



NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM No. 9

The Accreditation of Laboratories for Phytosanitary Testing

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Review

NAPPO Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2009. A review of any NAPPO Standard may be initiated at any time upon request of a NAPPO member country.

Approval

This standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on October 17, 2004, and is effective immediately.

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Implementation

No Implementation Plans are required as only minor revisions have been made to this standard.

Amendment Record

Amendments to this Standard will be dated and filed with the NAPPO Secretariat. The most recent version will be posted on the NAPPO website at: www.nappo.org/stds_e.htm

Distribution

This standard is distributed by the Secretariat of the NAPPO within NAPPO, including Sustaining Associate Members and Industry Advisory Groups, to the FAO IPPC Secretariat and to the Administrative Heads of the Regional Plant Protection Organizations (RPPOs).

Introduction

Scope

This standard describes the responsibilities of NPPOs and outlines criteria for the accreditation of diagnostic laboratories to perform specific functions in support of phytosanitary testing.

This standard also describes Accreditation Bodies, which may act on behalf of the NPPO to deliver the laboratory accreditation process and the responsibilities of the NPPO when utilizing an Accreditation Body.

References

Glossary of Phytosanitary Terms, 2004, ISPM No. 5, FAO, Rome

ISO/IEC Guide 25:1990, General Requirements for the Competence of Calibration and Testing Laboratories

Glossary of Phytosanitary Terms, 2004, RSPM N° 5, NAPPO.

Definitions, Abbreviations, and Acronyms

Accreditation	Official recognition of proficiency resulting in the approval and authority to perform specific tasks or provide specific services in full or partial support of official obligations. (NAPPO)
Accreditation Body	A person or organization who is employed or acts on behalf of a NPPO and is officially recognized to conduct specific activities in an accreditation process. (NAPPO)
IPPC	International Plant Protection Convention as deposited with the FAO in Rome in 1951 and as subsequently amended (FAO)
ISO	Abbreviation for the International Organization for Standardization
Laboratory	A public or private facility that calibrates, tests, identifies or conducts diagnoses. (NAPPO)
National Plant Protection Organization (NPPO)	Official service established by a government to discharge the functions specified by the IPPC. (FAO)
Official	Established, authorized or performed by a National Plant Protection Organization (FAO)
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products (FAO)

Quality management	All activities of the overall management function that determine the quality policy, objectives, and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system. (ISO) 8402:1994.
Quality system	Organizational structure, procedures, processes and resources needed to implement quality management. (ISO 8402:1994)
Test	Official examination, other than visual, to determine if pests are present or to identify pests. (FAO)

Outline of Requirements

NAPPO views regional and international agreement on standards for accreditation as fundamental to the international harmonization of phytosanitary measures and systems. National Plant Protection Organizations (NPPOs) may, by accrediting trade personnel, organizations, facilities and processes associated with phytosanitary testing, enhance their ability to protect plant resources and facilitate trade. Accreditation recognizes consistent levels of competency and confers specific authority.

When accrediting laboratories for phytosanitary testing, the NPPO must have the appropriate authority and carry out its responsibilities to implement and maintain the accreditation program. Laboratories have obligations with respect to applications, personnel training, and quality assurance to become and remain accredited. Accreditation agreements set out the responsibilities for both the NPPO and the laboratory.

1. General Requirements

1.1 National Plant Protection Organization (NPPO)

The NPPO must take appropriate measures to ensure the integrity of their programs. The NPPO must be able to provide the information and resources to implement and maintain the laboratory accreditation program.

1.1.1 Authority

The NPPO must have the authority to oversee accredited facilities providing diagnostic services in support of phytosanitary testing. The NPPO may enter into agreements with Accreditation Bodies, such as national accrediting bodies, for the delivery of accreditation services. (see Section 2, Requirements for Accreditation Bodies) The NPPO may enter into agreements with public or private laboratories for the delivery of diagnostic services in support of phytosanitary testing.

The NPPO must have the authority to suspend or revoke the phytosanitary testing privileges of a laboratory that does not comply with NPPO standards.

1.1.2 Responsibility

The NPPO must monitor or ensure, through their requirements, the regular monitoring of work that accredited laboratories perform on behalf of the NPPO.

1.2 Applicant Laboratory

In order to be accredited, laboratories must complete and sign an application form, have adequately trained personnel, suitable facilities and equipment, meet all applicable specific and general NPPO requirements and possess a valid certificate of accreditation, or other official notification, from the accrediting NPPO. Applicant laboratories must meet the requirements of section 1.6 and their personnel must meet the requirements of section 1.5.

1.3 Application

1.3.1 Applications for accreditation are approved by the NPPO. Criteria for accreditation must be available to the applicant laboratory and all criteria must be met before accreditation is granted.

1.3.2 An application must be completed, signed and submitted to the NPPO by the most senior level of management with direct authority of the laboratory seeking accreditation.

1.4 Facilities

Accredited laboratory facilities must be approved by the NPPO, and adhere to standards established by the NPPO. A comprehensive initial on-site visit and subsequent monitoring visits to accredited laboratories are required to ensure that NPPO standards are met.

1.5 Personnel

1.5.1 Training and qualifications of personnel of the laboratory seeking accreditation must conform to the standards specified by the NPPO and be appropriate for the work to be performed. The NPPO may conduct evaluations and/or provide test-specific training to ensure that personnel can perform to required standards.

1.5.2 Management personnel and laboratory staff who are accountable for testing or other analytical or identification procedures must be identified. The signatures of the accountable staff must be kept on file and be available to the NPPO upon request. The NPPO must be promptly informed of changes in such personnel

1.6 Quality System

The accrediting NPPO must ensure that a quality system is in place for itself to ensure the validity of its accreditation system and the reliability of results from accredited laboratories. The applicant laboratory will also have a quality system in place to ensure the validity and reliability of results. This system may be based on ISO/IEC Guide 17025:2000 - Guidelines for the Competence of Calibration and Testing Laboratories.

- 1.6.1 The NPPO reserves the right to perform audits and proficiency monitoring, at any time, within its area of jurisdiction, to verify that accredited laboratories continue to meet NPPO standards of performance.
- 1.6.2 The NPPO must monitor, on a regular basis, the competence of accredited laboratories by means of audits, proficiency testing, check samples, or other suitable means.
- 1.6.3 The laboratory must have a quality manual. Personnel must follow all policies and procedures required by the quality manual and the laboratory quality system.
- 1.6.4 The laboratory must perform all proficiency testing, check samples, or other competence testing required by the NPPO. The laboratory must submit results from such testing as specified by the NPPO.
- 1.6.5 The laboratory must utilize official methods of analyses which are documented and approved by the NPPO.
- 1.6.6 If subcontracting is allowed by the NPPO, subcontractors to accredited laboratories must also be accredited by the NPPO to ensure adherence to requisite standards.
- 1.6.7 The calibration and monitoring of equipment must be documented and conform to prescribed standards. Calibration and equipment maintenance records must be made available to the NPPO upon request. Verified discrepancies or incomplete records may result in the suspension (temporary removal of phytosanitary testing privileges of the accredited laboratory) by the NPPO or revocation of phytosanitary testing privileges.

1.7 Accreditation Agreement

- 1.7.1 Accreditation agreements describe in detail the rights and obligations of both the NPPO and the accredited laboratory. Accreditation agreements must be enforceable by the NPPO.
- 1.7.2 Accredited laboratories shall be issued a certificate of accreditation or equivalent. This certificate and/or accompanying documentation will clearly identify the terms and conditions under which the accredited lab may perform phytosanitary testing on behalf of the NPPO. Terms and conditions must include specific commodities and the tests which must be employed by the accredited laboratory to test these commodities.
- 1.7.3 A certificate of accreditation will be renewed on a regular basis. Renewal is contingent upon satisfactory performance as determined by the NPPO. Accreditation shall be renewed at least every three years.

1.8 Records

- 1.8.1 NPPO documentation relating to the accreditation process must be available to other NPPO's upon request.
- 1.8.2 Accredited Laboratories must provide test specific documentation to the NPPO. This documentation must indicate all tests performed on behalf of the NPPO.
- 1.8.3 Laboratory personnel conducting tests or analyses must sign completed test-specific worksheets. Laboratory results must be duly authorized by personnel approved by the NPPO prior to release to the NPPO.
- 1.8.4 Laboratory records are subject to periodic examination or audit without prior notice, as determined by the NPPO. Sample submission forms, worksheets and records of test results including all original observations must be kept on file in such a way as to ensure integrity and traceability of phytosanitary test data by the accredited lab for the period required by the NPPO.

1.9 Withdrawal

The agreement between the NPPO and the Accreditation Body must include obligations to be carried out in the event the agreement between NPPO and Accreditation Body is voluntarily terminated.

1.10 Suspension and Revocation

Laboratories that do not meet NPPO standards may have their phytosanitary testing privileges suspended or revoked. The NPPO must specify procedures and criteria for suspension or revocation of phytosanitary testing privileges and accreditation as well as the conditions under which accreditation may be reinstated and phytosanitary testing resumed.

2. Requirements for Accreditation Bodies

Outline of Requirements

NAPPO recognizes the desire or need of NPPOs to utilize the services of independent persons or organizations to deliver some of the accreditation activities associated with accredited laboratories. Accreditation Bodies may act on behalf of the NPPO to deliver specific functions in the lab accreditation process that are specified by the NPPO. Accreditation Bodies may deliver the laboratory accreditation process in whole or in part, as determined by the NPPO.

General Requirements

2.1 Accreditation Bodies

An Accreditation Body a person or organization who is employed or acts on behalf of a NPPO and is officially recognized to conduct specific activities in an accreditation process.

The Accreditation Body may be a government or non-government entity.

2.2 Responsibilities

2.2.1 Responsibilities of the NPPO

The NPPO must clearly detail the activities to be conducted by the Accreditation Body. The NPPO will also detail the responsibilities of the Accreditation Body and the official relationship between NPPO and Accreditation Body.

The NPPO must audit the functions carried out by the Accreditation Body to ensure that the delegated elements of the laboratory accreditation are carried out.

2.2.2 Responsibilities of the Accreditation Body

The Accreditation Body will carry out the functions specified by the NPPO.

The Accreditation Body will be able to provide evidence of delivery of the specified functions in accordance with the NPPO requirements.

The Accreditation Body will be able to demonstrate that the specified elements of laboratory accreditation are being delivered in conformance with the laboratory accreditation agreement.

The Accreditation Body will have a quality system which will ensure the viability and reliability of the oversight of the laboratory accreditation process.

2.2.3 Personnel

Accreditation Body staff overseeing the accreditation of laboratories must have education, training and experience relevant to the function(s) specified by the NPPO.

2.2.4 Records

The Accreditation Body must maintain records to demonstrate that the specified task(s) have been completed. This includes the functions of the Accreditation Body and the demonstration of compliance of the accredited laboratory.

2.2.5 Withdrawal

The agreement between the NPPO and the Accreditation Body must include obligations to be carried out in the event the agreement between NPPO and Accreditation Body is voluntarily terminated.

2.2.6 Suspension and Revocation

Accreditation Bodies that do not meet NPPO standards may have their accreditation privileges suspended or revoked. The NPPO must specify procedures and criteria for suspension or revocation of accreditation, as well as the conditions under which the Accreditation Body's accreditation may be reinstated and accreditation activities resumed.