



Steps to Accreditation



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What is Accreditation?

- Recognition given to a Conformity Assessment Body – CAB – that fulfills specified requirements
- Acknowledges a CAB is competent to carry out specific tasks
- Includes many different disciplines over a wide range of industries
- Best way to ensure a CAB is consistently producing reliable results



Why Accreditation?

- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- Specifies requirements for competence, impartiality, and consistent operation
- Differentiate between technical competence and mere compliance



Why Accreditation?

- Shows the CAB's commitment to continual improvement
- Increases competitive advantage
- Helps manage risk
- Acceptance of results between countries
- Strengthens credibility
- Provides consumer and industry confidence



Optional Accreditation Schemes

- AOAC International Guidelines
 - For labs performing microbiological and chemical analyses of food, dietary supplements, and pharmaceuticals
- ASA PFC Program
 - Americans for Safe Access Patient Focused Certification Program for cannabis testing labs
- GLPs and GMPs



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Why Accreditation?

- Confidence in test data is paramount to product acceptance
- Valuable for international acceptance of test data
- CABs strive to produce more reliable results, leading to greater customer confidence
- Regular oversight ensures results are consistently dependable and defensible



Who Offers Accreditation?

- Every economy has its own accrediting body (AB)
 - The US has multiple ABs
 - Visit www.ilac.org for a complete listing
- ABs required to adhere to an international standard
 - Evaluation by international peers
 - Ensures acceptance of valid test data worldwide



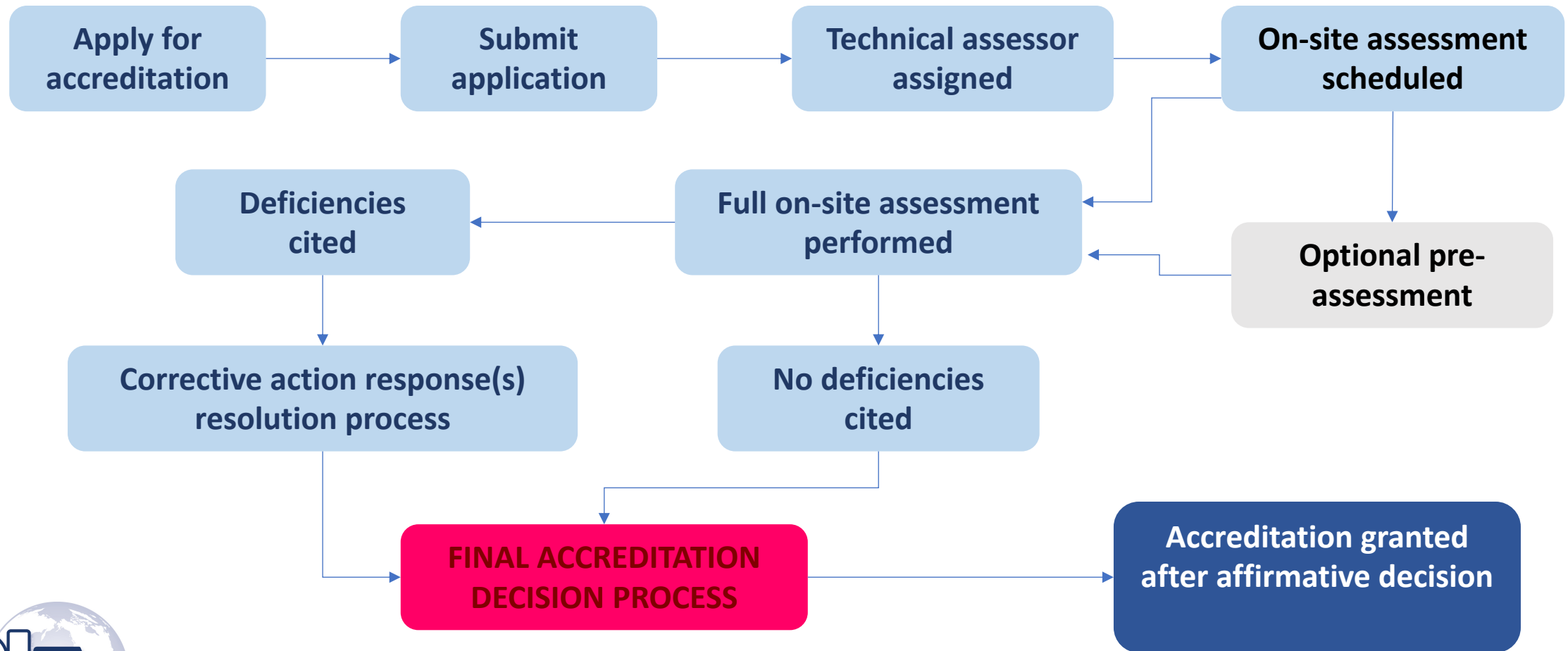
About A2LA

- Only independent, non-profit AB in the US
- Mutual Recognition Arrangements
 - International Laboratory Accreditation Cooperation (ILAC)
 - International Accreditation Forum (IAF)
 - Asia Pacific Accreditation Cooperation (APAC)
 - Inter-American Accreditation Cooperation (IAAC)
- Domestic recognition – federal, state, local, industry
- MRAs provide acceptance of your accredited work



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Steps to Accreditation



Applying for Accreditation

- Complete the application on the AB's website
 - Company information
 - Authorized representative
 - Assessment schemes
 - Tests/technologies to be accredited
- Assignment of an accreditation officer
 - Main point of contact to guide through the accreditation process



Applying for Accreditation

- Submit required documents
 - Organization chart
 - Equipment list
 - Completed accreditation scheme checklist
 - Supporting documents
 - 4-year proficiency testing plan
 - Technical staff matrix
 - Draft scope of accreditation



Assessors

- Minimum 10 years' experience
 - Most have 20+ years'
- Demonstrate expertise to make professional judgments on quality and competence
- Proposed before acceptance
 - Based on knowledge and location
 - Bio-sketch available for review
 - Lab approves or denies assessor



Preparing for the On-site Assessment

- Typically scheduled within 60 days of assessor assignment
- Prior document review
 - Examine management system documents for major gaps
 - Allows CAB to respond to any findings
- Optional pre-assessment
 - On-site or via remote
 - Findings do not need to be responded to



On-Site Assessment

- Assessors are fact finders
- Verify compliance
 - ISO/IEC 17025
 - AB policies
 - Optional accreditation schemes
- Confirm technical competence
 - Observe the test
 - Interview personnel
 - Verify SOP being followed
 - Inspect equipment



Non-conformances

- Pointed out when they are noticed
 - Prevents surprises at the end of the assessment
- Written into final report as deficiencies
- 30 days from close of assessment to respond to deficiencies
 - Corrective action
 - Root cause analysis
 - Objective evidence



Accreditation Council

- CAB reviews members to determine conflicts of interest
- Members selected based on technical expertise and knowledge of the standard
- AC reviews assessor report and corrective action responses

Accreditation cannot be granted without approval from the AC



Post-assessment

- Accreditation granted for 2 years
- Surveillance assessment – year 1
- On-site assessment – years 2, 4, etc.
- Annual review – years 3, 5, etc.



Summary

- Provide consumer and industry confidence
- Optional schemes add extra level of assurance in data and competence of technicians
- Straightforward process
- Single point of contact to provide personalized customer care
- Unbiased AC votes on all accreditation packages



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