



NAPPO

North American Plant Protection Organization

Organización Norteamericana de Protección a las Plantas

MEXICO - USA - CANADA

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM No. 9

Authorization of Laboratories for Performing Phytosanitary Testing

The Secretariat of the North American Plant Protection Organization

1730 Varsity Drive, Suite 145

Raleigh, NC 27606-5202

United States of America

##, 2020

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Review

NAPPO Regional Standards for Phytosanitary Measures (RSPMs) are subject to periodic review and amendment. This standard was last reviewed in 2020. A review of a NAPPO standard may be initiated at any time upon request of a NAPPO member country. The next review of RSPM 9 is scheduled for 2025.

Approval

This standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on xxxx and is effective from this date.

Approved and signed by:

Greg Wolff
Executive Committee Member
Canada

Osama El-Lissy
Executive Committee Member
United States

Francisco Ramírez y Ramírez
Executive Committee Member
Mexico

Implementation

No Implementation Plans are required.

Amendment Record

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

Distribution

Once approved, this standard is uploaded to the NAPPO website and is distributed by the NAPPO Secretariat to the Secretariat of the International Plant Protection Convention (IPPC) and to other Regional Plant Protection Organizations (RPPOs).

1 Introduction

3 Scope

5 This standard describes the criteria and processes used by the National Plant Protection
6 Organization (NPPO) for the authorization of a laboratory to perform phytosanitary testing
7 on behalf of the NPPO.

9 References

11 Draft ISPM on *Requirements for national plant protection organizations if authorizing entities*
12 *to perform phytosanitary actions*. (2014-002).
13 FAO. 2019. *IPPC style guide*. Rome. IPPC Secretariat. FAO. 43 pp.
14 International Organization for Standardization. 2015. ISO 9000: 2015. *Quality Management*
15 *Systems – Fundamentals and Vocabulary*. Geneva, Switzerland.
16 International Organization for Standardization. 2017. ISO/IEC 17025: 2017 *General*
17 *requirements for the competence of testing and calibration laboratories*. Geneva,
18 Switzerland.
19 ISPM 5. *Glossary of phytosanitary terms*. Rome, IPPC, FAO.
20 RSPM 5. *Glossary of phytosanitary terms*, in revision. Raleigh, NAPPO.

22 Definitions

24 Definitions of phytosanitary terms used in this standard can be found in RSPM 5 (*Glossary*
25 *of phytosanitary terms*) and in ISPM 5 (*Glossary of phytosanitary terms*).

27 Appropriate uses for the terms “shall” and “should” can be found in the IPPC Style Guide.

29 Authorization: Process used by NPPOs to officially recognize laboratories that perform
30 phytosanitary testing. An NPPO’s authorization program operates within its phytosanitary
31 system.

33 Audit (modified from ISO 9000): Systematic, independent and documented process for
34 obtaining evidence and evaluating it objectively to determine the extent to which established
35 criteria are fulfilled.

37 Impartiality (modified from ISO 17025): Conflicts of interest do not exist or are addressed to
38 prevent undue influence on phytosanitary testing results.

40 Laboratory: Physical location where phytosanitary testing takes place.

42 Phytosanitary testing: Scope of testing for which a laboratory has been authorized. If
43 permitted by the NPPO and where the laboratory has demonstrated expertise and
44 competence, the scope of testing may include activities in addition to diagnostic testing such
45 as sampling. Any additional activities will be delineated in the agreement between the NPPO
46 and the laboratory.

Outline of Requirements

National Plant Protection Organizations (NPPOs) may authorize laboratories to conduct phytosanitary testing to enhance the delivery of programs and services that protect plant resources and facilitate safe trade.

The NPPO shall have the authority and ability to implement, maintain, and monitor a laboratory authorization program to ensure compliance and continual improvement.

Applicant laboratories shall comply with all obligations and requirements established by the NPPO in order to receive and maintain their status as an authorized laboratory.

General Requirements

1. National Plant Protection Organization (NPPO)

The NPPO shall ensure the integrity of its authorization programs. The NPPO shall provide the information and resources to implement and maintain the laboratory authorization program.

1.1 Authority

The NPPO has the authority to monitor authorized laboratories performing phytosanitary testing.

The NPPO has the authority to suspend or revoke the authorization of a laboratory that does not comply with agreed-upon standards or provisions.

1.2 Responsibility

The NPPO is responsible for:

- Providing laboratories with the necessary information to apply for and maintain authorization;
- Conducting the authorization process.

The NPPO or its representative should:

- Evaluate the competence of the laboratory prior to entering into the authorization agreement;
- Periodically monitor the competence of the authorized laboratories to ensure that work continues to meet the agreement.

Evaluation and monitoring of laboratory competence may include but is not limited to:

- On-site audits;
- Document review;
- Records review;
- Follow-up on reported results;
- Proficiency testing provided either by the NPPO or by an internationally recognized proficiency test provider.

Where monitoring identifies a non-compliance, the NPPO should re-evaluate the authorization status of the laboratory.

1.3 Audit

Audits may be carried out to evaluate laboratory competence to implement phytosanitary testing. Appendix 1 provides an Audit checklist that may be used for this purpose.

The NPPO should determine the audit frequency.

An audit may be carried out on a selected part, or on the entire laboratory system, depending on the level of risk and complexity associated with phytosanitary testing, and on the performance and conformance of the laboratory.

Where the NPPO or its representative identifies a nonconformity, the laboratory shall promptly take action to correct the nonconformity.

The NPPO may suspend the phytosanitary testing described in the agreement if the nonconformity is not reasonably addressed or continues to pose a phytosanitary risk.

2. Applicant Laboratory

In order to be authorized, laboratories in NAPPO member countries shall:

- Meet the requirements of this standard;
- Meet the NPPO's general and specific legal requirements;
- Complete the authorization process established by the NPPO.

The laboratory should promptly inform the NPPO of changes that could affect the authorization agreement, including but not limited to changes in key personnel, equipment, methods, facilities, ownership, subcontracting, etc.

2.1 Applications

The laboratory shall designate a representative that will be accountable to the NPPO.

The laboratory shall designate a representative who has the authority to sign the authorization agreement with the NPPO.

Applications for authorization are approved by the NPPO.

The authorization agreement shall identify any information that is confidential. This may include, but is not limited to, results from phytosanitary testing, personnel descriptions, sampling sources and locations.

The laboratory and the NPPO shall secure and protect information designated as confidential.

2.2 Subcontracting

If subcontracting is permitted by the NPPO, the authorized laboratory:

- Shall be legally responsible for the subcontracted testing results;
- Should subcontract to a laboratory that is accredited to an internationally recognized standard or is authorized by the NPPO to perform phytosanitary testing, where possible;
- Should indicate clearly on their reports which testing is performed by the subcontractor.

If the authorized laboratory anticipates subcontracting, it shall be noted in the authorization agreement with the NPPO.

If the authorized laboratory subcontracts at any point during the agreement and this is not noted in the original authorization agreement, the NPPO shall be notified as soon as possible.

2.3 Quality System

The laboratory shall document and adhere to its quality system.

The quality system may be based on a nationally or internationally recognized standard.

The quality system shall meet the requirements of the NPPO.

The quality system shall be managed to safeguard impartiality.

The laboratory should routinely monitor its competency using check samples, participation in proficiency testing programs, or other mechanisms as required by the NPPO.

The laboratory should identify non-conformities. Where a non-conformity is identified, the laboratory shall promptly take action to correct the non-conformity.

The laboratory should use authorized methodologies when required by the NPPO.

Where the NPPO does not specify the methodologies to be used, the laboratory shall use other documented and approved methodologies.

2.4 Personnel

Laboratory personnel shall follow the quality system.

The laboratory personnel shall be trained and competent

The laboratory should:

- Document the qualifications and training of laboratory personnel;
- Monitor the competency of laboratory personnel.

3. Facilities

The laboratory facilities and environmental conditions shall be suitable for performing phytosanitary testing as indicated in the authorization agreement. This should include:

- Steps to minimize contamination;
- Steps to protect against pest entry;
- Appropriate lighting, temperature, moisture, ventilation, and noise conditions.

The laboratory facilities and environmental conditions should be monitored, controlled, and periodically reviewed by laboratory personnel.

4. Equipment

The laboratory shall have the equipment required for the correct performance of phytosanitary testing as established within the agreement.

The laboratory should monitor the performance of their equipment through an established and documented calibration and verification program.

The equipment shall conform to the laboratory's quality system.

5. Records

The laboratory shall maintain detailed records of the phytosanitary testing activities authorized by the NPPO.

The detailed records will confirm that phytosanitary testing results are reviewed and approved by authorized personnel prior to reporting.

When requested by the NPPO, the laboratory shall provide all records for testing activities for which it was authorized.

Detailed records should be maintained in a way that ensures integrity and traceability of the phytosanitary testing activities for the period specified by the NPPO.

Detailed records may include, but are not limited to, sample submission forms, worksheets, test results, equipment records, personnel training records, and all original observations.

6. Authorization Agreement

The authorization agreement shall describe the rights, obligations and requirements of both the NPPO and the authorized laboratory.

A record of authorization or equivalent document shall be issued to a laboratory which complies with the requirements established in the authorization agreement. This record shall identify the scope for which the authorized laboratory may perform phytosanitary testing activities.

1 Authorization should be renewed at a frequency established by the NPPO.

2 3 **7. Voluntary Termination**

4
5 The laboratory may voluntarily terminate the authorization agreement with the NPPO. Upon
6 termination:

- 7 - the laboratory shall not perform any phytosanitary testing activities authorized in the
8 original agreement.
- 9 - the NPPO should update the publicly available list of authorized laboratories.

10 11 **8. Suspension, Reinstatement or Revocation**

12
13 The NPPO may suspend, reject or revoke a laboratory's authorization to perform
14 phytosanitary testing activities.

15
16 The NPPO shall specify the procedures and criteria for suspension, rejection, revocation or
17 reinstatement of authorization.

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19 A laboratory that wishes to have its authorization reinstated shall meet the requirements for
20 reinstatement of authorization as specified by the NPPO.

21
22 During suspension, the laboratory remains under the purview of the NPPO and is obligated
23 to continue to meet the authorization agreement.

24
25 During suspension or upon revocation, the laboratory shall not perform any phytosanitary
26 testing activities for which they were authorized. The NPPO should update the publicly
27 available list of authorized laboratories.