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ACCREDITATION CRITERIA FOR CALIBRATION LABORATORIES

AC204

April 2008
(Effective May 1, 2008)

(Previously issued September 2002, May 2004 and August 2006)

PREFACE

The attached accreditation criteria has been issued to provide all interested parties with guidelines on implementing performance features of the applicable standards referenced in the accreditation criteria. 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 criteria. If the criteria is an updated version from a previous edition, solid vertical lines (**I**) 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 CALIBRATION LABORATORIES

1.0 INTRODUCTION

1.1 Scope: The purpose of this document is to provide requirements for accreditation of calibration laboratories by International Accreditation Service, Inc. (IAS), and to specify the qualifying data that must be submitted by calibration laboratories seeking accreditation by IAS.

1.2 Reference Documents:

1.2.1 ANS/ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) Standard 17025:2005, General Requirements for the Competence of Calibration and Testing Laboratories.

1.2.2 VIM:1993, International Vocabulary of Basic and General Terms in Metrology.

1.2.3 IAS Rules of Procedure for Laboratory Accreditation.

1.2.4 ILAC G10:1996, Harmonised Procedures for Surveillance and Reassessment of Accredited Laboratories.

1.2.5 ISO/IEC Standard 17011, Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies.

1.2.6 IAS Policy Guide on Calibration, Traceability, and Measurement Uncertainty for Calibration Laboratories.

1.2.7 IAS Calibration Program Forms.

1.2.8 IAS Calibration Laboratory Accreditation Program Definitions.

1.2.9 IAS Accreditation Criteria for Testing Laboratories (AC89).

1.2.10 ANSI/NCSL Z540.3-2006, American National Standard for Calibration – Requirements for the Calibration of Measuring and Test Equipment.

1.2.11 ANSI/NCSL Z540-2-1997 (R2002), U.S. Guide to Expression of Uncertainty in Measurement (GUM)

1.2.12 ILAC-P9:2005, ILAC Policy for Participation in National and International Proficiency Testing Activities.

2.0 BASIC INFORMATION

The following basic information is necessary:

2.1 Data showing compliance with the IAS Rules of Procedure for Laboratory Accreditation.

2.2 Data showing compliance with Section 4.0 of this criteria.

3.0 DEFINITIONS

Definitions provided in this section are only those necessary to understand the criteria. Definitions are from VIM:1993. Any text in the definition beyond what is in VIM is added for clarity.

3.1 Calibration: The set of operations which establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding known value of a measurand.

3.2 Calibration Programs: Calibration programs include external calibration providers and internal calibration providers; calibrations performed; and the management and control systems and procedures defining the calibration program.

3.3 NMI: National Metrology Institute, considered to be the primary source of standards in a country. In the United States, the National Institute of Standards and Technology (NIST) is considered an NMI.

3.4 Equivalence: An acceptance of the competence of NMIs, accreditation bodies, and/or accredited calibration laboratories in other countries as being essentially equal to the NMI, accreditation body, and/or accredited organizations within the United States.

3.5 SI Units: The International System of Units. A series of quantities in two classes:

3.5.1 Base Units: Regarded as dimensionally independent (meter, kilogram, second, ampere, kelvin, mole, and candela).

3.5.2 Derived Units: Formed as products of the powers of the base units according to the algebraic relations linking the quantities concerned.

3.6 Uncertainty of Measurement: Parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

3.7 Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties of measurement.

4.0 REQUIRED DATA

4.1 The laboratory seeking accreditation must submit data showing compliance with ANS/ISO/IEC Standard 17025:2005, and with IAS policies.

4.2 The following policy on traceability and calibration is supplemental to the requirements noted in ANS/ISO/IEC Standard 17025: Accredited calibration laboratories, whether external or internal, must ensure traceability to SI units (whenever such traceability is achievable) by obtaining calibration services either directly from an NMI or other calibration laboratories accredited to ANS/ISO/IEC Standard 17025 by an accreditation body formally recognized as complying with ISO/IEC Standard 17011.

In cases where calibration is not available from an accredited laboratory or NMI as described above, laboratories must be able to demonstrate the steps they take to ensure the traceability of their calibration program.

Testing laboratories that are seeking accreditation of their internal calibration functions must be accredited by IAS under ANS/ISO/IEC 17025.

4.3 Calibration certificates and reports must meet requirements of ANS/ISO/IEC Standard 17025. Calibration certificates or reports must state the uncertainty of the measurement(s).

4.4 Personnel Training

IAS accredited and applicant laboratories are required to provide training to bench technicians and to their authorized signatories to comply with the requirements described in Sections 4.4.1 and 4.4.2. Laboratory signatories are the personnel responsible for review and approval of calibration certificates.

4.4.1 Laboratories are required to have their technicians professionally certified by December 2009. This certification may be the Certified Calibration Technician (CCT) certification from the American Society of Quality (ASQ), the PROCERH certification administered by CENAM of Mexico, or an equivalent certification.

4.4.2 Laboratories' authorized signatories are required to receive at least an equivalent level of technical training as bench technicians.

4.4.3 The accredited laboratory must develop a documented training plan to achieve and maintain certification of its technicians by December 2009. The plan must assign or allocate resources, and state target time lines. Management must specifically review the progress made towards compliance, and document the review in the Management Review records.

5.0 ASSESSMENT

5.1 Prior to accreditation, laboratories shall be subject to an on-site assessment by IAS. This assessment is to determine compliance with this criteria (AC204) and to evaluate expertise and equipment in the discipline(s) of calibration where accreditation is sought. Both permanent laboratory facilities and mobile facilities shall be subject to assessment.

5.2 After the initial year of accreditation, laboratories are subject to an on-site surveillance assessment. The surveillance assessment shall include review of at least the following: internal audit reports; minutes of management review meetings; results of proficiency testing, if any; any changes in key personnel, facilities and/or major test equipment; and information on any other significant changes in the quality system of the laboratory.

5.3 IAS will conduct an on-site reassessment or surveillance assessment of accredited laboratories at a minimum of once every two years, for verification of continued compliance with IAS accreditation requirements.

5.4 An assessment to all requirements contained in ANSI/NCSL Z540.3-2006 will be available upon specific request by the laboratory.

5.5 As applicable, assessments will include review of the 4:1 Test Uncertainty Ratio (TUR) requirement for each technical demonstration, to assure compliance with the requirements of ANSI/NCSL Z540.3-2006 Clause 5.3.

6.0 PROFICIENCY TESTING ACTIVITY

Proficiency testing activity shall be completed in accordance with ILAC-P9:2005. ■