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

[3]**Status box**

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| [4]This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption. |
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| [18]**Steward history** | [19]2016-05 SC Mr Álvaro SEPÚLVEDA LUQUE (CL, Lead Steward)[20]2016-05 SC Mr Rajesh RAMARATHNAM (CA, Assistant Steward) |
| [21]**Notes** | [22]2017-03 Topic number changed from 2015-003 to 2015-014[23]2019-10 Edited[24]2020-05 Edited |

[25]Adoption

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

[27]Introduction

[28]Scope

[29]Audit in the phytosanitary context is a systematic examination of a process to determine whether it conforms with the phytosanitary requirements set by a national plant protection organization (NPPO). This standard covers audits in the phytosanitary context conducted by the 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 in its territory.

[30]References

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

[32]Definitions

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

[34]Outline of Requirements

[35]The standard describes the purpose and procedures for audit activities in the phytosanitary context. This includes the circumstances that may trigger an audit and the criteria and procedures for planning, preparing for and performing audits. The elements to be considered depend on the type of audit and its purpose, scope and objectives.

[36]This standard also provides guidance on selecting auditors, establishing audit frequencies, settling disputes over audit findings, and agreeing financial arrangements between the parties involved. The roles and responsibilities of the parties involved in audits are also described.

[37]Background

[38]National plant protection organizations have a number of obligations and responsibilities under the IPPC, such as surveillance, inspections, establishment of phytosanitary import requirements, phytosanitary certification, conduct or supervision of treatments, conduct of pest risk analysis, and training of staff. To help them fulfil these obligations effectively, NPPOs are increasingly using audits to provide confidence that phytosanitary systems and procedures achieve their objectives.

[39]Audits are referenced in many adopted ISPMs. This standard aims to provide standardized guidance to NPPOs, to ensure a common approach to audits in the phytosanitary context.

[40]Unlike supervision, an audit does not involve continuous observation and direction of activities, but provides an assessment of a specific phytosanitary system or procedure at a given time.

[41]Audit is a documented process to gain assurance and trust in phytosanitary systems and procedures. Objective evidence is collected on whether the outcomes of the system or procedure, including associated activities, conform with the relevant requirements of the NPPO and whether these requirements are implemented effectively to achieve phytosanitary objectives.

[42]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[43]Conducting audits in the phytosanitary context helps to ensure the effectiveness of phytosanitary systems and procedures, thereby reducing the risk of the introduction and spread of quarantine pests. This protects plant health, which in turn reduces negative environmental impacts and benefits biodiversity.

[44]Requirements

[45]1. Purpose of Audit

[46]Audits should objectively evaluate whether specific phytosanitary systems and procedures conform with the phytosanitary requirements set by an NPPO. Audits should provide an opportunity to identify findings, including nonconformities and observations on the effectiveness of the systems and procedures being audited.

[47]An NPPO may conduct an audit in the phytosanitary context to:

* [48]verify its own systems and procedures
* [49]verify the systems and procedures of authorized entities.

[50]In addition, the NPPO of an importing country may conduct an audit to verify the systems and procedures of the NPPO of an exporting country.

[51]An NPPO may also decide to authorize an entity to conduct an audit on its behalf to verify the systems and procedures of:

* [52]entities authorized to perform phytosanitary actions in its territory
* [53]entities participating in the system of the exporting country.

[54]2. Types of Audit

[55]The main types of audit in the phytosanitary context are system audits and verification audits.

[56]A **system audit** is a comprehensive review of a system or procedure to assess its effectiveness and conformity with established phytosanitary requirements. The scope of a system audit may include an entire system from production to export, a system of a particular entity, or particular processes and procedures relevant to a phytosanitary system.

[57]A **verification audit** is a comprehensive review of particular elements of a system or procedure to indicate its effectiveness and conformity with established phytosanitary requirements. It may be conducted periodically (at either regular or random intervals) or non-periodically (as a result of certain triggers).

[58]3. Triggers

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

* [60]scheduling of routine audits to verify ongoing conformity with system requirements
* [61]changes to conditions (e.g. production practices, pest status, management systems or operations of a facility) in an exporting country
* [62]changes to phytosanitary import requirements, management systems or operation of a facility
* [63]a new import pathway
* [64]a new export programme
* [65]notifications of non-compliance from the NPPO of an importing country (e.g. detection of a regulated pest in an imported consignment)
* [66]nonconformity detected or observations made that may compromise the phytosanitary system
* [67]corrective actions implemented to address nonconformity
* [68]new requests for participation in the phytosanitary system
* [69]complaints

[70]4. Roles and Responsibilities

[71]4.1 Roles

[72]The audit process 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 both parties. In the context of this standard, the term “auditor” may refer to an individual person, a group of people representing an organization, or an organization authorized to conduct an audit. Likewise, the term “auditee” may refer to an individual person, a group of people representing an organization, or an organization being audited.

[73]4.2 Responsibilities of the NPPO

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

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

[81]An NPPO conducting audits in the territory of an exporting country should:

* [82]establish an audit framework and requirements for the audit process
* [83]reach an agreement, with the NPPO of the exporting country, to conduct the audit, this agreement including the financial arrangements for the audit
* [84]when nonconformities are identified, agree with the NPPO of the exporting country what corrective measures are required.

[85]4.3 Responsibilities of the auditor

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

* [87]develop, implement and maintain an audit programme if the NPPO has established an audit framework
* [88]identify the purpose, scope and objectives of each audit within the programme
* [89]identify audit criteria for assessment of conformity
* [90]initiate, conduct and conclude audits of agreed systems and procedures, using identified criteria
* [91]prepare and finalize audit reports and provide these to the auditee or (in the case of an auditor who is an authorized entity) both the auditee and, where appropriate, the NPPO
* [92]provide sufficient human resources, with the required training and competence to conduct the audits
* [93]be free of any conflict of interest, maintaining impartiality and independence from the entities it audits
* [94]provide the opportunity for the auditee to respond to the findings of the report (e.g. to support the findings or dissent from them)
* [95]maintain confidentiality of information gained through the audit.

[96]4.3.1 Specific responsibilities of entities authorized to conduct an audit

[97]The entity authorized to conduct an audit should meet the relevant requirements set out in section 4.3 and should in addition:

* [98]conduct audits as agreed with the NPPO
* [99]immediately notify the authorizing NPPO of any critical nonconformities.

[100]4.4 Responsibilities of the auditee

[101]The auditee may be an NPPO auditing itself, an NPPO of an exporting country audited by the NPPO of the importing country, an entity authorized by an NPPO, or any other participant in the phytosanitary system that is being audited. The auditee should:

* [102]cooperate with the auditor and conform with audit requirements
* [103]provide access to information, facilities, records and personnel as required
* [104]facilitate, as appropriate, the logistics associated with visits by the auditor to the auditee
* [105]take action on audit findings, noting observations and addressing nonconformities within the agreed time.

[106]5. Selection of Auditors

[107]Auditors should be selected based on a combination of knowledge, training and experience relevant to the scope of the audit.

[108]An auditor should have knowledge of the auditing methodology and gathering of objective evidence. Where technical expertise is required, a relevant technical expert may accompany or assist the auditor.

[109]To meet the requirement for impartiality (see section 7), any conflict of interest between the auditor and auditee should also be considered in the evaluation.

[110]6. Frequency of Audit

[111]Audit may be conducted periodically or non-periodically. National plant protection organizations should determine the frequency of audits of the system or procedure being audited when they set up an audit programme, and review this as appropriate. The audit frequency may be influenced by:

* [112]triggers identified in section 3 of this standard
* [113]the pest risk associated with relevant pests or pathways
* [114]the history of conformity and compliance
* [115]whether an established quality management system is in place that has been shown to reduce pest risk
* [116]seasonality in relation to phytosanitary activities.

[117]7. Conflicts of Interest

[118]In order to maintain the integrity of the audit system, the auditor should be impartial. The auditor should verify the absence of potential, perceived or actual conflict of interest. The auditee should declare any possible conflicts of interest relating to the auditor of which they are aware. The parties concerned should develop guidance on this matter, as appropriate.

[119]8. Confidentiality

[120]The parties concerned should consider and manage confidentiality in order to maintain the integrity of the audit system and private and commercially sensitive information. They should develop guidance on this matter, as appropriate.

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

[122]9. Financial Arrangements

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

[124]10. Settlement of Disputes

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

[126]If parties do not agree that the intended methodology was followed, or with findings or conclusions of the audit, they should consult among themselves as soon as possible with a view to resolving the dispute.

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

[128]11. Steps in the Audit Process

[129]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 are steps in the audit process.

[130]11.1 Planning

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

* [132]defining and agreeing on the purpose, scope (entire system or specific elements of the system) and objectives of the audit
* [133]identifying the audit criteria for assessment of conformity
* [134]identifying the auditor or auditors and the auditee or auditees
* [135]Where appropriate, planning may also include recognition of existing equivalent audit systems or other systems developed by NPPOs or industry.

[136]11.1.1 Scheduling of audits

[137]The scheduling of periodic audits (i.e. the date and time of the audit performance step (section 11.3)) should be announced before the performance of the audit, with an advance equal to or greater than the agreed minimum notice. Non-periodic audits should be scheduled by an NPPO or an authorized entity. The scheduling of an audit may be unannounced in some situations (e.g. nonconformities, complaints).

[138]11.2 Preparation

[139]Preparation for an audit should include the following elements:

* [140]gathering and reviewing relevant information, such as manuals, procedures, work plans, notifications of non-compliance, records, pre-audit questionnaire, relevant standards, agreements and previous audit reports
* [141]preparing audit tools, such as checklists, reference materials, equipment and list of possible questions to ask, to facilitate the gathering of evidence in support of the audit
* [142]communicating with participants (which may include notifying auditees for announced audits) and confirming their availability, finalizing logistics arrangements and agreeing to the language in which the audit will be conducted
* [143]asking the auditee to ensure that personnel and relevant documentation be available during the audit
* [144]confirming 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, observers and technical experts.

[145]11.3 Performance

[146]The performance step of the audit should include the following three stages. Depending on the scope of the audit, the combination of elements within each stage may vary.

[147]11.3.1 Commencement stage

[148]The activities in this stage may include the following elements:

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

[156]11.3.2 Evaluation stage

[157]The activities in this stage may include the following elements:

* [158]interviewing relevant personnel if required and seeking clarification as necessary
* [159]assessing documented processes
* [160]assessing records from procedures (e.g. technical and administrative records, inspection records, treatment records, testing results, corrective actions log)
* [161]verifying if facilities, instruments, machinery and equipment comply with their relevant specifications
* [162]observing processes to assess conformity with agreed procedures and to note aspects that may compromise the phytosanitary system or procedure being audited
* [163]discussing audit findings within the audit team to reach consensus
* [164]identifying and informing the auditee of any nonconformities during the audit and immediately informing the NPPO of any critical nonconformities.

[165]11.3.3 Closure stage

[166]The activities in this stage may include the following elements:

* [167]discussing findings, identified nonconformities and preliminary conclusions
* [168]requesting and providing additional clarification and feedback
* [169]]reviewing the next steps, such as drafting the audit report and commenting on the draft audit report, and the corresponding timelines in situations where dispute occurs, attempting to resolve the dispute (See section 10).

[170]12. Reporting

[171]The audit report should include the scope, purpose, objectives and findings (observations, 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 timelines for implementation of these corrective actions. In addition, the audit report may provide useful feedback on phytosanitary regulations or requirements.

[172]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.

[173]13. Types of Nonconformity

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

[175]“Critical nonconformity” is a nonconformity that immediately impacts the integrity of and trust in the NPPO’s phytosanitary system or its elements and that requires a rapid corrective action to be identified and implemented.

[176]“Other nonconformity” is a nonconformity that does not directly or immediately impact the integrity of and trust in the NPPO’s phytosanitary system or its elements and is not considered a critical nonconformity by the NPPO. Other nonconformity requires corrective actions to be taken within a specified time frame.

[177]14. Follow-Up

[178]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 by any combination of the following:

* [179]assessment of the evidence provided
* [180]follow-up verification audit
* [181]follow-up system audit.

[182]**Potential implementation issues**

[183]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.