Table of Contents

TABLE OF CONTENTS ........................................................................................................ 2
OBJECTIVE .................................................................................................................. 3
SCOPE ....................................................................................................................... 3
REFERENCE DOCUMENTS ....................................................................................... 4
AUDITOR ASSIGNMENT ............................................................................................ 4
NOTIFICATION OF CHANGES ..................................................................................... 4
CERTIFICATION PROCESS ...................................................................................... 5
  AUDITS .................................................................................................................... 6
  REPORTING AND CORRECTIVE ACTION PROCEDURES .................................. 6
  CERTIFICATION .................................................................................................... 7
  MAINTAINING CERTIFICATION ....................................................................... 7
RELATIONSHIP BETWEEN ACIL AND LABORATORY ..................................... 8
  COMPLAINTS RECEIVED ABOUT CERTIFIED LABORATORIES ................. 9
  WITHDRAWAL OR SUSPENSION OF CERTIFICATION .................................. 9
  CERTIFICATIONS THAT HAVE BEEN DENIED, SUSPENDED OR WITHDRAWN 9
  DISPUTES AND APPEALS ................................................................................... 9
USE OF ACIL I MARK ON LABORATORY REPORTS & CERTIFICATES ...... 10

REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision Level</th>
<th>Revision Date</th>
<th>Revised By</th>
<th>Brief Description of Revision</th>
</tr>
</thead>
<tbody>
<tr>
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<td>3/10/00</td>
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OBJECTIVE

This instruction Manual defines the requirements that a laboratory must follow to obtain certification for Proof of Independence from the American Council of Independent Laboratories (ACIL). It defines the relationship between ACIL and their certified laboratories, and the certification process.

SCOPE

This manual applies to all applicant and certified laboratories. It defines the methods used by ACIL, and its auditors when certifying laboratories.

General Applicability (added from SOP)

a) Certification shall apply to the laboratory and not to any one individual or group of individuals within a laboratory.
b) Certification shall be granted as follows:
   i. an Umbrella Certification: To a parent company operating under a single common Management system (e.g., at a corporate or divisional level), and providing services across various jurisdictions from multiple non-contiguous fixed-based locations; or
   ii. an Individual Certification: To a single fixed-base entity or to each noncontiguous entity of a company, each with its own management system, providing services across various jurisdictions.
   iii. ACIL shall determine whether a laboratory qualifies for an umbrella certification or for an individual certification, taking into account the presence or absence of a common management system, ownership/management, and oversight.

Program

a) Certification Procedures are based on the procedures set forth by ACIL and the I-Mark program.
b) ACIL has identified a Certification Committee that assists in interpretation of requirements and advises the granting of certification and other technical matters relating to the operation of the Independence Certification Program.
c) ACIL shall maintain record of the audits, certification decisions, and certifications awarded.
d) ACIL or authorized subcontractor may perform an onsite audit of any laboratory in the Independence Certification Program to verify information provided or to verify appropriate implementation of the Independence Program.
REFERENCE DOCUMENTS

- ACIL Proof of Independence Application and request for Audit: I-Mark form 001, rev. 2
- ACIL Independence Mark Client Instruction Manual: I-Mark form 002, rev. 2
- ACIL Proof of Independence Procedures Document: I-Mark form 003, rev. 3
- ACIL Independence Audit Checklist: I-Mark form 005, rev. 1

AUDITOR ASSIGNMENT

ACIL has an independent contractor that provides audits of laboratories.

NOTIFICATION OF CHANGES

The laboratory shall inform ACIL immediately of any changes in:

1. Legal, commercial or organizational status
2. Organization and management, e.g. key managerial staff
3. Policies or procedures that directly affect the independent status
4. Physical location or premises
5. Authorized signatories

ACIL shall be notified of any other matters that may affect the laboratory’s independent status, or compliance with the requirements for certification.

The laboratory shall inform ACIL of the actions that it has taken or will be taking to adjust its procedures, to ensure that the laboratory remains compliant with the requirements of certification.

ACIL shall inform its certified laboratories of changes to the requirements for certification. ACIL will inform the laboratory of the allotted time in which it must become compliant with the new requirements.
Certification Process


2. The applicant shall complete and send it to ACIL along with the documentation required to meet the Independence criteria outlined in the Client Instruction Manual for Proof of Independence Program, (i.e. policies and procedures defining your independence and impartiality, applicable organizational charts, description of the laboratory), and the initial application fee, as applicable.

3. Upon receipt of the completed application and application fee, a quote is prepared for the audit and sent to the applicant with any additional information requests to complete the audit.

4. To confirm acceptance of the quote the applicant shall submit:
   a. the audit fees,
   b. Any additional information requested to complete audit.
   c. The applicant should perform a self-assessment using the ACIL Independence Audit Checklist, prior to submittal.

5. The information will be reviewed by the auditor for compliance with the requirements. Should deficiencies exist in the initial documentation, the laboratory will be required to make corrective actions and submit them to the auditor prior to completing the audit and/or scheduling an on-site audit.

6. Upon completion of the document audit, a date and time will be agreed upon by the laboratory and auditor to perform an on-site audit, if required. Reference the Audit section of this document on page 6. It is up to the auditor and ACIL to determine whether an onsite audit of the laboratory is necessary. The determination will be based on:
   a. The completeness of the submitted documentation
   b. Past audits, where applicable
   c. The existence of complaints against the laboratory, related to Independence, if any

7. Upon completion of the document audit, on-site, telephone, or video audit, the completed ACIL Proof of Independence Checklist is provided to the Client and the ACIL Certification Committee.

8. Corrective Action identified during the audit, if applicable, is completed by the Client, in accordance with the Reporting and Corrective Action Procedures section of this document (outlined on page 6).

9. Upon completion of identified corrective action, recommendation for certification and certification procedures will be followed in accordance with the Certification section of this document outlined (outlined on page 7).
# Audit

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<td><strong>1. AUDIT OPENING MEETING</strong></td>
<td>An opening meeting is held. The meeting attendees shall be the top management of the laboratory and the person(s) responsible for development and implementation of the Proof of Independence Program for the laboratory.</td>
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<td><strong>2. PHYSICAL, TELEPHONE, OR VIDEO AUDIT</strong></td>
<td>Audit involves the examination of objective evidence of compliance with the ACIL Proof of Independence Requirements. This will include, but is not limited to the following:</td>
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<td></td>
<td>1. Laboratories Independence and Impartiality policies and procedures</td>
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<td></td>
<td>2. Training records regarding the laboratory’s independence program</td>
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<td></td>
<td>3. Records of proof of implementation of the independence program</td>
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<td>4. Interviews with personnel involved in acquiring, analyzing and reporting test results, and their managers</td>
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<td>5. Records of audits of the Independence program</td>
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<td>6. Records of identified risk for compromised Independence and corrective actions implemented, if required</td>
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<td><strong>3. EXIT CONFERENCE</strong></td>
<td>The auditors present the client with a copy of the completed ACIL Proof of Independence Checklist, noncompliance and observation reports, and a summary of the audit. If necessary, the auditor will indicate whether an on-site follow-up verification of implementation of corrective actions will be required.</td>
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## Reporting and Corrective Action Procedures

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<td><strong>1. CORRECTIVE ACTION PLANS AND EVIDENCE OF IMPLEMENTATION</strong></td>
<td>The laboratory shall provide corrective action report(s) per its formal corrective action procedure, and evidence of effective implementation of the corrective actions. This is submitted to ACIL.</td>
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<td><strong>2. REVIEW OF CORRECTIVE ACTION AND EVIDENCE OF IMPLEMENTATION</strong></td>
<td>The auditor will review the corrective action for completeness and compliance with the requirements. Any questions about the effectiveness of the actions or implementation will be discussed with the laboratory representative for clarification</td>
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<td><strong>3. FOLLOW-UP AUDIT, if necessary.</strong></td>
<td>When required, the auditor will conduct a verification audit after appropriate evidence of corrective action and implementation has been received and reviewed. This audit will focus on evaluating the client’s implementation of the corrective actions defined in their report. Should further findings be observed, they shall be documented and handled as stated above.</td>
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Certification

1. **AUDITOR RECOMMENDATION**
   
The auditor shall provide ACIL with a formal recommendation on certification. In the case of a negative recommendation, the specific reasons for such will be reported, along with the specific evidence for such a recommendation.

2. **ACIL CERTIFICATION COMMITTEE REVIEW**
   
   When the auditor's certification recommendation is received by ACIL, the ACIL Certification Committee shall review the report. The Certification Committee shall discuss any nonconformities with the auditor and/or the laboratory. The reviewer(s) may grant approval or identify noncompliance that must be resolved prior to approval.

3. **CERTIFICATION COMMITTEE REQUEST FOR FURTHER INFORMATION**
   
The Auditor is responsible for providing further information and/or performing necessary follow-up. The Auditor collects the requested information and provides a follow-up report.

4. **GRANTING CERTIFICATION**
   
   After confirmation of decision on certification by the Certification Committee, ACIL formally announces the certification decision and communicates the results to client.

5. **APPEALS OF THE CERTIFICATION PROCESS**
   
   If the client disagrees with reported noncompliance’s from the auditor, reviewers or the decision to withhold or withdraw certification, the client may enter a formal complaint to ACIL. If the laboratory is not satisfied that the complaint has been resolved a formal complaint may be submitted to the Board of Directors of ACIL for consideration.

6. **CERTIFICATE ISSUANCE**
   
   After meeting all certification requirements, and paying all outstanding fees, the laboratory is issued a certification certificate and added to the published roster of ACIL certificate-holders. [www.acil.org](http://www.acil.org)

Maintaining Certification

1. **BI-ANNUAL SURVEILLANCE**
   
   The laboratory shall be evaluated bi-annually for maintenance of the certification. This may be done remotely for those laboratories where the previous audits have indicated a well maintained program. In cases where previous noncompliance's were considered major, or there were concerns about the effectiveness of the previous corrective actions and/or the implementation of them, ACIL reserves the right to perform an onsite audit.
RELATIONSHIP BETWEEN ACIL AND LABORATORY

The laboratory shall accommodate ACIL during the certification process to assure that they are provided with the necessary information to complete the audit.

If an on-site audit is required, the applicant will provide the auditor with the necessary cooperation and necessary documentation to perform the audit, as well as, allow the assessor access to the laboratory facilities, personnel, and records necessary for the purposes of confirming the applicant’s compliance with the requirements of independence certification and grant the same privileges for surveillance, and additional audit visits necessary to maintain certification status.

A certified laboratory shall:

1) Review and sign the ACIL Certification Agreement after ACIL has determined that the client has satisfied all certification requirements, including conformance to the Independence Criteria
2) At all times comply with the provisions of the ACIL Proof of Independence Requirements, as defined in its policies and procedures and certification by ACIL
3) Represent certification only for those facilities represented on the Independence Certification Certificate
4) Pays fees assessed by ACIL.
5) Not use its certification status in a way to bring ACIL into disrepute, nor make statements relevant to its certification status that may be misleading or unauthorized.
6) Upon suspension or withdrawal of certification, discontinue use of all advertising that contains reference to the ACIL Independence certification and return certificates of certification to ACIL
7) Not use its certification to imply product approval by the certification body
8) Ensure that marketing material, certificates, or reports or parts thereof are not used in a misleading manner
9) Permit the certification body to disclose and publish the applicants name as an certification client
10) Not hold liable ACIL, or its representatives, for any damages or loss resulting from, or in any way connected with, the services provided by ACIL to the applicant, except in such damage or loss arising from gross negligence by ACIL.
11) Endeavor to ensure that no certificate or report, nor any part thereof is used in a misleading manner.
12) Make sure that its references to their certification status comply with the requirements of ACIL in all communication media, such as advertising, brochures or other documents.

Complaints Received About Certified Laboratories

When a complaint is filed against a certified laboratory, ACIL shall determine if the complainant has contacted the laboratory to seek resolution. If resolution is not possible with the laboratory, ACIL will initiate an investigation into the matter. If the investigation or any other matter indicates that a laboratory no longer complies with the requirements of the Proof of Independence Program, ACIL shall initiate an immediate surveillance audit.

Withdrawal or Suspension of Certification

In the event that ACIL proposes to withdraw or suspend certification the laboratory shall be notified of the reasons for such actions. The laboratory shall be given the opportunity to provide evidence that the reasons for withdrawal or suspension are not warranted. If the laboratory disagrees with the reasons, they may appeal to ACIL, and an appeal will be initiated. Appeal actions must be initiated within 30 days of the notification to withdraw or suspend certification.

When a certification is suspended, the laboratory must cease using the ACIL I Mark on its reports and certificates.

Certifications that have been denied, suspended or withdrawn

A laboratory that has been denied certification or had its certification suspended or withdrawn may apply for and be granted certification if the laboratory can show that it is in full compliance with the Proof of Independence Requirements.

Disputes and Appeals

A laboratory under evaluation may appeal an ACIL decision not to grant, suspend, or withdraw certification. This appeal shall be sent to ACIL, in writing, within 30 days of notification of the decision of the Certification Committee. The appeal shall state the reasons why the laboratory believes that the ACIL decision was incorrect.
ACIL shall appoint a panel of three persons to investigate the appeal. The selection process shall assure that the Appeals Panel members do not have a conflict of interest. All efforts shall be made to assure that the panel members are acceptable to all parties concerned.

The panel will investigate the appeal and determine whether the appeal is justified or not. Based on the recommendation of the panel, ACIL may or may not decide to overturn the recommendation of the Accreditation Committee, and grant certification to the laboratory.

In the case of an appeal to a decision to suspend or withdraw certification, the certification shall remain in effect during the appeal process.

**USE OF ACIL I MARK ON LABORATORY REPORTS & CERTIFICATES**

Certified laboratories are granted the right to use the ACIL I Mark on reports and certificates that are produced in accordance with the laboratory’s Independence program.