



## DRAFT ISPM: Audit in the phytosanitary context (2015-014)

### Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
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## Adoption

[Text to this paragraph will be added following adoption.]

## INTRODUCTION

### Scope

This standard covers audits in the phytosanitary context conducted by a national plant protection organization (NPPO) in its own territory, or with and in the territory of another NPPO. It also covers audits conducted by entities that have been authorized by the NPPO to conduct audits on its behalf. This standard focuses only on the phytosanitary aspects of audits. For general aspects of audits, other sources of information are available.

### References

The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispm>.

**IPPC Secretariat.** 1997. *International Plant Protection Convention*. Rome, IPPC Secretariat, FAO.

### Definitions

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

### Outline of requirements

This standard describes the purpose and procedures for audit activities in the phytosanitary context. This includes the circumstances that may trigger an audit, the roles and responsibilities of the auditor and auditee and the procedures for planning, preparing for, undertaking and reporting the outcome of an audit. The audit elements to be considered depend on the type of audit and its purpose, scope and objectives.

This standard also provides guidance on selecting auditors, establishing the audit frequency, settling disputes over audit findings, and agreeing financial arrangements between the parties involved.

## BACKGROUND

National plant protection organizations have a number of responsibilities under the IPPC for activities in their territory such as surveillance, inspection, the conduct of pest risk analyses, the establishment of phytosanitary import requirements, phytosanitary certification, the conduct or supervision of treatments as phytosanitary measures, and the training of staff. To help them fulfil these responsibilities effectively, NPPOs are increasingly using audits to provide confidence that phytosanitary systems and procedures achieve their objectives.

Audits are referenced in many adopted ISPMs. This standard aims to provide guidance to NPPOs on a common approach to audits in the phytosanitary context.

An audit is a documented verification process. An audit in the phytosanitary context (hereafter referred to as an “audit”) is a documented, systematic review of a phytosanitary system or procedure to evaluate the level of control, ensure that it conforms with the requirements set by the auditing NPPO (the NPPO responsible for the audit), and evaluate whether the system or procedure is achieving the expected phytosanitary objectives.

Unlike supervision, an audit does not involve continuous observation and direction of activities but instead provides an evaluation of a specific phytosanitary system, procedure, or particular elements of a system or procedure, at a given time.

Objective evidence is collected on whether the outcomes of the phytosanitary system or procedure conform with the relevant requirements of the auditing NPPO and whether these requirements are implemented effectively to achieve the phytosanitary objectives.

## **IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT**

Conducting audits helps to ensure the effectiveness of phytosanitary systems and procedures, thereby reducing the pest risk. This protects plant health, which in turn reduces negative environmental impacts and benefits biodiversity.

## **REQUIREMENTS**

### **1. Purpose of an audit**

An audit should objectively evaluate whether a specific phytosanitary system or procedure conforms with the requirements set by the auditing NPPO. An audit should provide an opportunity to identify findings, including nonconformities and observations, regarding the effectiveness of the phytosanitary system or procedure being audited.

An NPPO may conduct audits to verify the conformity of:

- the NPPO's own systems and procedures;
- the systems and procedures of entities that have been authorized by the NPPO, including entities authorized to conduct audits on behalf of the NPPO;
- the systems and procedures of the NPPO of an exporting country in accordance with the requirements of ISPM 20 (*Guidelines for a phytosanitary import regulatory system*).

An entity authorized by an NPPO to conduct audits on its behalf may conduct audits to verify the systems and procedures of entities authorized by that NPPO to perform phytosanitary actions.

### **2. Types of audit**

The main types of audit are system audits and focused audits.

A system audit is a comprehensive review of a phytosanitary system or procedure to evaluate its effectiveness and conformity with the requirements of the auditing NPPO. It is conducted to determine whether the system or procedure is achieving its objectives and whether the auditee has sufficient capability to implement the system or procedure. In general, a system audit may be conducted before authorizing an entity or a new process, or when necessary. The scope of a system audit may include an entire system from production to export or a system of a particular entity.

A focused audit is a review of particular elements of a phytosanitary system or procedure to evaluate their effectiveness and conformity with the requirements of the auditing NPPO. It is conducted to determine whether the system or procedure is being properly implemented and maintained. A focused audit may be conducted periodically, at regular or random intervals, or as a result of certain circumstances.

### **3. Circumstances that may trigger an audit**

The following are examples of circumstances that may trigger an audit:

- changes to conditions (e.g. production practices, pest status, phytosanitary import requirements, management systems or operations of a facility);
- a new import pathway;
- a new export programme;
- a notification of non-compliance from the NPPO of an importing country (e.g. detection of a regulated pest in an imported consignment);

- a detected nonconformity that may compromise the phytosanitary system;
- the implementation of corrective actions to address nonconformity;
- new requests for participation in the phytosanitary system.
- scheduling of a routine audit to verify conformity with the requirements of the auditing NPPO.

## **4. Roles and responsibilities**

### **4.1 Roles**

The audit involves two parties: an auditor and an auditee. The auditor may be either an NPPO or its authorized entity. The auditee may be an NPPO auditing itself, the NPPO of an exporting country audited by the NPPO of an importing country, an entity authorized by an NPPO to perform phytosanitary actions, or any other participant in the phytosanitary system that is being audited. The sections below describe the responsibilities of each party. In the context of this standard, both the terms “auditor” and “auditee” may refer to either an individual person or a group of people representing an entity.

### **4.2 Responsibilities of an NPPO auditing in its own territory**

For audits in its own territory, the auditing NPPO should:

- establish an audit framework and requirements for the audit process;
- ensure that an appropriate legal and technical framework is in place if deciding to authorize entities to conduct audits on its behalf and for subsequently maintaining oversight of their action;
- develop contingency plans for continuity of audits in the event that an authorized entity is no longer able to conduct audit activities;
- identify costs and ensure that appropriate financial arrangements are in place to meet these costs;
- if nonconformities are identified, ensure that the auditee identifies and implements corrective actions to address these nonconformities within the agreed time frame; and
- take necessary actions, which may include revocation of authorization of an entity or suspension of participation in the phytosanitary system, when a critical nonconformity has been identified or when identified nonconformities have not been addressed satisfactorily.

### **4.3 Responsibilities of an NPPO auditing in an exporting country**

The NPPO of an importing country conducting audits in the territory of an exporting country should:

- establish an audit framework and requirements for the audit process;
- reach an agreement with the NPPO of the exporting country on how the audit will be conducted, including arrangements for aspects such as the financial cost of the audit and which entities are authorized to conduct the audit; and
- if nonconformities are identified, agree with the NPPO of the exporting country what corrective actions are required and within what time frame they should be completed.

### **4.4 Responsibilities of the auditor**

The following are general responsibilities of an auditor that should all apply, regardless of whether the auditor is an NPPO or an authorized entity. The auditor should:

- develop, implement and maintain an audit programme within the audit framework established by the auditing NPPO;
- identify the purpose, scope and objectives of each audit;
- identify the audit criteria to be used;
- prepare for and undertake audits using the agreed criteria;
- prepare and finalize audit reports and provide these in a timely manner to the auditee, or to both the auditee and the auditing NPPO if the auditor is an authorized entity;

- provide sufficient human resources with the required training and competence to conduct the audits;
- be free of any conflict of interest and maintain impartiality and independence from the entities being audited;
- provide an opportunity for the auditee to respond to the findings of the report (e.g. to support the findings or disagree with them) before it is finalized and published; and
- maintain the confidentiality of information gained through the audit (see section 8).

#### **4.4.1 Specific responsibilities of entities authorized to conduct an audit**

In addition to the general responsibilities of an auditor set out at the start of section 4.4 and the responsibilities set out in ISPM 45 (*Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions*), authorized entities conducting an audit on behalf of an NPPO should:

- conduct audits as agreed with the authorizing NPPO; and
- notify the authorizing NPPO of any nonconformities as defined in section 12.

#### **4.5 Responsibilities of the auditee**

The auditee should be required to:

- cooperate with the auditor and meet the audit requirements;
- provide access to information, facilities, records and personnel necessary for the audit being conducted;
- facilitate, within the auditee's country and as appropriate, the logistics associated with visits by the auditor;
- develop and deliver an action plan according to the audit findings; and
- develop and implement corrective actions to address nonconformities within the agreed time frame if nonconformities are identified.

### **5. Selection of auditors**

Auditors should be selected based on a combination of their knowledge, training and experience pertaining to the phytosanitary system or procedure they are auditing, the audit methodology and the gathering of objective evidence.

Where additional technical expertise is required, a relevant technical expert may be part of the audit team or may assist the auditor.

To meet the requirement for impartiality (see section 7), any conflict of interest between the auditor and auditee should also be considered during the selection process.

### **6. Frequency of audits**

When setting up an audit programme, the auditing NPPO should determine the frequency of audits and review this frequency as appropriate. The audit frequency may be influenced by:

- circumstances that may trigger an audit (see section 3);
- seasonality in relation to phytosanitary activities;
- the pest risk associated with relevant pests or pathways;
- the history of conformity and compliance by the auditee;
- whether an established, documented procedure is in place that has been shown to reduce the pest risk.

## **7. Conflicts of interest**

The auditing NPPO should develop guidance on impartiality and possible conflicts of interest related to audits. In order to maintain the integrity of the audit, the auditor should be impartial. For each audit, the auditor should identify the potential, perceived or actual conflicts of interest relating to the audit. Both the auditor and auditee should declare and agree that there are no conflicts of interest relating to the audit.

## **8. Confidentiality**

The parties should agree and ensure an appropriate level of confidentiality, including that of private and commercially sensitive information, in order to maintain the integrity of the audit. The auditing NPPO should develop guidance on this matter as appropriate.

Before the commencement of the audit, parties should discuss the intended and possible disclosure of information gathered during the audit, including the report.

## **9. Financial arrangements**

Financial arrangements should be discussed and agreed upon by the parties before commencement of the audit (see also sections 4.2 and 4.3).

## **10. Settlement of disputes**

The process for settlement of disputes should be established and agreed in advance of audits, as part of the audit framework.

If parties do not agree that the intended methodology was followed, or with findings or conclusions of the audit, they should consult among themselves during the audit.

If the dispute is still not resolved after this consultation, disputing parties should refer to the agreed dispute settlement process.

## **11. Steps in the audit process**

The audit methodology may differ depending on the purpose, scope and objectives of the audit. It may entail review of documents, interviews, meetings, site visits or a combination of these. The following subsections describe the steps in the audit process.

### **11.1 Planning an audit**

The planning of an audit should include the following elements:

- defining and agreeing on the purpose, scope (entire system or particular elements of the system), process and objectives of the audit;
- identifying the audit criteria that will be used;
- identifying the auditor and the auditee; and
- considering existing equivalent audit systems, or other systems developed by NPPOs or industry, as an alternative to on-site audits, where appropriate.

#### **11.1.1 Scheduling of audits**

Audits should be scheduled (i.e. the auditee should be notified of the date and time of the performing and evaluation stage of the audit (section 11.3.2)) by the auditing NPPO, or the authorized entity conducting the audit, in advance. Non-periodic audits may be scheduled by an NPPO or an authorized entity as a result of certain circumstances (see section 3). In some situations (e.g. critical nonconformities), audits may be unscheduled.

## 11.2 Preparing for an audit

To prepare for an audit, the auditor should:

- gather and review relevant information, such as manuals, procedures, work plans, notifications of non-compliance, records, a pre-audit questionnaire, relevant standards, agreements, previous audit reports and, if available, reports on corrective actions implemented to address nonconformities;
- prepare audit tools, such as checklists, reference materials, equipment and a list of possible questions;
- communicate with participants (which may include notifying auditees) and confirm their availability, finalize logistics arrangements and, if relevant, agree to the language in which the audit will be conducted;
- ask the auditee to ensure that personnel and relevant documentation be available during the audit; and
- confirm the roles and responsibilities of the participants during the audit, such as the principal contact persons for each party, the lead auditor, audit team members and, if relevant, the technical experts.

## 11.3 Undertaking an audit

There are three stages involved in undertaking an audit. The activities that take place during each stage may differ depending on the type of audit and its scope. The three stages are set out below, along with examples of activities that may be included.

### 11.3.1 Initiation

The activities of the auditor may include:

- confirming the purpose, scope and objectives of the audit and confirming the audit criteria;
- introducing the audit participants and confirming the availability of required personnel;
- discussing previous audit reports, including corrective actions implemented (if applicable);
- reviewing the methodology to be used in the performing and evaluation stage of the audit;
- confirming if submitted documentation is current;
- confirming the audit process and time frame;
- informing participants about legal requirements for confidentiality and data protection.

### 11.3.2 Performing and evaluation

The activities of the auditor may include:

- interviewing relevant personnel if required and seeking clarification as necessary;
- assessing documented processes;
- assessing records from procedures (e.g. technical and administrative records, inspection records, treatment records, testing results, corrective actions log);
- verifying whether facilities, instruments, machinery and equipment comply with the relevant specifications and with the requirements set by the auditing NPPO;
- observing processes to assess conformity with agreed procedures and to note aspects that may compromise the phytosanitary system or procedure being audited;
- investigating whether the phytosanitary system or procedure being audited is achieving the expected phytosanitary objectives;
- discussing audit findings within the audit team to reach consensus;
- identifying and informing the auditee of any findings during the audit and, in the case of entities authorized to audit, informing the responsible NPPO, within the agreed time frame, of any nonconformities.



### 11.3.3 Closure and reporting

The activities of the auditor and auditee may include:

- discussing findings, identified nonconformities and preliminary conclusions;
- requesting or providing additional clarification and feedback;
- the auditor drafting an audit report and the auditee commenting on the draft audit report, with both parties discussing the timelines for implementation of corrective actions when nonconformities have been identified, and, in situations where dispute occurs, attempting to resolve the dispute (see section 10);
- reviewing the next steps and agreeing on the deadline for the presentation of the final report of the audit.

An audit report should always be produced and should include the purpose, scope, objectives and findings (conformities, nonconformities and, if noted, observations) of the audit. The report should also draw conclusions based on analysis of the findings. If nonconformities are identified, these conclusions should include the need for corrective actions and the assessment by the auditor of the action plan proposed by the auditee (including the proposed timelines for implementation of these corrective actions). In addition, the audit report may provide suggestions for improving the effectiveness of the audited phytosanitary system or procedure, highlight good practices, and provide useful feedback on phytosanitary regulations or requirements.

Before finalizing the audit report and providing it to the auditee, additional information (e.g. comments, implemented corrective actions) received from auditees should be considered. Details of any disputes related to the audit and its findings should be clearly described in the report.

## 12. Types of nonconformity

Nonconformities should be recorded, along with supporting evidence. Nonconformities may be considered as critical nonconformities or other nonconformities.

“Critical nonconformity” is a nonconformity that immediately compromises the integrity of the NPPO phytosanitary system that has been audited, or its elements, and that requires a rapid corrective action to be identified and implemented.

“Other nonconformity” is a nonconformity that does not directly or immediately compromise the integrity of the NPPO phytosanitary system that has been audited, or its elements, and that is therefore not considered a critical nonconformity by the auditing NPPO. Other nonconformity requires corrective action to be taken within a specified time frame.

## 13. Following up nonconformity

Follow-up should take place if the audit report identifies that corrective actions are needed. These corrective actions should be implemented within the timelines identified in the report and their effectiveness verified.