Conformity Assessment – Building Regulators' Confidence in Device Safety and Performance

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Topics

- Conformity Assessment Overview
- Conformity Assessment in US Government
- Accreditation Scheme for Conformity Assessment (ASCA) Program
- Q&A

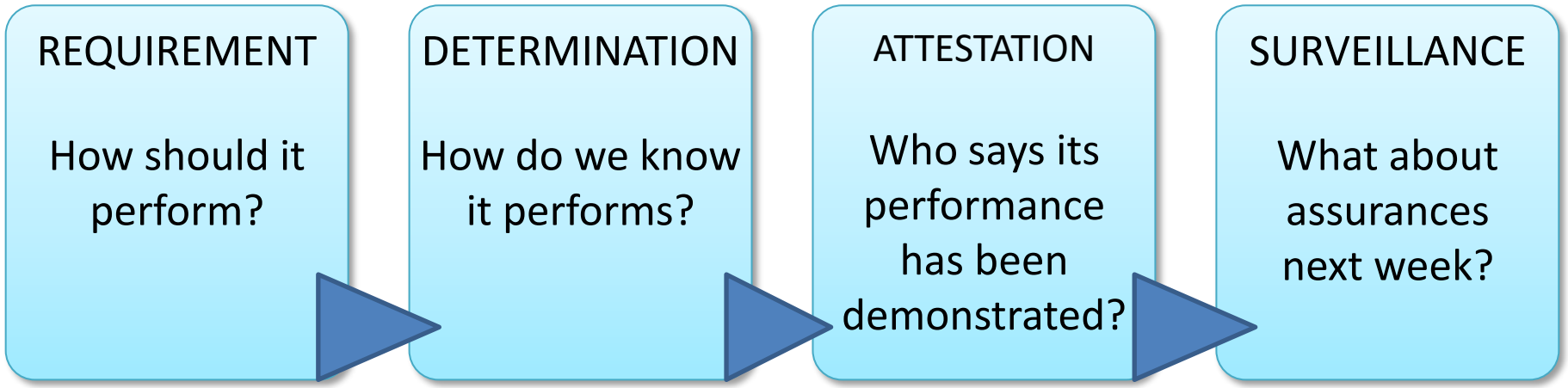
Conformity Assessment Defined

"…demonstration that specified requirements relating to a product, system, process, person, or body are fulfilled."

- ISO/IEC 17000

Conformity Assessment – Basic Terms and Concepts

Conceptual View of Conformity Assessment



Terms and definitions from *ISO/IEC 17000: Conformity Assessment – Vocabulary and General Principles*

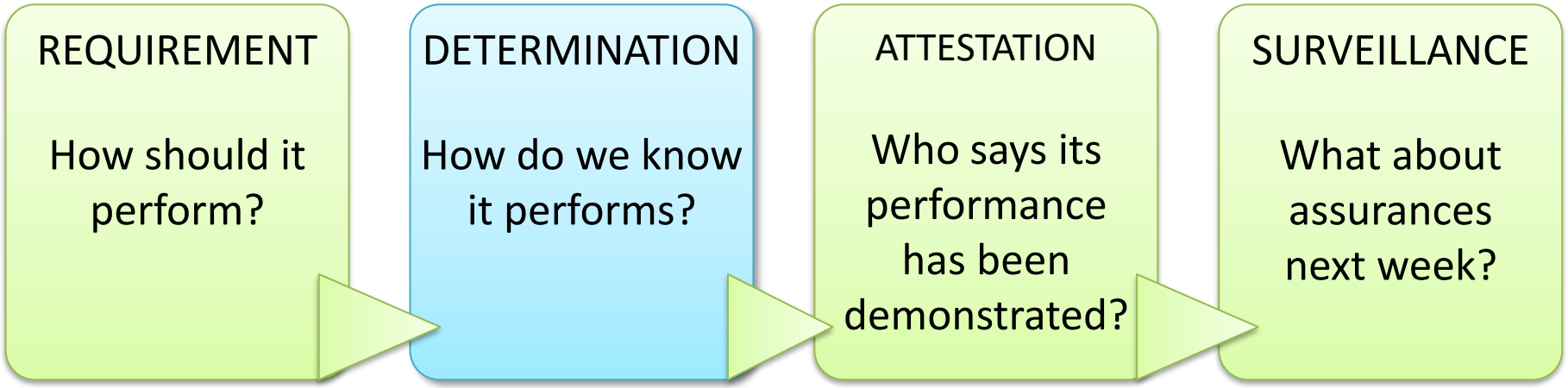
Conformity Assessment Parties – Who Does What

First Party	Conformity Assessment Body (CAB) is person or organization that provides the object (seller or manufacturer)
Second Party	CAB is a purchaser or user
Third Party	CAB is an independent entity that has no interest in transactions between the first and second parties

Government:

- Can be any of the three
- Has a unique role when including conformity assessment in regulation

Determination



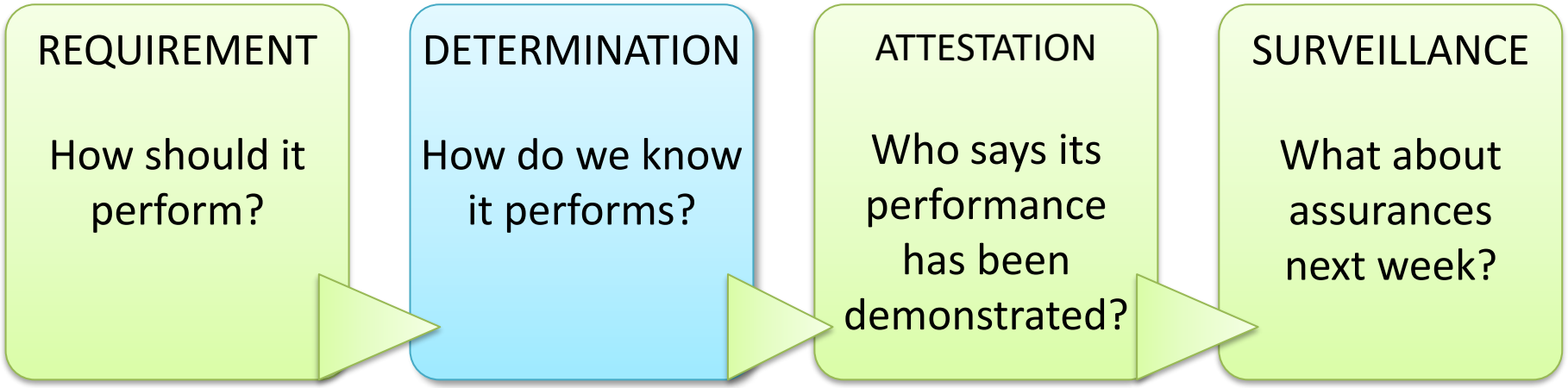
Testing: Determination of one or more characteristics of an object of conformity, according to a procedure

Inspection: Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

Audit: Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which requirements are fulfilled

Peer assessment: assessment of a body against specified requirements by representatives of other bodies

Determination Examples



Testing: Toys, materials, products, food, water, software…

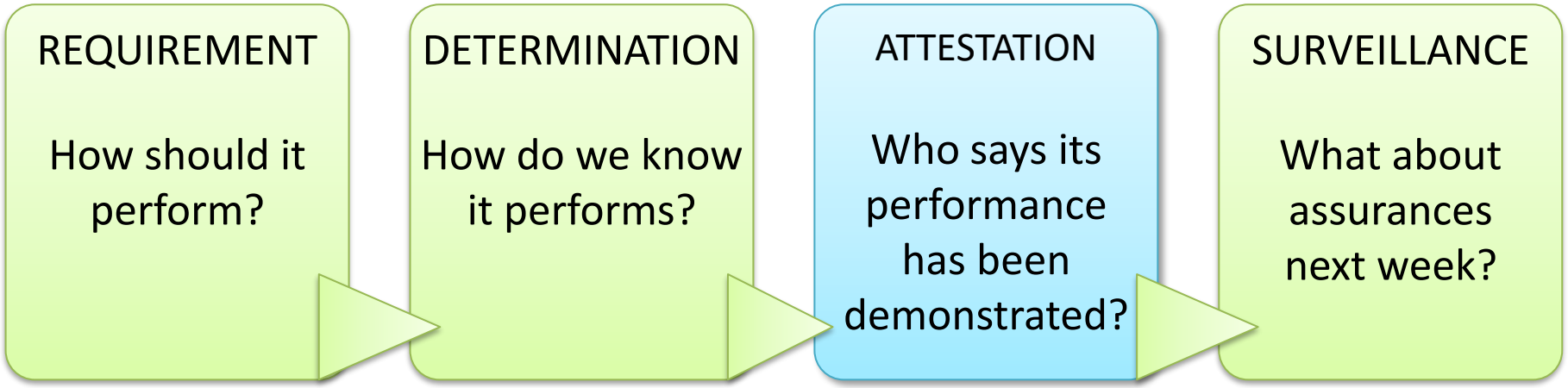
Inspection: Batches of goods presented for import, automobiles, elevators, cloud storage providers…

Audit: Management systems

Peer assessment: Other conformity assessment bodies

- All done at a single point in time
- Not limited to 3rd parties

Attestation



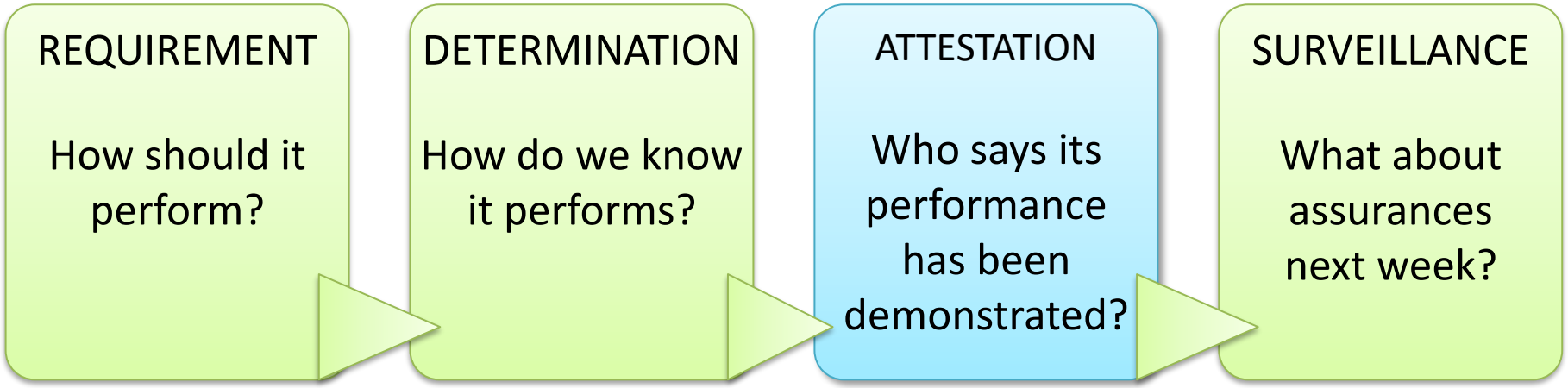
Attestation: Issue of a statement that fulfilment of specified requirements has been demonstrated

By **First Party:** → **Supplier's Declaration of Conformity (SDoC)**

→ **Certification**

By **Third Party:** → **Accreditation**

Attestation Examples



SDoC: Can be made by suppliers of…pretty much anything

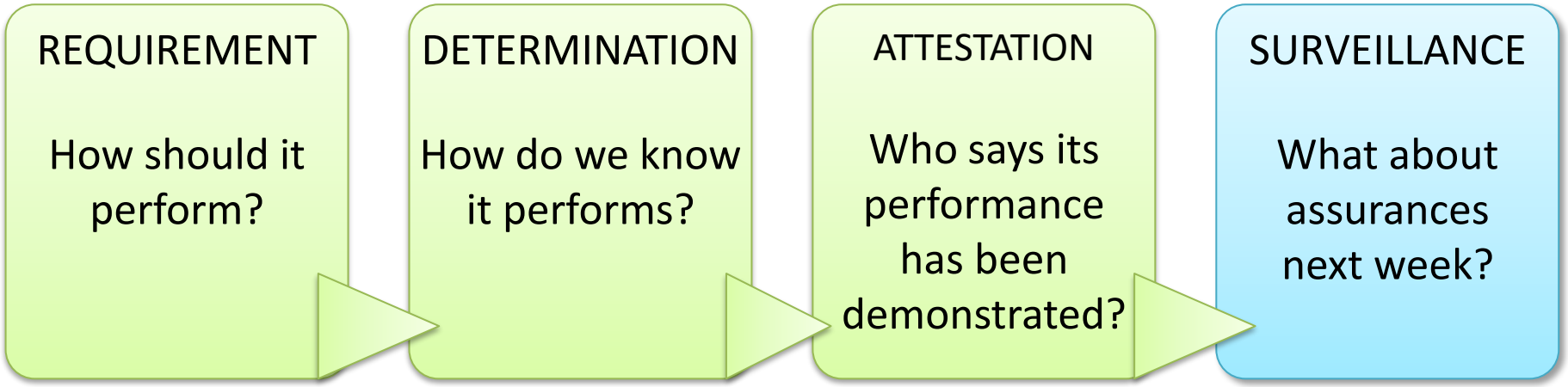
Certification performed on:

- Products, processes, services
- Management systems (also called registration)
- Persons

Accreditation:

- Performed on CABs related to their competence (e.g., labs, inspection bodies, certifiers)

Surveillance



Surveillance: Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (attestation)

- Repeat some or all aspects of original determination and attestation
- Can be pre- or post-market

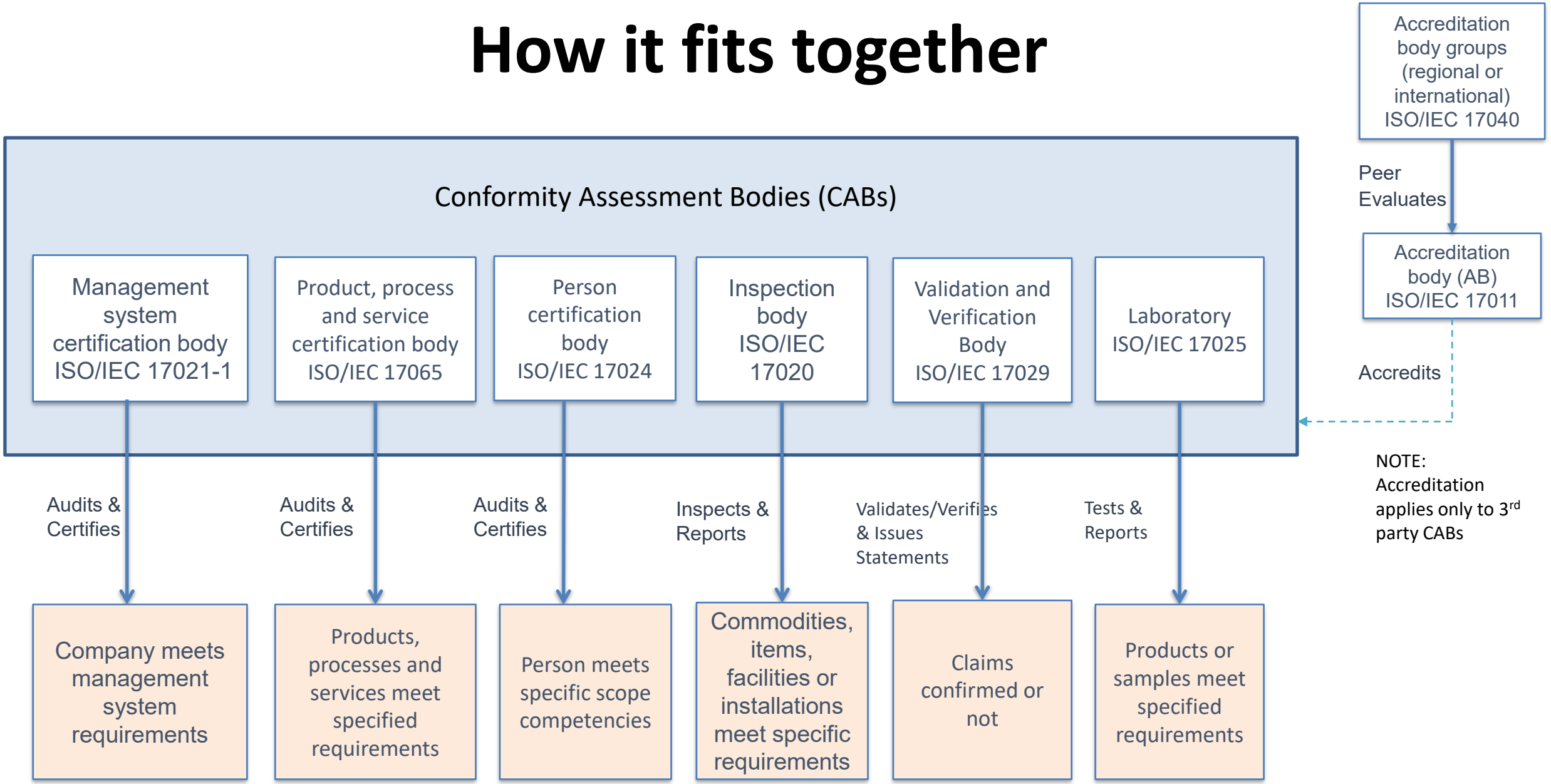
Standards for Conformity Assessment

Published by International Organization for Standardization (ISO) Committee on Conformity Assessment (CASCO) in cooperation with the International Electrotechnical Commission (IEC)

Type	Parties			Standard(s)
	1st	2nd	3rd	
Testing	✓	✓	✓	ISO/IEC 17025
Inspection	✓	✓	✓	ISO/IEC 17020
Supplier's Declaration of Conformity (SDoC)	✓			ISO/IEC 17050 Parts 1 and 2
Certification				
Products, processes, services			✓	ISO/IEC 17065 [ISO/IEC 17067]
Management systems			✓	ISO/IEC 17021
Persons			✓	ISO/IEC 17024
Accreditation			✓	ISO/IEC 17011

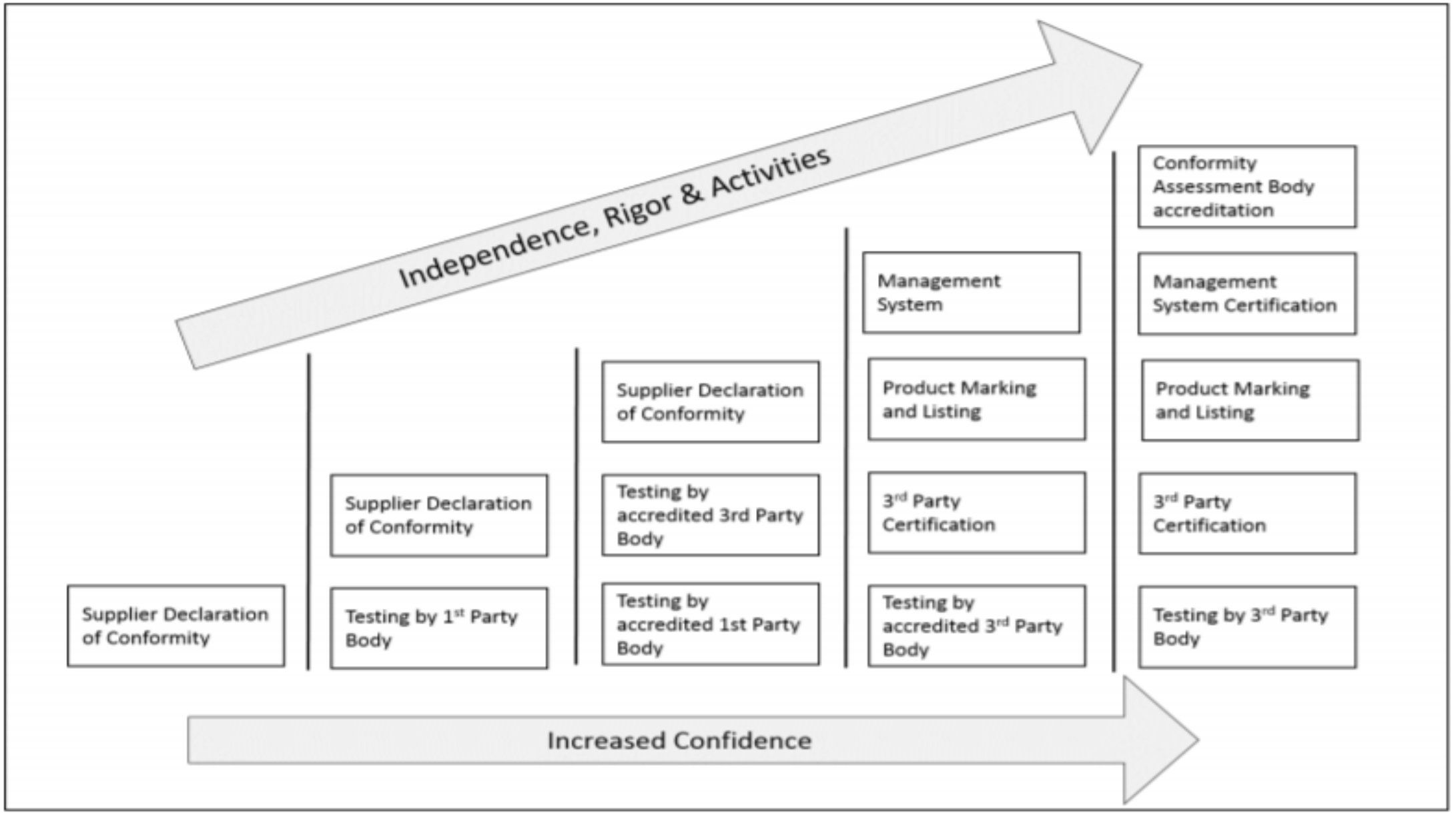
ISO CASCO Toolbox

How it fits together



Slide Source: CASCO Educational toolbox - 9 modules on conformity assessment (link)

Level of Confidence by CA Activities



Systems and Schemes

4.8
conformity assessment system
set of rules and *procedures* (5.2) for the management of similar or related *conformity assessment schemes* (4.9)

Note 1 to entry: A conformity assessment system can be operated at an international, regional, national, sub-national, or industry sector level.

4.9
conformity assessment scheme
conformity assessment programme
set of rules and *procedures* (5.2) that describes the *objects of conformity assessment* (4.2), identifies the *specified requirements* (5.1) and provides the methodology for performing *conformity assessment* (4.1)

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (4.8).

Note 2 to entry: A conformity assessment scheme can be operated at an international, regional, national sub-national, or industry sector level.

Note 3 to entry: A scheme can cover all or part of the conformity assessment functions explained in Annex A.

ISO/IEC 17000:2020

Conformity Assessment under IECEE CB Scheme

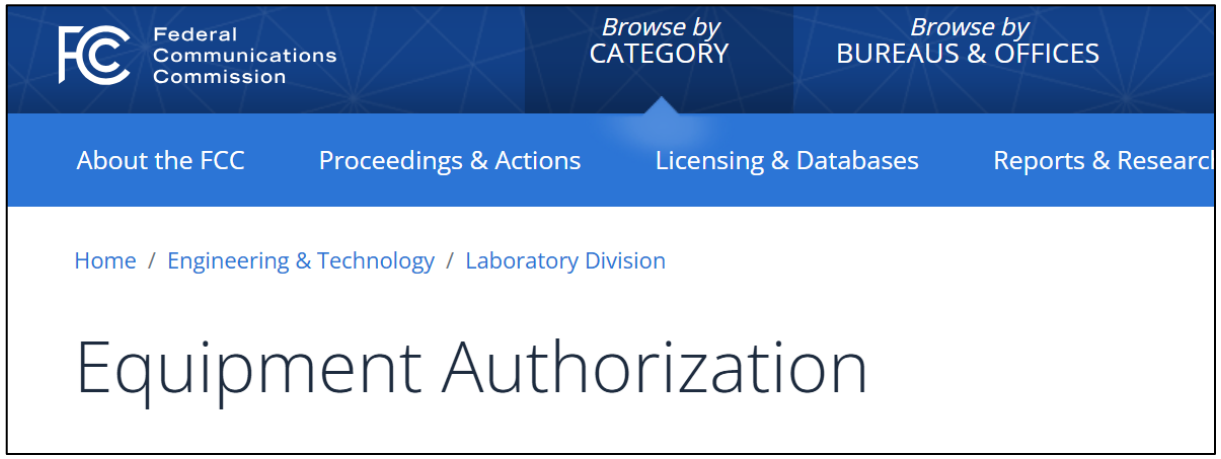
Products are tested to IEC standards - supplementary testing for national differences, when relevant.

Reciprocal recognition of test results among all participating Certification Bodies simplifies the granting of certification or approval at national levels.

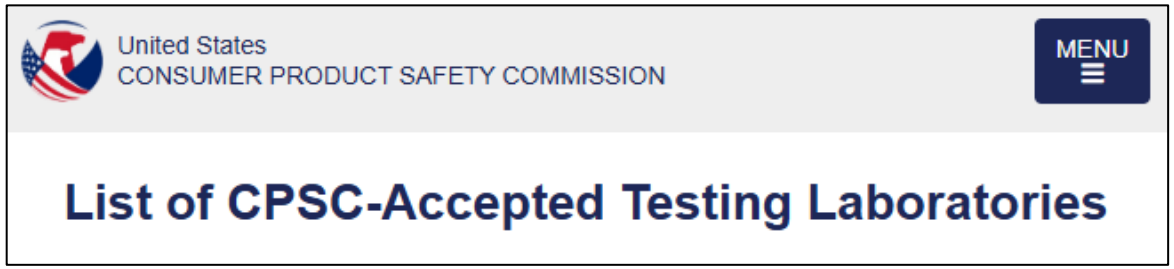
CB Test Certificates and associated Test Reports facilitate obtaining secondary certifications.

US GOVERNMENT AND CONFORMITY ASSESSMENT

US Regulators and Conformity Assessment



U.S. CYBER TRUST MARK



Reminder: Some Regulatory Options to Market Medical Devices

Submission Type	Classification	Statutory Threshold
510(k) (Premarket Notification)	Class I, II	Substantial Equivalence (SE)
De Novo	Class I, II	Reasonable Assurance of Safety and Effectiveness through Special Controls
PMA (Premarket Approval)	Class III	Reasonable Assurance of Safety and Effectiveness

Conformity Assessment: FDA/CDRH's Landscape (pre-ASCA)

Medical Device Manufacturers:

- Use standards testing to address regulatory requirements
- Support their premarket submission with testing
- Often works with test labs to determine device conformity to standards

FDA/CDRH:

- Recommends that sponsors conform to FDA-recognized consensus standards
- Reviews test methods and results
- Determines that reasonable assurance of safety and effectiveness or substantial equivalence is met
- For exempt devices, methods and results may be reviewed during a QMS inspection or if there are post market issues

Can we do more?

How can we drive more confidence and trust into premarket submission test data?

Accreditation Scheme for Conformity Assessment (ASCA)

What is ASCA?

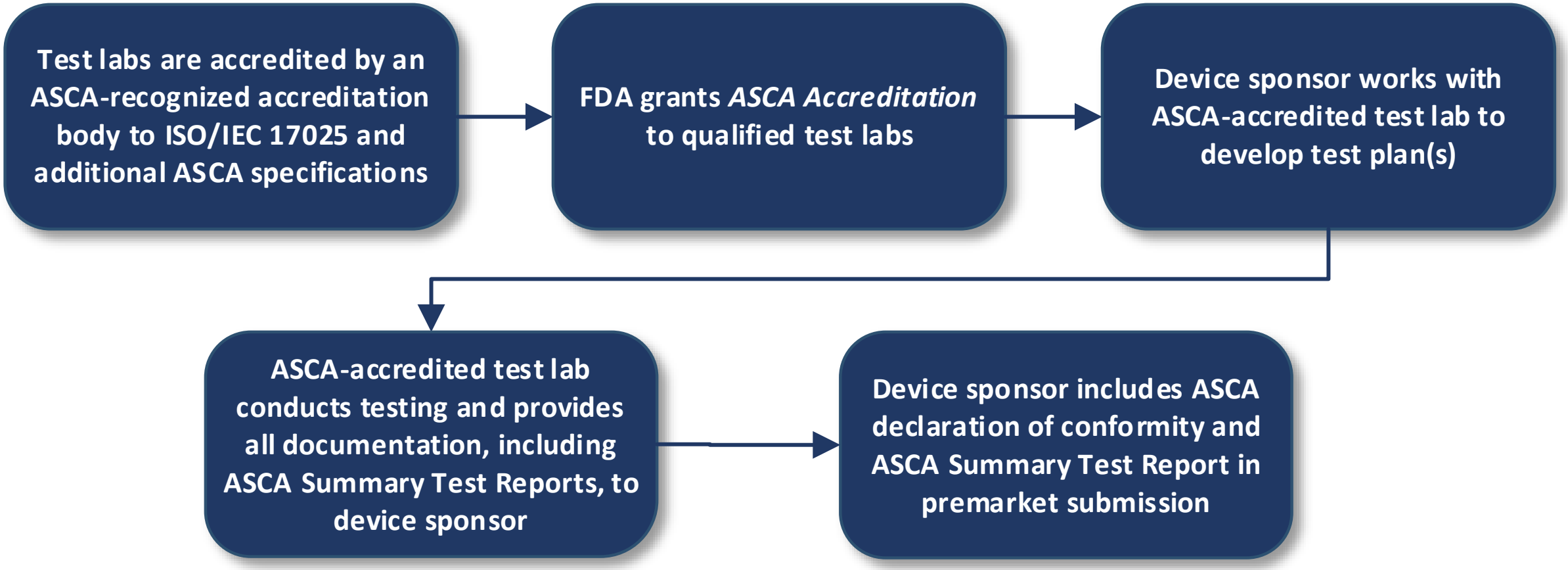
- Accreditation program that capitalizes on voluntary consensus standards in device development and review
- 'Puts standards to work' in conformity assessment
- *ASCA Accreditation* from FDA to qualified test labs means:
  - Confidence in their methods and results
  - No need for complete test report review

ISO/IEC 17011:2017
Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

How ASCA Works



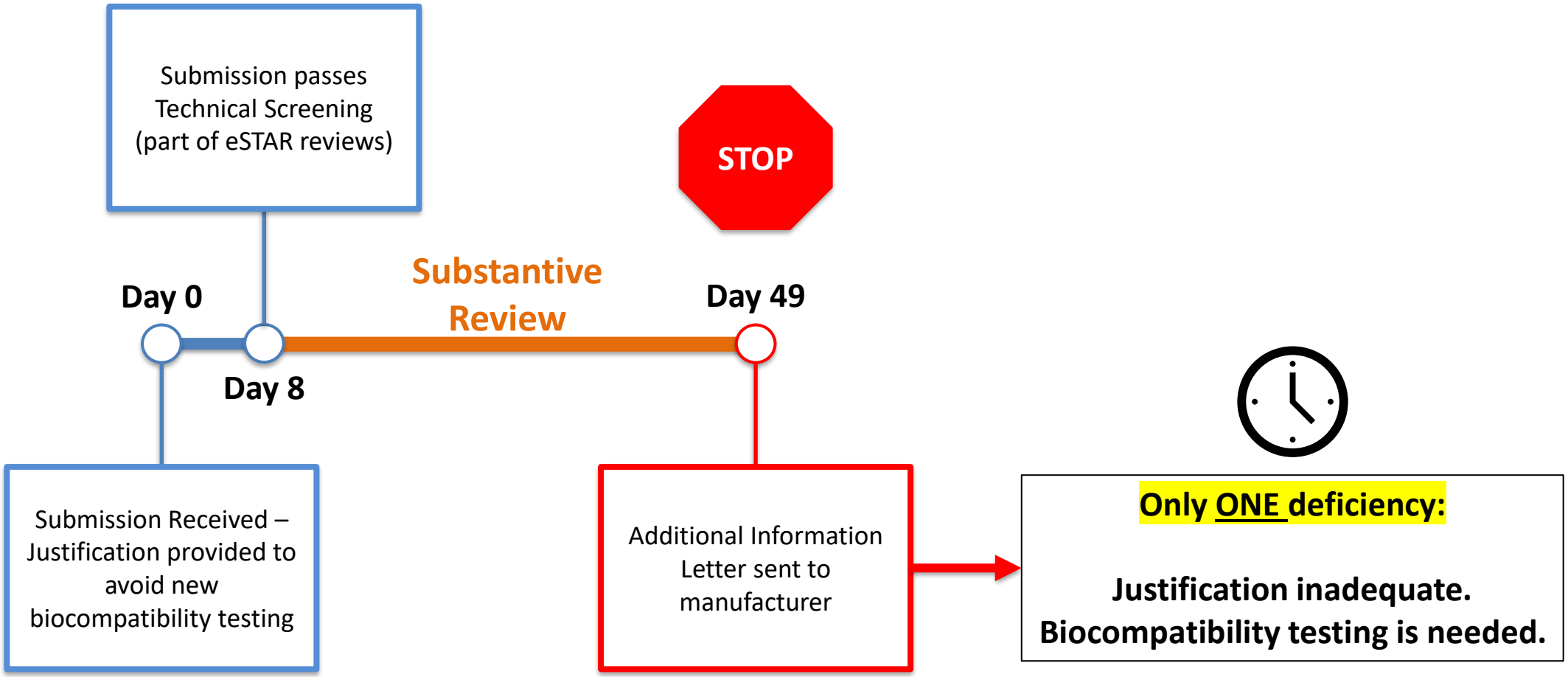
ASCA Goal: Streamline conformity assessment in premarket review

- Reduces time needed for review of conformity assessment element
- Less need lengthy internal consults, and complete test report review
- Fewer deficiencies
- Improves the quality of testing and reporting
  - Addresses testing issues for which FDA commonly identifies concerns

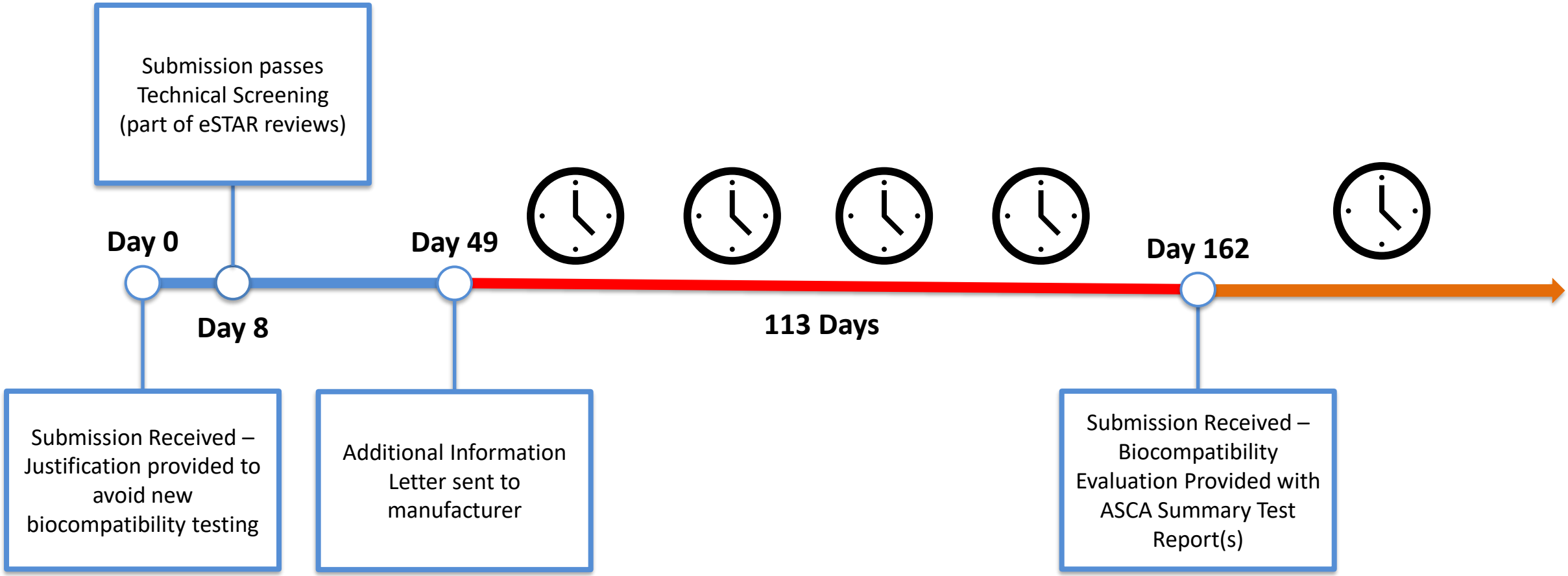
Case Studies of ASCA Use in Premarket Submissions

ASCA – IN PRACTICE

ASCA Submission: Biocompatibility



ASCA Submission: Biocompatibility



Example ASCA Summary Test Report: Cytotoxicity

ASCA Test Method: Cytotoxicity – MEM Elution (ISO 10993-5)
Administrative Information

1. Testing Laboratory Name: Test Lab ABC
2. ASCA Testing Laboratory Identification Number: TL-999
3. Testing Location(s): 123 Main St, XXX, Virginia
4. Testing Date(s): February 1st, 2022—February 28, 2022
5. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☒ Standard (and particular test method) was in testing laboratory's scope of *ASCA Accreditation*
   - ☒ *ASCA Accreditation* was not suspended

ASCA Test Article Prep SOP#: *SOP-SamplePrep-123-Rev2.0, SOP-SampleExtr-456-Rev3.0*

☒ Test Article was prepared per the above protocol (no deviations/
☐ Test Article was prepared per the above protocol, with the follow
filtering, extract manipulation, pH adjustment):

Description of deviations/amendments

Test Article:
☒ Entire final finished device
☐ Representative sample selection per SOP
☐ Other:[2] *[DESCRIBE]*

Extraction Solvent:
☒ MEM with 5-10% animal serum
☐ Other:[3] *[DESCRIBE]*

Extraction Ratio:
☒ 6cm²/ml (<0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:[4] *[DESCRIBE]*

Extraction Conditions:
☐ 37°C, 24 h
☒ 37°C, 72 h
☐ 50°C, 72 h
☐ 70°C, 24 h
☐ 121°C, 1 h
☐ Other:[5] *[DESCRIBE]*

8 pages
20-40 minutes

☒ The test article and extract DID NOT change color, and the extract DID NOT appear turbid or have particles.
☐ There were changes in color/turbidity or particles in the test article and/or extract OR there was swelling/degradation of the test article.[5]

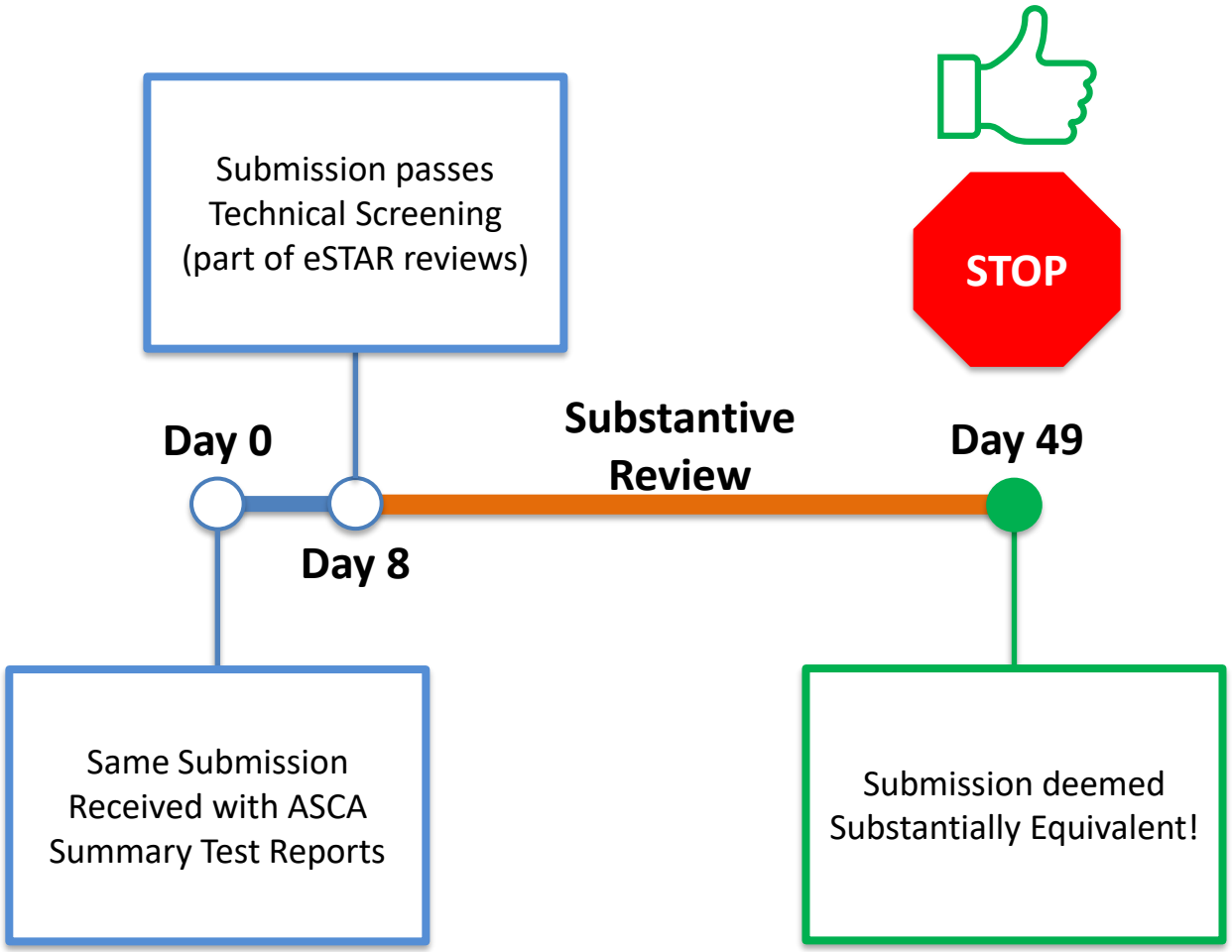
ASCA Test Method SOP #: *SOP-ASCA-MEM-789-Rev2.0*
☒ Test was conducted per the above protocol (no deviations/amendments) and 21 CFR 58; or
☐ Test was conducted per the above protocol and 21 CFR 58, with the following deviations/amendments:[6]

	hr ults	72 hr Results	Conclusion
	ade 0/0	Grade 0/0/0	Performed as expected
	ade 0/0	Grade 0/0/0	Performed as expected
	ade 4/4	Grade 4/4/4	Performed as expected
Test Article Extract (100% neat)	Grade 0/0/0	Grade 0/0/0	Non-cytotoxic

I confirm that:
☒ The above summary information includes all original and any retest data; and
☒ I have checked that there are no differences between the complete test report and this ASCA summary test report.

John Standards 3/15/2022
Name: [TYPED NAME POSITION] Date

What Could Have Been…



	Biocompatibility Justification at Day 0	Using ASCA Testing from Day 0
Deficiencies	1 major	0
FDA Days	76	~49 (or less)
Total Days after Day 0	189	~49 (or less)

Case Studies – Review time and Feedback

510(k) for Radiofrequency physiological signal transmitter and receiver

BSEP ASCA STRs Provided **After AI Letter**

- IEC 60601-1-2
- IEC TR60601-4-2

Review Conclusion for 510(k) - SESE	
Number of Pages	**9 pages**
ASCA Review time	**~30 minutes**
ASCA Deficiencies	**0 deficiencies**

Comments from Review Staff:

- "Much quicker" compared to full test report review
- "Beneficial to industry because they're less likely to get deficiencies for the test lab"
- Less likely to have concerns with data integrity with ASCA test lab

Case Studies – Review time and Feedback

510(k) for Microwave Ablation System

Both BSEP and Biocomp ASCA STRs Provided

- IEC 60601-1
- IEC 60601-1-2
- IEC TR 60601-4-2
- IEC 60601-1-6
- IEC 60601-2-6
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-11
- ISO 10993-23

Review Conclusion for 510(k) - SESE	
Number of Pages	**12 pages (Biocomp)** **21 pages (BSEP)**
ASCA Review time	**~30 minutes**
ASCA Deficiencies	**0 deficiencies**

Comments from Review Staff:

- "It was quick"
- "No issues"
- ASCA Program gave reviewer "lots of confidence"

What Do Reviewers Think?

Much **quicker** compared to a full test report review

Increased **confidence** in the test reports

No issues

ASCA

Fewer deficiencies

Really **turned the submission around**

Easier to review

Helps **mitigate** the **risk** of data integrity issues

ASCA By the Numbers

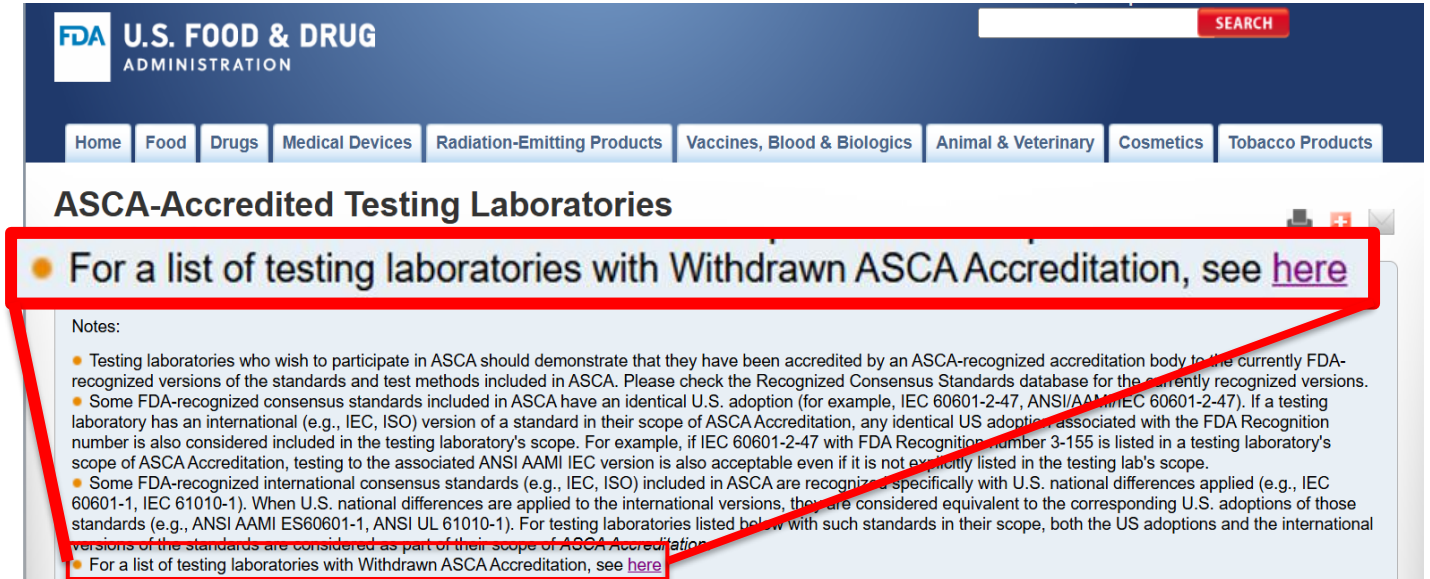
98 ASCA-accredited Testing Laboratories	**200+** Manufacturers have used ASCA	**50+** Manufacturers have used ASCA multiple times
88% ASCA STRs have not needed additional technical information	**297** Submissions with ASCA STRs	**97%** ASCA submissions for which FDA requested no complete test reports

Trustworthy Labs – Enhanced Oversight – Enhanced Communication

ADDITIONAL ASCA BENEFITS

Additional Benefits of the ASCA Program

- **Trustworthy list of high-quality ASCA-accredited test laboratories**
  - Includes helpful links to Recognized Consensus Standards database
- **Direct communication pathway with TLs**
  - Can directly train TLs on a variety of topics to educate on FDA expectations
- **Ensuring only high-quality labs are ASCA-accredited**
  - ASCA audits precipitated the withdrawal of *ASCA Accreditation* from (4) TLs
  - Withdrawn labs also explicitly listed (link)



Unreliable Test Lab Data - Background

Fraudulent and Unreliable Laboratory Testing Data in Premarket Submissions: FDA Reminds Medical Device Manufacturers to Scrutinize Third-Party-Generated Data

Date Issued: February 20, 2024

The U.S. Food and Drug Administration (FDA) is reminding sponsors of device studies and manufacturers of devices ("device firms") to carefully evaluate the third parties they engage to conduct performance testing and to independently verify all testing results before submitting to the FDA. It is the responsibility of device firms to qualify third parties

The FDA has identified an increase in submissions containing unreliable data generated by third-party test labs, including from numerous such facilities based in China and India. This alarming trend has resulted in the FDA being unable to reach a substantial equivalence determination or otherwise authorize marketing for medical devices whose submissions include such data. Sponsors and manufacturers making submissions are

Link

Unreliable Test Lab Data - Background

FDA NEWS RELEASE

FDA Issues Warning Letters to Two Chinese Firms Regarding Data Quality and Integrity Concerns, Violative Lab Practices

Firms Provided Third-Party, Nonclinical Premarket Testing; Agency Review Ongoing

Share | Post | Linkedin | Email | Print

Link

For Immediate Release: September 11, 2024

WARNING LETTER

Mid-Link Testing Company, Ltd

Link MARCS-CMS 687111 — SEPTEMBER 10, 2024

WARNING LETTER

Sanitation & Environmental Technology Institute dba SDWH

MARCS-CMS 687970 — SEPTEMBER 10, 2024 Link

WARNING LETTER

CCIC Huatongwei International Inspection Co., Ltd.

Link

MARCS-CMS 704332 — JUNE 25, 2025

Product: Medical Devices

Recipient:
Mr. Xiaojun Su
Test Facility and General Manager
CCIC Huatongwei International Inspection Co., Ltd.

Issuing Office:
Center for Devices and Radiological Health
United States

For Immediate Release: September 11, 2024

WARNING LETTER

Mid-Link Testing Company, Ltd

Link MARCS-CMS 687111 — SEPTEMBER 10, 2024

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For Immediate Release:

WARNING LETTER

Mid-Link Testing Company, L

Link

MARCS-CMS 687111 — SEPTEMBER 10, 2024

WARNING LETTER

Jiangsu Kerbio Medical Technology Group Co.

MARCS-CMS 705188 — JULY 11, 2025

Link

Product: Medical Devices

Recipient:

Mr. Shangyou Lin

Chief Executive Officer, General Manager

Jiangsu Kerbio Medical Technology Group Co.

Issuing Office:

Center for Devices and Radiological Health

United States

WARNING LETTER

CCIC Huatongwei International Inspection Co., Ltd.

Link

MARCS-CMS 704332 — JUNE 25, 2025

Product: Medical Devices

WARNING LETTER

Jiangsu Kerbio Medical Technology Group Co.

705188 — JULY 11, 2025

Link

Issuing Office:
Center for Devices and Radiological Health
United States

WARNING LETTER

Palamur Biosciences Private Limited

MARCS-CMS 708579 — DECEMBER 11, 2025

Product: Medical Devices

Link

Recipient:
S. Ramamoorthy, Ph.D.
Chief Executive Officer (CEO)
Palamur Biosciences Private Limited

Issuing Office:
Center for Devices and Radiological Health
United States

Unreliable Test Lab Data - Background

Notifications on Data Integrity – Medical Devices

Link

The FDA's Center for Devices and Radiological Health (CDRH) is vigilant in ensuring data submitted to the FDA can be relied upon to assess the effectiveness, safety, or risk of a device. The FDA has noted an increase in unreliable testing data generated by third-party testing facilities on behalf of device manufacturers and sponsors. This has resulted in the FDA being unable to reach a substantial equivalence determination or otherwise authorize marketing for medical devices whose submissions rely on such data. In addition to obvious negative impacts to sponsors, these adverse determinations caused by unreliable testing data may also delay or reduce access to new devices that the FDA ultimately authorizes for patients and health care providers and increase the potential for disruption in the supply chains for devices.

Additional Benefits of the ASCA Program

- **Trustworthy list of high-quality ASCA-accredited test laboratories**
  - Includes helpful links to Recognized Consensus Standards database
- **Direct communication pathway with TLs**
  - Can directly train TLs on a variety of topics to educate on FDA expectations
- **Ensuring only high-quality labs are ASCA-accredited**
  - ASCA audits precipitated the withdrawal of *ASCA Accreditation* from (3) TLs
  - Withdrawn labs also explicitly listed (link)
- **Direct communication pathway with ABs**
  - Two labs (not ASCA-accredited) listed on Notifications on Data Integrity
  - Using ASCA's communications channels, we notified their ABs
  - ISO/IEC 17025 accreditation for both subsequently withdrawn

Conformity Assessment Should Not Be Left to Amateurs!

THANK YOU

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health
Division of Standards and Conformity Assessment