

Appendix 7d

External Audits

Process, Responsibilities and Outcomes

Contents

7.1 Roles and Responsibilities	2
7.1.1 The Nursery	2
7.1.2 Canadian Nursery Certification Institute (CNCI)	2
7.1.3 The External Auditor	2
7.2 External Audit Details.....	2
7.2.1 Frequency and Timing.....	2
7.2.1 Preparing for an Audit	3
7.2.2 Review of the Clean Plants Manual	3
7.2.3 Opening Meeting with Facility Personnel	3
7.2.4 The Audit	3
7.2.5 Audit Scope.....	4
7.2.6 The Closing Meeting.....	5
7.2.7 Audit Report	6
7.2.8 CNCI Audit Review	6
7.2.9 Non-Conformance.....	7
7.2.10 Corrective Action Requests.....	8
7.3 Possible Changes in Certification Status Following an External Audit	9
7.3.1 Upgrade to Certified.....	9
7.3.2 Status Quo	9
7.3.3 Downgrade to Suspended	9

7.1 Roles and Responsibilities

7.1.1 The Nursery

The certified nursery is responsible for scheduling a CNCI Accredited Auditor to do the Systems Audit as required.

7.1.2 Canadian Nursery Certification Institute (CNCI)

The CNCI is responsible for ensuring that independent auditors are available for the purposes of the external audit. The CNCI will ensure uniform national certification processes are in place and that audits are conducted in accordance with the specifications outlined in this document.

7.1.3 The External Auditor

All audits must be performed by a CNCI Accredited Auditor. Audits may be performed by a single Auditor or by an audit team. Team size will be determined by the size and complexity of the audit being performed and the associated operational imperatives.

The Auditor will:

- have successfully completed a recognized Lead Auditor training course;
- have successfully completed CNCI technical competency and audit training appropriate to the nursery certification modules they are auditing.
- provide auditing services under the auspices of an independent auditing firm approved by the CNCI

7.2 External Audit Details

7.2.1 Frequency and Timing

The Clean Plants program will utilize external audits, carried out by auditors fully accredited by CNCI. In addition to an initial facility evaluation (Appendix 7b) there will be at least one systems audit done by external auditors. Facilities may choose the external auditor they wish to use, from a published list of CNCI Accredited Auditors.

It is the Facility's responsibility to schedule timely external audits in order to ensure one Systems Audit is done during the active growing season or before the end of the shipping season.

The facility must supply their auditor with copies of their Clean Plants Manual (with any recent revisions identified) and the most recent internal and external Audit Reports, prior to

the audit in a time frame agreeable with the auditor and facility **but not less than one week prior to the audit.**

7.2.1 Preparing for an Audit

When a facility contacts an auditor to arrange for an external audit to be done the auditor must confirm with the Certification Manager the appointment details and explain his or her expectations for the audit, including:

- what facility staff needs to be available for the audit,
- office space for the audit
- the purpose and scope of the audit.

The auditor must also ensure that he/she has:

- the most recent copy of the Clean Plants Manual,
- previous audit reports,
- any corrective action requests from the previous audit and
- any other necessary documents.

Prior to the audit, the auditor must develop an audit plan, outlining specific focus areas for the audit. The focus of the audit will be determined by taking into account previous audits, facility performance between audits or any other current issue happening within the industry. The auditor will provide the audit plan to the facility at least one week prior to the audit.

7.2.2 Review of the Clean Plants Manual

The auditor must conduct a review of the facility's Clean Plants Manual, particularly in areas where it has been modified since the last audit, as well as previous internal and external Audit Reports for the previous year. For efficiency, the document review will generally be completed prior to the actual audit visit.

7.2.3 Opening Meeting with Facility Personnel

The auditor must arrange for an opening meeting with the key senior management, the Certification Manager (CM), Crop Protection Manager (CPM) and any other interested staff of the participating facility, to discuss among other items: audit criteria, availability of staff, method of performing the audit, method of handling any non-conformances found during the audit, time and place of the closing meeting, and distribution of an audit report.

7.2.4 The Audit

The Auditor must record his or her observations and findings during the audit. The audit checklists are:

- Appendix 7a - Checklist for Manual Evaluations,
- Appendix 7b - Checklist for Initial Facility,
- Appendix 7c - Checklist For External Audits.

Evaluation should be used to ensure that the audit is carried out systematically and objectively. Audit inspection records must include the following information:

1. The date of the audit,
2. The names of all the members of the audit team,
3. The name and address and certification number of the facility audited,
4. Areas of the facility audited,
5. Observations and findings of the audit,
6. Fees charged,
7. Estimated dates of future audits,
8. Other comments; and
9. References to any Corrective Action Request.

7.2.5 Audit Scope

The audit must be conducted by means of:

- staff interviews,
- observation of activities,
- examination of documents and records,
- examination of the Clean Plants Manual, and
- confirmation of the facility's ability to carry out the Phytosanitary Management System and Pest Management Plan as described in their Clean Plants Manual.
-

Each audit does not have to cover all the elements in the manual. The auditor may choose to put emphasis on particular aspect for each visit. The areas selected will be determined from a review of previous audit reports, from examination of internal audit reports, from the season the audit is done in, and from the judgment of the auditor.

All aspects of the Clean Plants Manual must be audited over the course of two successive audits covering both a growing and a shipping season audit.

At every audit, the auditor must obtain sufficient evidence within the company's systems to:

- **Evaluate if the procedures in place are adequate to ensure that any pest problems are quickly identified and appropriate actions are taken.**
- **Verify that the facility has operated their Pest Management Plan as it was described in the Clean Plants Manual.**
- **Verify that the origin of plant material shipped into the facility is being properly recorded in such a way as to facilitate trace back, this applies to all incoming stock whether it be from a CNCP nursery, another Clean Plants nursery, an import or a completely non-certified source.**

The auditor may also examine the following systems:

- Assess the adequacy and effectiveness of the Phytosanitary Management System in meeting the requirements specified in the Clean Plants program.
- Determine whether required supporting documentation is sufficient, current, and readily available to staff.
- Determine that work is being performed in accordance with the procedures specified in their Clean Plants Manual and that appropriate records are being kept.
- Verify that staff assigned to the roles of CM and CPM in the Phytosanitary Management System are still employed and filling their roles.
- Verify that internal audits have been performed, Corrective Action Requests have been generated and corrective actions completed.
- Verify that appropriate steps are taken to ensure the eligibility of plants included in shipments that are sold and stamped as certified Clean Plants stock.
- Verify that non-certified plants have not had the Clean Plants stamp applied to their shipping documents.
- Confirm that the use of the Clean Plants stamp conforms to the Clean Plants Standard.
- Confirm that adequate records and documents are maintained; and
- Determine the cause of any non-conformances found and to discuss with management of the nursery, strategies to address the non-conformance.

7.2.6 The Closing Meeting

The Certification Manager and possibly the Crop Protection Manager must meet with the auditor to review the audit findings, discuss any non-conformances, and decide upon an action plan for correction. The auditor and the Certification Manager must agree to dates by which corrective actions will be completed, the method to be used to confirm completion of the corrective action and the consequences if corrective actions are not completed on time. The auditor must inform the Certification Manager of any potential changes in the facility status at the closing meeting. In addition, any critical non-conformances must be discussed as these are likely to result in immediate suspension of the facility's certification status by CNCI.

Decisions to suspend a facility are not made directly by the auditor. However, the auditor may require the nursery to suspend shipping of plant material as “certified” in situations where the integrity of the material is jeopardized.

The auditor will be required to submit the Audit Report, Corrective Action Requests and the agreement around corrective action implementation, to the CNCI for review and final decision.

7.2.7 Audit Report

In the case of satisfactory audits, the auditor is responsible for producing an Audit Report within ten (10) working days of the audit. Copies of such reports are to be distributed to the Facility, to the accredited audit service provider and to CNCI.

If an audit detected critical non-conformances that are likely to result in suspension, the Audit Report along with supporting Corrective Action requests and the corrective action implementation plan must be produced and distributed to CNCI within five (5) working days of the audit and the CNCI must report back to the facility within ten (10) working days of the audit.

In many cases the auditor will use the various Audit Checklists (see Appendix 7a - Checklist for Manual Evaluations, Appendix 7b - Checklist for Initial Facility Evaluation, and Appendix 7c - Checklist for External Audit) as the main body of the audit report but the auditor is free to comment on any aspect of the audit that may not appear in the Checklist. The Audit Report must include the following details, most of which will be already included in the various checklists, if one of them is utilized:

- Describe the scope of the audit,
- State the objectives of the audit,
- Include a distribution list for the Audit report,
- Provide specific details, such as the dates and location of the audit, the name(s) of the auditor, the names of personnel responsible who participated in the closing meeting,
- List all reference documents used for the audit,
- Describe the audit findings, listed under the headings described in one of the checklist appendices,
- Reference any Corrective Action Requests that may have been produced,
- Evaluate the auditee's compliance with the documentation requirements,
- Evaluate the efficacy of the Phytosanitary Management System in meeting the requirements of Clean Plants,
- Comments, observations and/or recommendations for improvement to be reported in an attached Corrective Action Request,
- A copy of the corrective action plan agreed to by the auditor and the Certification Manager of the establishment; and
- Include a proposed date for the next audit and any other follow-up activities.

7.2.8 CNCI Audit Review

The auditor must immediately report to CNCI staff, as described above, in all cases where the audit detects critical non-conformances that are likely to result in a change of certification status of the establishment; this reporting process will allow input from CNCI in

any cases of recommended de-certification before that decision is formally communicated to the establishment. CNCI will notify the facility, in writing, of the approved corrective action plan and time lines and if any restrictions on sale of certified material will be necessary while corrective actions are being made. CNCI will also reconfirm the agreement that if corrective actions are not made within the time line, suspension will result. If the corrective actions have not been confirmed by the agreed-to date, CNCI will proceed with suspension of the establishment. The establishment will no longer be eligible to use their Clean Plants stamp or number on any documents or correspondence.

7.2.9 Non-Conformance

Types of non-conformance include:

1. **Critical** – those infractions that put the integrity of the systems supporting certification in jeopardy to the point that products must not be shipped as Clean Plants certified product until the situation has been corrected. The Clean Plants stamp cannot be used during this time. Some non-conformances may be such that the auditor or the adjudication committee feel that it is necessary to suspend shipments of product as certified until the corrective action is completed. In such cases the nursery will be informed of this decision through written notification on a Shipment Suspension Report (see Appendix 9b). Suspension of shipping privileges, as certified stock may apply to the whole nursery or to a portion of its production depending on the circumstances.

Examples of Critical non-conformances:

- Failure to inspect when plants arrive, during production and at shipping
 - Failure to keep records for traceability.
 - Failure to perform internal audits
2. **Major** – those infractions which are more isolated in nature and do not put the certified status of plants in immediate jeopardy. Corrective action will be required within a negotiated time frame.

Examples of Major non-conformances:

- Poor quality records
- Failure to identify non-certified plants
- Inadequate training of key staff

3. **Minor** – those imperfections that do not directly impact on the certification status of plants, but if left unattended could lead to more serious non-conformance. Unless the number of minor non-conformances alone or combined with major non-conformances equal a critical non-conformance, nurseries will be required to correct minor non-conformances prior to their next audit. Corrective actions will be detailed in the Clean Plants Manual.

Examples of Minor Non-conformances:

- Activities are not performed in a timely fashion
- Staff is uncertain of their role

Definitions and further examples of these non-conformances can be found in Appendix 8, Classification of Clean Plants Non-Conformances. Nurseries are encouraged to look at the detection of non-conformances as an opportunity to improve their operation.

7.2.10 Corrective Action Requests

When non-conformance of any kind is detected in an internal audit or an external audit a Corrective Action Request must be produced by the auditor. See Appendix 9 for the Corrective Action Request form. It is the responsibility of the nursery to specify how the problem will be corrected and the timeline.

Corrective actions must be implemented by the next audit or as stipulated by CNCI.

In many cases the corrective action may lead to the need to correct a portion of the systems used at the nursery. In such cases the Clean Plants Manual must also be amended to reflect these improvements. The facility must inform CNCI of changes to be made to the Manual and such changes will be approved by CNCI before they are implemented.

If an audit is conducted to confirm appropriate corrective actions have been accomplished according to the agreement set out at a closing meeting or following a suspension, the audit and its subsequent report will focus entirely on the non-compliance areas. In addition to the actual corrective action, the auditor should look for evidence that the Facility's Phytosanitary Management System and/or Pest Management Plan within the Clean Plants Manual has been modified in such a way to avoid similar future problems.

7.3 Possible Changes in Certification Status Following an External Audit

7.3.1 Upgrade to Certified

A facility could move to “certified status” when it first enters the program and successfully undergoes its initial facility evaluation or following the successful correction of non-conformances that led to a suspension.

7.3.2 Status Quo

When audits demonstrate satisfactory performance of the phytosanitary systems, the facility retains its current level.

7.3.3 Downgrade to Suspended

Suspension will occur when a **critical** non-conformance is reported and not satisfactorily dealt with as laid out in the corrective action implementation plan. All decisions to suspend are made by the CNCI.

When more than two **major** non-conformances are reported and the facility does not take satisfactory corrective action within the agree-to time frame, the CNCI may suspend the nursery.

When an audit uncovers non-conformances that could result in suspension of certified status, facilities are not allowed to ship material with the CNCI stamp. The CNCI-Clean Plants stamp assigned to the facility will be returned to CNCI and the facility will be removed from the national list of Clean Plants certified facilities. The nursery's number will be reserved by CNCI in the event the establishment qualifies for re-certification in the future.

Following suspension, the facility may re-apply to CNCI for re-certification in the program after the Phytosanitary Management System and Clean Plants Manual have been reviewed and restructured to address all previous non-conformances. The CNCI will determine what steps will be used to confirm the adequacy of corrective actions taken. If an audit is required as part of this process it will be a focused audit. Upon receipt of evidence satisfactory, the CNCI will consider re-certification of the facility.