



ORGANISATION NORD AMERICAINE POUR LA PROTECTION DES PLANTES
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CANADA UNITED STATES MEXICO

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM No. 9

The Authorization of Laboratories for Phytosanitary Testing

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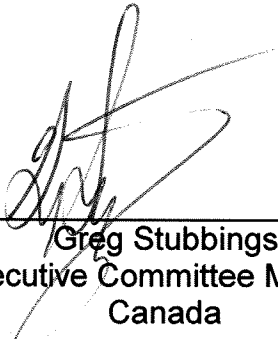
Review

NAPPO Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2014. This Standard was last reviewed in 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 August 10, 2009 and is effective from this date.

Approved by



Greg Stubbings
Executive Committee Member
Canada



Paul R. Eggert
Executive Committee Member
United States



Javier Trujillo Arriaga
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Implementation

No Implementation Plans are required.

Amendment Record

Amendments to this Standard will be dated and filed with the NAPPO Secretariat.

Distribution

This standard is distributed by the NAPPO Secretariat, to the Industry Advisory Group and Sustaining Associate Members, the International Plant Protection Convention (IPCC) Secretariat, and to other Regional Plant Protection Organizations (RPPOs).

Introduction

Scope

This standard describes the criteria for the authorization of diagnostic laboratories to perform specific functions in support of phytosanitary testing. It also outlines the responsibilities of NPPOs in managing the authorization process.

References

Glossary of Phytosanitary Terms, 2009, ISPM No. 5, FAO, Rome
Glossary of Phytosanitary Terms, 2009, RSPM No. 5, NAPPO, Ottawa

Definitions

Definitions of phytosanitary terms used in this standard can be found in NAPPO RSPM No. 5 (*Glossary of phytosanitary terms*) and in ISPM No. 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

National Plant Protection Organizations (NPPOs) may authorize other organizations, facilities and processes associated with phytosanitary testing to enhance the delivery of programs and services that protect plant resources and facilitate trade.

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

General Requirements

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 authorization program.

1.1. Authority

The NPPO must have the authority to oversee authorized facilities providing diagnostic services in support of phytosanitary testing. 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.

1.2 Responsibility

The NPPO must conduct regular monitoring of work that authorized laboratories perform on behalf of the NPPO

1.3 The NPPO must monitor, on a regular basis, the competence of authorized laboratories by means of audits, proficiency testing, check samples, or other suitable means

1.4 The NPPO reserves the right to perform audits and proficiency monitoring, at any time, within its area of jurisdiction, to verify that authorized laboratories continue to meet NPPO standards of performance.

2. Applicant Laboratory

In order to be authorized, laboratories must complete and sign an application form, have adequately trained and qualified personnel, suitable facilities and equipment, meet all applicable specific and general NPPO requirements and possess a valid certificate of authorization, or other official notification, from the authorizing NPPO. Applicant laboratories must meet the requirements of section 2.3 and their personnel must meet the requirements of section 2.2.

2.1 Applications

2.1.1 Criteria for authorization must be available to the applicant laboratory and all criteria must be met before authorization is granted.

2.1.2 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 authorization.

2.1.3 Applications for authorization are approved by the NPPO.

2.2 Personnel

2.2.1 Training and qualifications of personnel of the laboratory seeking authorization 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.

2.2.2 Management personnel and laboratory staff who are responsible 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

2.3 Quality System

- 2.3.1 The applicant laboratory is required to 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.
- 2.3.2 The laboratory must have a quality manual. Personnel must follow all policies and procedures required by the quality manual and the laboratory quality system.
- 2.3.3 The laboratory must perform all proficiency testing, check samples, or other competence testing required by the NPPO and submit results as specified by the NPPO.
- 2.3.4 The laboratory must utilize official methods of analyses which are documented and approved by the NPPO.
- 2.3.5 Subcontracting is permitted if documented in the quality system manual and approved by the NPPO.
- 2.3.6 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.

3. Records

- 3.1 Authorized laboratories must provide program specific information to the NPPO. This documentation must include records of all tests performed on behalf of the NPPO, upon request.
- 3.2 Laboratory personnel conducting tests or analyses must sign completed test-specific worksheets. Laboratory results must be approved by the responsible staff prior to release to the NPPO.
- 3.3 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.
- 3.4 Records must be kept in such a way as to ensure integrity and traceability of phytosanitary test data by the authorized laboratory for the period specified by the NPPO.
- 3.5 NPPO documentation relating to the authorization process should be available to other NPPO's upon request.

4. Facilities

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

5. Authorization Agreement

5.1 Authorization agreements describe in detail the rights and obligations of both the NPPO and the authorized laboratory.

5.2 Authorized laboratories shall be issued a certificate of authorization or equivalent document. These documents will clearly identify the terms and conditions under which the authorized laboratory 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 authorized laboratory to test these commodities for specified pests.

5.3 Authorization should be renewed at least every four years. Renewal is contingent upon satisfactory performance as determined by the NPPO.

6. Voluntary Termination

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

7. Suspension, Reinstatement or Revocation

Authorized 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, reinstatement or revocation of authorization to conduct phytosanitary testing.