



NAPPO

North American Plant Protection Organization
Organización Norteamericana de Protección a las Plantas
MEXICO - USA - CANADA

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**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
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1		
2	Contents	
3		
4	Review	3
5	Approval	3
6	Implementation	3
7	Amendment Record.....	3
8	Distribution.....	3
9	Introduction.....	4
10	Scope	4
11	References	4
12	Definitions.....	4
13	Outline of Requirements	5
14	General Requirements.....	5
15	1. National Plant Protection Organization (NPPO)	5
16	1.1 Authority	5
17	1.2 Responsibility	5
18	1.3 Audit.....	6
19	2. Applicant Laboratory	6
20	2.1 Applications.....	6
21	2.2 Subcontracting	7
22	2.3 Quality System	7
23	2.4 Personnel.....	7
24	3. Facilities	8
25	4. Equipment.....	8
26	5. Records.....	8
27	6. Authorization Agreement.....	8
28	7. Voluntary Termination	9
29	8. Suspension, Reinstatement or Revocation	9
30		
31		
32		

1 **Review**

2

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

7

8 **Approval**

9

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

12

13 ***Approved and signed by:***

14

15

16

Greg Wolff
Executive Committee Member
Canada

Osama El-Lissy
Executive Committee Member
United States

17

18

19

Francisco Ramírez y Ramírez
Executive Committee Member
Mexico

20

21

22 **Implementation**

23

24 No Implementation Plans are required.

25

26 **Amendment Record**

27

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

29

30 **Distribution**

31

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

35

1 **Introduction**

2

3 **Scope**

4

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.

8

9 **References**

10

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.

21

22 **Definitions**

23

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*).

26

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

28

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.

32

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.

36

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

39

40 Laboratory: Physical location where phytosanitary testing takes place.

41

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.

47

48

1 **Outline of Requirements**

2
3 National Plant Protection Organizations (NPPOs) may authorize laboratories to conduct
4 phytosanitary testing to enhance the delivery of programs and services that protect plant
5 resources and facilitate safe trade.

6
7 The NPPO shall have the authority and ability to implement, maintain, and monitor a
8 laboratory authorization program to ensure compliance and continual improvement.

9
10 Applicant laboratories shall comply with all obligations and requirements established by the
11 NPPO in order to receive and maintain their status as an authorized laboratory.

12
13 **General Requirements**

14
15 **1. National Plant Protection Organization (NPPO)**

16
17 The NPPO shall ensure the integrity of its authorization programs. The NPPO shall provide
18 the information and resources to implement and maintain the laboratory authorization
19 program.

20
21 **1.1 Authority**

22
23 The NPPO has the authority to monitor authorized laboratories performing phytosanitary
24 testing.

25
26 The NPPO has the authority to suspend or revoke the authorization of a laboratory that does
27 not comply with agreed-upon standards or provisions.

28
29 **1.2 Responsibility**

30
31 The NPPO is responsible for:

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

35
36 The NPPO or its representative should:

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

41
42 Evaluation and monitoring of laboratory competence may include but is not limited to:

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

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

3 4 **1.3 Audit**

5
6 Audits may be carried out to evaluate laboratory competence to implement phytosanitary
7 testing. Appendix 1 provides an Audit checklist that may be used for this purpose.

8
9 The NPPO should determine the audit frequency.

10
11 An audit may be carried out on a selected part, or on the entire laboratory system, depending
12 on the level of risk and complexity associated with phytosanitary testing, and on the
13 performance and conformance of the laboratory.

14
15 Where the NPPO or its representative identifies a nonconformity, the laboratory shall
16 promptly take action to correct the nonconformity.

17
18 The NPPO may suspend the phytosanitary testing described in the agreement if the
19 nonconformity is not reasonably addressed or continues to pose a phytosanitary risk.

20 21 **2. Applicant Laboratory**

22
23 In order to be authorized, laboratories in NAPPO member countries shall:

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

27
28 The laboratory should promptly inform the NPPO of changes that could affect the
29 authorization agreement, including but not limited to changes in key personnel, equipment,
30 methods, facilities, ownership, subcontracting, etc.

31 32 **2.1 Applications**

33
34 The laboratory shall designate a representative that will be accountable to the NPPO.

35
36 The laboratory shall designate a representative who has the authority to sign the
37 authorization agreement with the NPPO.

38
39 Applications for authorization are approved by the NPPO.

40
41 The authorization agreement shall identify any information that is confidential. This may
42 include, but is not limited to, results from phytosanitary testing, personnel descriptions,
43 sampling sources and locations.

44
45 The laboratory and the NPPO shall secure and protect information designated as confidential.
46
47
48

1 **2.2 Subcontracting**

2
3 If subcontracting is permitted by the NPPO, the authorized laboratory:

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

10
11 If the authorized laboratory anticipates subcontracting, it shall be noted in the authorization
12 agreement with the NPPO.

13
14 If the authorized laboratory subcontracts at any point during the agreement and this is not
15 noted in the original authorization agreement, the NPPO shall be notified as soon as possible.

16
17 **2.3 Quality System**

18
19 The laboratory shall document and adhere to its quality system.

20
21 The quality system may be based on a nationally or internationally recognized standard.

22
23 The quality system shall meet the requirements of the NPPO.

24
25 The quality system shall be managed to safeguard impartiality.

26
27 The laboratory should routinely monitor its competency using check samples, participation
28 in proficiency testing programs, or other mechanisms as required by the NPPO.

29
30 The laboratory should identify non-conformities. Where a non-conformity is identified, the
31 laboratory shall promptly take action to correct the non-conformity.

32
33 The laboratory should use authorized methodologies when required by the NPPO.

34
35 Where the NPPO does not specify the methodologies to be used, the laboratory shall use
36 other documented and approved methodologies.

37
38 **2.4 Personnel**

39
40 Laboratory personnel shall follow the quality system.

41
42 The laboratory personnel shall be trained and competent

43
44 The laboratory should:

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

1 **3. Facilities**

2
3 The laboratory facilities and environmental conditions shall be suitable for performing
4 phytosanitary testing as indicated in the authorization agreement. This should include:

- 5 - Steps to minimize contamination;
6 - Steps to protect against pest entry;
7 - Appropriate lighting, temperature, moisture, ventilation, and noise conditions.
8

9 The laboratory facilities and environmental conditions should be monitored, controlled, and
10 periodically reviewed by laboratory personnel.
11

12 **4. Equipment**

13
14 The laboratory shall have the equipment required for the correct performance of
15 phytosanitary testing as established within the agreement.
16

17 The laboratory should monitor the performance of their equipment through an established
18 and documented calibration and verification program.
19

20 The equipment shall conform to the laboratory's quality system.
21

22 **5. Records**

23
24 The laboratory shall maintain detailed records of the phytosanitary testing activities
25 authorized by the NPPO.
26

27 The detailed records will confirm that phytosanitary testing results are reviewed and
28 approved by authorized personnel prior to reporting.
29

30 When requested by the NPPO, the laboratory shall provide all records for testing activities
31 for which it was authorized.
32

33 Detailed records should be maintained in a way that ensures integrity and traceability of the
34 phytosanitary testing activities for the period specified by the NPPO.
35

36 Detailed records may include, but are not limited to, sample submission forms, worksheets,
37 test results, equipment records, personnel training records, and all original observations.
38

39 **6. Authorization Agreement**

40
41 The authorization agreement shall describe the rights, obligations and requirements of both
42 the NPPO and the authorized laboratory.
43

44 A record of authorization or equivalent document shall be issued to a laboratory which
45 complies with the requirements established in the authorization agreement. This record shall
46 identify the scope for which the authorized laboratory may perform phytosanitary testing
47 activities.
48

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.

18
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.
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