



NAPPO

North American Plant Protection Organization

Organización Norteamericana de Protección a las Plantas

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM 28

Authorization of Entities to Perform Phytosanitary Services

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Review

NAPPO Regional Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2019. This Standard was last reviewed in 2014. A review of any NAPPO Standard may be initiated at any time upon the request of a NAPPO member country.

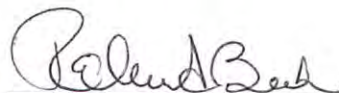
Approval

This Standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on July 28, 2014, and is effective from this date.

Approved by:



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Implementation

No implementation plan is required for this standard.

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 (AIG) and Sustaining Associate Members (SAM), the International Plant Protection Convention (IPPC) Secretariat, and to other Regional Plant Protection Organizations (RPPOs).

Introduction

Scope

This standard describes the essential elements required for the authorization of entities by the National Plant Protection Organization (NPPO), including individuals, facilities, businesses, and other organizations to perform specific phytosanitary services on behalf of the NPPO. Such entities may in turn authorize third parties to carry out certain phytosanitary services. It outlines the responsibilities of the NPPO in terms of developing requirements for authorization, assessing compliance of the authorized entity to the NPPO requirements, and granting/removal of authorization. In addition, it defines the responsibilities of the entity to be authorized, but does not extend to issuing phytosanitary certificates (ISPM 12: 2011). This standard is designed to complement, but not replace, other RSPMs such as RSPM 8: 2013 and RSPM 9: 2009.

References

- IPPC. 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.
- ISPM 1. 2006. *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*. Rome, IPPC, FAO.
- ISPM 5. (Updated annually). *Glossary of phytosanitary terms*. Rome, IPPC, FAO.
- ISPM 12. 2011. *Phytosanitary Certificates*. Rome, IPPC, FAO
- ISPM 14. 2002. *The use of integrated measures in a systems approach for pest risk management*. Rome, IPPC, FAO.
- ISO. 2011. *ISO 19011- Guidelines for auditing management systems*, 2d edition.. Geneva.
- RSPM 5. (Updated annually). *NAPPO glossary of phytosanitary terms*. Ottawa, NAPPO.
- RSPM 8. 2013. *The authorization of individuals to issue phytosanitary certificates*. Ottawa, NAPPO.
- RSPM 9. 2009. *The authorization of laboratories for phytosanitary testing*. Ottawa, NAPPO.
- RSPM 24. 2013. *Integrated pest risk management measures for the importation of plants for planting into NAPPO member countries*. Ottawa, NAPPO.

Definitions

Definitions of phytosanitary terms used in this standard can be found in NAPPO RSPM 5 and in ISPM 5.

Background

Authorization, as a means of recognizing a consistent level of competency and conferring specific authority, is acknowledged by NAPPO member countries to be a legitimate means for National Plant Protection Organizations (NPPOs) to enhance their ability to facilitate trade while protecting plant resources. NAPPO views regional and international standards for the authorization of entities to be fundamental to the international harmonization of phytosanitary measures and systems.

Outline of Requirements

An NPPO may authorize an entity to perform specific phytosanitary actions on their behalf, provided the NPPO establishes requirements against which the entity is audited.

Authorized entities must develop a Quality Systems Manual (QSM) that demonstrates how they will consistently meet the requirements established by the NPPO.

The NPPO will authorize only those entities which comply with the established requirements. The NPPO must develop and implement processes for authorizing entities. These processes should include mechanisms for conferring authorization to an entity, auditing authorized entities to evaluate whether the entity meets the established requirements through a QSM, documenting the authorization process, following up on non-conformity to the QSM, and removing authorization.

The NPPO must also conduct audits of its own authorization processes.

General Requirements

1. Responsibilities of the NPPO:

- Identify the authority, program objectives and what constitutes a non-compliance
- Develop and implement processes for the authorization of entities;
- Establish the requirements that must be met in order for an entity to be authorized to carry out specific services on behalf of the NPPO;
- Develop audit checklists, corrective action reports, etc. based on the requirements;
- Provide personnel with the required training, experience and education to conduct audits;
- Enter into an agreement with the entity to be authorized and carry out regular audits to verify that they comply with the requirements;
- Maintain documentation, including records and a list of authorized entities;
- Establish mechanisms to address a non-conformity, including removal of authorization and where appropriate, reinstatement;
- Carry out audits to verify the integrity of the NPPO's entity authorization process;
- Develop and carry out an action plan/procedures for dealing with a non-conformity that compromises the integrity of the program.

2. Responsibilities of Authorized Entities:

- Develop and maintain infrastructure and resources to consistently carry out the services as described in the requirements;
- Maintain personnel with the required training, experience and education to consistently carry out the services as described in the requirements;
- Develop and utilize a QSM containing the standard operating procedures in place to meet the requirements and to ensure that requirements are being met;
- Maintain documentation, including appropriate records;
- Apply to the NPPO for authorization to perform particular services on behalf of the NPPO;

- Undergo audits by the NPPO as described in the requirements;
- Develop and carry out an action plan/procedures for dealing with non-conformity that compromises the integrity of the program, including notification of the authorizing NPPO.

Specific Requirements

A particular entity may be authorized to conduct specific services on behalf of an NPPO provided the following minimum requirements are met.

3. Process for Granting Authorization

Each NPPO is responsible for the authorization of entities carrying out services under its responsibility and authority. The NPPO must specify the minimum requirements that must be met in order for an entity to be authorized to conduct specific services on its behalf.

This section describes the processes that the NPPO should use to authorize entities to act on its behalf.

3.1 Initiation of the authorization process

Entities seeking to act on behalf of the NPPO to conduct specific services must apply to the NPPO for authorization and submit a QSM outlining the procedures that have been put in place to meet the requirements. The NPPO must review each application package to ensure that the entities meet the requirements.

3.2 Review of Quality Systems Manual

The NPPO must review the written QSM and verify that it contains all the elements to consistently meet the requirements. The NPPO may require the entity to revise or rewrite their QSM prior to proceeding to the next step in the authorization process. Once the NPPO considers that the entity's manual satisfies the requirements the entity may enter into the next stage of the authorization process.

3.3 Initial systems audit for authorization

In some cases the initial systems audit is carried out by the NPPO. In other cases, it may be done by an entity authorized by the NPPO. The auditor should carry out an initial systems audit to determine whether the entity should be authorized by the NPPO.

The auditor should prepare a written report summarizing the findings of the audit, determine whether the entity meets the requirements and recommend whether the entity should be authorized by the NPPO to carry out the specified services.

3.4 Authorization

Once the NPPO is satisfied that the entity has the capacity to effectively implement the elements of their QSM and that their procedures are adequate to consistently meet the requirements, the entity may be authorized to carry out specific services on behalf of the NPPO. The NPPO should determine the duration of authorization and have a mechanism

for tracking authorization status and for notifying the authorized entity of any changes in that status. Should an entity withdraw, or authorization is suspended or revoked, it may not continue to carry out services on behalf of the NPPO.

4. Process for Audits

The NPPO is responsible for the development of their audit programmes and for ensuring that audits of authorized entities are conducted. These programmes should include processes for planning audits, developing audit checklists, selecting the auditor(s), planning and carrying out the audits, and processes to establish audit frequencies.

Individual audits are conducted following the steps of audit preparation, opening meeting, gathering information, assessing findings, closing meeting, audit documents and follow-up verification. For additional guidance see ISO 19011:2011.

Audits should include both systems and surveillance audits. Audits are conducted by the NPPO or other organization authorized by the NPPO.

The table below highlights the differences between systems audit and surveillance audit.

	Systems audit	Surveillance audit
Objectives	<ul style="list-style-type: none"> To determine if the QSM is designed to achieve the program objectives. 	<ul style="list-style-type: none"> To determine if the QSM is being implemented as described
Scope	<ul style="list-style-type: none"> Broad Thorough examination of the system as described in the QSM 	<ul style="list-style-type: none"> Focused Examination of the implementation of the system as described in the QSM Correction of non-conformity to the QSM Follow-up on corrective measures
Focus	<ul style="list-style-type: none"> Documentation 	<ul style="list-style-type: none"> Program delivery May include inspection components
Frequency	<ul style="list-style-type: none"> Annual/biannual Scheduled 	<ul style="list-style-type: none"> More frequent than systems audit Scheduled or <i>ad hoc</i> Based on history of conformity and complexity of the program
Notification	<ul style="list-style-type: none"> Always announced 	<ul style="list-style-type: none"> Both announced and unannounced

5. Auditors

Audit team members may include staff from the NPPO, state or provincial agricultural departments or other NPPO-authorized organizations. A lead auditor, other team members, technical experts and observers should be identified, as appropriate. All members are required to have successfully completed an introductory audit course or have an adequate combination of training and experience in auditing.

The NPPO will develop and maintain a list of qualified auditors and lead auditors. The entire audit team must be familiar with the requirements, the entity's QSM and the checklists being used in the audit.

6. Non-Conformity

Procedures that do not meet the requirements of the QSM are considered as a non-conformity. A non-conformity can be detected during audits, inspections, and investigations. The number and type of non-conformity found should be used to determine the status of the entity and the subsequent auditing frequency. Classification of non-conformity is based on an evaluation of the associated risk and whether the integrity of the entity's NPPO-authorized services have been compromised.

Authorized entities may be found to be non-conformant if there are incidents of non-conformity, or where audit findings indicate that the authorized entity is not meeting specified requirements.

Non-conformities may be considered critical, major or minor depending on the nature of the non-conformity or the number of incidents that are reported. For example:

Critical non-conformity

Audit findings that indicate that the integrity of the phytosanitary service of the authorized entity is in jeopardy are considered to be critical non-conformity. The entity should be immediately suspended if any critical non-conformities are found.

Major non-conformity

Major non-conformities are incidents of non-conformity by the authorized entity, but which have no direct impact on the integrity of the phytosanitary system that is authorized. Corrective actions should be carried out to the satisfaction of the NPPO within a specified period of time. The required corrective actions will generally require a change to the QSM and will include measures to prevent recurrence. If the entity fails to carry out the required corrective actions within the specified time period, the entity should be immediately suspended.

Minor non-conformity

Minor non-conformity are isolated incidents, which do not immediately or significantly affect the integrity of the phytosanitary system that is authorized. If multiple minor non-conformities are detected in any one audit this may be considered equivalent to one major non-conformity. Corrective actions should be undertaken by the authorized entity before the next scheduled audit, or within the time limit specified by the NPPO.

Any non-conformity should be accompanied by an action plan. Failure to follow the action plan may result in the suspension of authorized entity.

The NPPO will develop a protocol for use in cases where an entity is denied authorization or authorization is removed. The protocol will include justification and documentation of decisions and an appeal process. Authorization will not be granted or reinstated pending the completion of any appeals unless otherwise determined by the NPPO.

7. Re-instatement

The entity may apply for re-instatement of authorization for the phytosanitary service after all non-conformities have been corrected and the QSM has been revised to prevent re-occurrences. The NPPO will establish the timelines and process for re-instatement of authorization. Repeated suspension may result in permanent removal of the entity's authorization as determined by the NPPO.