Accreditation Body (AB) Perspective

Impact of FSMA on Stakeholders and Laboratories

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National Accreditation Board (ANAB)

- Offers
  - ISO programs
  - Sector specific programs (schemes)
- 72 Paid professional staff, 100+ technical assessors, 4 locations
- Accredited customers in 58 countries
- Largest AB in the Western Hemisphere
- ANSI is the official U.S representative to the International Organization of Standardization (ISO)

Food Safety Modernization Act (FSMA)

- Accredited Third-Party Certification*
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
- Foreign Supplier Verification Programs (FSVP)*
- FSMA Proposed Rule on Laboratory Accreditation*
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Sanitary Transportation of Human and Animal Food
- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
- Voluntary Qualified Importer Program (VQIP)*

Food Safety Rule on Laboratory Accreditation

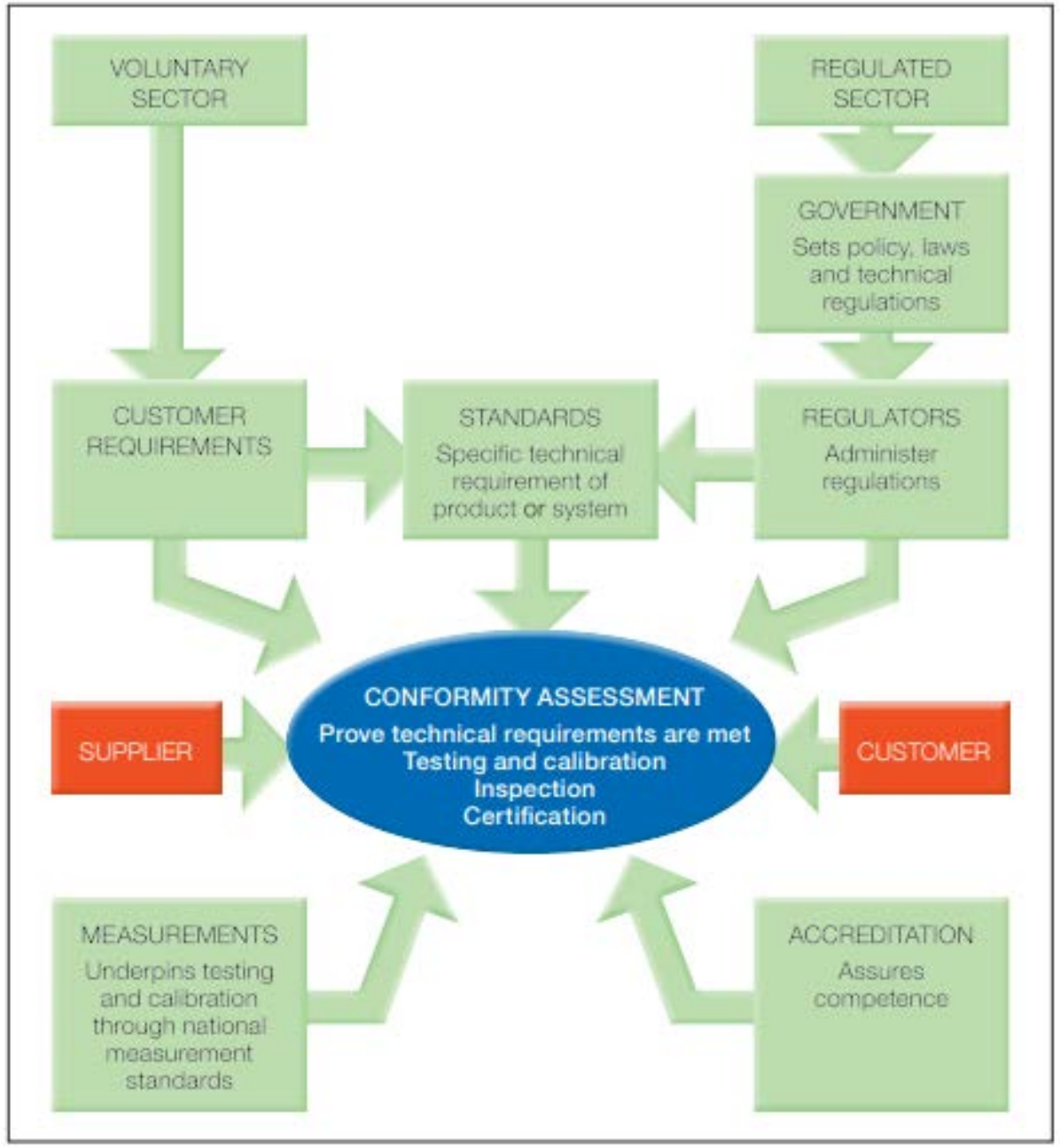
- Labs and Accreditation Bodies will follow Model Standards
- Help the FDA ensure safety of U.S. Food Supply
- Protect U.S. Consumers
- Quality of Data for Food Testing Improved
- Consistently reliable and valid result
- Oversight by FDA

• FSMA Proposed Rule on Laboratory Accreditation*

- Requirements for Laboratories and Accreditation Bodies
- Voluntary Consensus Standards
- Accredited Testing Labs needed to:
  - Provide testing for evidence to support imported food admission to U.S.
  - Help the FDA in response to food testing order
  - Help with testing for recall/other order for suspect food
  - Help with testing identified food (certain shell eggs, bottled water, and sprouts)
- Testing sent directly to FDA
- Pathway to streamline trusted submissions
- Oversight by the FDA

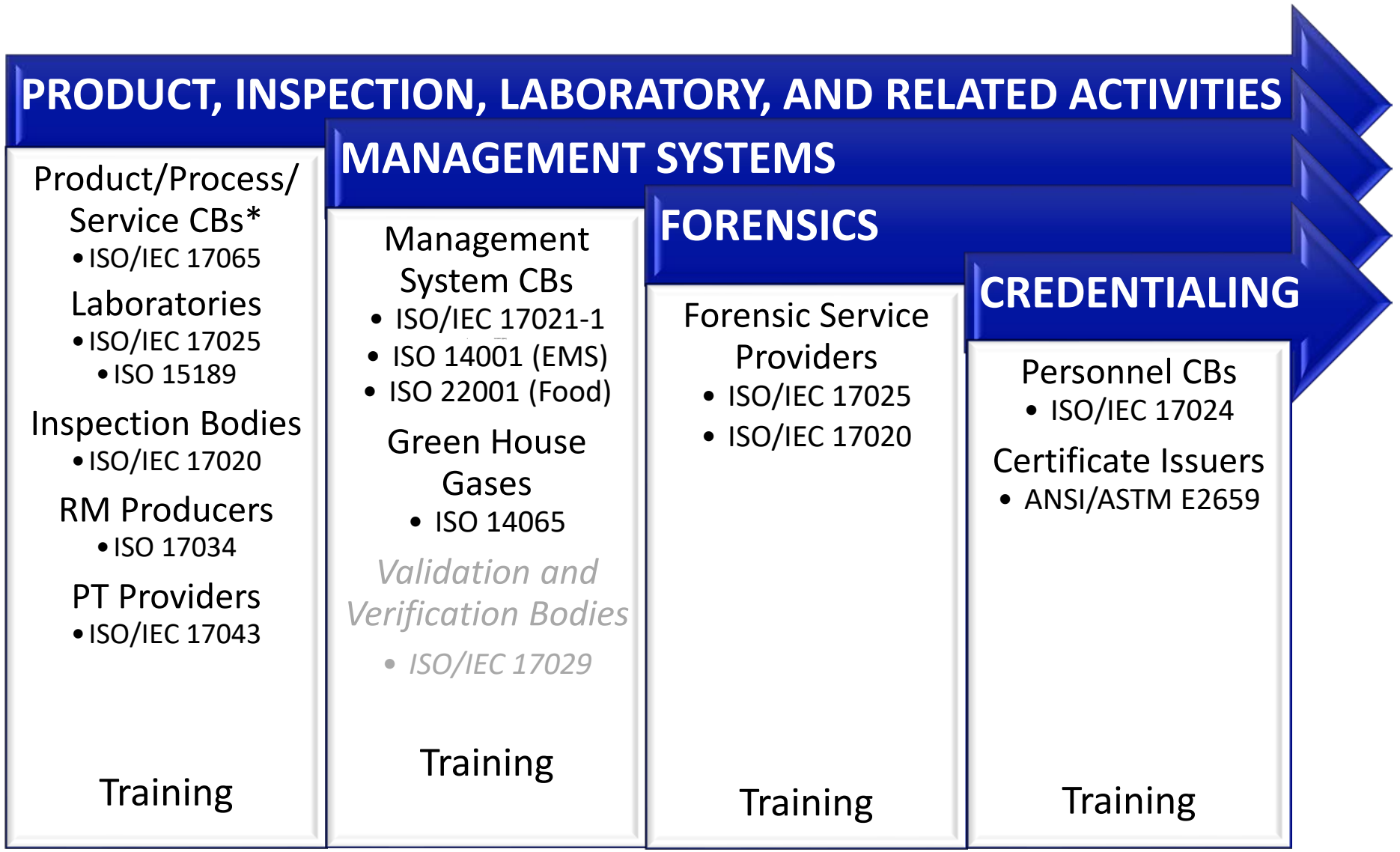
ABs Perspective on Laboratory Accreditation for Analyses of Food 21CFR Parts 1, 11, 16 and 129

- Significant Step in the Right Direction
- Public/Private Partnership
- Needs Clarification and Definition
  - Roles and Responsibilities
  - Nomenclature
  - Supplemental Requirements
- Conformity Assessment Structure and Design can help



Typical Conformity Assessment Model

1. Written Standards
   - ISO/IEC 17025
   - Additional FSMA Requirements
2. Standards of Measurement
   - Reference Materials
3. Legal Metrology Service
   - NIST or other NMI
4. Testing, Inspection, Calibration Services
5. Equipment/Goods capable of making the measurements
6. Third Party Conformity Assessment Services
   - Peer recognized ABs
7. Assurance of Quality
   - Certification of Conformance
   - Accreditation of Competence
   - Recognition of ABs to use and be found to comply with 1-6.



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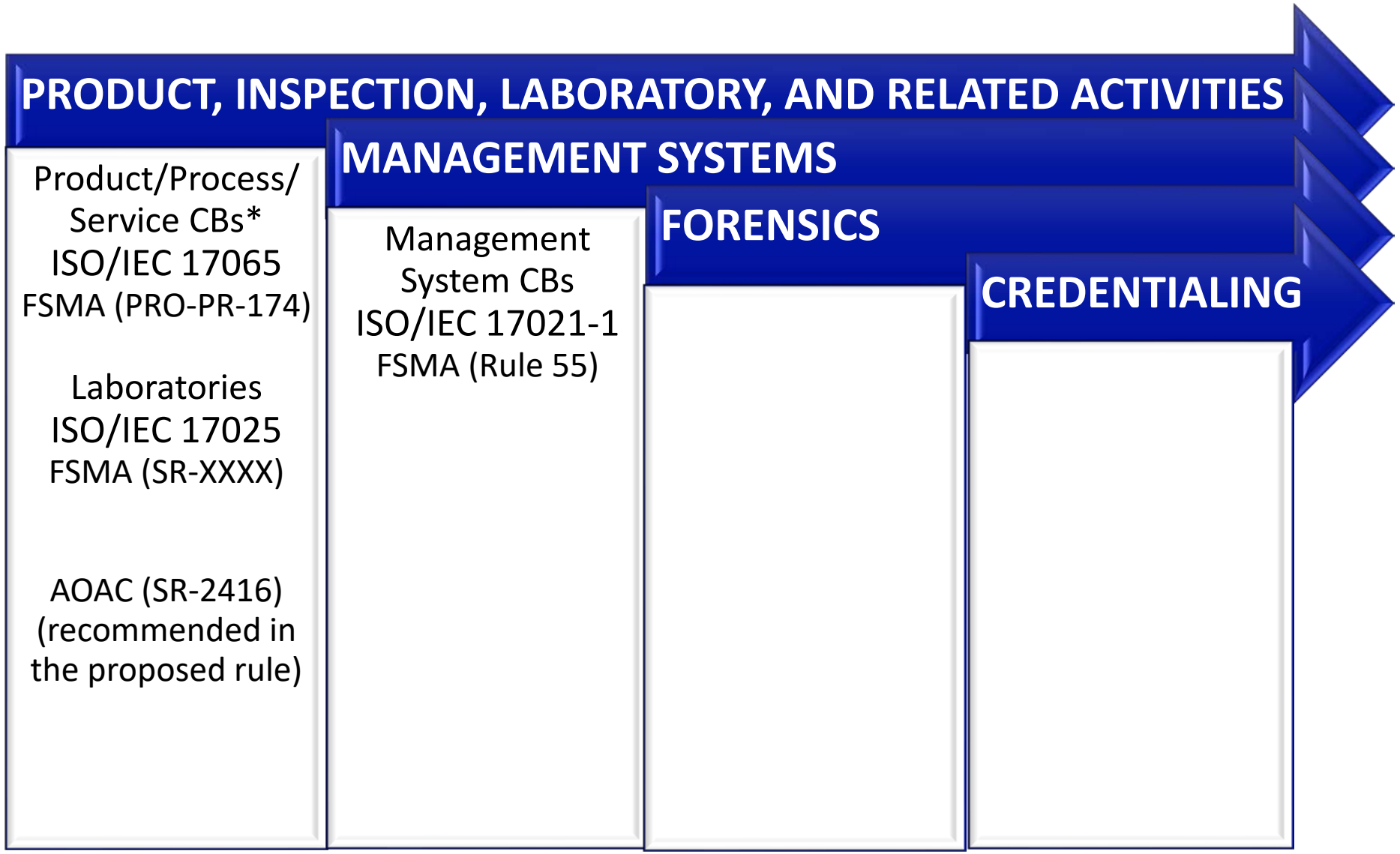
Conformity Assessment Toolbox

*CB: Certification Body



*CB: Certification Body

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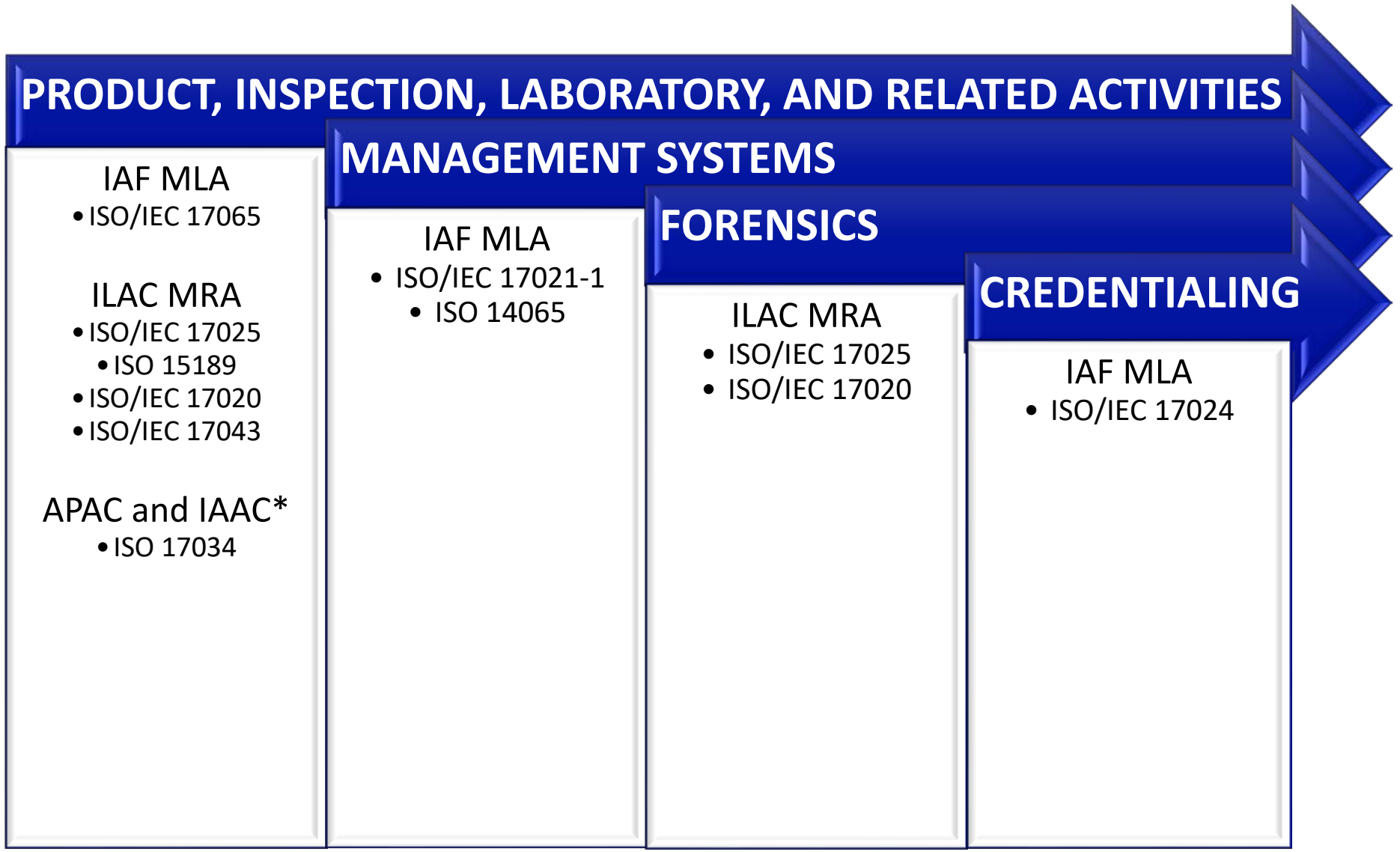
The CA Toolbox Supplements



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International Cooperative Recognitions

*Currently APAC is working on RMP approval from ILAC

III. Background

- Corrective Action Testing
- AOAC Guidelines
- Current Practices support Competence
- NTTAA
- Limitation of ISO/IEC 17025 Sections not needed

VI. Description of the Proposed Rule A. Proposed General Provisions

- FDA defines “accreditation” to mean a determination by a recognized accreditation body … “accreditation under section 422 of the FD&C Act requires a determination by a recognized accreditation body that a laboratory meets our model standards.”

- The FDA defines “recognition” to mean a determination by FDA that an accreditation body meets the applicable requirements of the program and is authorized to accredit laboratories under the program.

VI. Description of the Proposed Rule B. Proposed Provisions about General Requirements of This Rule

- Rule applies to Independent and captive (in-house) laboratories
- Domestic and Foreign laboratories
- When does the rule apply … balance of safety and health
- Description of how FDA will make public the list of accredited laboratories and recognized accreditation bodies

VI. Description of the Proposed Rule C. Proposed Provisions About Recognition of Accreditation Bodies

- Ability to substantively assess
- CPSC example a good one
- Scientific and Technical Expertise
- Method Validation and Verification Review
- Technical Resources

Subpart R – General Provisions

1.1102 through 1.1103

- Accreditation
- Accredited laboratory
- FDA Oversight
  - Role and Responsibilities
  - Listing Approval
- Owners and consignees
  - Customers of Laboratories complying with section 7
  - No conflict in 7.3 Sampling
  - No conflict in 7.8 Reporting

- Rule should not circumvent or limit the customer/supplier (laboratory) relationship requirements
- Requirements for submission should lie with the owner/consignee who in turn issues a contract to the lab (internal or external)

Subpart R — General Requirements

1.1107 through 1.1109

- Five circumstances – balance of risk, safety, health, cost.
- Clarification may be needed if a known method will be specified for testing or if specifications will used (scope considerations)
- Probationary status with listings will cause confusion

Subpart R — Recognition of Accreditation Bodies

1.1113 and 1.1118 through 1.1125

- International Recognition is difficult for a reason
- Impartiality and Conflicts of Interest (ownership definition not realistic)
- Onsite vs. Remote Assessments Responsibility
- Appeals Policy
- Withdrawal and Reduction of Scope
- Probation not “normal” for Conformity Assessment

Subpart R — Procedures for Recognition of Accreditation Bodies

1.1128 through 1.1138

- General Application Release and Deadline
- Observation of Regional Cooperation Evaluation Recommended
- Probation not normal and can cause problems
- ANAB Supplemental Requirements process is typical (validation, verification, and PT can be added if needed)
- Exclusion of 7.3 and 7.8 is not needed

Subpart R — Procedures for Accredited Laboratories

1.1146 through 1.1153

- Supplemental Impartiality Requirements
- PT provider accreditation requirement needed to ISO/IEC 17043
- Sampling can be covered with ISO/IEC 17025 plus supplemental requirements …
- Contracting relationship issues exist with Sampling and Method Exceptions
- Reporting requirements to the FDA directly can be mitigated through a listing agreement.
- What is part of the reporting requirements for an accredited lab? For Example why would an accredited lab submit the supporting inputs to the report? Accredited labs have an attestation of competence from a third party.
- The FDA is making the statement the requirements of this Proposed Rule will be specified by a laboratory's customer (owner or consignee)

Subpart R — Procedures for Accreditation of Laboratories

1.1158 through 1.1165

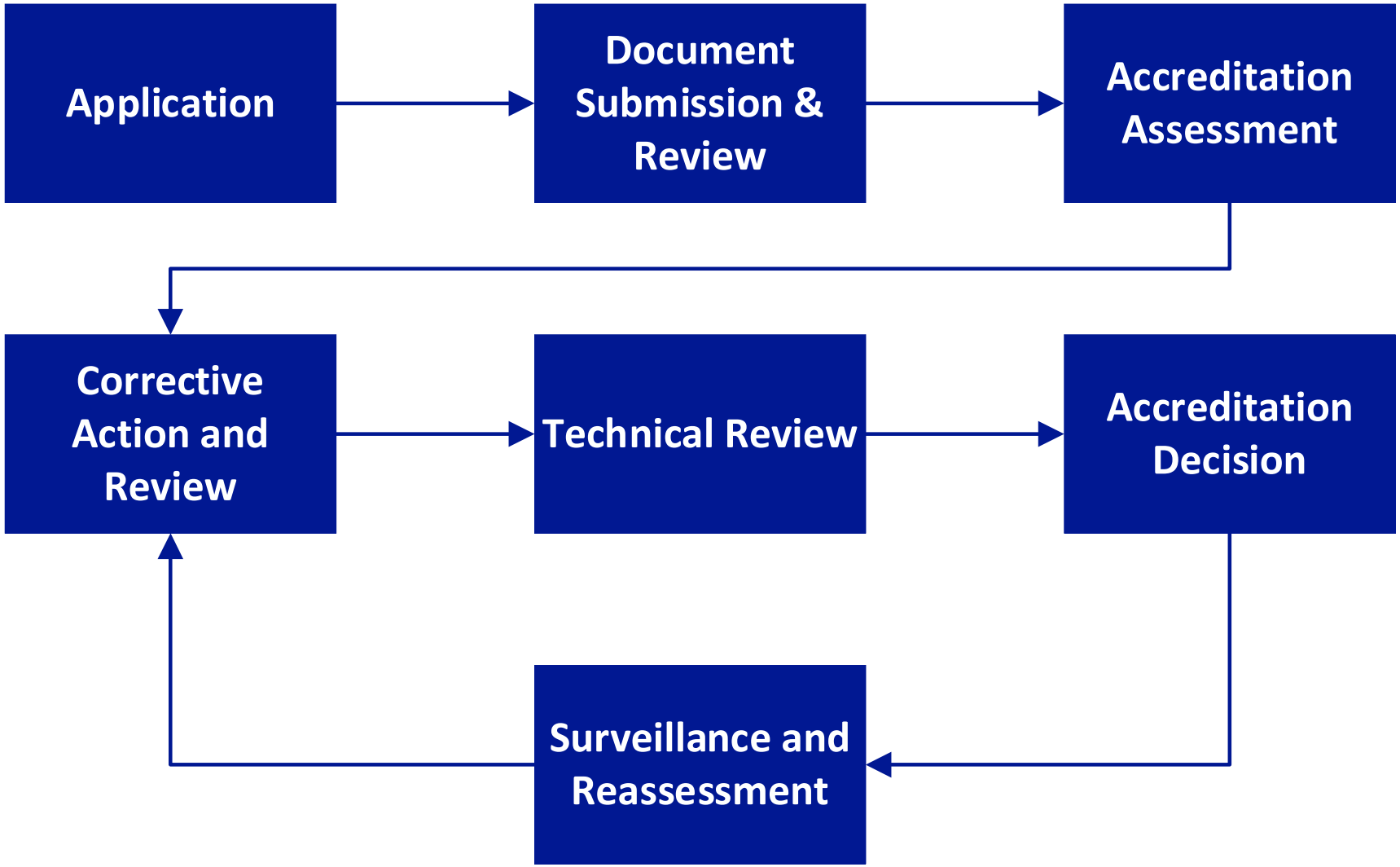
- Separation between FDA's oversight and an ABs ability to accredit should be made
- A laboratories accreditation falls with the AB
- FDA should look to other words (if possible) to a laboratories status than accreditation
- FDA deficiencies on reporting should be looped back to the AB
- Contract law allows the AB to control the status of the laboratory. The FDA confuses the lines of contract if they revoke/withdraw a labs accreditation

Requesting FDA Reconsideration, FDA Internal Review, or Regulatory Hearing of FDA Decision Under This Subpart

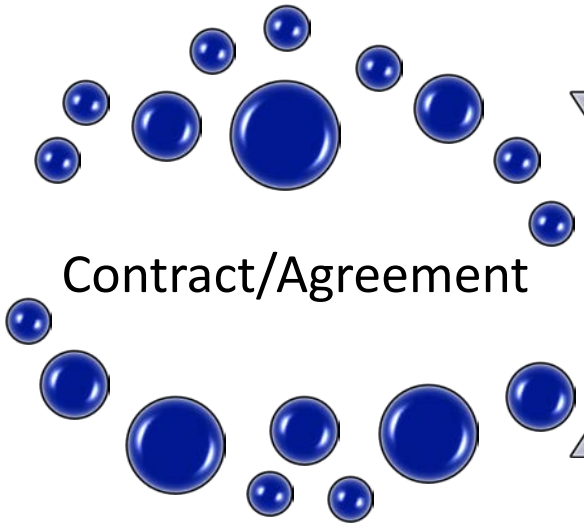
1.1171 through 1.1174

- Allowing for remedy and cause per Conformity Assessment principles
- Simplifying the Rule with defining structure and relationships
  - Requirements on owners
  - Reporting requirements
  - Limit to Listing similar to other Recognition programs.

Accreditation Process



Simple CA Relationship Model



Invokes Terms and Conditions including Accreditation Requirements (FSMA)

Accredited Scope including any additional requirements

An AB's Product

FDA could use this product if the FSMA rules are agreed in the contract

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