

REVISED RULES FOR BPS SCHEME ON ACCREDITATION OF TESTING AND CALIBRATION LABORATORIES

KKI DEPARTMENT ADMINISTRATIVE ORDER NO. 13, S. 1995, October 16, 1995

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Pursuant to Section (7), Chapter 2, Book IV of the 1987 Administrative Code; Republic Act 4109, Republic Act 7394; Executive Order No. 101:1976; and Executive Order No. 913; the following Rules for Accreditation of Testing and Calibration Laboratories are hereby promulgated for the guidance of all concerned:

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Scope

1.1 This Department Administrative Order prescribes rules to implement the BPS Accreditation Scheme for testing and calibration laboratories;

1.2 The Scheme covers the Accreditation of:

- a. Testing and calibration laboratories
- b. Testing laboratories
- c. Calibration laboratories

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Definition of Terms

For the purpose of this Order, the following definitions shall apply;

2.1 "DTI" — Department of Trade and Industry

2.2 "BPS" — Bureau of Product Standards

2.3 "Director" — Director of BPS

2.4 "LAAC" — Laboratory Accreditation Advisory Committee

2.5 "Accreditation" — A process by which a body is formally recognized as competent to carry out specific tasks.

2.6 "Laboratory" — A body that tests and/or calibrates.

2.7 "Testing Laboratory" — a laboratory which measures, examines, or determines the characteristics or performance of materials or products.

2.8 "Calibration Laboratory" — A laboratory that calibrates inspection, measuring and test equipment.

2.9 "Accredited Laboratory" — A testing and/or calibration laboratory formally recognized under established procedures for its competence to carry out specific tasks.

2.10 "Certificate of Laboratory Accreditation" — A document signed by the Director of BPS issued to an

accredited laboratory.

2.11 "Test" — Technical operation that consists of the determination of one or more characteristics or performance of a given product, process or service according to a specified procedure.

2.12 "Calibration" — Technical operation that determine the accuracy or reliability of inspection, measuring and test equipment.

2.13 "Test Method" — Specified technical procedure for performing a test or calibration.

2.14 "Interlaboratory Test Comparisons" — Organization, performance and evaluation of tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

2.15 "Laboratory Proficiency Testing" — Determination of laboratory testing performance by means of Interlaboratory Test Comparisons.

2.16 "Philippine National Standard" — The standard promulgated by BPS relative to product specifications, test methods, terminologies, procedures, guidelines or practices.

2.17 "International/Foreign Standard" — A standard developed by ISO (International Organization for Standardization), IEC (International Electrotechnical Commission) or other international or foreign standards body which maybe accepted by BPS for purposes of the Laboratory Accreditation Scheme.

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Authorities and Responsibilities of LAAC and BPS

3.1 LAAC

3.1.1 Operate as the advisory body of the BPS Laboratory Accreditation Scheme.

3.1.2 Establish and maintain, consistent with international practices and developments on laboratory accreditation, policies and rules covering the following:

3.1.2.1 The acceptance of application and grant, maintenance suspension and withdrawal of accreditation.

3.1.2.2 The assessment and evaluation of the applicant laboratories.

3.1.2.3 The appointment of sub-contract assessors for calibration laboratory, or committees to undertake assigned specific tasks, when necessary.

3.1.2.4 The operation of the interlaboratory test comparisons and proficiency testing.

3.1.2.5 The adoption of and implementation of Philippine National Standards, ISO/IEC Guide 58, Regional and/or Foreign Standards as basis for the accreditation of testing and calibration laboratories.

3.1.2.6 The maintenance and retention of documents and records and confidentially thereof.

3.1.2.7 Appeals in connection with denial of application or accreditation of an applicant.

3.1.2.8 Financial Reports.

3.1.2.9 The applicant for, maintenance of regional and international recognition of the BPS Laboratory Accreditation Scheme.

3.1.2.10 Other matters relevant to the effective, competent and transparent operation of the BPS Laboratory Accreditation Scheme.

3.2 BPS

- 3.2.1 Operate under the policy direction of LAAC, the National Laboratory Accreditation Scheme.
- 3.2.2 The Director shall designate the Chief of the BPS Action Team on Laboratory Accreditation (AT 4) to manage the day to day operation.
- 3.2.3 Provide, upon approval by the LAAC, formal recognition to an applicant laboratory that is found competent to carry out testing and/or calibration works.
- 3.2.4 Assess the competence of an applicant laboratory, in terms of their organizational in reference, their method of testing and/or calibration, equipment capability, personnel competence, in accordance with the "general requirements for the competence of calibration and testing laboratories", Philippine National Standards, Regional and/or Foreign Standards on laboratory accreditation, and their future revisions.
- 3.2.5 Organize interlaboratory test comparisons and laboratory proficiency testing where accredited laboratory are required to participate.
- 3.2.6 Submit to the LAAC, for approval, applicant bodies recommended for accreditation. The suspension or cancellation of accreditation shall be likewise be subject to the LAAC's approval.
- 3.2.7 Conduct semestral surveillance audits of accredited laboratories.
- 3.2.8 Appoint or subcontract, where necessary, external assessors to assess applicants for laboratory accreditation, provided these assessors are acceptable to the latter.
- 3.2.9 Maintain and publish a registry of accredited laboratories.
- 3.2.10 Apply to regional and international bodies for the recognition of the BPS Accreditation Scheme and of the assessors.
- 3.2.11 Continuously undertake measures to upgrade to international levels the capability of the National Laboratory Accreditation Scheme.

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Composition of the LAAC

- 4.1 The Director of BPS as Chairman.
- 4.2 The Chief of BPS Action 4 as member
- 4.3 The Chief of EMB Laboratory for Environment as member.
- 4.4 A representative from the IIEE as member.
- 4.5 A representative from PSME as member.
- 4.6 A representative from FATL as member.
- 4.7 The Chief of ATID, MIRDC as member.

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Criteria for and Conditions of Accreditation

5.1 Criteria for Accreditation

Accreditation under the Scheme shall be available to any organization that:

5.1.1 Applies for accreditation and pays the prescribed application fee.

5.1.2 Establishes, documents, implements and maintains a laboratory management system that complies with the requirements of PNS 1600 (ISO/IEC Guide 25).

5.1.3 When requested by BPS to do so, participates in available and appropriate proficiency tests and demonstrates acceptable performance in such tests.

5.1.4 Pays all prescribed assessment and annual registration fees.

5.1.5 Complies with the conditions of accreditation set out in clause 4.2 of these guidelines.

Note: Compliance with the accreditation criteria shall be determined through assessments, review visits and reassessments.

5.2 Conditions of Accreditation

5.2.1 The Certificate of Accreditation remains the property of BPS. Accreditation is renewable annually subject to the terms of these conditions. If a laboratory does not intend to renew its accreditation at the end of any year following accreditation, it shall notify BPS in writing of its intention. A laboratory's rights to use the certificate of accreditation shall not be transferrable.

5.2.2 Following accreditation, the laboratory shall abide by the following commitments in connection with the criteria for accreditation:

5.2.2.1 Implementation, maintenance, and documentation of the technical and quality management systems in accordance with its scope of accreditation and making available controlled copies of all or any part of the documented system as required by BPS for reference purposes.

5.2.2.2 Prompt notification in any changes in the laboratory structure such as personnel, signatories, accommodation, equipment or in any changes in policies and procedures.

5.2.2.3 The laboratory shall give BPS representatives access during normal working hours to sites in which work relevant to the laboratory's scope of accreditation is being carried out.

5.2.2.4 The accredited laboratory shall, upon termination of its accreditation (however determined), immediately discontinue to identify itself as a BPS accredited laboratory or make any reference thereto. In addition, the laboratory shall return to BPS the certificate of accreditation.

5.2.3 Following accreditation, BPS Shall:

5.2.3.1 Send a representative to assess the laboratory at its discretion, but in general not usually less than annually for the purpose of verifying that the conditions of accreditation are being complied with.

5.2.3.2 Notify the laboratory if any changes in the BPS requirements for its Laboratory Accreditation Scheme.

5.2.4 If a laboratory is temporarily unable to comply with these conditions, BPS will require the laboratory to discontinue the use of the BPS Laboratory Accreditation Logo or any claim that the laboratory complies with BPS requirements, until BPS is satisfied that compliance is again achieved by the laboratory.

5.2.5 If the laboratory fails to comply with these conditions, BPS may:

5.2.5.1 Suspend Accreditation, or

5.2.5.2 Withdraw Accreditation, or

5.2.5.3 Reduce the Scope of Accreditation, or

5.2.5.4 Decline the grant or renew accreditation, or

5.2.5.5. Decline to extend the scope of accreditation.

Such decisions and the ground for these shall be communicated to the laboratory in writing as described in clause 4.3.

5.3 Suspension and Withdrawal of Accreditation

5.3.1 Accreditation may be suspended until such time that the laboratory brings its operations and/or procedures back into compliance with the accreditation criteria. If the laboratory fails to achieve full compliance or declines to take appropriate corrective action, then accreditation is withdrawn.

5.3.2 If a laboratory is temporarily unable to maintain compliance with accreditation criteria due to circumstances beyond its control, then accreditation is suspended.

5.3.3 A laboratory whose accreditation is suspended shall be directed to remove from public view the certificate of accreditation and to cease from referring itself as a BPS Accredited Laboratory.

5.3.4 A laboratory whose accreditation is withdrawn shall be directed to return to BPS the certificate of accreditation and its schedule and shall be directed to cease from referring itself as a BPS Accredited Laboratory.

5.3.5 Reactivation of the accreditation status of a laboratory whose accreditation is suspended will only be done after it submits to BPS proof that it is able to comply with the accreditation criteria.

5.3.6 Reactivation of accreditation status of a laboratory whose accreditation is withdrawn will be done only after a full reassessment is conducted and that the laboratory is found to comply with the accreditation criteria. For this purpose, the laboratory has to reapply for accreditation and pay all the required fees and other costs that may be entailed during the conduct of assessment.

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Transitory Provision

6.1 All laboratory that are at present in the BPS list of accredited laboratories shall be assessed in accordance with this DAO within three years. Failure on their part to comply with the requirements of this Order, these laboratories shall be relisted from the BPS list.

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Fees

7.1 APPLICATION FEE

Non-refundable and shall be paid upon securing application form from BPS

300.00

7.2 Assessment fee including documentation review, follow-up and surveillance audit

P500.00 per man hour

7.3 Accreditation fee

P5,000.00 per scope

Certificate of Accreditation

7.4 Annual Accreditation Fee

P3,000.00 per scope

7.5 Other Fees

Transportation, lodging and accommodation of BPS assessors during actual assessment.

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Repealing Clause

These guidelines supersede all previous guidelines issued on the accreditation of laboratories.

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Effectivity

This order shall take effect fifteen (15) days after publication in two (2) newspapers of general circulation.

Approved by: 16 Oct. 1995

(SGD.) RIZALINO S. NAVARRO

Secretary

Recommending Approval:

(SGD.) RENATO V. NAVARRETE

Assistant Secretary

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