ACCREDITATION MANUAL FOR
PRODUCT CERTIFICATION,
INSPECTION, LABORATORIES, AND
RELATED ACTIVITIES (PILR)
CONFORMITY ASSESSMENT BODIES

AUTHORITY: VICE PRESIDENT
EFFECTIVE DATE: 2020/03/06
DOCUMENT NUMBER: MA 2100
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>2</td>
</tr>
<tr>
<td>Foreword</td>
<td>3</td>
</tr>
<tr>
<td>Accreditation Programs and Recognition</td>
<td>3</td>
</tr>
<tr>
<td>Accreditation Requirements</td>
<td>3</td>
</tr>
<tr>
<td>Organizational Structure</td>
<td>4</td>
</tr>
<tr>
<td>Assessment Process</td>
<td>5</td>
</tr>
<tr>
<td>Estimate and Application for Accreditation</td>
<td>5</td>
</tr>
<tr>
<td>Fees Relating to Accreditation</td>
<td>6</td>
</tr>
<tr>
<td>Proposed Scope Development</td>
<td>6</td>
</tr>
<tr>
<td>Optional Preliminary Assessment Services</td>
<td>6</td>
</tr>
<tr>
<td>Initial Assessment</td>
<td>6</td>
</tr>
<tr>
<td>Granting of Accreditation</td>
<td>7</td>
</tr>
<tr>
<td>Control and Use of Accreditation Symbol</td>
<td>7</td>
</tr>
<tr>
<td>Accreditation Cycle</td>
<td>7</td>
</tr>
<tr>
<td>Assessment Delays</td>
<td>8</td>
</tr>
<tr>
<td>Translations for International Assessments</td>
<td>8</td>
</tr>
<tr>
<td>Guidance and Notices</td>
<td>8</td>
</tr>
<tr>
<td>Changes on Conformity Assessment Bodies</td>
<td>8</td>
</tr>
<tr>
<td>Scope Modification</td>
<td>9</td>
</tr>
<tr>
<td>Transfer of Existing Accreditation</td>
<td>9</td>
</tr>
<tr>
<td>Accreditation Information</td>
<td>10</td>
</tr>
<tr>
<td>Accreditation Status</td>
<td>10</td>
</tr>
<tr>
<td>Notification of Change in Accreditation Requirements</td>
<td>10</td>
</tr>
<tr>
<td>Confidentiality and Disclosure of Information</td>
<td>10</td>
</tr>
<tr>
<td>Appeals and Complaints</td>
<td>10</td>
</tr>
<tr>
<td>Impartiality</td>
<td>11</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>11</td>
</tr>
<tr>
<td>Ethics and Code of Conduct</td>
<td>11</td>
</tr>
<tr>
<td>Revision History</td>
<td>12</td>
</tr>
</tbody>
</table>
FOREWORD

Accreditation benefits organizations by providing assurance that they are consistently performing their conformity assessment activities competently and according to appropriate standards. Accreditation provides a benchmark for maintaining that competence.

The ANSI National Accreditation Board (ANAB) publishes directories of accredited organizations that include contact details and information on accredited capabilities as a means for accredited clients to promote accredited services to their potential clients. Through a system of international agreements, accredited organizations receive a form of international recognition that allows their data, reports, certificates, and services to be more readily accepted in global markets.

This manual defines the relationship between ANAB and its accredited organizations (clients) and explains the operational activities and responsibilities of ANAB and its clients (excluding forensics and management systems certification bodies¹). It also provides direct reference to processes and requirements that are followed to ensure the accreditation meets the requirements of ISO/IEC 17011.

The term “client” as used in this manual refers to any body or organization seeking accreditation from or accredited by ANAB.

All references to ISO/IEC, ISO, and ANAB documents and other controlled materials are to the current versions. Most ANAB documents are accessible free of charge at www.anab.org. ILAC and IAF documents are accessible free of charge at www.ilac.org and www.iaf.nu.

ACCREDITATION PROGRAMS AND RECOGNITION


ANAB is recognized as conforming with ISO/IEC 17011 and is a full member of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA). ANAB is a signatory of the Asia Pacific Accreditation Cooperation (APAC) MRA and the InterAmerican Accreditation Cooperation (IAAC) MLA. In addition, ANAB is recognized nationally by regulators and specifiers.

ACCREDITATION REQUIREMENTS

This manual outlines the general processes for accreditation and refers to applicable accreditation requirements documents.

The following accreditation requirement documents are used to support each program offered by ANAB:

¹Accreditation requirements for ANAB management systems certification bodies and ANAB forensic science laboratories can be found in their respective accreditation manuals.
AR 2251, Accreditation Requirements: ISO/IEC 17025 Calibration Laboratories
AR 2250, Accreditation Requirements: ISO/IEC 17025 Testing Laboratories
AR 2259, Accreditation Requirements: ISO/IEC 17025 Dimensional Measurement Laboratories
AR 2252, Accreditation Requirements: ISO/IEC 17020 Inspection Bodies
AR 2258, Accreditation Requirements: ISO 17034 Reference Material Producers
AR 2255, Accreditation Requirements: ISO/IEC 17043 Proficiency Test Providers
AR 2253, Accreditation Requirements: ISO 15189 Medical Testing Laboratories
AG 1008, ANAB Terms and Conditions for Accreditation

Additional requirements may apply to specific technical fields and conformity assessment schemes developed by regulators and specifiers.

All ANAB documents that define accreditation requirements are available on ANAB’s website (www.anab.org).

ORGANIZATIONAL STRUCTURE

ANAB offers accreditation to organizations made up of one legal entity with multiple locations and to organizations within a family of companies with separate legal entities.

ANAB will review all facilities that belong to the entity seeking accreditation and deliver or support key activities to provide assurance that they are subject to the same management system and use the same management manual, which must comply in all respects with the requirements of the applicable standard and accreditation requirements. In addition, ANAB reviews the organization to ensure key activities are performed as part of a single management system to determine if a multi-site accreditation is appropriate or if separate accreditations for each site are warranted. ANAB requires that the entity designate one person as the main point of contact related to accreditation activities.

Applicants that wish to seek multi-site accreditation are expected to declare their intention to seek a multi-site accreditation during the application process.

PR 2307, Administrative Process Rule: Multi-Site Accreditation

Note: PR 2307 is applicable for accreditation of laboratories, inspection bodies, proficiency test providers, and reference material producers.
ASSESSMENT PROCESS

The purpose of the assessment process is to determine the client's competence and conformity with the requirements of the applicable accreditation standard(s), ANAB accreditation requirements, and the overall competence to a declared scope of accreditation and certification scheme, as applicable. Various assessment activity types are used, both on site and remotely. Assessment activities include all locations (physical and virtual) where key activities of the client are performed.

The ANAB assessment process was developed to sample in various details the client's quality system and technical competence to a scope of accreditation. ANAB determines through interviews, reviewing documents and records, and witnessing of the scope of accreditation if the client's process or system is effectively implemented and meets applicable requirements. The assessment team uses these assessment activities to determine if the client continues to meet all ANAB requirements.

ANAB establishes surveillance and reassessment plans based on the client's accreditation history and competence. ANAB designs the reassessment and surveillance plans for each accredited organization to ensure representative samples of the scope of accreditation and management system are assessed on a regular basis.

ANAB may conduct surveillance assessments on a more frequent basis or schedule an early reassessment if ANAB determines this is warranted.

ESTIMATE AND APPLICATION FOR ACCREDITATION

Applicants begin the application process by contacting ANAB and requesting a quote for accreditation.

Estimates are based on several factors, including but not limited to the number of conformity assessment programs and sites, the complexity of work defined in the proposed scope of accreditation, the certification scheme, the number of technical staff, and the type of services performed in house and/or off site.

The signed application for accreditation and the requirements of the relevant accreditation program establish the relationship between ANAB and the client. The applicant for accreditation shall sign a program agreement that details the duties and responsibilities of the parties.

ANAB will provide a confidential estimate of the cost of the accreditation based on the information submitted.

See www.anab.org for contact information.
FEES RELATING TO ACCREDITATION

ANAB invoices various fees based on the assessment activity and travel. Clients are directed to these document for details:

- **PR 2310, Administrative Process Rule: Fees and Travel**
- **PR-122, (ISO/IEC 17065) Fee Schedule**

PROPOSED SCOPE DEVELOPMENT

During the application and quoting process, the client must define a proposed scope of accreditation in accordance with the appropriate ANAB scope instructions.

The proposed scope of accreditation is a working document and is not an indication of accreditation status. Therefore, the proposed scope shall not be shared with any entity other than ANAB or its authorized representatives.

The scope of accreditation is a formal document owned by ANAB and issued to the accredited client that defines the technical activities for which accreditation is sought. When accreditation has been granted, ANAB issues an approved final scope of accreditation.

OPTIONAL PRELIMINARY ASSESSMENT SERVICES

ANAB offers optional assessment activities prior to an initial accreditation assessment to help an applicant organization understand accreditation requirements and prepare for accreditation. These activities provide an opportunity for the client to evaluate its preparedness for the initial accreditation assessment.

ANAB does not provide consultation services because this is considered a conflict of interest for an accreditation body.

INITIAL ASSESSMENT

Leading up to the initial assessment, the client is expected to have effectively implemented a management system meeting the requirements of the applicable accreditation standard and applicable ANAB accreditation requirements.

Prior to the initial assessment, ANAB will perform a document review. The document review typically is performed by the lead assessor assigned to the initial assessment activity. The lead assessor will review the management system documentation and determine if the client’s documentation fulfills the requirements of the accreditation standard and is ready for the initial assessment. In addition, a technical assessor may be involved with regard to scheme requirements.

The client shall be able to demonstrate technical competence and the ability to competently perform all items identified on the proposed scope of accreditation and certification scheme(s).
Within a 12-month period prior to the initial accreditation assessment, the client is expected to complete an internal audit and management review covering all elements of the applicable standards. The client shall meet all applicable ANAB accreditation program requirements.

GRANTING OF ACCREDITATION

ANAB reviews on a timely basis the assessment documentation to ensure that the assessment has taken place according to ANAB requirements. The technical review ensures that the client has met all requirements for accreditation, demonstrated adequate technical competence and provided appropriate corrective action(s) for all issued opportunities for improvement and nonconformities if applicable. ANAB technical staff also have the option, if necessary, to require that additional assessment activities be performed before an accreditation decision can be confirmed.

Upon completion of the ANAB technical review, the decision to grant accreditation will be made by ANAB. After the decision to grant accreditation is confirmed, ANAB will provide the certificate and scope of accreditation. The client is added to the directory of accredited clients on the ANAB website.

ANAB may conduct extraordinary assessment activities outside of a typical assessment cycle as a result of complaints, proficiency testing performance, location changes, organizational changes, and/or other situations in which it is necessary to ensure the integrity of the accreditation. ANAB advises clients if extraordinary assessments are required.

CONTROL AND USE OF ACCREDITATION SYMBOL

Upon granting of accreditation, ANAB allows its accredited clients to refer to, promote, and advertise their accreditation status through the use of an accreditation symbol. ANAB owns and controls the certificate and scope of accreditation and use of the ANAB logo and accreditation symbols.

Accredited clients benefit from the use of the accreditation symbol by the acceptance established through mutual recognition agreements (MRAs) among accreditation bodies.

ANAB-accredited organizations wishing to display their accredited status on certificates and reports shall use the appropriate accreditation symbol as provided by ANAB.

- PR 1018, Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status

ACCREDITATION CYCLE

ANAB follows a two-year accreditation cycle when performing assessment activities. Various assessment activities are performed annually by ANAB to ensure continuing compliance with accreditation requirements. The accreditation cycle and accreditation activities are designed to provide ANAB with a system to monitor the activities of the client in order to maintain confidence that accreditation requirements continue to be fulfilled.

The client may request and receive additional assessment activities in order to extended their scope during the accreditation cycle.

- PR 2303, Administrative Process Rule: Assessment Activities
**ASSESSMENT DELAYS**

If a client causes delay in the accreditation process, ANAB will follow the provisions of the program agreement.

- **PR 2305, Administrative Process Rule: Delays Caused by the Customer**

**TRANSLATIONS FOR INTERNATIONAL ASSESSMENTS**

ANAB may require management system and related technical documents to be in English at the time of allocation of assessment activities. Assessment scheduling may be delayed until ANAB receives all translated documents.

If the required documentation cannot be provided in English, the client must notify ANAB in writing immediately at the time of allocation. Additional translation fees will be invoiced at cost. Assessment scheduling may be delayed until ANAB receives all translated documents.

When required for objective evidence for the closure of nonconformities, records must be submitted in English. Corrective action review will be delayed until ANAB receives all translated documents and records related to corrective action of nonconformities.

Where necessary, ANAB may require an English translator for the assessment activity. The translator may be a member of the facility staff.

**GUIDANCE AND NOTICES**

ANAB has published a series of accreditation guidance and notices to assist in the understanding and application of accreditation requirements. ANAB guidance documents are available on request and on the ANAB website (www.anab.org).

ANAB encourages clients to review and understand all relevant guidance documents.

**CHANGES ON CONFORMITY ASSESSMENT BODIES**

According to ANAB terms and conditions for accreditation, the client shall promptly notify ANAB of any matters that may affect the client’s competence, accredited activities, conformity assessment scheme, or compliance with the requirements for accreditation. The client shall use the ANAB notification process to inform of changes in the following:

- Legal, commercial, or organizational status;
- Organization and management (e.g., key managerial staff or accounting contact);
- Policies or procedures that directly affect the validity of data;
- Physical location or premises;
- Changes to purchase order requirements and/or special invoicing methods required;
- Unsuccessful proficiency testing (or proficiency testing alternative) results;
- Key personnel, equipment, facilities, working environment, or other resources that would impact the validity of data, or the client’s ability to perform accredited work.

Key personnel is defined by ANAB to include the quality manager, technical manager, accounting contact, personnel involved in the review and decision and staff authorized to perform a technical evaluation activity supporting the scope, including uncertainty of measurement, and/or the facilitator of the proficiency testing/inter-laboratory comparison scheme.

Other significant changes affecting the client management system or technical operations and any other matter that may affect the client’s capability, scope, compliance with requirements, or other criteria of competence specified by ANAB.

Upon official receipt of client notification, ANAB evaluates the impact on accreditation and may do any of the following:
- Make note within the ANAB system for future reference;
- Make a brief visit to the client to assess the impact of the change;
- Request further proof of conformity with requirements;
- Revise the scope of accreditation;
- Perform a surveillance visit;
- Perform a full reassessment.

**SCOPE MODIFICATION**

The client can request changes to the scope of accreditation at any time prior to an assessment. Changes may have an impact on cost and time on site.

Voluntary removal of scope items is unlikely to require more than administrative work by ANAB. Additions require review by ANAB technical staff to ensure the requirements of the scope item and ANAB are satisfied.

Technical competence to perform new scope activities is ensured by ANAB prior to addition to the scope of accreditation. This may require a remote or on-site visit to verify the competence of the client to perform the activities or may require only a technical review of documentation. A scope expansion visit may result in either partial or full approval and may result in identified nonconformities requiring corrective action prior to approval.

**TRANSFER OF EXISTING ACCREDITATION**

Organizations accredited by other accreditation bodies can apply to transfer their accreditation from the other accreditation body to ANAB under strictly defined conditions. Only clients currently accredited by an ILAC MRA or IAF MLA signatory accreditation body can qualify for transfer of accreditation. ANAB takes the necessary steps to determine eligibility and ensure a seamless transfer of accreditation.

- PR 2308, Administrative Process Rule: Transfer of Accreditation
ACCREDITATION INFORMATION

ANAB maintains on its website publicly directories of ANAB-accredited clients, including scopes of accreditation and information regarding suspensions and withdrawals of accreditation.

ACCREDITATION STATUS

All ANAB clients are identified on the website by an accreditation status. The accreditation status categories are Applicant, Accredited, Inactive, Voluntarily Withdrawn, Suspended, and Withdrawn. ANAB will notify the client of any changes in the accreditation status.

- PR 2301, Administrative Process Rule: Accreditation Status

NOTIFICATION OF CHANGE IN ACCREDITATION REQUIREMENTS

ANAB will communicate any changes in accreditation requirements or procedures for accreditation, including the date on which the changes take effect. ANAB’s intent is to give clients a reasonable amount of time to implement any required changes.

ANAB will review client implementation of changes at the next scheduled assessment (or first assessment following any implementation period), unless the changes to the accreditation requirements warrant earlier verification, as determined by ANAB. Accreditation requirements will be published on ANAB’s website (www.anab.org).

CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

All information ANAB acquires in relation to ANAB accreditation activities is treated as confidential by all ANAB employees, agents, councils, and committees, and any scheme owners, contractors, or outsourced organizations.

Such information will not be disclosed to any unauthorized party without the written consent of the client, except when the law requires disclosure. When ANAB is required by law to release such information, the client will be informed of the information provided.

ANAB may provide access to confidential information to accreditation peer evaluators from accreditation bodies recognized by ILAC, IAF, or regional cooperation (e.g., APAC, IAAC) or other oversight bodies that have signed appropriate agreements to not disclose confidential information as required by specific schemes. ANAB will make public the client certificate and scope of accreditation.

APPEALS AND COMPLAINTS

ANAB has an established process in place for reviewing and processing appeals and complaints. Clients can submit a formal complaint about any aspect of the accreditation process.
ANAB may receive a complaint from any source, such as a client, another accreditation body, or a stakeholder, via verbal communication, email, or the ANAB survey form. ANAB will take action to ensure a clear understanding of the complaint and take action to appropriately resolve it.

Clients can submit a formal appeal about any assessment finding or accreditation decision. ANAB will take action to ensure a clear understanding of the appeal and take action to appropriately resolve it.

Notification of an appeal shall be provided to ANAB within 30 days of the reported NC, change in accreditation status, or accreditation decision.

- ANSI-PR-004, Appeals
- ANSI-PR-005, Complaints
- PR 6000, Administrative Process Rule: Appeals and Complaints

IMPARTIALITY

ANAB is organized, structured, and operated to safeguard the objectivity and impartiality of its activities in accordance with ISO/IEC 17011 and ANAB demonstrates this through peer evaluations by IAF, ILAC, APAC, and IAAC.

CONFLICT OF INTEREST

As an accreditation body, ANAB ensures that its activities do not compromise the confidentiality, objectivity, and impartiality of its accreditations. Assessors, technical experts, and Accreditation Council members ensure the impartiality of their conduct by declaring no conflict of interest with any activity related to the client and the accreditation process.

ETHICS AND CODE OF CONDUCT

All ANAB contract, leased, temporary, and permanent employees, experts, assessors, and instructors agree to their willingness to observe and be bound by the following to:

- Act in a strictly trustworthy and unbiased manner in relation to both ANAB and any organizations involved in an assessment by them or personnel for whom they are responsible.
- Disclose any relationships they may have with the organization to be assessed before undertaking any assessment function concerning said organization.
- Not accept any inducement, gift, commission, discount, or any other profit from the organization assessed or its representatives or from any other interested person, nor knowingly allow personnel for whom they are responsible to do so.
- Maintain confidentiality and not disclose the findings or any part of them, the assessment team responsible, or any other information gained in the course of an assessment process to any third party, unless authorized in writing by both the assessed organization and ANAB.
- Not act in any way prejudicial to the reputation or interests of ANAB or to the assessed organization.
<table>
<thead>
<tr>
<th>Revision Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Added AR 2259 under Requirement Documents and reference to frequency assessors are assigned to a single CAB under Accreditation Cycle.</td>
</tr>
<tr>
<td>2</td>
<td>Revised section on Control and Use of Accreditation Symbol; revised section on Responsibilities of the Customer to refer to AG 1008 and add section on translations; and revised section on Responsibilities of ANAB to refer to PR 1017.</td>
</tr>
<tr>
<td>3</td>
<td>Under Control and Use of Accreditation Symbol added PR 1018 and effective dates for PR 1018 and AR 2201.</td>
</tr>
<tr>
<td>4</td>
<td>Deleted reference to ISO Guide 34. Updated references to APAC (from APLAC). Deleted AR 2201 under Control and Use of Accreditation Symbol. Updated accreditation process flowchart.</td>
</tr>
<tr>
<td>5</td>
<td>Comprehensive revision and reorganization to incorporate references to the product certification accreditation program.</td>
</tr>
</tbody>
</table>