ORGANISATON NORD AMERICAINE POUR LA PROTECTION DES PLANTES
NORTH AMERICAN PLANT PROTECTION ORGANIZATION
ORGANIZACION NORTEAMERICANA DE PROTECCION A LAS PLANTAS
CANADA UNITED STATES MEXICO

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM No. 28
Guidelines for Authorization

The Secretariat of the North American Plant Protection Organization
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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 2014. This Standard was last reviewed in 2009. 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 October 19, 2009, and is effective from this date.

Approved by:

Greg Stubbings
Executive Committee Member
Canada

Paul R. Eggert
Executive Committee Member
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Executive Committee Member
Mexico

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 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 essential elements required for the authorization of entities, including individuals, facilities, businesses, and other organizations to perform specific phytosanitary services on behalf of the National Plant Protection Organization (NPPO). It outlines the responsibilities of the NPPO in terms of developing criteria for authorization, assessing compliance and granting/removal of authorization In addition, it defines the responsibilities of the entity to be authorized. This standard is designed to complement, and not replace other RSPMs such as RSPM 8 and 9.

References

Authorization of Individuals to Issue Phytosanitary Certificates. 2008. NAPPO RSPM Nº 8.

Glossary of Phytosanitary Terms. 2008. ISPM Nº 5, FAO, Rome.

Integrated Pest Risk Management Measures for the Importation of Plants for Planting into NAPPO Member Countries. 2005. NAPPO RSPM Nº 24.

International Plant Protection Convention, New Revised Text, 1999, FAO, Rome.

NAPPO Glossary of Phytosanitary Terms. 2008. NAPPO RSPM Nº.5

Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006. ISPM Nº 1, FAO, Rome.

The Authorization of Laboratories for Phytosanitary Testing. 2009. NAPPO RSPM Nº 9.

The use of integrated measures in a systems approach for pest risk management. 2002. ISPM Nº 14, FAO, Rome.

Definitions

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

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 develops a set of criteria against which the entity is evaluated.

The NPPO will authorize only those entities which consistently meet and maintain the criteria. The NPPO must develop and implement processes for authorizing entities. These processes should include mechanisms for conferring authority to an entity, auditing authorized entities to evaluate whether the entity consistently meets the criteria described in the standard, documenting the authorization process, and removing authority. The NPPO must also develop and implement procedures for conducting its own authorization processes.

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

General Requirements

1. Responsibilities of the NPPO

The NPPO must:

- 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 activities on behalf of the NPPO;
- Develop audit checklists, corrective action reports, etc. based on the requirements;
- Provide adequate 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;
- Carry out audits at required frequencies to verify that the authorized entity consistently meets the requirements;
- Maintain adequate documentation, including records and a list of authorized entities;
- Establish mechanisms for removal of authorization; and
- Carry out audits to verify the integrity of the NPPO entity authorization process.

2. Responsibilities of Authorized Entities

Authorized entities must:

- Have adequate infrastructure, resources to consistently carry out the activities as described in the requirements;
- Have adequate personnel available, with the required training, experience and education, to consistently carry out the activities as described in the requirements;
- Develop a manual containing the standard operating procedures in place to meet the requirements;
- Utilize a systems approach with documented critical control points;
- Fulfill all requirements, including established national or international industry standards (e.g. ISO);

- Maintain adequate documentation, including appropriate records;
- Apply to the NPPO for authorization to perform particular services on behalf of the NPPO; and
- Undergo audits by the NPPO as described in the requirements.

Specific Requirements

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

3. NPPO Requirements for Authorized Entities

Each NPPO is responsible for the authorization of entities within its borders. The NPPO must specify the minimum criteria that must be met in order for an entity to be authorized to conduct specific activities on its behalf

This section describes the procedures and criteria that the NPPO should use to review applications for authorization, evaluate phytosanitary systems and authorize entities to act on its behalf.

3.1 Applying for Authorization

Entities seeking to act on behalf of the NPPO to conduct specific activities must apply to the NPPO for authorization and submit a Quality Systems Manual outlining the procedures that have been put in place to meet the requirements. The NPPO must review each application to ensure the entities meet any conditions described in the requirements.

3.1.1 Review of Quality Systems Manual

The NPPO must review the written Quality Systems Manual and verify that it contains all the elements to consistently meet the requirements, including a system of internal audits, at the discretion of the NPPO. The NPPO may require the entity to revise or rewrite their Manual prior to proceeding to the next step in the approval process. Once the NPPO considers that the entity's manual satisfies the requirements the entity may enter into the next stage of the approval process.

3.1.2 Initial Evaluation for Authorization

The NPPO shall carry out an initial systems evaluation. This evaluation should be designed to determine whether the entity has the infrastructure, staff and resources in place to successfully implement its Quality Systems Manual and to meet the requirements The evaluator should prepare a written report summarizing the findings of the evaluation, determine whether the entity meets the requirements and recommend whether the entity should be authorized by the NPPO to carry out the specified activities.

3.1.3 Authorization

Once the NPPO is satisfied that the entity has the capacity to effectively implement the elements of their Quality Systems Manual and that their procedures are adequate to consistently meet the requirements, the entity can be authorized to carry our specific activities on behalf of the NPPO. The NPPO must have a mechanism for tracking authorized entities and their authorization status and for notification of any changes in status. Should an entity withdraw, or authorization is suspended or revoked, it may not continue to carry out activities on behalf of the NPPO.

3.1.4 Audits

The NPPO is responsible for the development of audit procedures and the delivery of audits at authorized entities. These procedures should include processes for planning audits, developing audit checklists, selecting the auditor(s), planning and carrying out the audit, opening and closing meetings, classifying non-compliance, reporting findings and distribution of audit reports. Audits should be carried out according to protocols developed by the NPPO and should include both systems and surveillance audits each year. The NPPO may use its discretion in adjusting audit frequencies based on a history of compliance by the authorized entity.

Systems Audits are an annual systematic examination of the organizational structure, procedures, processes, and resources used within the authorized entity to meet the requirements. The objective of a systems audit is to determine whether the particular components of the program comply with the entity systems as described in their quality systems manual and to determine whether the requirements are implemented effectively and are suitable to achieve the objectives of the program. Systems Audits are conducted by the NPPO or other organization approved by the NPPO.

Surveillance Audits are an ongoing monitoring and verification of the status of the authorized entity's operations, records and administrative procedures to ensure conformity with the Quality Systems Manual. Surveillance Audits evaluate whether the entity has the resources, infrastructure and staff in place to successfully implement the procedures outlined in Quality Systems Manual and; whether those procedures as described are implemented and documented. Surveillance audits are conducted by the NPPO or other organization approved by the NPPO. The timing, scope and frequency of the Surveillance Audit will be determined by the NPPO, based on the complexity of the program, history of compliance, etc.

The lead auditor is responsible for preparing an audit report following each audit and providing a copy to the NPPO and the audited entity. The audit report should summarize the findings and conclusions of the audit, including any non-compliance.

4. Auditors

Audit team members can include the NPPO, state or provincial agricultural staff or other approved organizations; A lead auditor, other team members,, technical experts and observers should be identified, as appropriate. All members are required to have passed an introductory audit course, or other audit training, such as ISO 19011.

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 Quality Systems manual and the checklists being used in the audit.

5. Non-Compliance

Activities or products that do not meet the requirements of the Quality Systems manual are considered as non-compliant. Non-compliance can be detected during audits, inspections, investigations. The number and type of non-compliance found should be used to determine the status of the entity and the subsequent auditing frequency. Classification of non-compliance is based on an evaluation of the associated risk and whether the integrity of the authorized program has been compromised. The NPPO is responsible for defining what constitutes a critical, major and minor non-compliance.

Any audit findings that indicate that the integrity of the program at the authorized entity is in jeopardy, are considered to be critical non-compliance and must result in immediate suspension, or removal of authorization.

Major non-compliance are isolated incidents of non-compliance, which have no direct impact on the integrity of the systems in place at the authorized entity. Corrective actions must 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 Quality Systems manual and will include measures to prevent recurrence.

Minor non-compliance does not immediately and/or significantly affect the integrity of the program or the authorized product. If there are multiple instances of minor non-compliance, it may be an indication that the integrity of the systems in place at the authorized entity have been compromised and may result in the entity being suspended.

The NPPO shall deny initial authorization or remove the authorization of, any entity that has failed to take the remedial action required to correct identified deficiencies.

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 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.

6. Re-instatement

The entity may apply for re-instatement of authorization in the program after all non-compliances have been corrected and the Quality Systems manual 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.