

[PleaseReview document review. Review title: 2021 Second Consultation: Audit in the Phytosanitary context (2015-014) . Document title: 2015-014_Draft_ISPM_Audit_2021-06-29.docx]

[1]**DRAFT ISPM: Audit in the phytosanitary context (2015-014)**

[2]**Status box**

[3]This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
[4] Date of this document	[5]2020-06-03
[6] Document category	[7]Draft ISPM
[8] Current document stage	[9]To second consultation
[10] Major stages	[11]2015-11 Standards Committee (SC) recommended the topic be added to the work programme. [12]2016-04 CPM-11 added the topic <i>Audit in the phytosanitary context</i> (2015-003, subsequently changed to 2015-014) to the work programme with priority 2. [13]2017-11 SC approved Specification 66 and recommended priority 1. [14]2018-04 CPM-13 approved the priority change. [15]2019-06 Expert working group (EWG) met and drafted the standard. [16]2020-04 SC revised the draft via Online Comment System (to replace the cancelled 2020-05 SC meeting) and approved it for first consultation via e-decision (2020_eSC_May_19). [17]2020-07 First consultation. [18]2021-05 SC-7 revised and approved for second consultation.
[19] Steward history	[20]2016-05 SC Mr Álvaro SEPÚLVEDA LUQUE (CL, Lead Steward) [21]2020-11 SC Mr Steve CÔTÉ (CA, Assistant Steward) [22]2016-05 SC Mr Rajesh RAMARATHNAM (CA, Assistant Steward)
[23] Notes	[24]2017-03 Topic number changed from 2015-003 to 2015-014 [25]2019-10 Edited [26]2020-05 Edited [27]2021-06 Edited

[28]**Adoption**

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

[30]**INTRODUCTION**

[31]**Scope**

[32]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, and 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.

[33]**References**

[34]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>.

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

[36]**Definitions**

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

[38]**Outline of requirements**

[39]This standard describes the purpose and procedures for audit activities in the phytosanitary context. This includes the circumstances that may initiate an audit, the criteria 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.

[40] 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. The roles and responsibilities of the parties involved in an audit are also described.

[41] **BACKGROUND**

[42] National plant protection organizations have a number of responsibilities under the IPPC, for activities such as surveillance, inspections, the establishment of phytosanitary import requirements, phytosanitary certification, the conduct or supervision of treatments, the conduct of pest risk analyses, 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.

[43] 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.

[44] 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, assure the quality of the processes set by the auditing NPPO (the NPPO responsible for the audit), and evaluate whether the system or procedure is achieving the expected phytosanitary outcomes.

[45] 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.

[46] 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.

[47] **IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT**

[48] 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.

[49] **REQUIREMENTS**

[50] **1. Purpose of an audit**

[51] 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, regarding the effectiveness of the phytosanitary system or procedure being audited.

[52] An NPPO may conduct audits to:

- [53] verify the conformity of the NPPO’s own systems and procedures;
- [54] verify the systems and procedures of entities that have been authorized by the NPPO, including entities authorized to conduct audits on behalf of the NPPO;
- [55] verify 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*).

[56]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.

[57]2. Types of audit

[58]The main types of audit are system audits and verification audits.

[59]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 designed to achieve 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 at other times as and when necessary. The scope of a system audit may include an entire system from production to export or a system of a particular entity.

[60]A **verification audit** is a focused review of a phytosanitary system or procedure, in which particular elements of the system or procedure are reviewed to evaluate their effectiveness of the system or procedure and its 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 verification audit may be conducted periodically, at regular or random intervals, or as a result of certain circumstances.

[61]3. Circumstances that may initiate audit

[62]The following are examples of circumstances that may initiate an audit in:

- [63]scheduling of a routine audit to verify ongoing conformity with the requirements of the auditing NPPO;
- [64]changes to conditions (e.g. production practices, pest status, management systems or operations of a facility);
- [65]changes to phytosanitary import requirements, management systems or operation of a facility;
- [66]a new import pathway;
- [67]a new export programme;
- [68]a notification of non-compliance from the NPPO of an importing country (e.g. detection of a regulated pest in an imported consignment);
- [69]a detected nonconformity that may compromise the phytosanitary system;
- [70]the implementation of corrective actions to address nonconformity;
- [71]new requests for participation in the phytosanitary system.

[72]4. Roles and responsibilities

[73]4.1 Roles

[74]The audit involves two parties: an auditor and an auditee. The auditor may be either an NPPO or its authorized entity. The sections below describe the responsibilities of each party. In the context of this standard, both the terms “auditor” and “auditee” may refer to an individual person, a group of people representing an organization or an entity.

[75]4.2 Responsibilities of the NPPO

[76]For audits in its own territory, the NPPO should:

- [77]establish an audit framework and requirements for the audit process;
- [78]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;
- [79]develop contingency plans for continuity of action in the event that an authorized entity is no longer able to conduct audit activities;

- [80]identify costs and ensure that appropriate financial arrangements are in place to meet these costs;
- [81]if nonconformities are identified, ensure that the auditee identifies and implements corrective actions to address these nonconformities in the time frame agreed;
- [82]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.

[83]In addition, an NPPO of an importing country conducting audits in the territory of an exporting country should:

- [84]establish an audit framework and requirements for the audit process;
- [85]reach an agreement with the NPPO of the exporting country to conduct the audit, including arrangements for aspects such as the financial cost of the audit and which entities are authorized to conduct the audit;
- [86]if nonconformities are identified, agree with the NPPO of the exporting country what corrective actions are required and within what time frame.

[87]4.3 Responsibilities of the auditor

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

- [89]develop, implement and maintain an audit programme within the audit framework established by the auditing NPPO;
- [90]identify the purpose, scope and objectives of each audit;
- [91]identify the audit criteria to be used;
- [92]prepare for and undertake audits using the agreed criteria;
- [93]prepare and finalize audit reports and provide these in a timely manner to the auditee, or to both the auditor and NPPO if the auditor is an authorized entity;
- [94]provide sufficient human resources, with the required training and competence to conduct the audits;
- [95]be free of any conflict of interest, maintaining impartiality and independence from the entities being audited;
- [96]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;
- [97]maintain confidentiality of information gained through the audit (see section 8).

[98]4.3.1 Specific responsibilities of entities authorized to conduct an audit

[99]Authorized entities conducting an audit on behalf of an NPPO should meet the following requirements in addition to those set out in section 4.3 and ISPM 45 (*Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions*):

- [100]conduct audits as agreed with the NPPO;
- [101]immediately notify the authorizing NPPO of any nonconformities as defined in section 12.

[102]4.4 Responsibilities of the auditee

[103]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 auditee should be required to:

- [104]cooperate with the auditor and conform with audit requirements;
- [105]provide access to information, facilities, records and personnel as required for the audit being conducted;

- [106]facilitate, within the country of the auditee and as appropriate, the logistics associated with visits by the auditor to the auditee;
- [107]draw up and deliver an action plan according to the audit findings;
- [108]if nonconformities are identified, identify and implement corrective actions to address these nonconformities within the agreed time frame.

[109]5. Selection of auditors

[110]Auditors should be selected based on a combination of knowledge, training and experience relevant to the scope of the audit, including the audit methodology and the gathering of objective evidence.

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

[112]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.

[113]6. Frequency of audits

[114]When setting up an audit programme, the auditing NPPO should determine the frequency of audits of the phytosanitary system or procedure being audited and review this frequency as appropriate. The audit frequency may be influenced by:

- [115]circumstances triggering an audit to be initiated, as identified in section 3;
- [116]seasonality in relation to phytosanitary activities, if appropriate;
- [117]the pest risk associated with relevant pests or pathways;
- [118]the history of conformity and compliance;
- [119]whether an established, documented procedure is in place that has been shown to reduce the pest risk.

[120]7. Conflicts of interest

[121]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 system, 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 the auditee should declare that there are no conflicts of interest relating to the audit.

[122]8. Confidentiality

[123]The parties should consider and manage 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.

[124]Before the commencement of the audit, parties should be made aware of the intended and possible disclosure of information gathered during the audit, including the report.

[125]9. Financial arrangements

[126]Financial arrangements should be discussed and agreed upon by the parties before commencement of the audit.

[127]10. Settlement of Disputes

[128]The process for settlement of disputes may be established in advance of audits, as part of the audit framework.

[129]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.

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

[131]11. Steps in the audit process

[132]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.

[133]11.1 Planning an audit

[134]The planning of an audit should include the following elements:

- [135]defining and agreeing the purpose, scope (entire system or particular elements of the system) and objectives of the audit;
- [136]identifying the audit criteria for assessment of conformity;
- [137]identifying the auditor and the auditee;
- [138]considering existing equivalent audit systems, or other systems developed by NPPOs or industry, where appropriate.

[139]11.1.1 Scheduling of audits

[140]Audits should be scheduled by the auditing NPPO or the authorized entity conducting the audit in advance (i.e. the date and time of the performing and evaluation stage of the audit (section 11.3.2)). 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. nonconformities), an audit may be unscheduled.

[141]11.2 Preparing for an audit

[142]To prepare for an audit, the auditor should:

- [143]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 reports on corrective actions implemented to address nonconformities;
- [144]prepare audit tools, such as checklists, reference materials, equipment and a list of possible questions;
- [145]communicate with participants (which may include notifying auditees) and confirm their availability, finalize logistics arrangements and agree to the language in which the audit will be conducted;
- [146]ask the auditee to ensure that personnel and relevant documentation be available during the audit;
- [147]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, technical experts and observers.

[148]11.3 Undertaking an audit

[149]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 what is being audited. The three stages are set out below, along with examples of activities that may be included.

[150]11.3.1 Initiation

[151]The activities of the auditor may include:

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

[159]11.3.2 Performing and evaluation

[160]The activities of the auditor may include:

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

[169]11.3.3 Closure and reporting

[170]The activities of the auditor and auditee may include:

- [171]discussing findings, identified nonconformities and preliminary conclusions;
- [172]requesting or providing additional clarification and feedback;
- [173]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);
- [174]reviewing the next steps and agreeing on the deadline for the presentation of the final report of the audit.

[175]The audit report should always be produced and should include the purpose, scope, objectives and findings (conformities and nonconformities) 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 phytosanitary system or procedure, highlight good practices, and provide useful feedback on phytosanitary regulations or requirements.

[176]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 should be clearly described in the report.

[177]12. Types of nonconformity

[178]Nonconformities should be recorded, along with supporting evidence. Nonconformities may be considered as critical nonconformities or non-critical nonconformities.

[179]A “critical nonconformity” is a nonconformity that immediately compromises the integrity of the auditing NPPO’s phytosanitary system or its elements and that requires a rapid corrective action to be identified and implemented.

[180]A “non-critical nonconformity” is a nonconformity that does not directly or immediately compromise the integrity of the auditing NPPO’s phytosanitary system or its elements and that is therefore not considered a critical nonconformity by the NPPO. A non-critical nonconformity requires corrective actions to be taken within a specified time frame.

[181]13. Follow-up of nonconformity

[182]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.

[183]Potential implementation issues

[184]This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details of potential implementation issues and proposals on how to address them.

[185]