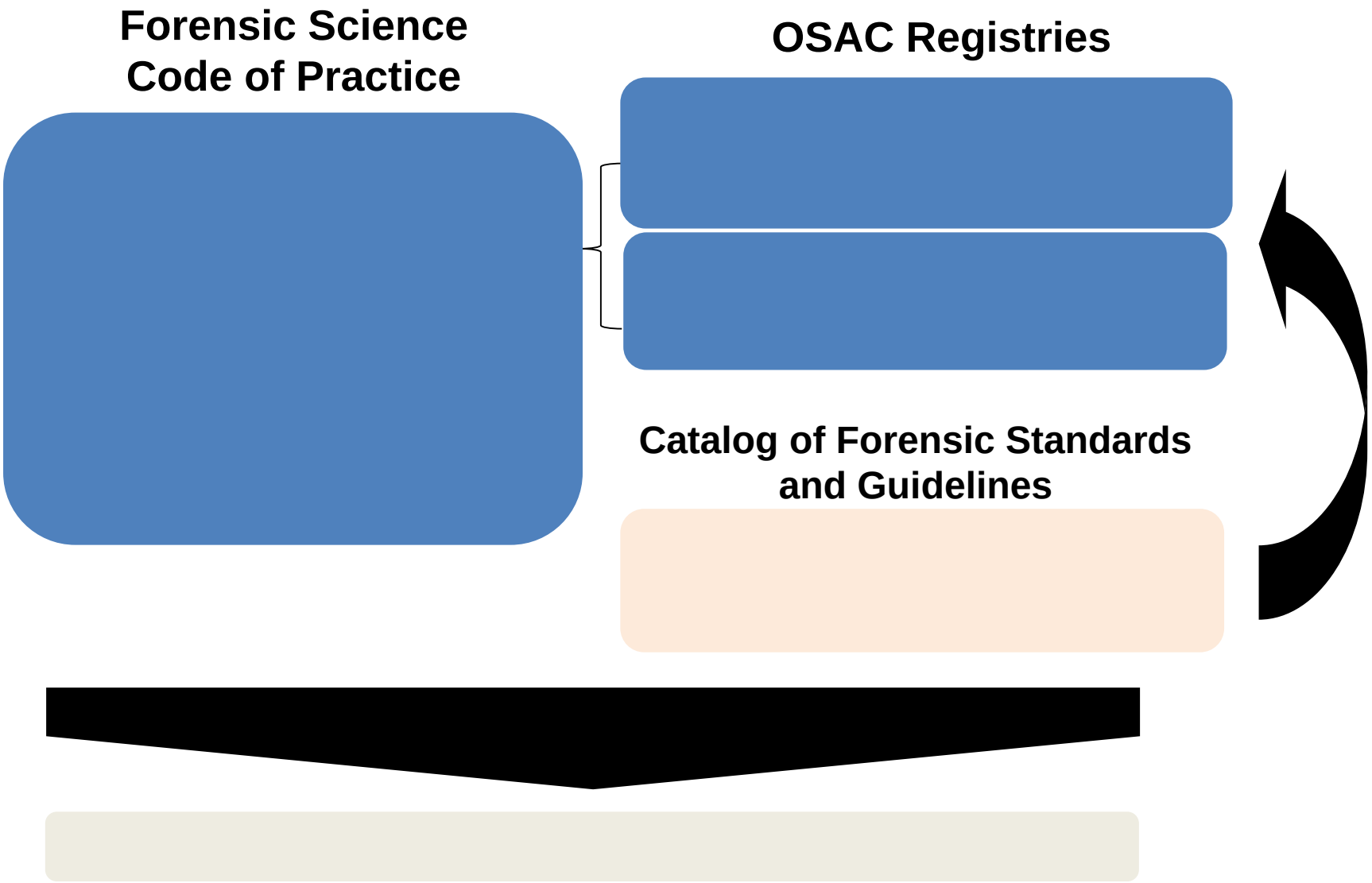
FSSB/SACs

Subcommittees

Quality Infrastructure Committee

Legal Resource and Human Factors Committees

A Framework for a Quality Infrastructure



National Commission on Forensic Science (NCFS):
www.justice.gov/ncfs

Organization of Scientific Area Committees (OSAC):
www.nist.gov/forensics/osac/index.cfm

NIST FORENSIC SCIENCES

www.nist.gov/forensics