

INTERNATIONAL ACCREDITATION SERVICE, INC.

5360 Workman Mill Road · Whittier, CA 90601 USA
562-364-8201 *local* · 866-427-4422 *toll free* · 562-699-8031 *fax*
www.iasonline.org *web site* · info@iasonline.org *e-mail*



ACCREDITATION CRITERIA FOR PRODUCT CERTIFICATION AGENCIES

AC370

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PREFACE

The attached accreditation criteria has been issued to provide all interested parties with guidelines on implementing performance features of the applicable standards referenced herein. The criteria was developed and adopted following public hearings conducted by the International Accreditation Service, Inc. (IAS), Accreditation Committee and is effective on the date shown above. All accreditations issued or reissued on or after the effective date must comply with this criteria. If the criteria is an updated version from a previous edition, solid vertical lines (|) in the outer margin within the criteria indicate a technical change or addition from the previous edition. Deletion indicators (→) are provided in the outer margins where a paragraph or item has been deleted if the deletion resulted from a technical change. This criteria may be further revised as the need dictates.

IAS may consider alternate criteria provided the proponent submits substantiating data demonstrating that the alternate criteria are at least equivalent to the attached criteria and otherwise meet applicable accreditation requirements.

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ACCREDITATION CRITERIA FOR PRODUCT CERTIFICATION AGENCIES

1.0 INTRODUCTION

1.1 Scope: This criteria sets forth the requirements for obtaining and maintaining International Accreditation Service, Inc. (IAS), certification agency (“agency”) accreditation and for the qualifying data that must be submitted relating to the scope of certification for which accreditation is sought. This criteria supplements the IAS Rules of Procedure for Product Certification Agency Accreditation.

1.2 Reference Documents:

1.2.1 International Accreditation Forum (IAF) Guidance on the Application of ISO/IEC Guide 65.

1.2.2 IAS Rules of Procedure for Product Certification Agency Accreditation.

1.2.3 ISO/IEC Guide 65: General requirements for bodies operating product certification systems.

1.2.4 ISO/IEC Guide 67: Conformity assessment – Fundamentals of product certification.

1.2.5 ISO/IEC 17000: Conformity assessment – Vocabulary and general principles.

1.2.6 ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

1.2.7 ISO/IEC Standard 17020: General criteria for the operation of various types of bodies performing inspection.

1.2.8 ANS/ISO/IEC Standard 17025: General requirements for the competence of testing and calibration laboratories.

2.0 DEFINITIONS

2.1 Accreditation: Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2 Laboratory: A body that calibrates and/or tests.

2.3 Product Certification: The issuance of a statement (e.g., mark or certificate) by a third party that the fulfillment of specified requirements has been demonstrated for a product, process, or service.

2.4 Product Certification System: Rules, procedures and management for carrying out third-party product conformity assessment.

3.0 ELIGIBILITY

3.1 Accreditation services are available to third party Product Certification Agencies that:

3.1.1 Operate testing laboratories and inspection agencies; or

3.1.2 Maintain a subcontract agreement with a testing laboratory and/or inspection agency meeting the requirements of ISO/IEC Guide 65, section 4.4 Subcontracting.

3.2 In addition to the requirements given in this document, Product Certification Agencies must demonstrate compliance with the following criteria:

3.2.1 IAS Rules of Procedure for Product Certification Agency Accreditation;

3.2.2 ISO/IEC Guide 65: General requirements for bodies operating product certification systems;

3.2.3 ISO/IEC Standard 17020: General criteria for the operation of various types of bodies performing inspection; and

3.2.4 ISO/IEC: Standard 17025: General requirements for the competence of testing and calibration laboratories.

Note: Requirements for testing laboratories apply only to certification systems that require third-party testing as part of the evaluation criteria.

4.0 SUPPLEMENTAL REQUIREMENTS

4.1 When the certification system used as the basis for a certification activity requires surveillance at the point of manufacturing or assembly, the certification agency must have requirements that every manufacturing or assembly plant producing certified products be visited to perform surveillance activities for certified products. In the absence of a generally recognized minimum surveillance frequency, the certification agency shall require that each manufacturing or assembly location authorized to produce the certified product be visited for the purpose of surveillance a minimum of once per year.

4.2 Inspection agencies and testing laboratories must meet one of the following criteria:

4.2.1 Accreditation by IAS, or by another signatory to the International Laboratory Accreditation Cooperation (ILAC) or the Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement (MRA); or

4.2.2 Comply with ISO/IEC 17020 and/or ISO/IEC 17025 as determined through assessment of the inspection agency and testing laboratory by qualified certification agency personnel. In addition to the requirements given in ISO/IEC 17020 and/or ISO/IEC 17025, evidence of compliance shall include the qualifications of personnel conducting the assessment, a system for determining continued compliance that includes periodic on-site assessments, assessment reports, and corrective action reports.

4.3 Certification programs for processes and services must have requirements for determining continued compliance that include assessment of the management system and the actual process or service at least once per year.

5.0 ASSESSMENT

5.1 Prior to accreditation, certification agencies shall be subject to an on-site assessment by IAS. This assessment is to determine compliance with this criteria (AC370), including evaluation of expertise in the area(s) of certification where accreditation is sought.

5.2 After the initial year of accreditation, product certification agencies are subject to an on-site surveillance assessment. The surveillance assessment of the agency shall include, at a minimum, review of the quality system including the following: internal audit reports, minutes of management review meetings, any changes in key personnel, facilities or any other significant changes in the scope of accreditation or the management system of the agency.

5.3 A full reassessment visit is required at the end of every two-year term commencing from the date of the surveillance assessment for verification of continued compliance with IAS accreditation requirements.

5.4 During the time between on-site assessments, IAS will continually verify compliance through witness assessments during plant inspections and performing audits of certification files at six (6) month intervals.

6.0 WITNESSING INSPECTION ACTIVITIES

When the certification system used as the basis for a certification activity requires the on-site evaluation of the production process or quality system, IAS will periodically witness actual on-site inspections by each accredited certification agency.

6.1 For initial accreditation, one activity in each major category of certification shall be witnessed prior to the granting of accreditation.

6.2 For surveillance purposes, a minimum of one activity in each major category of certification shall be witnessed annually. Each subcategory of accreditation shall be witnessed at least once every four years.

6.3 The selection of locations for a witness activity shall be made by IAS in consultation with the certification agency. The geographic distribution of manufacturing or assembly locations authorized to produce certified products shall be considered.

7.0 WITNESS TESTING

All witness testing activities conducted at a manufacturer's facility must be witnessed by technically competent certification agency staff that are trained not only in the test being witnessed, but in the appropriate sections of ANS/ISO/IEC Standard 17025. If the certification scheme to which the product is to be certified contains specific requirements or limitations pertaining to witness testing, the requirements of the certification scheme shall also apply. Appropriate measures must be taken for long-term testing, where constant witnessing is not feasible, to ensure tampering of the sample or testing equipment does not take place.

8.0 USE OF MANUFACTURER'S DATA

If a certification agency plans to use data generated and submitted by a manufacturer that is not part of witness testing, the certification agency must have a program in place to ensure validity of the data. The certification agency shall consider the following possible elements for such a program and shall have justification for those it chooses not to utilize: auditing the manufacturer to appropriate elements of ANS/ISO/IEC Standard 17025; performing random duplicate analyses; having the manufacturer participate in proficiency testing programs,

where available; technical review of the raw data rather than acceptance of just a number or result; limiting testing to only those client's analysts who have been approved by the certification agency to perform the testing; outside accreditation of the manufacturer's laboratory; random unannounced visits to the manufacturer's laboratory during product testing; and review of in-plant quality assurance/quality control results. If the certification scheme to which the product is to be certified contains specific requirements or limitations pertaining to the use of manufacturer's data, the requirements of the certification scheme shall also apply. ■